Section Editors: Theresa Wicklin Gillespie and Constance Visovsky

QUALITY IMPROVEMENT

Improving Practice in a Head and Neck Oncology Clinic Using the PRO-CTCAE Tool

ROSE ANN RUDDY,[1] DNP, MSN, RN, ACNP-BC, BRIGIT CARTER,[2] PhD, RN, CCRN, FAAN, MARYANNE GIULIANTE,[1] DNP, MBA, RN, GNP, ANP-C, NEA-BC, HEC-C, and ANNMARIE LEE WALTON,[2] PhD, RN, MPH, OCN®, CHES, FAAN

From [1]Memorial Sloan Kettering Cancer Center, Montvale, New Jersey; [2]Duke University School of Nursing, Durham, North Carolina

Authors' disclosures of conflicts of interest are found at the end of this article.

Correspondence to: Rose Ann Ruddy, DNP, MSN, RN, ACNP-BC, Memorial Sloan Kettering Cancer Center, 225 Summit Ave, Montvale, NJ 07645
E-mail: ruddyrn@aol.com

https://doi.org/10.6004/jadpro.2024.15.5.2

Abstract

Background: Patients with head and neck cancer undergoing treatment report many side effects. Using patient-reported outcomes can assist with care management. **Objectives:** The purpose of this quality improvement project was to implement the patient-reported outcome version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) measurement system, reduce patient hydration visits, and measure provider satisfaction with the PRO-CTCAE survey. **Methods:** Statistical analysis was conducted using IBM SPSS software. Descriptive statistics for means were used to summarize the data for survey completion rate and for the provider satisfaction questionnaire. A Fisher's exact test was used to compare hydration visits before and after implementation of the PRO-CTCAE survey. **Findings:** The PRO-CTCAE surveys had a response rate of 91.2% (323/354) when telehealth visits were omitted. Hydration in the presurvey group was 23.5% (150/637) and in the postsurvey group was 38.5% (165/429), a 15% absolute percentage increase (Fisher's exact $p < .001$). Among providers, the positive response rate was 100% for five questions and 88.9% for two questions. **Implications:** The PRO-CTCAE survey allowed the patient to report their symptoms prior to discussing them with their provider. Providers were able to expedite symptom management and get information to patients in a timely manner. The PRO-CTCAE survey should be considered a part of a multidisciplinary approach to caring for patients.

Head and neck cancers account for 4% of all cancers in the US, with estimations that over 71,000 people will be diagnosed in the US in 2024 (Siegel et al., 2024). Head and neck cancers occur twice as often among men than women and are more common in people over the age of 50.

Patients with head and neck cancer are at an increased risk for

J Adv Pract Oncol 2024;15(5):303–310

malnutrition and dehydration for several reasons, among which can be masses in the mouth, throat, or neck that make eating and drinking difficult (Greco et al., 2018). Patients with feeding tubes may not be getting enough water outside of their scheduled feedings. In addition, chemotherapy may cause side effects that may increase dehydration (Brzozowska et al., 2019; Crowder et al., 2018), including dysphagia, nausea, diarrhea, vomiting, and/or lack of appetite (Wang et al., 2018). Assessing these symptoms that may cause dehydration can be challenging in the outpatient setting due to a lack of understanding of what may be normal or abnormal. There are also concerns that the patients may not understand what is being asked of them by the provider or have difficulty expressing their concerns during a visit (Xiao et al., 2013).

BACKGROUND

The goal of patient-centered care is to improve individual health outcomes (Bau et al., 2019). The Institute of Medicine has defined patient-centered care as "care that is respectful of and responsive to individual patient preferences, needs, and values and which honors patients' preferences, needs, and values and forges a strong partnership between patient and clinician" (Baker, 2001). One strategy to accomplish patient-centered care is to incorporate patient-reported outcomes (PROs) in addition to clinician-reported assessment (Basch et al., 2016). The National Cancer Institute and the US Food and Drug Administration define a PRO as "any report on the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (NCI, 2020; FDA, 2006). Patients, clinicians, payers, regulators, and researchers agree that person-centered outcome measurements can accelerate the development of new knowledge, improve the efficiency and quality of care, and contribute to clinician or health-system performance metrics and regulatory review of new therapies (Basch et al., 2016; Jensen & Snyder, 2016; Smith et al., 2016; Wood et al., 2021).

