HUM00136852

Frequently Asked Questions #1
January 2018

Aim 2

What is the purpose of the OCTET study?

The purpose of the Oncology Communication, Technology, and EvenTs (OCTET) study is to examine how ambulatory chemotherapy infusion sites' communication processes and communication technologies influence safe chemotherapy administration. The study has 3 specific aims, each taking approximately 1 year to complete.

What does Aim 2 of the study involve?

In Aim 2, we will conduct exploratory observational research to delve deeper into technology and communication usage and how variation in clinician communication processes and technologies affect chemotherapy delivery. In Aim 3, we will discuss with oncology clinicians' findings from Aims 1 and 2 and identify ways to implement practice improvements. Details on the Aim 3 selection process and clinic responsibilities will be provided in future FAQs sheets.

Why was my site chosen to participate in Aim 2?

We are looking for a range of practices based on their differing use of technology, communication levels and adverse events identified in Aim 1.

What does the Aim 2 observational research involve?

Aim 2 data collection will last approximately 1 business week per site. A researcher trained in qualitative methods from the OCTET study will be on site in your practice. There will be 3 data collection activities: 1) general observation, 2) clinician shadowing and 3) patient interviews. General observation of the infusion area will be conducted first, followed by clinician shadowing and patient interviews for the remainder of the week. During general observation, the researcher will observe the practice as a whole to document how clinicians communicate with each other and interact with communication technology. The observer will shadow clinicians to understand workflow and their roles. Examples of what the researcher will observe include the communication between prescribers (MDs, PAs, NPs) and nurses, and how technology is used in the delivery of chemotherapy. Patients who agree will be interviewed for 10-15 minutes while they wait for their treatments. Ideally, these interviews would be conducted in a room or space that is quiet and not distracting to the patient. Up to 3 infusion RNs and 3 prescribers will be shadowed and 20 patients interviewed at each site.

How will data will be collected?

Our researcher will document observations as field notes on paper. These field notes are broad in nature and will focus on actions and processes around communication technologies, such as chart documentation and medication orders. Patient interviews will be audio recorded to ensure full data capture. Once transcribed, the audio tapes will be destroyed.

What does my practice need to do?

We request three things from participating practices. First, we will need your help in introducing this next stage of research and our researcher to your clinicians and patients. Our researcher will handle all recruiting and consenting of participants. Second, for patient interviews, we will need a quiet space to protect privacy and confidentiality. Third, we will also request copies of policies/procedures related to chemotherapy delivery to provide context for data analysis.

Will my institution's Institutional Review Board (IRB) need to approve this study?
The study has been approved by University of Michigan's IRB for Health Science and Behavioral Science (HUM00136852) and all clinics have been determined to be "not engaged" in the research as the OCTET team will be conducting all research activities. According to the HHS Common Rule, this means that individual institutions do not have to approve the study. We suggest that you consult with your IRB to determine how they would like to proceed given your non-engaged status.

What if the researcher shadows my practice at an inconvenient time?
We are very committed to collecting data efficiently and avoiding disruption to the clinic. If at any time during data collection the researcher is in the way, clinicians can feel free to tell the researcher to leave the area and come back later. No reason is required for requesting they leave.

How will the study protect private and/or confidential information?
We take security of the data and confidentiality of participants very seriously. No identifying information will be collected from clinicians and patients. All data will be collected in a manner so it will not be possible to link a specific individual to their observation responses. Participants will be referred to using titles only such as Nurse #1 or Prescriber #2. The researcher will use a standardized script to consent participants (patients and clinicians) orally.

Will my clinic be reimbursed for study participation?
We will reimburse clinics and clinicians for their participation in our study. In Aim 2, sites will receive a $3,000 honorarium, and each clinician who participates will receive a $50 gift card. Additionally, patients will be given $10 cash for their participation if clinic rules allow.

When will Aim 2 data collection occur?
Data (observation in clinics and brief interviews with patients) will be collected during December 2017 to September 2018.

What are the benefits of participating in Aim 2?
The evidence-based practice recommendations resulting from the study will be based on your clinic's data and can be used to support quality improvement efforts and minimize risks to patients. Other benefits include:

- You will learn about communication practices between nurses and physicians/advance practice providers, and how these relate to the care your patients receive.
- You will receive a set of evidence-based practice recommendations to support quality improvement efforts and minimize risks to patients.

Why is MOQC involved?
Dr. Griggs, the Program Director of MOQC, is a Co-Investigator of the study, and we are building on MOQC infrastructure to help recruit participants into the study. Grant money from the Agency for Healthcare Research and Quality (AHRQ) is covering all MOQC efforts on behalf of the study. Therefore, no funds from the Blue Cross/ Blue Shield of Michigan will be used to support the study.

Whom should I contact with questions?
You can contact the Principal Investigator, Dr. Friese, or the Project Coordinator, Kari Mendelsohn-Victor, at octet-study@umich.edu or (734) 615-4017.