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Pain Medication Management Processes Used by Oncology Outpatients and Family Caregivers Part I: Health Systems Contexts

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Abstract

Context—Oncology patients with persistent pain treated in outpatient settings and their family caregivers have significant responsibility for managing pain medications. However, little is known about their practical, day-to-day experiences with pain medication management.

Objective—To describe day-to-day pain medication management from the perspectives of oncology outpatients and their family caregivers who participated in a randomized clinical trial of a psycho-educational intervention called the Pro-Self[®] Plus Pain Control Program. In this article, we focus on pain medication management by patients and family caregivers in the context of multiple, complex health systems.

Methods—We qualitatively analyzed audio-recorded intervention sessions that included extensive dialogue between patients, family caregivers, and nurses about pain medication management during the 10-week intervention.

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Results—The health systems context for pain medication management included multiple complex systems for clinical care, reimbursement, and regulation of analgesic prescriptions. Pain medication management processes particularly relevant to this context were getting prescriptions and obtaining medications. Responsibilities that fell primarily to patients and family caregivers included facilitating communication and coordination among multiple clinicians, overcoming barriers to access, and serving as a final safety checkpoint. Significant effort was required of patients and family caregivers to insure safe and effective pain medication management.

Conclusion—Health systems issues related to access to needed analgesics, medication safety in outpatient settings, and the effort expended by oncology patients and their family caregivers require more attention in future research and healthcare reform initiatives.

Keywords

cancer pain management; analgesics; medication management; self-care; self-management; family caregivers; health systems; medication safety; qualitative research; randomized clinical trial

Introduction

Oncology patients with persistent pain treated in outpatient settings and their family caregivers have significant responsibility for managing pain medications (1-3). Yet despite extensive research on cancer *pain* management (4-7) only a few researchers focused specifically on the practical, day-to-day management of pain *medications*. Given the number of patients who experience persistent pain at some point in the cancer trajectory (8) and the fact that analgesic regimens are a mainstay of outpatient cancer pain management (9-11), the number of patients and family caregivers who face the challenge of pain medication management is substantial. Thus, management of pain medications by patients and family caregivers is a phenomenon that needs more attention from researchers.

Patient behaviors associated with pain medications are typically studied as “adherence,” (12-15), narrowly defined as the “self-administration of medications in prescribed amounts and at prescribed intervals” (13, p. 205) or “nonadherence,” such as avoiding, forgetting, or stopping the medication, or altering the dose (16-18). However, a few researchers recently examined medication management by patients and/or family caregivers as a broader and more complex activity than simply adherence. They conceptualized medication management as a whole range of behaviors required for effective and safe handling of medications. Those behaviors include teamwork, organization, routinization, decision-making, and gaining access (19-22). Living alone, depression, physical impairments, highly complex medication regimens, and multiple prescribers place patients at risk for problems with medication management (23).

The few studies on medication management by patients and family caregivers were conducted in a wide variety of clinical populations, including caregivers of patients receiving hospice services (19,22), breast cancer patients treated with oral chemotherapy (21), and frail older adults receiving home healthcare services (23,24). Medication regimens differ significantly across these populations and present unique challenges. For example, medications administered in a cyclic manner, such as some oral chemotherapeutic agents,

present different management challenges than medications taken on a daily basis indefinitely or medications for symptom management taken according to an individually tailored regimen. The availability of services to assist patients and family caregivers also varies across populations, ranging from no in-home services to home care by a multidisciplinary hospice team. Consideration of the particular clinical contexts for medication management is crucial as research in this area moves forward.

To our knowledge, only two studies specifically addressed pain medication management in the outpatient oncology setting. Our research team previously reported on difficulties in obtaining pain medications and accessing medication information among oncology outpatients participating in a randomized clinical trial (RCT; 25). Liang and colleagues (20) reported on opioid-taking skills and behaviors in an outpatient sample in Taiwan. While these studies provided important insights, both had limitations. Ours was conducted more than ten years ago and the findings were serendipitous when a small qualitative component was added to an ongoing RCT (26,27). The study by Liang and colleagues evaluated only 10 participants and was situated in the Taiwanese context. In our current RCT, an expanded qualitative component yielded extensive data on pain medication management over time, allowing for a more in-depth analysis in the current United States context than previously reported.

