

1. TITLE PAGE

Title of Project: Communication Processes, Technology, and Patient Safety in Ambulatory Oncology Settings

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2. STRUCTURED ABSTRACT

Purpose: To understand variation in clinician communication processes, technology use, and patient outcomes and to assess barriers and facilitators to safe chemotherapy delivery.

Scope: Cancer care delivery occurs principally in ambulatory settings, yet sparse information is available on quality and safety, including formal assessments of technology use and communication strategies to manage adults receiving high-risk chemotherapy treatments.

Methods: We used a mixed-methods design (surveys, field observation, and interviews, followed by focus groups) with a statewide oncology quality improvement collaborative to solicit patient and clinician perspectives on technology use, communication strategies, and outcomes for patients with cancer undergoing chemotherapy treatment. Patient surveys captured toxicities and healthcare service use associated with chemotherapy treatment. Prescriber and nurse surveys captured technology use, communication strategies, and safety perceptions.

Results: Survey data were collected from 2,245 patients, 113 prescribers, and 184 nurses from 29 practices. Higher satisfaction with technology and higher-quality clinician communication were associated with increased safety actions, whereas increased reliance on all-digital records was associated with lower safety actions. Treatment delays were attributed to care plan discrepancies and missing orders, uncommunicated day-of-treatment order changes, orders not signed in advance by physicians, and laboratory testing processes. Patient toxicity rates varied across practices. Toxicity severity and service use incidence exceed previously published trial data, particularly for pain, fatigue, and gastrointestinal issues.

Keywords: Ambulatory care, cancer, patient safety

3. PURPOSE

The purpose of this study is to characterize clinician communication processes, communication technologies, and adverse patient events in a sample of ambulatory chemotherapy practices and to examine how communication practices and technologies influence safe chemotherapy administration.

Specific aims were to:

- 1. Characterize clinician communication processes, communication technologies, and adverse patient events.** We surveyed clinicians across 29 diverse practices in Michigan to assess their communication processes and use of technologies. We correlated these measures with perceptions of patient safety practices. We also surveyed patients in these practices to solicit patient-reported toxicities and related healthcare service use.
- 2. Examine how variations in clinician communication processes and communication technologies affect chemotherapy practice.** We selected a purposive sample of eight practices with a diverse range of communication processes (e.g., face-to-face clinician discussion) and technologies (e.g., real-time messaging). Through observation, clinician shadowing, and patient interviews, we explored how communication processes and technologies influenced the adverse patient events (chemotherapy delay, ED visits/admissions for acute reactions, ED visits for toxicity), focusing on human and healthcare system factors.
- 3. Assess barriers and facilitators to safe chemotherapy delivery.** We disseminated data from aims 1 and 2 to clinical leaders, who were asked to identify barriers and facilitators to safe chemotherapy delivery, so we can develop practice-level interventions for future testing.

4. SCOPE

Background

An estimated 23 million adult visits occur annually for chemotherapy in the United States; 19 million (84%) are in ambulatory settings. Diverse in scope and oversight, ambulatory oncology practices include those embedded in hospital and health systems, freestanding practices, private solo or group practice practices, and variations therein.

There is no consistent regulatory framework for these practices; few are surveyed by the Joint Commission. The American College of Surgeons Cancer Program recognizes only hospital-based cancer programs, ignoring practices outside of hospitals. Apart from a Centers for Medicare and Medicaid Services statement that a physician, nurse practitioner, or physician assistant's presence is required during chemotherapy administration, there are few explicit federal regulations to monitor chemotherapy safety. To address this gap, the Oncology Nursing Society and the American Society of Clinical Oncology (ASCO) jointly issued safety standards for ambulatory chemotherapy administration. We do not know the adoption rate of these standards, and approximately 300 practices nationally (out of thousands) participate in a voluntary, fee-based certification process by ASCO's Quality Oncology Practice Initiative. This fragmented care delivery system results in potentially suboptimal care and, perhaps more important, the absence of critical data to assess patient-centered quality of care measures. Poor communication between physicians and nurses is a common cause of adverse events for hospitalized patients and a major root cause of all sentinel events, consistently ranking #2 or #3 year after year.

Poor communication between physicians and nurses threatens patient safety through several mechanisms. First, the hierarchical nature or authority gradient of the relationship between nurses and physicians possibly impedes communication and contributes to suboptimal care. Nurses may feel unable to overcome the hierarchical difference and greater authority of physicians, remaining silent regarding issues about which they actually have a great deal of knowledge. Nurses' silence contributes to suboptimal care, because nurses withhold crucial information that could impact patient care. Second, nurses and physicians come from disciplines with distinct knowledge bases gained through training in separate spheres and paradigms. Unless communication is used to bridge disciplinary differences in knowledge, patient safety may be compromised. Nurses and physicians, studied together and separately, consistently provide differing perceptions about their communications. In one study, residents did not share with nurses the same goals for communication, viewing communication as a way to give orders to nurses; few physicians expanded their notion of communication to consider nurses as partners in identifying problems and treatment options, which is what nurses prefer. In another study, nurses and physicians did not agree on what constituted an urgent message, prioritizing and responding to messages differently than the sender intended, creating an obvious risk to patient safety. When physicians do not engage in discussions with other healthcare disciplines, they are more likely to make risky patient care decisions based on incomplete information.

Health information technology (HIT) refers to a broad range of electronic tools used in healthcare, including electronic health records (EHR) and information and communication technologies (ICT). We define ICT as information technologies that, although not designed to be used primarily as communication tools, support interdisciplinary communication (e.g., physician and nurse progress notes; computerized provider order entry/management) as well as specific electronic communication technologies, such as pagers, email, and real-time messaging.

