

ORIGINAL RESEARCH

Assessment of Standards of Care for Oral Chemotherapy by Pharmacists in Clinical Settings

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Abstract

Introduction: As oral anticancer agents become more prominent in the treatment landscape, their expanded use may raise concerns, such as nonadherence, adverse events, drug monitoring, and high costs. Clinical pharmacists (CPs) provide patient education and medication management to address these concerns. To understand the services and communication offered, interviews were conducted with clinical pharmacists in oncology clinics. **Methods:** Telephone interviews were conducted with pharmacists from oncology clinics across the US. The interviews evaluated clinical support services provided by CPs for patients on oral chemotherapy, and facilitators and barriers CPs face in implementing communication with the oncology team. The function and support of CPs in this context were assessed. **Results:** A total of 16 pharmacists were interviewed. As a result, three overarching themes were identified pertaining to typical roles: (1) CPs provide key support to oncology patients; (2) CPs face logistical, coordination, and communication challenges when supporting oncology patients, and (3) CPs contribute to patient safety and quality of care outside of direct patient care. A total of eight subthemes were identified. **Conclusion:** CPs provide high-quality care to patients according to national guidelines. However, they continue to be pulled in various directions to fill gaps that exist in the patient care pathway. This leads to pharmacists feeling unsupported, leading to burnout. Many CPs expressed not billing for services provided, making it difficult to advocate for additional supportive resources.

The approval of oral anticancer agents (OAAs) brings a convenience factor when caring for oncology patients. The use of these OAAs continues to rise as research with these agents is ongoing (Tichy et al., 2023). Despite these benefits, significant concerns arise, such as nonadherence, adverse events, drug monitoring requirements, and overall high costs (Mathur et al., 2022; Muluneh et al., 2018). Oncology pharmacists work in a myriad of practice settings with roles in managing these concerns that can arise with OAA regimens. Pharmacists are often consulted due to their expertise in patient education and medication management to enhance care for oncology patients who receive these agents with a focus on both the safety and quality of care (Mackler et al., 2019).

As OAAs expand, there is a need to better characterize how clinical pharmacists (CPs) are structuring their workflows to better serve patients on OAAs and uncover any emerging challenges. As such, our team conducted a prospective, qualitative study to better understand the OAA services delivered by pharmacists and specify any unintended consequences.

METHODS

An institutional review board–approved qualitative, prospective study was conducted to characterize CPs' current roles and responsibilities, barriers and challenges, and to further categorize time spent in various direct and non-direct patient care activities.

Participants

Participants were screened by a research team member and found to represent a population of CPs involved in the care of patients receiving OAAs. An email for recruitment of interviewees was sent to a listserv of Hematology/Oncology Pharmacy Association (HOPA) members with 3,444 individual email addresses. Recruitment remained open until the maximum number of participants had volunteered and been screened to meet inclusion criteria. After confirmation that inclusion criteria were met, interviews were set up with each participant. The interviews were conducted via a web-based platform with recording capability for the ability to extract direct quotes.

Data Analyses

Data were collected from June 1, 2022, to October 5, 2022, and one-on-one interviews were conducted via Zoom. Interview questions focused on describing patient care services and CPs' perceptions about implementing communication with oncology clinics. Questions were asked using branched chain logic pertaining to the pharmacists' experiences to understand barriers that may exist when delivering patient care in this setting. Interviews were conducted by one research team member, while a second team member took notes. All interviews had precise transcripts deidentified at the time of transcription. These deidentified transcripts were coded and analyzed using a rapid qualitative analysis method (Gale et al., 2019). Participants were incentivized with a \$25 gift card for their time and contribution.

Data analysis began by coding transcripts and identifying common themes raised by study participants. The authors identified themes raised by each participant in response to specific questions that were asked in the interview guide (e.g., providing chemotherapy education) as well as emerging themes outside of targeted questions (e.g., frustration with lack of support).

This process continued until there were no new emerging themes recognized. Illustrative quotes are presented using CP identification number. Respondents described a number of roles and responsibilities that they take on to deliver care to their patients.