The purpose of this qualitative study was to describe the day-to-day management of pain medications from the perspectives of oncology outpatients and their family caregivers who participated in a RCT of a psycho-educational intervention called the Pro-Self[®] Plus Pain Control Program. We analyzed audio-recorded intervention sessions that included extensive dialogue between patients, family caregivers, and nurses about pain medication management during the 10-week intervention. Our research questions were: 1) What are the current contexts for pain medication management as experienced by oncology outpatients and their family caregivers? and 2) How do oncology outpatients and their family caregivers manage pain medications within these contexts?

Methods

Design

An embedded mixed methods research design was used, in which a qualitative study was conducted as part of a RCT (27,28). The RCT compared the efficacy of two doses of the Pro-Self[®] Plus Pain Control Program, a 10-week psycho-educational pain management intervention grounded in self-care/self-management theories (29). The intervention consisted of education, skill development, and individualized coaching about cancer pain management delivered by a registered nurse trained in the intervention, hereafter referred to as the intervention nurse. The high-dose group received six home visits and ten phone calls during the 10 weeks. The low-dose group received four home visits and six phone calls. The qualitative study was embedded within the RCT to better understand pain management issues and strategies from study participants' perspectives, as revealed in audio-recorded interactions with the intervention nurses. The use of dialogue naturally occurring as part of the intervention provided an unobtrusive approach to qualitative data collection. This approach provided rich, real-time data about patient and family caregiver experiences over

the 10-week RCT without confounding the intervention by concurrently conducting traditional qualitative interviews.

Setting and Sample

Participant recruitment took place in eight outpatient cancer settings in Northern California that included a university-based, National Cancer Institute-designated Comprehensive Cancer Center, two Veterans Administration facilities, a public hospital, and four community-based cancer centers. The sample consisted of patients with somatic and visceral pain from a variety of cancer diagnoses. Patients' family caregivers were invited to participate. Patients were eligible if they were at least 18 years of age; able to read, write, and understand English; gave informed consent; had a Karnofsky Performance Status Score \geq 50; had an average pain intensity score of at least 3 on a 0 to 10 numeric rating scale; had somatic or visceral pain; had a life expectancy of at least 6 months; were receiving outpatient treatment for cancer (not AIDS-related) with any single or combination therapy; and had a telephone line. Family caregivers were eligible if they were designated as the person most involved in the patient's pain management; at least 18 years of age; able to read, write, and understand English; and gave informed consent.

From the 222 patients and 139 family caregivers in the RCT sample, a subsample of 42 patients, 20 of whom participated with a family caregiver, was selected for analysis in the qualitative study. Early in the RCT, consecutive participants were included in the qualitative analysis. As the study progressed, purposeful sampling was used to achieve gender, racial/ethnic, and socioeconomic diversity. Balance was sought between patients who participated alone and those who participated with a family caregiver, and between those in the high-dose and low-dose groups. Later, we used theoretical sampling strategies (30), devised with the assistance of the intervention nurses, to select participants whose experience could help us further develop emerging coding categories. Sampling continued until the coding categories were judged to be "saturated," i.e. until the data became redundant and no new information was forthcoming as new transcripts were analyzed (31,32).

Procedures

The study was approved by the University of California San Francisco Committee for Human Research (UCSF CHR), the Protocol Review Committee of the Helen Diller Comprehensive Cancer Center, and the institutional review board at each clinical site. Oversight of the qualitative analysis was provided by the UCSF CHR and the institutional review board at the University of Nebraska Medical Center, where the qualitative analysis was conducted. Potential participants were approached at each clinical site by a staff member, who introduced the study and inquired about interest in enrolling. Interested patients were referred to a research nurse, who assessed eligibility, and conducted the informed consent process. Once written informed consent was provided, patients were randomized to the high- or low-dose group and an appointment was made for the first home visit.

Qualitative Data Collection

Audio-recorded dialogue among patients, family caregivers, and intervention nurses comprised the main source of qualitative data. A supplementary data source was the nurses' narrative notes of their observations during interactions with participants. Patients and family caregivers participated in the intervention sessions together. The intervention home visits and telephone calls were digitally recorded and transcribed verbatim for the 42 cases in the qualitative sample. These data were organized by case in MAXQDA[®] (33), with a "case" consisting of all the qualitative data for an individual patient or a patient-family caregiver dyad. The qualitative database consisted of transcripts for 181 home visits and 231 phone calls, plus nurses' notes for each case.

