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Assessing Chemotherapy Induced Nausea and Vomiting (CINV) management and guideline awareness by pediatric oncology providers at NYP- Columbia Morgan Stanley Children's Hospital

Abbreviated Title: CINV Management at NYP-MSCH

A. Study Purpose and Rationale

Chemotherapy- induced nausea and vomiting (CINV) is common in children undergoing cancer treatment, and is a source of significant morbidity that greatly affects quality of life (Sommariva et al. 2016). The Pediatric Oncology Group of Ontario (POGO) has established, and Children's Oncology Group (COG) has endorsed, guidelines for medication regimens to help prevent these symptoms, as well as guidance for treating anticipatory and breakthrough CINV, based on emetogenicity of different chemotherapy regimens (Dupuis et al. 2009, Patel et al. 2017). Yet, this information is not always utilized to treat patients. A survey of COG sites showed great differences in CINV prophylaxis between sites, not always consistent with current COG-endorsed guidelines (Patel et al. 2016). The same was true for a study of patients in Canadian hospitals following the same guidelines (McKinnon et al. 2018). A retrospective study at this intuition, CUIMC, of 180 pediatric, adolescent, and young adult patients undergoing chemotherapy found that just 36% received guideline- concordant CINV prophylaxis (Beauchemin et al. 2020).

Few studies have examined patient perception of CINV control, a metric that should be an important point for providers as it is one of the highest morbidity's suffered by patients with cancer. This study seeks to identify knowledge gaps of provider treatment of CINV, and use these gaps to create educational interventions and areas of improvement for CINV symptom management, with the ultimate goal of improving patient perception of CINV. This will be achieved by 1) investigating NYP-MSCH pediatric oncology provider awareness of antiemetic prophylaxis consensus guidelines 2) gauge how effectively pediatric oncology patients and providers perceive CINV symptom control and 3) ultimately use this information to identify areas where future education may be directed.

It is predicted that knowledge of guidelines will be highest in attending providers and lowest in resident providers; that provider perception of CINV symptom control will be greater than that of patients; that education and addition of symptom reporting to EMR will be preferred.

B. Study Design

This observational study will prospectively survey pediatric oncology providers and patients/ families longitudinally. Needs assessments will be conducted over a three-six month time period. Pediatric oncology providers (including attendings, fellows, residents, nurse practitioners, and nurses) that care for pediatric oncology patients admitted in the inpatient setting for scheduled chemotherapy will be surveyed via an anonymous electronic survey about knowledge

surrounding antiemetic prophylaxis consensus guidelines, perception of CINV control in their patients, and resources that are utilized. Pediatric oncology patients who are admitted to NYP-MSCH for scheduled inpatient chemotherapy will be surveyed via a paper survey towards the end of their admission regarding nausea and vomiting symptoms during that admission and the medical team's involvement.

C. Study Subjects
Target enrollment: pediatric oncology patients- 50
Target enrollment pediatric oncology providers- 50

D. Recruitment of Subjects
All pediatric hematology/oncology providers who interact with the care of inpatient pediatric oncology patients (attendings, fellows, residents, nurse practitioners, nurses) will be sent an electronic survey with a request to voluntarily participate. These providers are within the department of pediatrics - section of hematology/oncology, or employed by NYP-MSCH.

The study team will utilize lists of patients admitted for scheduled inpatient chemotherapy that are compiled by the pediatric oncology department to identify eligible pediatric participants. The medical record will be utilized to view these patient lists. Survey participation will be requested by a study team member who does not oversee any providers of that type to prevent undue coercion or influence. All patients admitted for scheduled chemotherapy at NYP-MSCH will be asked for permission for the study team to approach the patient by a member of the treatment team. If the patient/family agrees, a member of the study team will describe the study and provide an information sheet detailing study procedures, risks, and benefits of participation to obtain informed consent to participate by completing a paper survey around the day prior to discharge.

E. Study Procedure
Provider needs assessment: electronic, secure survey of pediatric oncology providers (attending, fellow, resident, nurse practitioners, and nurses) about knowledge surrounding antiemetic prophylaxis consensus guidelines, perception of CINV control, and resources. Goal cohort number will be 50% of each group via electronic survey that is not linked to the individual. Survey will be administered over email and request voluntary participation. No personally identifiable information will be collected.

Patient needs assessment: the study team will recruit pediatric oncology patients admitted for scheduled inpatient chemotherapy to participate in survey about nausea/vomiting symptoms, with permission to approach patient obtained by their treatment team. On average, 5 patients are admitted for scheduled chemotherapy each week. Existing departmental lists of patients being admitted for scheduled chemotherapy each week will be used to identify potential participants. These lists contain patient name, MRN, and diagnosis and are collated each week by the pediatric oncology department. The survey will occur over a 3-6 month period with the goal of obtaining 50 individual surveys. The study team will approach patients admitted for scheduled chemotherapy around the day prior to discharge and provide study information sheet to obtain informed consent. The information sheet will describe the study aims and risks/benefits to self or patient, a concise and focused presentation of key information about the study, and present information in sufficient detail to obtain informed consent. Subjects will have an opportunity to

discuss the information provided with the study team. If patient or parent consents to participation, paper survey will be provided that is linked to patient by study ID number only. The survey will be completed by patient, or by parent if patient is too young or unable to participate. Survey can be completed on paper or verbally completed by survey administrator. Survey will collect no personally identifiable information. Surveys and study information sheets will be available in both English and in Spanish. Survey team will access medical records to obtain the following information: patient age during admission, demographic data, cancer diagnosis, chemotherapies received during admission, antiemetics given during admission, charting of nausea/emesis events.