In this study, we had the opportunity to observe how physicians and nurses use media arising from the deployment of HIT and its overlapping subsets, EHR and ICT as well as traditional media (i.e., face to face, telephone, paper and pen), in communicating with each other. There have been mounting concerns that immature technology designs and/or inappropriate use of technologies could cause harm to patients. The current generation of HIT provides little cognitive support for collaboration. Furthermore, HIT enhances but also may disrupt standard modes of communication. Established communication practices can change when organizations move from a paper-based to electronic patient record keeping system, because the content and patterns of communication are altered. Conducting communication exchanges electronically can create ambiguity and reduce flexibility.

Context

Adverse patient events in ambulatory oncology settings are a critically important public health matter because of the high volume of treatments administered and the high index of treatment toxicity. It is surprising how little we know about variations in adverse event rates in these settings. Lack of progress in this area relates to four key barriers: 1) We have sparse data to inform us on the frequency of adverse events. 2) We have virtually no information about the potentially enormous variation in these practices. 3) Communication processes and use of technologies are diffuse and varied. 4) We have had few opportunities to address these gaps due to limited or obsolete data. Our study addressed three aspects of the Agency for Healthcare Research and Quality's stated mission; our study generated necessary data to improve the quality, safety, and efficiency of ambulatory oncology care.

Settings

The study setting includes ambulatory oncology practices that belong to the Michigan Oncology Quality Consortium (MOQC). MOQC is an alliance of ambulatory oncology practices formed with the purpose of sharing and benchmarking their data to improve the quality of oncology care. As we were interested in targeting ambulatory oncology practices throughout the state of Michigan, we partnered with MOQC, which currently has 52 affiliated practices all over Michigan.

Participants

Two groups of participants were included: patients and clinicians.

Patients were eligible to participate in the survey if they were diagnosed with stage I-III invasive cancer and planned to receive systemic chemotherapy. Patients either spoke or read English or had a nonclinician proxy available to assist with survey completion.

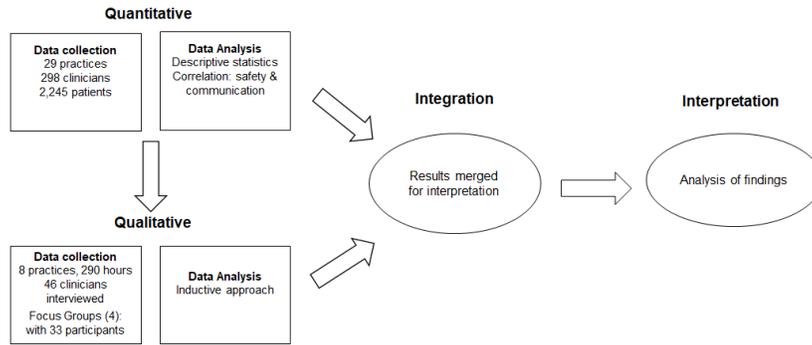
Clinician participants were employed at the ambulatory practices and included registered nurses, physicians, and advanced practice providers (i.e., physician assistants, nurse practitioners). For interviews, the sample primarily consisted of chemotherapy-certified oncology nurses working in the ambulatory infusion center. Some prescribers (e.g., physicians and advanced practice providers) were not available for interviews due to patient care responsibilities. For the quantitative and qualitative phases, inclusion criteria for clinicians were: practiced at least a 0.5 full-time equivalent in the setting, currently licensed for their position, and completed their orientation. Exclusion criteria included: declined participation, worked for a travel or temporary staffing agency, and/or expressed hesitation in study procedures.

5. METHODS

Study Design

This study employed a mixed-methods design with sequential data collection as a quantitative survey phase followed by a qualitative phase, as shown in Figure 1. We began with a quantitative phase by distributing questionnaires to all prescribers (i.e., physicians, physician assistants, and nurse practitioners) and registered nurses who work

Figure 1. Mixed methods study design.



in a sample of ambulatory oncology practices. In addition, for 6 weeks, site study coordinators completed a one-page daily event log, and patients completed a one-page self-reported symptom questionnaire.

We invited all MOQC-affiliated ambulatory oncology practices to participate in our study. We sought to recruit as many MOQC-affiliated practices as possible, because we were interested in understanding the variation in clinician communication processes, communication technologies, and adverse patient outcomes in ambulatory oncology practices. Of 52 eligible sites, 29 elected to participate in the survey phase.

Participating practices identified employees to serve as study coordinators who were responsible for distributing clinician questionnaires once, completing daily event logs, and distributing self-report questionnaires to patients daily for 6 weeks. Clinician questionnaires were about the usability of and satisfaction with the electronic medical record, communication among clinicians, perceptions of a safety climate, and perceptions of the work environment. The daily event logs summarized clinic activities and events related to chemotherapy (e.g., the number of patients prescheduled and the number of patients who called the clinic for toxicity management). In the patient questionnaires, patients were asked to report symptoms related to their chemotherapy treatment.

Trained research assistants entered patient and clinician surveys into the Research Entry and Data Capture (REDCap) web application. REDCap is a password-protected, user-authenticated, encrypted and firewalled application used to collect and enter sensitive data in compliance with the Health Insurance Portability and Accountability Act. Research assistants double-entered all data, and discrepancies were resolved by the Project Manager.

We then used the survey results to identify eight practices for subsequent exploration via in-depth qualitative methods, and we conducted multimethod qualitative research at the eight selected ambulatory oncology practices. In this phase, researchers spent five weekdays embedded within each practice to conduct observation, shadowing, and interviews with clinicians. M.L., an anthropologist, was at all eight sites and was joined by one or two research team members at four sites, for a total of 290 hours of data collection.

Visiting sites allowed us to gain a holistic, nuanced understanding of chemotherapy delivery processes at each practice.