RESULTS

A total of 16 pharmacists from oncology clinics across the US were interviewed with a goal of identifying overarching themes based on illustrative quotes. The three primary categories were (1) patient care, (2) non-direct patient care, and (3) coordination of care.

Patient Care: Chemotherapy Education

Clinical pharmacists reported providing chemotherapy education to patients especially prior to treatment initiation. These education sessions are provided during routine visits, via telemedicine, or via phone calls. One of the first junctures of direct patient interaction occurs when patients receive education when initiating new

oral chemotherapy agents. One CP commented, “I do both initial education sessions via telemedicine, and follow-up visits as well. I may conduct a pretty intense initial education and give the patient my contact information” (CP2).

Additionally, CPs commonly expressed educating all new patients in their role: “We are in charge of oral chemotherapy education. We are aiming to educate 100% of the patients who are started on oral chemotherapy” (CP3). Routine follow-up is also commonly done by CPs after a patient starts a new oral chemotherapy regimen: “We do a follow-up for all patients 1 week after starting therapy. Then, we do routine phone calls. In theory, it is supposed to be about every month, but we do not typically get to everyone exactly every month due to the size of the program...and then we’ll do the new teaching” (CP8).

Patient Care: Monitoring Drug Interactions and Organ Function

Clinical pharmacists reported evaluating drug interactions and the appropriateness of organ function with lab monitoring: “making sure the medication they are receiving is the appropriate medication, making sure there are no drug interactions, making sure the dose is correct. No dose changes are needed based on renal or hepatic function...we have them on our schedule to follow up specifically for labs, also following up just to check in” (CP4).

Clinical pharmacists reported being involved in several steps of the patient care process when initiating a new OAA. Documentation is commonly done when reviewing medications and is incorporated into the daily workflow of pharmacists: “I have to document that I’ve checked their labs. If anything is strange, I’ve made any adjustments, I document that” (CP1).

Patient Care: Preventive and Supportive Care

Clinical pharmacists reported providing preventive and supportive care measures including managing toxicities of oral chemotherapy regimens: “We are able to also prescribe all supportive care. This includes nausea medications, such as ondansetron, prochlorperazine. We’re able to send those. And anti-diarrheal, sometimes creams for rashes. Sometimes they need steroids or antibiotics” (CP4).

Additionally, CPs reported being actively involved in identifying and managing both common and abnormal toxicities that may arise while on an OAA: “We’ll run through those [side effects] with the patient and see if they’re experiencing them or if they’re not, and then I open the floor for the patient to touch on any abnormal things happening with them that they think could be drug related” (CP11).

Patient Care: Adherence

Clinical pharmacists expressed managing adherence issues for patients. Adherence to OAAs is continually assessed by CPs and appropriate interventions are made when needed. Participants reported stressing the importance of medication adherence for their patients early on when starting treatment: “I help them understand how important adherence rates are, not only in ensuring successful treatment, but also in helping maintain response of therapy and not induce resistance to treatment” (CP2).

Clinical pharmacists reported suggesting strategies to overcome adherence challenges and increase comfortability with their medication regimen: “I think during the visits just trying to figure out why they’re nonadherent—is it side effects? Is it dosing complexity? What is contributing to that? And then just offering suggestions. Fortunately, when we’ve done our service, patients have been more adherent than I would have anticipated” (CP5).

On the non-direct patient care side, CPs reported facing logistical, coordination, and communication challenges when supporting oncology patients.

Non-Direct Patient Care: Financial Assistance

Clinical pharmacists reported spending time coordinating financial assistance for patients and expressed difficulty communicating with insurance companies for patient medication coverage: “It just depends on what drug it is, and obviously what steps you have to take, and the individual patient assistance programs that are out there, and what their income limitations are. Sometimes we’re the ones who are helping to facilitate that information. I’ll call the patients and explain to them. I will send them the links to complete the documentation online if I have to. I have called pharmacies to find out what is the best cash price

offer, and for things that are pretty inexpensive, nononcologic drugs” (CP13).