Research reveals discrepancies between symptom assessment reported by patients and those reported by clinicians (Kluetz et al., 2016; Strachna et al., 2021; Wood et al., 2021; Trojan et al., 2021; Xiao et al., 2013). Patients' symptoms may not be completely accurate or communicated well because the language that is used when asking about symptoms is not clear (Xiao et al., 2013). Misinterpreted information or misinformation can lead to adverse events such as low blood pressure, dehydration, renal failure, and admission to the hospital (Bressan et al., 2016). By allowing patients to self-report their symptoms, problems may be discovered sooner, and interventions can occur earlier (Basch et al., 2016). Symptom assessment is essential to the experience of cancer treatment. By listening to the patient, providers will improve care, outcomes, and satisfaction for patients (Basch et al., 2016; Wood et al., 2021).

PRO-CTCAE

There are several types of assessment tools that have been developed to assess PROs. The National Institutes of Health (NIH) developed the PRO-CTCAE, which combines PROs with Common Terminology Criteria for Adverse Events (NIH, 2020). The PRO-CTCAE survey can be tailored to a specific need such as patients who are undergoing cancer treatment and their specific side effects. Dueck and colleagues (2015) explored the value of patients' input in describing their own experiences using the PRO-CTCAE. The results of this validation study suggested that PRO-CTCAE can achieve its intended aim of integrating the patient experience into routine clinical adverse event reporting, thereby augmenting the capacity for more informed provider decision-making (Ducek et al., 2015). A pilot study conducted by Webster and colleagues (2018) used PROs in patients with gynecological cancers and chemotherapy toxicities. This study concluded that 69% of patients' and 97% of providers' responses showed the questionnaire impacted clinical care in a positive way. Trojan and colleagues (2021) concluded that shared monitoring and review of symptoms between patients and clinicians has the potential to improve the understanding of patient self-reporting. The data indicated that the integration of electronic PROs into oncological clinical research and continuous clinical practice provides reliable information for self-empowerment and the timely intervention of symptoms.

The purpose of this quality improvement project was to implement a PRO survey using

the PRO-CTCAE tool at Memorial Sloan Kettering Cancer Center in the outpatient setting with head and neck cancer patients prior to weekly scheduled encounters. The goal of implementing this tool was to reduce visits for hydration and improve clinicians' knowledge of the patients' own symptoms. This real-time patient-provided data can be used to complement clinical data and support clinicians in showing and tracking symptom progression, as well as in integrating patient-specific intervention opportunities into routine clinical care (Bennet et al., 2012).

OBJECTIVES

The purpose of this quality improvement project was to integrate the PRO-CTCAE survey tool into the head and neck oncology clinic provider assessment. The purpose of integrating the PRO-CTCAE survey was to reduce patient hydration visits and measure provider satisfaction. The aims were to: (1) Achieve 65% of patients completing the PRO-CTCAE surveys over 10 weeks from November 15, 2021, to January 20, 2022; (2) Decrease the number of hydration visits of patients who have completed the PRO-CTCAE survey by 25% over 10 weeks from November 15, 2021, to January 20, 2022; and (3) Achieve 70% of providers reporting positive perceptions of the PRO-CTCAE survey over 10 weeks from November 15, 2021, to January 20, 2022.

METHODS

Setting

Memorial Sloan Kettering Cancer Center is a Magnet-designated cancer treatment and research institution in New York. It consists of one main location in Manhattan and six satellite locations spanning various locations in New York and New Jersey. It employs over 1,200 physicians and 950 advanced practice providers (APP) who treat patients with 400 types of cancer annually. Advanced practice providers include nurse practitioners and physician assistants. The setting for this project was an ambulatory outpatient head and neck medical oncology clinic in two satellite locations in New York and New Jersey.

Sample

The outpatient clinic serves patients with head and neck cancers that range from stage I to stage IV with both curative and palliative intent of treatment. It employs two medical oncologists and one nurse practitioner. There is an office practice coordinator and an office practice nurse paired with each medical oncologist and a clinic coordinator assigned to each clinic. Patient inclusion criteria for this project were patients undergoing chemotherapy for head and neck cancer in one of the two participating clinics who could speak and read in English. Provider inclusion criteria were providers who attended an in-service on the project and agreed to review the PRO-CTCAE tool with patients when completed.