Observation and Shadowing

We conducted observation in infusion areas, exam rooms, and clinician offices to understand the day-to-day chemotherapy delivery processes and organizational work structures of each practice. This method allowed us to capture verbal and nonverbal communication processes and identify clinician task behaviors. We could compare what we saw with what clinicians told us and were able to bring up any site-specific discussion points during succeeding clinician interviews.

The data collection team also shadowed individual clinicians for several hours at a time to understand their role responsibilities, workflow, and communication practices. For instance, we shadowed physicians as they saw patients and entered orders and progress notes, and we shadowed nurses as they administered treatments (infusion nurses), managed patients (clinic nurses), and conducted patient educational sessions for patients before their first chemotherapy treatment. We gleaned patient perspectives from observations of patient and clinician interactions. During observation and shadowing, we wrote handwritten field notes that, after each day of data collection, were typed into more detailed narrative accounts that we used during data analysis.

Interviews

After several days of observation, we conducted interviews with clinicians, which were digitally recorded. Although most interviews (n = 40) were one on one with individual clinicians, we conducted two small-group interviews with nurses after their shifts to accommodate their schedules. In total, 46 clinicians were interviewed. Interview questions were designed to elicit clinicians' perspectives of communication processes and any barriers and facilitators to providing patient care. During interviews, we asked about specific challenges that we had observed at that practice and asked for possible solutions to help improve patient care delivery.

Focus groups

After the eight site visits, we held focus groups with clinicians and clinical leaders from practices that participate in the same statewide consortium. By speaking with clinicians and clinical leaders who work at six additional practices, we were able to see if the challenges we identified—such as delays of care—resonated beyond our sample of the eight visited sites. We held four focus groups at two practices across the state and two focus groups at a scheduled professional meeting. Participants included seven prescribers (six physicians, one nurse practitioner), 18 nurses (12 infusion, three triage, three clinic), and eight practice administrators.

The Institutional Review Board of the University of Michigan deemed the quantitative phase exempt from review and approved the subsequent qualitative phases.

Interventions

This study was descriptive in nature and had no interventions.

Measures

Patient Survey Measures. In addition to gender, race, and ethnicity, patients completed 11 items from the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). The PRO-CTCAE was developed by the National Cancer Institute, which houses an online platform to generate questionnaires. Consistent with the National Cancer Institute's guidance, all PRO-CTCAE items referenced a timeframe for the past 7 days and were rated on a five-point scale across three pertinent domains: frequency, severity, and

interference with daily activities. Patients rated the frequency of their nausea, vomiting, diarrhea, and pain (1 = never, 5 = almost constantly). Patients rated their perceived severity of nausea, vomiting, constipation, peripheral neuropathy, and pain in the past seven days (1 = none, 5 = very severe). Patients rated how much peripheral neuropathy and pain interfered with their usual or daily activities (1 = not at all, 5 = very much). The specific toxicities queried were selected following pilot work that identified the most prevalent and bothersome toxicities experienced across diverse cancer diagnoses. To enable the study team to identify important concerns that may not have been included, patients were invited to write in up to two additional toxicities that had bothered them in the past 7 days and to rate the severity of these toxicities on a five-point Likert scale (1 = none, 5 = very severe).

Finally, using previously developed measures, patients reported whether they required additional healthcare services for a toxicity they experienced in the past 7 days or whether they needed healthcare services to manage a drug infusion-related reaction. Examples include a hypersensitivity reaction to paclitaxel or a febrile reaction to rituximab. Patients also indicated whether they needed to seek care outside of the ambulatory oncology practice, either in an emergency department or through inpatient admission.

Clinician Survey Measures. Our primary clinician outcome of interest was safety, specifically actions consistent with a safety culture. This was measured using the Safety Organizing Scale (SOS). The SOS is a reliable ($\alpha = 0.88$), nine-item scale for clinicians to self-report the actual performance of behaviors theorized to support a safety culture in healthcare settings. For each item, clinicians are asked the degree to which they and their colleagues engage in the behavior or practice (e.g., "We talk about mistakes and ways to learn from them"). Items are scored on a seven-point Likert scale (1 = not at all to 7 = to a very great extent) and summed, with higher scores indicating greater actions consistent with a safety culture.

Quality of overall clinician communication was measured through a version of the Nurse-Physician Communication Questionnaire ($\alpha = 0.92$), which was adapted for our study setting with the developer's permission. Four aspects of communication are expressed in four subscales: timeliness, understanding, accuracy, and openness of communication. Clinicians rated 21 items on a five-point Likert scale (1 = strongly disagree to 5 = strongly agree). A final item rated their overall satisfaction with clinician-to-clinician communication on a five-point Likert scale (1 = very dissatisfied to 5 = very satisfied). Each of the four subscales was averaged, and then all four were summed together to form one overall nurse/prescriber communication score, with higher scores indicating higher quality of clinician communication.

Clinicians' communication satisfaction with clinic technology was measured through a single item adapted from Venkatesh et al. (2003), measured on a five-point Likert scale (1 = very dissatisfied to 5 = very satisfied): "How satisfied are you with the technology available for communication with other clinicians?" Higher scores indicated greater communication satisfaction with clinic technology.

Electronic health record capability was measured at the practice level and was defined as the extent to which a practice's documentation practices are electronic. Two different measures were used in the study. First, we had a dichotomous measure of whether the practice had an entirely electronic health record or had either an all-paper or a hybrid health record. For the second measure, each practice also provided information to the study team on whether the following five elements of a practice's documentation system were electronic or paper based: any portion of their record captured electronically, electronic chemotherapy orders, electronic documentation of chemotherapy administration, electronic system to document communication

with patients/families, and electronic system to document communication among clinicians in the practice. This second measure was a scale reflecting whether five elements of their record were nonelectronic (0 points) or partially or fully electronic (1 point). The score was summed, and practices were distributed from 0 = no elements electronic to 5 = all elements electronic.