The first home visit consisted of an extensive assessment of patients' pain experiences and current pain management situation; a structured educational program about pain management; discussion of common misconceptions about the management of persistent cancer pain; and individualized coaching about pain management strategies tailored to patients' specific needs and preferences. Patients were instructed on how to record their pain intensity and medication use in a daily diary. They were provided with a pillbox to use as a memory aid and a written script to facilitate communication with clinicians. Management of analgesic side effects was also a focus of the intervention, including proactive strategies to prevent constipation. Family caregivers' knowledge of and involvement in pain management were assessed. Follow-up home visits and phone calls consisted of assessment, reinforcement of the structured education, and on-going, individualized coaching for effective pain management.

Data Analysis

Two authors (KS and VPC) conducted the qualitative data analysis, proceeding concurrently with implementation of the RCT. We used an interpretive approach, focused on themes emerging from the data, rather than from an a priori, theory-based coding framework (30). We set aside or "bracketed" theoretical concepts as much as possible in order to focus our interpretation on participants' experiences expressed in their own words. The set of transcripts for each case was read initially in its entirety to get an overview of participants' pain experiences. Line-by-line coding and categorization was used early in the analysis to inductively identify major themes in the dialogue. We created a tabular data matrix for each case in MicroSoft Excel[™] to organize the data for each theme across time (34). In addition, we wrote case summaries to develop a narrative account of the context and dynamics for each individual case.

As the analysis progressed, the prominence of issues surrounding the practical, day-to-day handling of pain medications became evident. In fact, issues with pain medications were mentioned by every patient or patient/caregiver dyad in the qualitative sample and confirmed by the intervention nurses as highly salient. Although the Pro-Self[®] Plus Pain Control Program included extensive education about *pain* management, the sheer scope of day-to-day issues with pain *medication* management was not anticipated *a priori*. Rather, issues with pain medication management came to light spontaneously through the semi-structured assessments that comprise part of the Pro-Self[®] Plus Pain Control Program.

The complexity of the day-to-day handling of pain medications was so challenging for study participants that we concluded that their stories about this particular aspect of their pain management experience needed to be told. Therefore, we chose the theme “pain medication management” for further in-depth analysis. At this point, the qualitative analysis moved from developing descriptive summaries and matrices to a higher order interpretive analysis of pain medication management behaviors and the contexts in which they occur. Additional coding categories were developed. We made extensive use of memos to deepen the analysis and to integrate the coding categories into a story line. We focused on all the medications addressed in the intervention, including both analgesics and medications prescribed concomitantly for analgesic side effects, such as constipation. We excluded medications for other conditions, such as cardiovascular conditions, as these were beyond the scope of the intervention. We ultimately interpreted pain medication management as a multi-dimensional process that occurred within the contexts of multiple complex health systems and highly individualized home environments and lifestyles.

Several strategies were used to insure the rigor and completeness of the qualitative analysis (32,35). The two research team members primarily responsible for the qualitative analysis had different research backgrounds, which served as a check on the introduction of personal biases. They met weekly to discuss the data and develop a consensus about key findings. Emerging results were shared periodically with the principal investigator (CM), project director (CW), and the intervention nurses during research team meetings. The intervention nurses were asked to identify any additional issues not sufficiently represented in the qualitative analysis. Strategies for purposeful and theoretical sampling were devised during these meetings. An extensive audit trail, in the form of memos, was kept on analytic strategies and decisions.

For reporting purposes, we organized our findings according to context because of the scope and length of our findings and differences in policy and clinical implications based on context. In this article, we focus on pain medication management processes that took place in the context of multiple complex health systems. In a subsequent article (36), we address processes that took place in home and lifestyle contexts. Admittedly, the distinction between pain medication management processes occurring in health systems contexts and those occurring in home environments and lifestyles is somewhat arbitrary and suggests a more linear and compartmentalized experience than our data indicate. In reality, at any given time, participants were involved in multiple pain medication management processes in relation to both health systems and their home and lifestyle contexts.