PROCEDURES AND IMPLEMENTATION PHASE

The project utilized a nonexperimental design and was implemented from November 15, 2021, through January 20, 2022. All providers were invited to attend a 30-minute PowerPoint presentation about the project and its workflow. The providers included two physicians, three registered nurses, two office coordinators, and two nurse practitioners. Every 2 weeks, there was an educational booster session that allowed providers to ask additional questions related to the PRO-CTCAE tool, discuss the benefit of the integration of the tool, and identify if there were needed improvements. At the beginning of each patient office visit, the office coordinator provided each patient with the survey while they were in the waiting room. When the survey was completed, it was given to the physician, nurse, or nurse practitioner to review prior to the clinic appointment.

DATA COLLECTION AND INSTRUMENTATION

There were two steps to data collection. First, patients completed a survey that assessed their symptoms. Second, providers completed a questionnaire that evaluated their satisfaction with the PRO-CTCAE survey. A cover letter (see Appendix A online) was attached to the tool for patients. The PRO-CTCAE tool was given to all patients seen in clinic for head and neck cancer between November 15, 2021, through January 20, 2022. The tool consisted of 26 questions taken from the PRO-CTCAE item library, which includes 124 items representing 78 symptomatic toxicities (Appendix A).

An example question was "In the last 7 days, what was the severity of your difficulty swallowing at its worst?" The patients would circle a response of None, Mild, Moderate, Severe, or Very severe. The patient survey took approximately 15 minutes to complete. Written permission from the NIH was not required for the use of this tool. Terms of use were followed, and no questions or response options were altered.

Each provider completed a questionnaire (Appendix B) at the end of the project. The questionnaire consisted of eight items with five-point Likert scale response options. An eight-item questionnaire was used to measure provider satisfaction with the PRO-CTCAE survey. This contained seven items with five-point Likert scale response options ranging from Strongly disagree to Strongly agree (1 = Strongly disagree, 2 = Somewhat disagree, 3 = Disagree, 4 = Agree, 5 = Strongly agree). A score of one to three was regarded as negative, and a score of four to five was regarded as positive. The eighth question was an open-ended question, and providers were encouraged to provide qualitative responses.

For the first aim, an Excel sheet was used to track the total number of in-person patient visits per clinic and the total number of patients who completed the survey. After the 10-week period, a total number of patients in clinic and a total number of completed surveys were tallied. For the second aim, a count of all hydration appointments before the project in a similar 10-week period was collected and compared with a count of all hydration appointments made during the project period. This count included any clinic patient receiving hydration. The chart reviews were identified by Current Procedural Terminology codes that evaluated hydration appointments. For the third aim, a provider survey was given to all nine providers, and the results were recorded.

DATA ANALYSIS

Statistical analysis was conducted using IBM SPSS software. Descriptive statistics for means were used to summarize the data for survey completion rate and for the provider satisfaction questionnaire. A Fisher's exact test was used to compare hydration visits before and after implementation of the survey. The numerator was defined as visits for hydration and the denominator was defined as the total number of visits over the 3-month prior to and during the implementation of the PRO-CTCAE survey.

RESULTS

The surveys had a response rate of 91.2% (323/354) between November 15, 2021, and January 20, 2022, when telehealth visits were omitted. This rate of completion was higher than the goal for the first aim of this project, which was 65%. Of the 31 patients who did not complete the survey, eight patients refused and 23 did not receive it. Patients with telemedicine appointments were excluded as there was no way to provide them the survey prior to the visit.

The demographic characteristics of the sample can be seen in Table 1. The mean age of the patients was 69 years old. A total of 118 patients were surveyed. Of the patients included in this project, 68% were male, and 32% were female. The patients identified as Caucasian (n = 102), African American (n = 7), Asian (n = 5), and other (n = 4). Of the patients surveyed, 59% had a curative intent and 31% had a palliative intent to their treatment. A total of 323 surveys were reviewed as some patients participated in more than one survey.