All clinicians reported their sex, race, ethnicity, age, years in practice, and years employed in their current setting. Through daily practice event logs and a practice characteristics questionnaire collected by onsite study coordinators, we also ascertained patient volume during the 1-month survey data collection period, practice ownership, and rural versus urban location.

Limitations

Because the project examined an array of patient and clinician-reported measures, granular details on patients—including cancer stage, cancer drugs received, and comorbid conditions—were not collected. The project highlighted an efficient strategy to collect experience data from a large sample of patients across multiple practices. However, the heterogeneity of health records across consortium practices and human subjects challenges precluded detailed chart abstraction and, thus, risk adjustment of patient-reported outcomes. Subsequent investigators may overcome these challenges as health record interoperability and human subjects flexibilities increase. Data were cross-sectional; therefore, the true direction of association between some variables may not be easily discerned. Survey measures of clinician communication and satisfaction with technology were not specific to electronic health records. Objective safety measures were not available across all practices.

Despite a large sample of practices and patients, all participating practices belonged to a statewide quality improvement consortium. Therefore, the sample may not reflect the diversity of medical oncology practices across the United States.

6. RESULTS

Principal Findings

We summarize key findings below. Please note that additional details are available in the published papers that we have provided previously to the Agency for Healthcare Research and Quality. Visual abstracts are shown at the end of the Results section.

1. Relationships among technology use, communication, and patient safety

Fifty-nine percent of clinicians reported that they were satisfied with the available technology in their clinic, and 75% reported high-quality clinician-to-clinician communication.

Significant differences were observed between registered nurses and prescribers in terms of safety scores, with registered nurses reporting higher use of behaviors consistent with a safety culture compared with prescribers (5.4 vs. 5.1, $p < .04$). Significant differences were also evident between prescribers' and nurses' reports of communication satisfaction with practice technology (68% vs. 54%, $p < .03$) and quality of communication with other clinicians (88% vs. 68%, $p < .0001$), with prescribers reporting more favorably on both measures compared with nurses. In this unadjusted analysis, differences were evident between practices that used all electronic systems versus both electronic systems and paper in terms of communication satisfaction with technology (42% vs. 69%, $p < .0001$).

In a linear regression model examining factors associated with actions consistent with a safety culture and adjusted for clinician age, higher communication satisfaction with technology ($p < .001$) and more favorable clinician communication ($p < .001$) were significantly associated with

increased safety scores. Conversely, increased EHR capability was associated with lower safety scores ($p < .001$). Prescribers reported lower safety scores compared with nurses ($p < .001$).

2. Patient-reported outcomes among adults treated in ambulatory oncology settings

Of 3,565 patients identified as eligible respondents by practice study champions, 2,245 individuals (63%) completed surveys. Relative to other racial categories, a higher proportion of American Indian/Alaska Native patients reported at least one toxicity as severe or very severe ($\chi^2 = 28.4$ (DF), $p < .001$). No other significant differences in toxicity reporting by patient characteristics were observed.

Pain frequency had the highest mean score, reflecting higher patient burden. Over one in five participants reported the frequency of pain at a level of grade 3 (severe) or 4 (very severe). Pain severity was the next most frequently reported toxicity to be assessed as severe or very severe (13% of respondents), followed by diarrhea frequency (10% of respondents).

Of all respondents, 156 (7%) reported that one of their toxicities required management via unplanned healthcare service use. Of these, 41 (26%) received treatment in an emergency department, and 32 (21%) were admitted to the hospital for toxicity management. These findings were similar for the management of a drug infusion-related reaction: 132 (6%) experienced a drug infusion-related reaction, 21 (16%) required emergency department care, and 20 (15%) were hospitalized.

After thematic analyses and reliability assessment were completed on the 1,653 open-text comments received, study staff collapsed comments into 737 discrete toxicity reports (in some cases, patients reported similar toxicities in both questions). The overall mean (SD) severity of open-text toxicity reports was 3.1. The most frequently open-text toxicity reported was fatigue, followed by general stomach discomfort (distinct from nausea, vomiting, diarrhea, and constipation) and skin or nail changes. Most patients who wrote in fatigue (81%) rated it as severe/very severe.

As an incentive, participating practices received dashboards with site-specific patient data in addition to the data obtained across all 29 practices. Study team members reviewed the dashboard data with individual practices upon request and presented the data at a scheduled biannual meeting of the entire quality consortium. At this meeting, oncology clinicians and practice leaders reviewed the data and posited strategies for subsequent quality improvement efforts.

3. Qualitative Findings on Delays in Chemotherapy Care

Through our analysis, we identified four themes that led to chemotherapy treatment delays throughout the practices in our study: discrepancies in care plans and missing orders for uncoupled visits, undocumented and uncommunicated day-of-treatment order changes, orders not signed in advance by physicians, and laboratory testing processes. The delays we identified occurred at various stages within care processes and stemmed from barriers within organizational structure, communication and coordination, and communication technologies. In addition to describing the challenges sites experienced with treatment delays, we also identified strategies and policies that sites had in place and suggestions from clinicians to reduce delays.

a. Discrepancies in care plan and missing orders for uncoupled visits

When patients came for a chemotherapy infusion on days they did not have an appointment to see their physician (an 'uncoupled' visit), delays occurred if there were discrepancies in the care

plan and the prescribing physician was not onsite to clarify the intended treatment. Often, on-call physicians were hesitant to make treatment decisions for unfamiliar patients when orders, care plans, and progress notes were unclear or undocumented:

“A lot of times [errors occur] because...the provider has dictated something different...discrepancies in what they've communicated is the plan, and if they're not there to ask, we've not known what to do...[We've] sent patients home...that drove a couple of hours, and the on-call provider wasn't willing to make the call because it was not clear what his primary doctor wanted.” (Infusion Nurse)

Care plan discrepancies between the original and on-call physician resulted in patients having their treatments canceled on the same day as their appointments, which led to treatment delays of days or weeks in some circumstances. This was a notable problem at one site, where delays were compounded by the long distances patients traveled to receive treatment. Practices had various strategies in place to identify and address potential delay-causing issues that may arise for patients. Preparation usually entailed looking at the next day's scheduled patients to assess laboratory values and any anticipated problems, to ensure necessary drugs were in stock, and to rectify any errors or discrepancies from orders that were not signed in advance. For practices that experienced frequent delays due to order discrepancies and poor coordination of care, such processes and responsibilities outlined above were not clearly assigned. In some instances, infusion nurses felt it was the responsibility of office/clinic nurses to prepare for patient infusion visits. Despite efforts by an infusion lead nurse to check and 'clean up' orders ahead of scheduled infusion visits, unclear role responsibilities and poor coordination between infusion and clinic led to details falling through the cracks, resulting in delays.

In contrast, practices that were more successful with preventing these types of delays had standardized processes in place and preparation responsibilities that were clearly assigned to specific clinician roles. For instance, in certain practices, it is the clinic nurse's responsibility to ensure that everything is prepared for patients to receive chemotherapy at their appointment time. In other practices, it is the infusion nurses who are responsible for preparing orders and ensuring that the patient will be ready for their infusion visit the next day. Daily huddles were used at several sites to improve coordination between clinic and infusion nurses and to help ensure that patient preparation was handled properly and any issues were addressed.

b. Undocumented and uncommunicated day-of-treatment order changes

When a patient sees their prescriber on the same day as their scheduled infusion appointment (a 'coupled' visit), the prescriber may make a change to their treatment plan due to aberrant laboratory results or physical assessment findings. Although physicians may adjust the orders in the electronic health record, sometimes they move on to the next patient without updating the progress notes or communicating the last-minute order changes to infusion nurses. In these situations, physicians struggle to balance their time between seeing patients and their charting responsibilities.

When prescribers do not communicate order changes, either through informing infusion nurses or making progress notes, infusion nurses must then verify changes with prescribers prior to administering treatment. Getting clarification from the physician can take up to 60 minutes or more, causing a delay in chemotherapy treatment. Infusion nurses commented that, every time they had to go find a physician to verify an order, it took them away from the infusion floor caring for their patients:

“I know that [prescribers are] very busy...But if they would just stop and take that moment to communicate with nurses that there’s been a dose change or that I am holding a chemo for this reason...then we wouldn’t have to be tracking them down and waiting.”

“I think another challenge is sometimes trying to figure out what’s on the doctor’s mind. Because the patient will come in and tell us, ‘oh he said this.’ They didn’t write that in their note...their progress note has not been typed up yet, or some of the progress notes are just poor, and don’t give you an idea of what their plan is. So, then we still have to go back [to clarify].”

Additionally, when patients and nurses have a divergent understanding of the treatment plan, it can erode the patients’ trust and confidence in the level of care they are receiving, forcing infusion nurses to mask their confusion while seeking clarification from a physician.

“There seems to be some kind of communication breakdown...The patient knows more sometimes than we do. And then...you don’t want to let them know that you have no idea what’s going on...”

c. Orders not signed in advance by physicians

Some physicians will not sign orders in advance and insist on seeing their patients the day of treatment before they sign. This causes delays in treatment when physicians move on to see their next patient without signing the previous patient’s order and the patient meanwhile has gone to infusion and has to wait while nurses track down the physicians to sign the orders:

“So, one of the biggest challenges we have as infusion nurses...is having our orders preapproved by the physicians in the electronic record so that we can go ahead with treatment. They’re supposed to have them approved before the patient’s scheduled. That doesn’t always happen, and we find ourselves at the last-minute standing in front of a patient saying, ‘I’ll be right back.’” (Infusion Nurse)

In response to order signing delays, some infusion nurses use workarounds to counter the negative effects on their workflow and help improve patient care and wait times, such as fully staffing the infusion center when certain oncologists see patients, continually messaging the office reminders to sign orders, and keeping patients’ charts open in the EHR so the physician has to call the nurse to access the chart and thus serve as a notification for beginning treatment. Some practices implemented policies and strategies to ensure all chemotherapy orders are signed and routed to the pharmacy in advance and, pending laboratory results and assessments, are within normal parameters. These strategies tended to come from those in management roles and aimed to alter physician behavior:

“We have our docs, they’ll sign the orders 24 to 48 hours [in advance] and now they’ve started weekly rounds with the nurses and they look at the next week’s schedule and they say...‘Don’t mix the chemo. I’ll sign it, but I want to see [the patients] the same day.’”

d. Laboratory testing processes

Waiting for laboratory results before beginning infusions can delay the treatment start time, which is particularly salient if laboratory facilities are running behind schedule. Laboratory results are reviewed to indicate if the chemotherapy is safe to administer to the patient on the day of service. After the results are verified as within safe parameters, chemotherapy orders

must be entered by the chemotherapy-privileged physician, signed, and sent to the pharmacy, which may also add to delay times depending on the workload of physicians and pharmacists. At one site, patients from rural areas often schedule their chemotherapy infusions on the same day as their physician appointments and laboratory work to save extra travel time and distance with their caregivers. When the laboratory takes longer than usual to process results, a delay can occur:

“[Patients] might think it’s hugely significant because they’re the ones sitting in the chair. Now we’ve drawn blood, and it’s been a lab issue, where a line is down and 2 hours waiting for a count to result. And if you’re a 5-hour treatment, that’s huge.”