In the illustrative data below, all names are pseudonyms. Extensive verbatim quotes are included to give voice to the perspectives of study participants. In the verbatim quotations, (FC) is used to indicate that the speaker is the family caregiver. “Week” refers to the week of the intervention in which the dialogue took place. Medication trade names are used only in verbatim quotations or when needed to make sense of a data-based example.

Results

Sample Characteristics

The 42 patients in the qualitative analysis ranged in age from 40 to 88 years. The majority were male and white (Table 1). Years of education ranged from 7 to more than 22. Eighty-eight percent had at least some post-secondary education. Twenty-one were in the high-dose group. Two received hospice services at some point during the 10-week study. The 20 family caregivers ranged in age from 52 to 75 years and were mostly white, female spouse/partners of the patients. Ninety percent had at least some post-secondary education.

Overview of Qualitative Results

We interpreted pain medication management in the oncology outpatient setting as a multi-dimensional behavioral process that included getting prescriptions and obtaining medications and then understanding, organizing, storing, scheduling, remembering, and taking them. These processes involved both patients and caregivers and were situated in the contexts of bureaucratic health systems and home environments and lifestyles unique to each individual. Pain medication management processes that took place primarily in relation to health systems were getting prescriptions and obtaining medications (Figure 1).

The health systems context experienced by study participants was complicated and fragmented. It included multiple clinicians in multiple disciplines and specialties working in multiple healthcare organizations; pharmacists and pharmacies; reimbursement policies; and regulations governing prescription drugs. Participants dealt with large public and private healthcare networks in which cancer treatment, supportive care, primary care, and treatment for medical conditions other than cancer were not necessarily provided within the same organization. Medications were obtained from hospital-based pharmacies, local community-based retail pharmacies, and/or large mail-order services. The reimbursement and regulatory systems governing the prescription and dispensing of cancer pain medications contributed to the complex web that study participants navigated with varying degrees of success. The complexities of the health systems context for pain medication management pervaded the processes of getting prescriptions and obtaining medications, as described below.

Getting Prescriptions

The pain medication management process began with getting a prescription. On one level, this process was a seemingly straight-forward first step. Although a few clinicians were described by patients as reluctant to prescribe opioids, most were attuned to current guidelines for cancer pain management and were highly responsive to patients' needs. However, despite the seemingly straight-forward nature of getting a prescription from a responsive clinician, getting both initial prescriptions and authorizations for refills was a time-consuming process that required considerable effort and resulted in both worry and frustration. Participants faced multiple coordination and communication issues. These issues were compounded by the sheer number of pain medications accumulated as the need for pain management changed and different prescriptions were written. The unique nature of tailoring pain management regimens to individual needs meant that some patients received

new prescriptions frequently from diligent clinicians attentive to the importance of effective pain relief.

Coordination issues abounded, as multiple oncology clinicians and clinicians in other specialties were involved in patients' pain management. Some provided ongoing outpatient care, while others responded to urgent patient needs in episodic or acute care settings. For example, Keith's oncologist, primary care provider, an emergency room physician, and the medical director of a hospice all prescribed pain medications over time in an effort to control his severe pain. Coordination among them was extremely challenging for his family caregiver.

Clinicians were frequently located in different healthcare networks and different geographic areas. For example, Dorcas had both an urban home and a weekend/vacation home some distance away, resulting in interactions with clinicians (and pharmacies) in two different areas. More common was the need to coordinate between cancer specialists in the city and clinicians near home. For example, Howard's local oncologist prescribed methadone, the cancer center oncologist prescribed hydromorphone, and a nurse practitioner prescribed hydrocodone with acetaminophen. He commented, "Too many doctors. Jesus."

In short, patients and family caregivers dealt with an assortment of pain medication prescribers who had few connections with each other and in some instances did not even work in the same healthcare network. Collectively, clinicians were quite responsive to patients' pain and diligent about trying to managing it, but coordination fell to patients and family caregivers.