The second aim was to assess for a change in hydration visits among clinic patients. Collecting this data proved difficult. It was also difficult to differentiate between scheduled hydration visits and emergent ones. Hydration in the pre-survey group was 23.5% (150/637) and in the post-survey group was 38.5% (165/429), a 15% absolute percentage increase (Fisher's exact $p < .001$). Table 2 includes the number of patients receiving hydration before and after the survey.

The third aim was to assess provider satisfaction with using the PRO-CTCAE survey during clinic. All providers who were sent the questionnaire about the PRO-CTCAE responded (n = 9). Provider demographic information was not requested due to the small samples size and identifiability of the providers. The provider questionnaire demonstrated that 89.5% of providers believed the PRO-CTCAE prevented hydration visits and other adverse outcomes. Among providers, the positive response rate was 100% for

Table 1. Demographic Information of Patients Surveyed

Characteristic	No. Curative	No. Palliative	No. Total	% Curative	% Palliative	% Total
Age (years)						
< 50	6	3	9	9%	6%	8%
50–55	4	1	5	6%	2%	4%
56–59	6	4	10	9%	8%	8%
60–65	13	7	20	19%	15%	17%
66–69	14	5	19	20%	10%	16%
70–75	9	7	16	13%	15%	14%
> 75	18	21	39	26%	44%	33%
Total	70	48	118	100%	100%	100%
Mean	69.5					
Gender						
Male	52	28	80	74%	58%	68%
Female	18	20	38	26%	42%	32%
Total	70	48	118	100%	100%	100%
Ethnicity						
Caucasian	61	41	102	87%	85%	86%
African American	3	4	7	4%	8%	6%
Asian	3	2	5	4%	4%	4%
Other	3	1	4	4%	2%	3%
Total	70	48	118	100%	100%	100%

five questions and 88.9% for two questions. The providers found the survey to be extremely convenient and useful during clinic. Table 3 lists results of provider satisfaction using the PRO-CTCAE survey.

DISCUSSION

The project took place during the height of the Omicron phase of the COVID-19 pandemic. Cancer care was impacted by the COVID-19 pandemic (Aapro et al., 2021). Since patients with head and neck cancer are immunocompromised and at higher risk, there were more telehealth visits during the implementation phase than were anticipated. During the pandemic, recommendations were made by experts in head and neck to prioritize urgent and emergency visits and procedures (Kowalski et al., 2020). Integrating the PRO-CTCAE survey into the electronic medical record was not feasible.

There may be several reasons why hydration visits did not decrease during the implementation of the PRO-CTCAE. First, patients may have become more aware of symptoms of dehydration due to completion of the PRO-CTCAE (Aapro et al., 2021; Brzozowska et al., 2019; Rivers et al., 2021). Another reason for this may be related to the COVID-19 pandemic. Patients may have required hydration due to symptoms of COVID-19 and not related to side effects of chemotherapy (Aapro et al., 2021). Lastly, providers may have identified dehydration in more patients due to the use of the PRO-CTCAE. Hydration visits may have helped decrease inpatient admissions and therefore the cost of care, as treatment of dehydration prevented acute kidney injury (Rivers et

Table 2. Number of Patients Receiving Hydration Before and After Survey

	Before PRO-CTCAE (637)	After PRO-CTCAE (429)	Significance
No. of pts receiving hydration	150 (23.5%)	165 (38.5%)	$p < .001$

Table 3. Provider Satisfaction Using the PRO-CTCAE Survey

Provider Survey Item	*n*	Mean
How likely would you be to recommend PRO-CTCAE to a friend or colleague?	9	5
How convenient is PRO-CTCAE to use?	9	5
How useful is PRO-CTCAE?	9	5
To what extent did discussing the information on the PRO-CTCAE prevent additional hydration visits?	9	4.88
To what extent did discussing the information on the PRO-CTCAE prevent other adverse outcomes?	9	4.88
Overall, are you satisfied or dissatisfied with PRO-CTCAE survey?	9	5
To what extent did discussing the information on the PRO-CTCAE make you feel more informed about the needs of your patient?	9	5

Note. 1 = Strongly disagree, 2 = Somewhat disagree, 3 = Disagree, 4 = Agree, 5 = Strongly agree.

al., 2021). While the intent of the implementation of PRO-CTCAE was to decrease hydration visits, the increase in hydration is not a negative outcome. This outcome can be explained by patients having increased interaction with providers, an increase in awareness of patient symptoms by providers, and providers having access to more PROs, allowing them to be more informed about hydration status. Although the aim of this quality improvement project was to decrease hydration visits, this patient population receiving combined chemotherapy and radiation may have had earlier intervention and better outcomes as a result of using the survey. Dehydration sometimes has a varied and vague presentation of symptoms, and this survey may have cued providers to the presence of dehydration and the need for hydration, ultimately benefitting the patient.