“We sometimes get labs within a half hour, and then the next time it will be over an hour...Because when we’re sitting here, like today not very busy but yet we’re doing nothing, people look at us like, ‘why aren’t you getting this done?’ And it’s like, it’s out of our hands.” (Infusion Nurse)

In response to laboratory processing times and chemotherapy treatments contingent on the patient’s results, practices are encouraging patients to have their laboratory work completed the day before their scheduled treatment (i.e., uncoupled visits) to prevent day-of-appointment delays. The uncoupling of laboratory work and infusion visits also facilitates efficient scheduling and chair assignment, as any complications or holds in treatment can be addressed before the scheduled visit and the chair schedule can be adjusted accordingly. Having the laboratory results to evaluate prior to the visit also ensures up-to-date orders are prepared and approved to save time coordinating care on the day of infusion.

Despite the benefits of uncoupling visits, some patients experience difficulty coming into the practice 2 days in a row due to challenges stemming from transportation, caregiver schedules, and work schedules. Infusion center administrators face challenges trying to balance patient preferences with maintaining efficient operations and schedules at their practices. The situation is increasingly complex for patients traveling longer distances:

“...Patients having to come back. The physicians and providers or most everybody in the clinic are very sensitive to that. Because these patients aren’t well, and they’re coming back and forth and they’re traveling. That in and of itself is a delay that comes from a compassionate place. Yet it impacts our daily operations in a very huge way.”

Outcomes

This study was descriptive in nature, so no outcomes changes are reported.

Discussion

We found that practices vary in their performance of what we refer to as patient safety actions. This is especially evident as it relates to communication with other clinicians, capabilities of their EHR, and their satisfaction with communication through technology used in the practice, invariant of clinician age or years in practice. Factors contributing to increased safety scores included higher satisfaction with technology used in the practice and more favorable communication with other clinicians. We confirm findings from other clinical settings showing that health information technology integration in care delivery settings can have unintended consequences on patient safety and communication.

Notably, we found that increased EHR capability was associated with lower safety scores, and that this relationship was even stronger in an adjusted model. It is important to note that

clinicians' length of experience with an EHR system might influence patient safety; information on length of EHR experience was not available to the study team. Even though the EHR is meant to help with patient safety and lead to less variation, we saw the most variation in patient safety in practices that had full technology capability. The inverse relationship between EHR capability and safety suggests that technology may detract from patient safety. Scholars critical of current health information technology argue that EHRs were not designed with clinician usability in mind, nor designed to capture and highlight data in an intuitive manner. The tasks and interactions required with EHRs differ fundamentally from paper records and include e-prescribing, numerous alerts, reminders, data entry forms, and documentation requirements resulting from healthcare regulations such as Meaningful Use requirements. Furthermore, clinicians have reported that EHR transitions placed additional burdens on their workloads and, in some instances, did not replace paper-based documentation practices.

Coupled with the rapid rollout of health information technology in clinical settings since the 2009 federal requirement, it is no surprise that patient safety suffers as clinicians struggle with adapting to new technology features and fundamentally different documentation process. These adaptations disrupt clinicians' ability to deliver safe cancer care. These findings are consistent with other work demonstrating numerous unintended consequences of an electronic prescribing system, including communication and clinical disruption.

We found that perceptions of prescribers and nurses varied when it came to performing behaviors consistent with a safety culture and their perception of quality communication with other clinicians. Specifically, prescribers reported lower safety scores compared with nurses; however, prescribers reported higher communication satisfaction with practice technology and higher-quality communication with other nurses. Nurses are responsible for a large portion of the documentation that addresses quality measures, safety measures, and the overall clinical picture of the patient and thus are among the most frequent users of EHRs. Our findings are consistent with other studies that have shown that nurses notice significant challenges with the EHR when it comes to facilitating communication and supporting efficient care delivery. Prescribers and nurses have different perspectives and experiences that should be considered as leaders consider EHR modifications, quality improvement efforts, and/or additional training.

When considering patient-reported outcomes, in this multisite, mixed-methods, observational study of medical ambulatory oncology practices, a high proportion of patients receiving chemotherapy treatment successfully completed brief assessments about their toxicity experience. Practice study champions strongly endorsed paper-based questionnaires for patient completion, and the high participation rate validates their preference. The patient-reported data provided valuable insights into the patient experience of cancer treatment outside of the usual data reported in clinical trials with strict eligibility criteria.

In this large sample of patients treated under routine clinical circumstances, three toxicities emerged as particularly troublesome: pain frequency, pain severity, and diarrhea frequency. These results suggest that, despite numerous evidence-based guidelines, current symptom management approaches remain suboptimal and novel approaches are needed to address these problems. The urgent need for non-opioid-based pain treatments remains especially important in the context of lingering concerns for opioid misuse and barriers to optimal pain management reported by patients with cancer. Cancer-related pain is often multifactorial and requires multiple pharmacologic and nonpharmacologic interventions. Clinic efforts to implement proactive patient education and routine symptom monitoring for problems before they escalate are promising strategies to mitigate negative consequences of these toxicities. To

date, results of such efforts have been mixed, principally due to variation in clinicians' response to adverse toxicity reports.

The most frequently reported toxicity provided directly by patients was fatigue, and most respondents endorsed their fatigue as severe/very severe. Fatigue is a notable toxicity for patients undergoing routine chemotherapy treatment. Given its high frequency and severity, fatigue should be assessed routinely as part of routine oncology care. Systematic fatigue assessment is essential to provide early interventions, such as moderate exercise, which have demonstrated quality of life benefits in this population.