Participants commonly expressed difficulty communicating with insurance companies when managing patient medication access issues. Participants were asked to describe their daily tasks involving financial assistance for patients and their interactions with insurance companies: “We do write appeal letters for our insurance denials. When insurance denies an oral chemotherapy agent, we’re usually the ones that write the letter... get a final signature from the physician, and then we send it to insurance to appeal that denial...a lot of times you just call the general number. You can literally be waiting for 30 to 40 minutes, just to get reach of someone in an outside pharmacy” (CP3).

Non-Direct Patient Care: Filling Gaps in Care and Taking on Expanded Roles

Clinical pharmacists expressed frustration and difficulties with a lack of support resulting in a gap of being able to deliver quality patient care and increase of responsibilities: “It’s a frustrating part about the job, but it also just hammers home how important this role is to fill because there are so many areas for mistakes to be made, or for us to fall short in delivering excellent care to a patient. It ends up resulting in worsened quality of life or lower overall survival as a whole” (CP2).

Clinical pharmacists’ roles and responsibilities have continued to grow. As a result of broadening the scope of practice as well as increased non-direct patient care responsibilities, many CPs expressed a lack of supportive resources to fulfill these additional roles. “I think it would be nice to have more staffing support [because] we have all these other responsibilities as well. It would be nice to have more staff resources, like a counterpart. I think we don’t have enough resources for that transitions of care component of making sure patients are able to always get their drugs every month. I think having more time to work on that clinical aspect of just talking to patients would be nice” (CP4).

Non-Direct Patient Care: Communication and Coordination With Outside Specialty Pharmacies

Clinical pharmacists expressed a significant challenge when it comes to communication and coordination

of care with outside specialty pharmacies: “Many challenges with outside specialty pharmacies. Getting a hold of them, I mean, I’ve sat on hold for over an hour...getting someone who knows what’s going on. Obviously, I understand you go through the phone tree, but sometimes it takes four or five people until you get to a person who can help you...honestly, I would say time because it’s just time on hold, time being transferred, time getting it figured out. That’s one barrier” (CP14).

Clinical pharmacists described long hold times for contact, spread of misinformation to clinic staff or patients, medication shipping delays, financial assistance issues, and lack of proper patient education. “You’re on the phone on hold for a significant amount of time. That can definitely be a challenge because we don’t have a lot of time... many times, I’m just doing technician type of jobs or clerical jobs. Sitting on hold is definitely one of the biggest struggles. Getting financial assistance in an appropriate amount of time. Then, the shipping process can always be a problem” (CP9).

The lack of an affiliated specialty pharmacy can affect the quality of care patients receive, and result in delays in treatment and adequate follow-up: “Not having our own specialty pharmacy is absolutely a gap because it does lead to delays in treatment starts. Because we’re having to deal with 15 different specialty pharmacies in any given day, and all of their insurance problems, there can be a delay...I think, also, just our ability to staff. Having a technician who’s really dedicated to calling pharmacies and dealing with insurance problems...that pulls our time a lot. We have less time to focus on truly clinical things that we could potentially have an impact on” (CP9).

Coordination of Care: Ensuring Patient Safety and Quality of Care

Clinical pharmacists contribute to patient safety and quality of care outside of direct patient care. Clinical pharmacists frequently described being involved in various hospital committees (e.g., Pharmacy and Therapeutics), precepting learners, and engaging in research. Clinical pharmacists are involved in a variety of indirect activities in addition to their daily patient care tasks. Pharmacists said that roughly 20% of their days are spent being involved with indirect patient care responsibilities:

“committee work, Pharmacy and Therapeutics, formulary management, pharmacy practice. I meet with informatics twice a month to make sure we’re up to date on [electronic health record] protocols and informatics. Research, quality improvement, precepting, committee work” (CP13).

A majority of CPs interviewed described taking on precepting roles for learners: “We are also heavily involved in residents and learners. Actually, where I am, there’s a pharmacy school in this city. We have a ton of students who come through heme/onc, and then we have residents as well” (CP4).