Implementing a new workflow can be challenging due to its impact interrupting the current work process (Strachna et al. 2021; Watson et al., 2021). However, after implementing the PRO-CTCAE, providers reported a positive response to implementation. Specifically, all providers found the survey to be convenient and useful. Overall, the PRO-CTCAE helped facilitate visits, which in turn helped provide better, more efficient, and proactive care for patients.

IMPLICATIONS FOR PRACTICE

This project added a new survey to clinic visits for patients with head and neck cancer. This tool allowed patients to describe their symptoms prior to their visit with providers and then this information was discussed during their clinic visit. For sustainability, this survey should be embedded in the visit and added to the electronic medical record (EMR) and be completed prior to each visit. This will allow for its use during telehealth visits as well. Integration into the EMR will also allow patients to complete it electronically and then add it to the provider's note and provide access for patients using telehealth technology. It will eliminate the need for someone to remember to have the paper and then collect it.

This project focused only on head and neck oncology patients. Moving forward, other clinics should implement similar surveys for all patients. Results of this project show it provided a more meaningful interaction for patients and providers by improving the communication of symptoms. The survey allowed the patient to report their symptoms prior to their visit and supported their discussion with the provider. This may have led to more understanding of symptoms and potentially identification of dehydration. While the PRO-CTCAE tool is limited in what one can assess, it allows the provider to ask more questions in areas of concern for the patient. Provider judgment is required to determine which symptoms are of concern and require more robust information from patients.

The PRO-CTCAE survey allowed the patient to report their symptoms prior to discussing them with their provider. Providers were able to expedite symptom management and get information to patients in a timely manner. This project also provided a role for nursing, secretaries, and physicians to be part of a multidisciplinary team working toward patients' symptom management.

CONCLUSION

This project achieved its goals of a high survey completion rate and provider satisfaction. Integrating this survey into the pre-appointment process helped with survey completion. Completion of this survey gave providers more information to discuss with their patients. This led them to identifying areas of concern earlier. Earlier identification of symptoms may have led to the increase in hydration visits. Overall, this project shows the benefit of including PROs in clinic visits for patients with head and neck cancer. Providing a pre-appointment survey assisted in patient care and collaboration among team members in clinic. It provided an efficient and proactive approach to managing patients' symptoms.

Disclosure

The authors have no conflicts of interest to disclose.

References

Aapro, M., Lyman, G. H., Bokemeyer, C., Rapoport, B. L., Mathieson, N.,...Kuderer, N. M. (2021). Supportive care in patients with cancer during the COVID-19 pandemic. *ESMO Open, 6*(1), 100038. https://doi.org/10.1016/j.esmoop.2020.100038

Baker, A. (2001). Crossing the quality chasm: A new health system for the 21st century. *BMJ, 323*, 1192. https://doi.org/10.1136/bmj.323.7322.1192

Basch, E., Deal, A. M., Kris, M. G., Scher, H. I., Hudis, C. A., Sabbatini, P.,...Schrag, D. (2016). Symptom monitoring with patient-reported outcomes during routine cancer treatment: A randomized controlled trial. *Journal of Clinical Oncology, 34*(6), 557–565. https://doi.org/10.1200/JCO.2015.63.0830

Bau, I., Logan, R. A., Dezii, C., Rosof, B., Fernandez, A., Paasche-Orlow, M., & Wong, W. F. (2019). Patient-centered, integrated health care quality measures could improve health literacy, language access, and cultural competence. *NAM Perspectives*. Discussion Paper, National Academy of Medicine, Washington, DC. https://doi.org/10.31478/201902a

Bressan, V., Stevanin, S., Bianchi, M., Aleo, G., Bagnasco, A., & Sasso, L. (2016). The effects of swallowing disorders, dysgeusia, oral mucositis and xerostomia on nutritional status, oral intake and weight loss in head and neck cancer patients: A systematic review. *Cancer Treatment Reviews, 45*, 105–119. https://doi.org/10.1016/j.ctrv.2016.03.006

Brzozowska, A., Mlak, R., Gołębiowski, P., & Małecka-Massalska, T. (2019). Status of hydration assessed by bioelectrical impedance analysis: A valuable predictive factor for radiation-induced oral mucositis in head and neck cancer patients. *Clinical & Translational Oncology, 21*(5), 615–620.