The data presented are unique in that the toxicity data do not derive from clinical trials with strict eligibility criteria. The study results reflect the population of adults treated every day in cancer centers—from academic institutions to privately owned practices—across the United States. Compared with clinical trial populations, respondents to our survey are likely to be older, have advanced cancer, and have co-occurring chronic conditions. Such characteristics would render them ineligible for most clinical trials. The investigators selected outcome measures that have been tested for readability, reliability, and validity. Clinicians caring for adults with cancer can interpret the toxicity scales used in this study. Importantly, patient toxicity studies rarely report healthcare service use for toxicity management. Study data suggest that many patients require healthcare service use, which can be costly, inconvenient, and inefficient.

When considering the issue of delays in chemotherapy treatment, we found that delays were most associated with four specific themes: discrepancies in care plans and missing orders for uncoupled visits, undocumented and uncommunicated day-of-treatment order changes, orders not signed in advance by physicians, and laboratory testing processes. Ambulatory oncology practices that experienced the most frequent delays in patient care and treatment tended to experience challenges around clinician communication and coordination and organizational structures, such as unclear staffing roles and responsibilities and individual clinicians operating outside of standardized practice. We also identified strategies that some practices used to prevent delays, such as particular clinicians being responsible for next-day order preparation, group huddles to coordinate upcoming patient treatments, practice policies to ensure physicians sign orders in advance of the patient's visit, and uncoupling of laboratory and treatment appointments.

As our findings suggest, plans of care are not always up to date on the day of infusion appointments. Infusion nurses do not rely solely on the electronic health record but use other communication methods to clarify orders and prevent errors. Behavioral interventions that focus on improving teamwork, communication, and trust in ambulatory oncology settings have yielded positive outcomes. These strategies could be widely adopted and modified for individual practices.

The results of this study suggest that delays in chemotherapy delivery do not have a singular cause and do not occur in isolation; rather, they are compounded by the multilevel and multifocal organizational structure of ambulatory oncology practices. To ensure that orders are prepared and that a patient is ready for treatment, we found more practices adopting a model of uncoupled visits. As our study findings showed, patients' access to laboratory services in rural areas and dependence on caregiver schedules may affect their preference for appointment uncoupling. Our findings also suggest that there is resistance from some physicians wishing to provide same-day service and see their patients before signing orders.

Conclusions

The research presented here utilizes a multimethod, qualitative approach to highlight and understand the causes and consequences of delays in chemotherapy administration. These findings suggest that clearly defined roles and functions within the ambulatory oncology team as well as interventions to improve teamwork and communication in ambulatory oncology practices will facilitate more timely chemotherapy infusion delivery.

Key conclusions from our work:

1. All-digital health records were correlated with poorer clinician-reported perceptions of patient safety.
2. Patients can reliably report chemotherapy-associated toxicities, which occur more frequently than previously recorded. Pain and GI disturbances are particularly problematic.
3. Delays in chemotherapy treatment receipt are an important and understudied problem, with multiple contributory factors and opportunities for quality improvement.
4. Multisite, multiple-methods (mixed-methods) studies offer the opportunity to both confirm and generate hypotheses, particularly when considering complex phenomena including patient safety.

Significance

To our knowledge, this is among the first multisite, multiple-methods studies to examine the impact of communication processes and communication technologies on patient safety actions in ambulatory oncology practices—care settings that deliver high-risk and high-cost cancer treatments. The collection, analysis, and integration of quantitative and qualitative data permitted rich exploration of key patient safety and quality issues in ambulatory oncology care.

Data generated from this study have informed subsequent investigations, including an internally funded study of oral anticancer agent management (PI Manojlovich), team-based training for chemotherapy safety (PI Friese, NCI R25-CA-214227), and active efforts to develop and evaluate a team-based intervention on cancer care teamwork and communication (proposal under review).

Implications

Study findings provide important implications for clinical practice. There is substantial variation in patient safety in practices with full technology capability. Practices interested in improving patient safety should consider monitoring clinicians' safety perceptions as technology is introduced or updated. In addition, efforts to strengthen clinician communication, regardless of form, is an evidence-based strategy to improve patient safety. Careful attention to technology adoption and updates, coupled with high-quality communication skills across clinicians, are promising strategies to administer high-risk treatments safely in ambulatory oncology settings and improve cancer care quality.

Our data suggest that improvement strategies may benefit from tailoring by clinician type to account for the notable differences observed in this study.

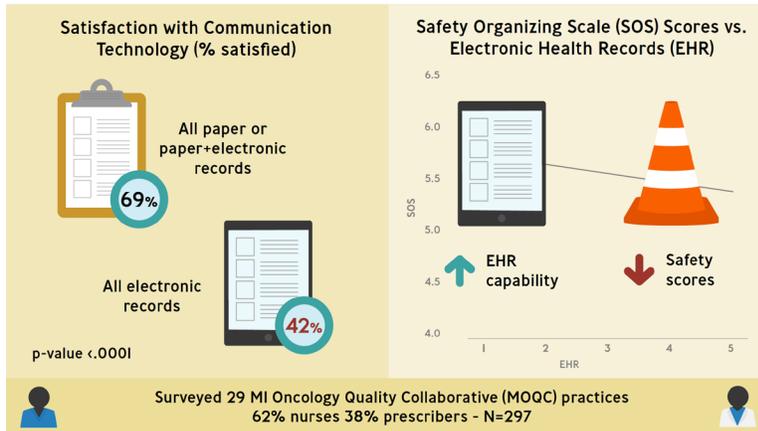
When considering patient-reported outcomes, medical oncology practices can collect toxicity data from patients in a straightforward manner to inform clinical quality improvement. Collection of patient toxicity data outside of clinical trials could accelerate community recognition of toxicity patterns not observed in pivotal studies. Correlation of rich patient-reported toxicity data with key covariates would strengthen the approach and interpretability of findings.