DISCUSSION

This study reviewed interviews of CPs who care for patients receiving oral chemotherapy regimens. Overarching themes and subthemes were identified pertaining to roles and barriers to patient care (Gale et al., 2019). It was found that CPs are collaborative team members and work with providers and patients to provide safe and effective medication management. They provide high-quality care to patients according to guideline recommendations such as those from HOPA (HOPA, 2019). These guidelines focus on the importance of the safety and appropriateness of anticancer therapy that CPs deliver in a responsible manner (HOPA, 2019). However, pharmacists are pulled to fill various gaps that continue to exist in the patient care pathway as the solution. This results in additional non-direct patient care activities such as scheduling, coordination of care, and financial assistance. As direct patient care responsibilities multiply, CPs expressed feeling unsupported due to the constant obligation to fill health system gaps (i.e., non-direct patient care).

As the role of the CP continues to grow and more time is spent in direct patient care, pharmacists are still unable to bill directly for their services (Clinical pharmacists in oncology practice, 2008). When asked about billing for patient care services, participants described involvement in prescription management and monitoring being the main source. Clinical pharmacists are spending much of their time seeing several patients for direct patient care activities but are unable to bill for these services. This may be due to specific state regulations and insurance company restrictions. Many CPs expressed the aspiration to bill for ser-

vices in the future and voiced an interest in collaborative practice agreements. However, further discussions are needed with appropriate administration, making it difficult to advocate for additional supportive resources.

An assessment of attrition and retention factors in the oncology pharmacy workforce by Rao and colleagues (2022) showed that although this specialty is highly trained and capable with a high level of work satisfaction, over 60% indicated that they were seeking alternate employment outside of the patient care environment. Untenable work burdens, burnout, lack of work-life integration, and ineffective leadership were all large contributing factors to attrition risk (Rao et al., 2022). Greater satisfaction and lower attrition were associated with increased time spent on direct patient care activities. This assessment highlights the risk of attrition and overall satisfaction of clinical oncology pharmacists.

Burnout is present in the health-care field, with at least half of pharmacists reporting burnout (Durham et al., 2018). Specifically, among hematology-oncology pharmacists, high levels of burnout have been observed in > 60% of pharmacists (Durham et al., 2018). This rate of burnout has been shown as increasing as pharmacists work more hours per week and take on more administrative roles (Durham et al., 2018). Durham and colleagues (2018) found that factors that typically did not impact the risk of burnout significantly included time spent in the most meaningful area of work. We see clinical oncology pharmacists continue to take on more indirect patient activities such as financial management and specialty pharmacy coordination. Many of these additional duties come along with barriers and miscommunications with insurance companies and specialty pharmacists that could possibly contribute to burnout. Hematology-oncology pharmacists who reported high burnout rates were also more likely to report a concern for a medication error within the past 3 months (Golbach et al., 2022). Quotes from the participants pointed to the need for more support to provide a safer and more practical pharmacist-to-patient care ratio. Departments must work to build flexibility in the work environment for CPs. There is a need for overall improvement in work burden and resources available to the oncology pharmacy workforce.

LIMITATIONS

There were limitations identified in the utility of the qualitative data presented. The analysis focused solely on oncology CPs from different oncology clinics who had responded to an email to participate in the interview. Due to a maximum inclusion limit and email as the method for interview distribution, there were oncology pharmacists who were unable to participate.

CONCLUSION

With the continual development of oral chemotherapy regimens, the interprofessional involvement of CPs will continue to also expand. Clinical pharmacists continue to provide high-quality care to patients yet are relied on for both direct and non-direct patient care support. While CPs are actively involved in delivering appropriate patient care, they are unable to bill for these services. As a result, CPs feel a lack of support and frustration. The themes identified within this qualitative study were utilized in the creation of a quantitative questionnaire sent out to HOPA membership. This interview data will provide clarity and further awareness to the type and quality of care that CPs provide to oncology patients. ●

Disclosure

The authors have no conflicts of interest to disclose.

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