Crowder, S. L., Douglas, K. G., Yanina Pepino, M., Sarma, K. P., & Arthur, A. E. (2018). Nutrition impact symptoms and associated outcomes in post-chemoradiotherapy head and neck cancer survivors: A systematic review. *Journal of Cancer Survivorship: Research and Practice, 12*(4), 479–494. https://doi.org/10.1007/s11764-018-0687-7

Dueck, A. C., Mendoza, T. R., Mitchell, S. A., Reeve, B. B., Castro, K. M., Rogak, L. J.,...Schrag, D. (2015). Validity and reliability of the US National Cancer Institute's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). *JAMA Oncology, 1*(8), 1051–1059. https://doi.org/10.1001/jamaoncol.2015.2639

Greco, E., Simic, T., Ringash, J., Tomlinson, G., Inamoto, Y., & Martino, R. (2018). Dysphagia treatment for patients with head and neck cancer undergoing radiation therapy: A meta-analysis review. *International Journal of Radiation Oncology, Biology, Physics, 101*(2), 421–444. https://doi.org/10.1016/j.ijrobp.2018.01.097

Jensen, R. E., & Snyder, C. F. (2016). PRO-cision medicine: Personalizing patient care using patient-reported outcomes. *Journal of Clinical Oncology, 34*(6), 527–529. https://doi.org/10.1200/JCO.2015.64.9491

Kluetz, P. G., Chingos, D. T., Basch, E. M., & Mitchell, S. A. (2016). Patient-reported outcomes in cancer clinical trials: Measuring symptomatic adverse events with the National Cancer Institute's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). *American Society of Clinical Oncology Educational Book, 36*, 67–73. https://doi.org/10.1200/EDBK_159514

Kowalski, L. P., Sanabria, A., Ridge, J. A., Ng, W. T., de Bree, R., Rinaldo, A.,...Ferlito, A. (2020). COVID-19 pandemic: Effects and evidence-based recommendations for otolaryngology and head and neck surgery practice. *Head & Neck, 42*(6), 1259–1267. https://doi.org/10.1002/hed.26164

National Cancer Institute. (2020). Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). https://healthcaredelivery.cancer.gov/pro-ctcae/

Rivers, C. I., Iovoli, A. J., Chatterjee, U., Hermann, G. M., & Singh, A. K. (2021). Intravenous fluids for pain management in head and neck cancer patients undergoing chemoradiation. *Annals of Translational Medicine, 9*(10), 912. https://doi.org/10.21037/atm-20-3910

Siegel, R. L., Giaquinto, A. N., & Jemal, A. (2024). Cancer statistics, 2024. *CA: A Cancer Journal for Clinicians, 74*(1), 12–49. https://doi.org/10.3322/caac.21820

Smith, A. W., Mitchell, S. A., De Aguiar, C. K., Moy, C., Riley, W. T., Wagster, M. V., & Werner, E. M. (2016). News from the NIH: Person-centered outcomes measurement: NIH-supported measurement systems to evaluate self-assessed health, functional performance, and symptomatic toxicity. *Translational Behavioral Medicine, 6*(3), 470–474. https://doi.org/10.1007/s13142-015-0345-9

Strachna, O., Cohen, M. A., Allison, M. M., Pfister, D. G., Lee, N. Y., Wong, R. J.,...Cracchiolo, J. R. (2021). Case study of the integration of electronic patient-reported outcomes as standard of care in a head and neck oncology practice: Obstacles and opportunities. *Cancer, 127*(3), 359–371. https://doi.org/10.1002/cncr.33272