Nurses are well suited to identify barriers to timely chemotherapy administration across diverse medical oncology settings, because they are the clinicians primarily responsible for infusion

services. Oncology nurses will benefit from structural and behavioral approaches to provide clarity surrounding oncology team members' roles and functions that lead to timely chemotherapy delivery. Ambulatory oncology practices will benefit from workflows that allow all treatment plans to be finalized prior to the day of chemotherapy treatment so that nurses can focus on delivering timely, high-quality oncology care as indicated.

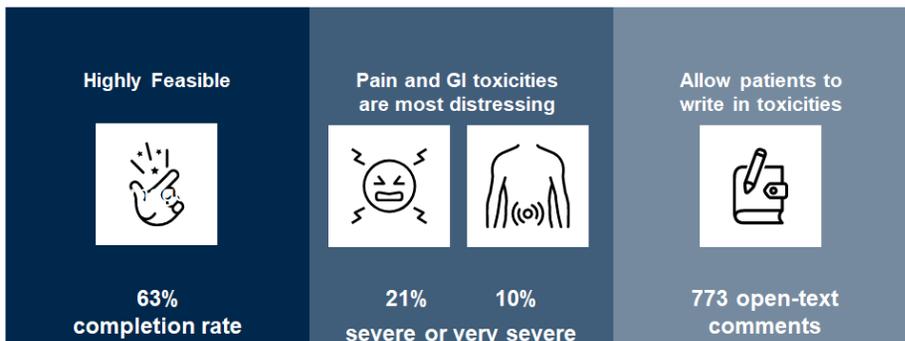
Visual Abstracts of Key Findings are Shared Below.

Clinician Perspectives on Electronic Health Records, Communication, and Patient Safety across Diverse Medical Oncology Practices



Minal R. Patel, PhD, MPH et al.

Patient-reported outcomes collected in ambulatory oncology practices: Feasibility, patterns, and correlates



Paper survey of 2,245 adult patients w/ cancer in 29 practices

Friese, et al., Health Serv Res, 2020

doi.org/10.1111/1475-6773.13574

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Study Background

- This study explores how clinician communication, EHR use and practice environment features affect patient care and chemotherapy delivery in ambulatory oncology practices
- What are common barriers and facilitators to providing high-quality patient care in ambulatory oncology practices?
- Aim 1: Survey administered to clinicians and patients across 29 MOQC practices
- Aim 2: Qualitative fieldwork at 8 practices
- Aim 3: Focus groups with clinicians and management to share initial findings and discuss possible interventions

Research Methods: Aim 2

- Visited 8 ambulatory oncology practices in 2018, totaling 290 hours of fieldwork
- Conducted observation in infusion areas and exam areas
- Interviewed 42 clinicians (nurses & prescribers) and 38 patients
- Analysis is currently on-going

Aim 2 Initial Results

- Chemotherapy delays frequently were reported by clinicians and patients, causing dose interruptions and compounding scheduling challenges in practices with high patient volume
- Common factors affecting communication and coordination that affected high-quality, timely patient care are identified below with examples

Prescriber EHR use & order entry

- Problems arise around entering up-to-date patient info and timely order approval



"And the patients will come back here, and they'll be like 'but they [prescriber] said this and they said this'...and we're kind of sitting there going 'well, the orders don't say this.'"

- Discrepancies in care plans cause uncertainty and often result in delays of care



"You know there's discrepancies in what they've [prescribers] communicated is the plan, and if they're not there to ask, we've not known what to do...sent patients home that...drove a couple of hours and the on-call provider wasn't willing to make the call because it was not clear what the primary doctor wanted."

Lack of integrated physician care/standardized practice

- Delays often occurred when a patient's primary oncologist was out of the practice and other physicians unfamiliar with the patient's treatment were reluctant to sign or change orders



"There's been backlash or there's been resistance by the on-call doctors to put orders in for other providers, so it makes it difficult where we're in a situation where we need orders on a patient."

- Some practices did not have standardized order entry protocols allowing for orders to be pre-signed



"We used to have protocols, parameters, and so the orders can be all set and ready, but we would call there if something was out of parameter. So there's just a little bit of a delay now when they're not in and approved."

Unclear clinician roles & responsibilities

- Tasks were not clearly defined to a particular role (i.e. nurse or MA) causing those patient care tasks to slip through the cracks
- Tasks include: script refills, checking orders day before treatment, managing side effects over phone or in person, patient education/chemo teaches, prior authorizations, phone triage, scheduling



"I just had a prior auth, and I went to 3 different people and everyone was like 'I don't know'...and I'm like 'well, it's got to be somewhere.'"

7. PUBLICATIONS AND PRODUCTS

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3. Lafferty M, Fauer A, Wright N, Manojlovich M, Friese CR. Causes and Consequences of Chemotherapy Delays in Ambulatory Oncology Practices: A Multisite Qualitative Study. *Oncol Nurs Forum*. 2020;47(4):417-427. doi:10.1188/20.ONF.417-427
4. Manojlovich M, Bedard L, Griggs JJ, McBratnie M, Mendelsohn-Victor K, Friese CR. Facilitators and Barriers to Recruiting Ambulatory Oncology Practices Into a Large Multisite Study: Mixed Methods Study. *JMIR Cancer*. 2020;6(1):e14476. doi:10.2196/14476
5. Friese CR, Fauer AJ, Kuisell C, Mendelsohn-Victor K, Wright NC, Griggs JJ, Manojlovich M. Patient-reported Outcomes Collected in Ambulatory Oncology Practices: Feasibility, Patterns, and Correlates. *Health Services Research*. 2020. doi:10.1111/1475-6773.13574 issn: 14456773