Prescribing by multiple clinicians inevitably led to communication issues that patients had to resolve. For example, Robert had multiple clinicians in multiple medical specialties prescribing medication for three different types of pain. His original pain management regimen was for MS Contin™ (Purdue Pharma) and Vicodin™ (AbbVie). One clinician forgot exactly what he was taking and told a second clinician that he needed prescription refills for Oxycontin™ (Purdue Pharma) and oxycodone. Robert described the telephone communication between the two clinicians this way:

Robert: Well, there was a confusing conversation...right after (orthopedist) did the injection in my knee, (oncology NP) called him back. And she had actually forgotten that I was taking MS Contin so she said well, I'll mail him an Oxycontin prescription. And (orthopedist) said, "I'll just write it for you. I'll just write it myself so that you can fill it."

Robert filled the prescription, but when he got home, he realized that he had a different medication than what he usually took:

Robert: I said that's kind of confusing because I'm taking MS Contin now and I'm not sure what...is this a fast acting? I sent (oncology NP) an email saying I'm confused about what I'm doing here and she wrote back very apologetically and said, "Oh my goodness, I forgot that you were already doing MS Contin." [Week 2]

Even when only one clinician prescribed pain medications, communication issues existed. Communication when a new prescription or refill was necessary between clinic visits was a particular challenge. Some patients were reluctant to “bother” a clinician about a new prescription or refill. Some assumed that they had to contact their physician directly, not realizing that a nurse or office assistant could facilitate communication. Some assumed that nurse practitioners could not prescribe opioid analgesics and thus did not try to contact them. Sometimes phone calls were not returned in a timely fashion after a message was left. Technical difficulties with the telephone, including dropped calls, occurred, discouraging continued communication attempts. Derrick experienced multiple issues related to telephone communication:

Derrick: I've been trying to get a hold of (MD), and the weirdest thing... When I put in the call I got back a nurse, and I was trying to talk to her, explain all these things that I needed to talk to him about and the phone went dead. So I put the phone down and waited for a call back and this is a little after 4:00. Well, they shut down at 4:00 so I just assumed, you know unions. Well, I called back the next morning and stayed on the phone until I could talk to someone and finally I put another message in and somebody called me back. Yesterday I was talking yadda yadda and the phone went dead and I don't know if she got half of what I said... The doctor never called me back. [Week 8]

He resorted to leaving notes for his physician:

Derrick: So I wrote him a note one day, because I went over to see (another specialist) so instead of playing phone tag with the (primary care physician), I wrote a note. And I asked the nurse to give this to him and nobody calls me about it. Well, I'm thankful it (the new prescription) just showed up. [Week 10]

Given these communications issues, a common strategy was to wait until the next scheduled appointment to get a new prescription or refill in person, resulting in delayed pain relief.

Timing was another issue in getting prescriptions refilled. Requests had to be initiated early enough to ensure that there was no gap in supply. Patients learned to anticipate when a refill authorization was needed, so that they could notify their clinician in time. As Frank explained:

Frank: But then I tell the doctor, if I go there and I'm low, I say “Doc, I'm low.” He says, “Okay, how much do you have?” I go “10 more days.” “Oh, no problem,” you know, they mail it to you. [Week 1]

However, refills could not be obtained too early, as insurance plans dictated how soon a prescription could be refilled. For example, Brian got a prescription to refill his fentanyl patch during an appointment with his physician, but waited to take it to the pharmacy because it was too early to refill. When the time came to get the prescription refilled, the following “snafu” occurred because the number of patches to be dispensed was not written on the script:

Beverly (FC): So when we got to the pharmacy, they said, “We can't fill this.” I said, “Well, I know it's for two boxes or 10 patches. They said, “Well, it's a narcotic. We can't take your word for it.” And then (MD)'s on vacation!

Now Brian was getting anxious and needed a back-up strategy to manage his pain:

Brian: So we're coming up to a weekend and I'm getting a little bit edgy about it... It looks like maybe we have enough to get through Sunday and maybe Monday if we use a whole lot of pieces and whatnot. For example a 75 or a 50 and just put them together. **Beverly (FC):** We have one 100. We have nine 75s. We have two 25s. Two 25s and one, two, three, four, five, six 12s. You'll look like a patchwork quilt. (Brian's prescription was for 200 micrograms). **Brian:** So we're close enough to the edge that it's beyond my comfort level. [Week 6]

A common practical issue was the need to go in person to a clinic or a physician's office to get a written prescription because the pharmacy could not accept a telephone or faxed order. Such trips were time-consuming and exhausting in the dense urban environment in which study participants lived. The urban hassles of traffic, parking, and public transportation were compounded by symptoms such as fatigue, weakness, and low endurance. Thus, these trips were physically taxing, especially when a patient then had to make a subsequent trip to the pharmacy. Compounding the energy expenditure of picking up prescriptions in person was the multiple other trips patients had to make, including trips for lab work, treatments, and clinic appointments with a multidisciplinary range of specialized clinicians. Being a cancer patient was a lot of work and special trips to pick up a written prescription were just one more thing to do in the context of outpatient cancer treatment.