Trojan, A., Leuthold, N., Thomssen, C., Rody, A., Winder, T., Jakob, A.,...Jackisch, C. (2021). The effect of collaborative reviews of electronic patient-reported outcomes on the congruence of patient- and clinician-reported toxicity in cancer patients receiving systemic therapy: Prospec-

tive, multicenter, observational clinical trial. *Journal of Medical Internet Research, 23*(8), e29271. https://doi.org/10.2196/29271

U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research, U.S. Department of Health and Human Services FDA Center for Biologics Evaluation and Research, & U.S. Department of Health and Human Services FDA Center for Devices and Radiological Health. (2006). Guidance for industry: Patient-reported outcome measures: Use in medical product development to support labeling claims: Draft guidance. *Health and Quality of Life Outcomes, 4*, 79. https://doi.org/10.1186/1477-7525-4-79

Wang, T. Q., Samuel, J. N., Brown, M. C., Vennettilli, A., Solomon, H., Eng, L.,...Howell, D. (2018). Routine surveillance of chemotherapy toxicities in cancer patients using the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). *Oncology and Therapy, 6*(2), 189–201. https://doi.org/10.1007/s40487-018-0065-7

Watson, L., Delure, A., Qi, S., Link, C., Chmielewski, L., Photitai, É., & Smith, L. (2021). Utilizing patient-reported outcome measures (PROMs) in ambulatory oncology in Alberta: Digital reporting at the micro, meso and macro level. *Journal of Patient-Reported Outcomes, 5*(Suppl 2), 97. https://doi.org/10.1186/s41687-021-00373-3

Webster, E. M., Burke, W. M., Ware, H. M., Jones, B. A., Vattakalam, R., Tergas, A. I., Wright, J. D., & Hou, J. Y. (2018). Patient-reported outcomes in evaluation of chemotherapy toxicity in women with gynecologic malignancies: A pilot study. *Gynecologic Oncology, 150*(3), 487–493. https://doi.org/10.1016/j.ygyno.2018.07.008

Wood, W. A., Deal, A. M., Stover, A. M., & Basch, E. (2021). Comparing clinician-assessed and patient-reported performance status for predicting morbidity and mortality in patients with advanced cancer receiving chemotherapy. *JCO Oncology Practice, 17*(2), e111–e118. https://doi.org/10.1200/OP.20.00515

Xiao, C., Polomano, R., & Bruner, D. W. (2013). Comparison between patient-reported and clinician-observed symptoms in oncology. *Cancer Nursing, 36*(6), E1–E16. https://doi.org/10.1097/NCC.0b013e318269040f

View the appendices for this article online by visiting JADPRO.com or via this direct link: https://doi.org/10.6004/jadpro.2024.15.5.2

Appendix A. Symptom Survey

Dear Patients,
We are implementing a quality improvement project into our clinic. Attached you will find a survey about symptom experience. Completion of the survey will be considered consent for use of the information you provide. Our goal is to collect information which will help your providers as they are supporting your experiences with treatment symptoms.
Thank you,
Your Oncology Team

NCI PRO-CTCAE ™ ITEMS
As individuals go through treatment for their cancer, they sometimes experience different symptoms and side effects. For each question, please CIRCLE the one response that best describes your experiences over the past 7 days.

1a. In the last 7 days, what was the SEVERITY of your DRY MOUTH at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

2a. In the last 7 days, what was the SEVERITY of your DIFFICULTY SWALLOWING at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

3a. In the last 7 days, what was the SEVERITY of your MOUTH OR THROAT SORES at their WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

3b. In the last 7 days, how much did MOUTH OR THROAT SORES INTERFERE with your usual or daily activities?

1) Not at all 2) A little bit 3) Somewhat 4) Quite a bit 5) Very much

4a. In the last 7 days, what was the SEVERITY of SKIN CRACKING AT THE CORNERS OF YOUR MOUTH at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

5a. In the last 7 days, did you have any VOICE CHANGES?

1) Yes 2) No

6a. In the last 7 days, what was the SEVERITY of your HOARSE VOICE at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

7a. In the last 7 days, what was the SEVERITY of your PROBLEMS WITH TASTING FOOD OR DRINK at their WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

8a. In the last 7 days, what was the SEVERITY of your DECREASED APPETITE at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

8b. In the last 7 days, how much did DECREASED APPETITE INTERFERE with your usual or daily activities?