F. Study Questionnaires
Qualtrics survey to be distributed via email to providers containing Likert scale, multiple choice, and free response questions related to knowledge surrounding antiemetic prophylaxis consensus guidelines, perception of CINV control, and resources.

Paper survey to be distributed in person to patients containing Likert scale and multiple choice questions related to nausea/ vomiting symptoms and management.

G. Statistical Procedures
Provider and patient perception will be separately assessed using Likert scales and reported using means and T tests to evaluate the perception of CINV control. Chi square analysis will be performed amongst providers and patients, those well controlled and those not, to evaluate for a gap in perceptions. Predictors of patient perception (demographics, antiemetics, chemotherapy) and of provider perception (role, years of practice, resources) will be compared using chi-square analysis. Data regarding provider awareness of CINV guidelines and avenues for improvement will be reported as frequencies and percentages to evaluate paths for intervention.

H. Study Drugs
No study drugs, approved or investigational, will be used in this study.

I. Medical Devices
No medical devices will be used in this study.

J. Location of Study
New York Presbyterian Hospital at Columbia- Morgan Stanley Children's Hospital

K. Confidentiality
Confidentiality will be ensured by not collecting any sensitive data. Data from provider survey will be conducted via Qualtrics and stored on a secure endpoint with voluntary participation. Data from patient paper survey will be coded by study ID number and stored in a password protected excel spreadsheet on an encrypted and password protected laptop. The data will not be stored with direct identifiers included, only study ID number. The document linking study ID to patient name and personal health information will be stored in a password protected document accessible only to study team and maintained on an encrypted and password protected laptop. Data will be destroyed after completion of data collection, analysis, and dissemination.

L. Potential Risks

Participants will fill out a survey that will take no more than 10 minutes to complete. The survey will include no personal identifiable information.

M. Potential Benefits
There will be no benefit to individuals participating in the study. The survey of providers will identify knowledge gaps in management of chemotherapy induced nausea and vomiting, which may provide an opportunity for education in the future. The survey of patient symptoms will provide information for the pediatric oncology department on the patient experience of chemotherapy induced nausea and vomiting, and may identify possible areas for improvement. Evaluating the gaps in management of these symptoms may provide a benefit to pediatric oncology providers to provide optimal patient care.

N. Minors as Research Subjects
Child or parent/guardian will voluntarily complete brief survey with no impact on clinical care.

O. Potential Conflict of Interest
There are no potential conflicts of interest for any of the study investigators.

P. Alternative Therapies
There will be no therapies offered through this study.

Q. Compensation to Subjects
There will be no compensation to study subjects.

R. Costs to Subjects
The only cost to study subjects will be their time; approximately 10 minutes for all subjects to complete their surveys.

S. Radiation or Radioactive Substances
There will be no radiation or radioactive substances used in the study.

T. References
Beauchemin M, Sung L, Hershman DL, Weng C, Dupuis LL, Schnall R. Guideline concordant care for prevention of acute chemotherapy-induced nausea and vomiting in children, adolescents, and young adults. *Support Care Cancer*. 2020;28(10):4761-4769. doi:10.1007/s00520-020-05310-6

Dupuis LL, Boodhan S, Sung L, Portwine C, Hain R, McCarthy P, and Holdsworth M. Guideline for the classification of the acute emetogenic potential of antineoplastic medication in pediatric cancer patients. Pediatric Oncology Group of Ontario; Toronto. 2009.

McKinnon, K, Jupp, J, Ghosh, S, Digout, C, Eason, S, Romanick, M. Adherence to pediatric acute chemotherapy-induced nausea and vomiting guidelines in Canadian hospitals. *Pediatr Blood Cancer*. 2019; 66:e27488. https://doi.org/10.1002/pbc.27488

Patel, P., Robinson, P.D., Orsey, A., Freedman, J.L., Langevin, A.-M., Woods, D., Sung, L. and Dupuis, L.L. (2016), Chemotherapy-Induced Nausea and Vomiting Prophylaxis: Practice Within

the Children's Oncology Group. Pediatr Blood Cancer, 63: 887-892. https://doi.org/10.1002/pbc.25915

Patel P, Robinson PD, Thackray J, et al. Guideline for the prevention of acute chemotherapy-induced nausea and vomiting in pediatric cancer patients: a focused update. *Pediatr Blood Cancer*. 2017;64:e26542. https://doi.org/10.1002/pbc.26542

Sommariva S, Pongiglione B, Tarricone R. Impact of chemotherapy-induced nausea and vomiting on health-related quality of life and resource utilization: A systematic review. *Crit Rev Oncol Hematol*. 2016;99:13-36. doi:10.1016/j.critrevonc.2015.12.001