1) Not at all 2) A little bit 3) Somewhat 4) Quite a bit 5) Very much

9a. In the last 7 days, how OFTEN did you have NAUSEA?

1) Never 2) Rarely 3) Occasionally 4) Frequently 5) Almost constantly

9b. In the last 7 days, what was the SEVERITY of your NAUSEA at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

10a. In the last 7 days, how OFTEN did you have VOMITING?

1) Never 2) Rarely 3) Occasionally 4) Frequently 5) Almost constantly

10b. In the last 7 days, what was the SEVERITY of your VOMITING at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

11a. In the last 7 days, what was the SEVERITY of your CONSTIPATION at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

12a. In the last 7 days, how OFTEN did you have LOOSE OR WATERY STOOLS (DIARRHEA)?

1) Never 2) Rarely 3) Occasionally 4) Frequently 5) Almost constantly

Appendix A. Symptom Survey (cont.)

13a. In the last 7 days, how OFTEN did you have PAIN IN THE ABDOMEN (BELLY AREA)?

1) Never 2) Rarely 3) Occasionally 4) Frequently 5) Almost constantly

13b. In the last 7 days, what was the SEVERITY of your PAIN IN THE ABDOMEN (BELLY AREA) at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

13c. In the last 7 days, how much did PAIN IN THE ABDOMEN (BELLY AREA) INTERFERE with your usual or daily activities?

1) Not at all 2) A little bit 3) Somewhat 4) Quite a bit 5) Very much

14a. In the last 7 days, what was the SEVERITY of your COUGH at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

14b. In the last 7 days, how much did COUGH INTERFERE with your usual or daily activities?

1) Not at all 2) A little bit 3) Somewhat 4) Quite a bit 5) Very much

15a. In the last 7 days, how OFTEN did you have ARM OR LEG SWELLING?

1) Never 2) Rarely 3) Occasionally 4) Frequently 5) Almost constantly

15b. In the last 7 days, what was the SEVERITY of your ARM OR LEG SWELLING at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

15c. In the last 7 days, how much did ARM OR LEG SWELLING INTERFERE with your usual or daily activities?

1) Not at all 2) A little bit 3) Somewhat 4) Quite a bit 5) Very much

16a. In the last 7 days, what was the SEVERITY of your FATIGUE, TIREDNESS, OR LACK OF ENERGY at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

16b. In the last 7 days, how much did FATIGUE, TIREDNESS, OR LACK OF ENERGY INTERFERE with your usual or daily activities?

1) Not at all 2) A little bit 3) Somewhat 4) Quite a bit 5) Very much

17. Do you have any other symptoms that you wish to report?

17a. In the last 7 days, what was the SEVERITY of this symptom at its WORST?

1) None 2) Mild 3) Moderate 4) Severe 5) Very severe

Appendix B. Provider Survey

1. How likely would you be to recommend PRO-CTCAE to a friend or colleague?
A. Highly recommends
B. Recommends
C. Somewhat recommends
D Probably recommends
E. Not recommend at all

2. How convenient is PRO-CTCAE survey to use?
A. Extremely convenient
B. Very convenient
C. Somewhat convenient
D Not very convenient
E. Not at all convenient

3. How useful is PRO-CTCAE survey in clinic?
A. Extremely useful
B. Very useful
C. Somewhat useful
D Not very useful
E. Not at all useful

4. To what extent did discussing the information on the PRO-CTCAE prevent additional hydration visits?
A. To a very great extent
B. To a great extent
C. To some extent
D. To very little extent
E. No extent at all

5. To what extent did discussing the information on the PRO-CTCAE prevent other adverse outcomes?
A. To a very great extent
B. To a great extent
C. To some extent
D. To very little extent
E. No extent at all

6. Overall, are you satisfied or dissatisfied with PRO-CTCAE survey?
A. Very satisfied
B. Moderately satisfied
C. Neither satisfied nor dissatisfied
D Moderately dissatisfied
E. Very dissatisfied

7. To what extent did discussing the information on the PRO-CTCAE make you feel more informed about the needs of your patient?
A. To a very great extent
B. To a great extent
C. To some extent
D. To very little extent
E. No extent at all

8. Is there anything else you want to share about using the PRO-CTCAE in your practice?