Obtaining Medications

Once patients got a prescription for a pain medication, the next step in the process was obtaining the prescribed medication itself. Over-the-counter pain medications and medications to prevent constipation also had to be obtained. Reimbursement policies dictated where prescriptions could be filled. Some patients could fill their prescriptions in person at a local pharmacy, which provided the opportunity to speak with a pharmacist. However, going to a pharmacy could also involve traffic, parking, long lines, long wait times, and/or the need to make more than one trip. When a patient was unable to go to the pharmacy him or herself, a caregiver or someone else might make the trip on a patient's behalf. However, then the patient did not have the opportunity to speak with the pharmacist directly.

Some retail pharmacies did not routinely stock large quantities of opioids. Sometimes a delay in filling a prescription occurred because the pharmacy did not carry the needed medication or the prescribed dose. Patients dealt with this situation in a variety of ways. Most effective was when they established an ongoing relationship with a pharmacist, who knew what medications the patient was taking and kept a supply on hand. However, such personal relationships developed over time after an initial experience of having to wait while the pharmacist special-ordered the prescribed analgesic. After trying to work with a pharmacy that didn't stock the medications he needed, Pete found a pharmacist that worked with his individual needs:

Pete: We'd go to (first pharmacy) and they would say, "We can't get that," or "We can call to another store to see if they have that." And at that point you just want to go, "No, I don't even mess around with it." So when we went down to (current pharmacy), we ended up jumping through the hoop one time and once they got their act together down there they've just been spectacular. All I have to do is to tell them if I need anything and they can get it, especially the oxycodone. I mean they get those 5 milligram pills in a big bottle like that. They don't (routinely) stock that now, so they have to keep that for me, which they've been doing. [Week 1]

Some patients obtained their medications directly from a hospital pharmacy or hospice. Advantages included convenience and the presence of a clinician to explain the medication or demonstrate its administration. However, such services were available only in special circumstances, often separate from the regular clinician, so communication and coordination challenges ensued. For example, Jerry's hospital provided some medications directly and did not charge a co-pay, but medications ordered by his physician were not necessarily carried by the hospital's pharmacy:

Jerry: Well, theoretically there's trouble because as I'm sure you understand, Hospital A's system, they buy their drugs nationally. The pharmaceutical houses are competing for contracts, so Hospital A won't have all the range of the medication that's available with the same labels. They may be getting something that's parallel.

Nurse: But not what the doctor actually prescribed or what she wanted. **Jerry:** Well, (medical oncologist), I think she understands now. There's certainly constraint on her. If she were at Hospital B she could write the prescription and give it to the patient to go and find the pharmacist. [Week 1]

Other patients received medications by mail or express delivery service, as offered (or required) by their insurance plan. Advantages included the convenience of not having to go to a pharmacy in person. However, mailed prescriptions required several days to process. A wait of several days or more could occur when a new medication or new dose was prescribed. Restrictions on how a prescription could be communicated to mail-order services and policies governing the mailing of controlled medications resulted in more delays. After a series of such delays, Paul learned he would be unable to obtain his pain medication by mail delivery:

Paul: First they faxed it and then they said they wouldn't accept a fax, they had to have the actual prescription, so mail the actual prescription. But it got there after it expired, and so we went around and round, and finally they said after we had been going on for 2 months about it, "Well this is a controlled drug, you can't get a mail order supply of it, you can't get a 90-day supply." [Week 1]

Patients had to be home to sign for mail-order medications. Many were active individuals, so inevitably a delivery was attempted when the intended recipient was not at home. Delivery attempts just before a weekend were especially problematic when a patient was running out of a medication:

Derrick: Last weekend, that's when it happened, Friday when I got home... When I was out running around, somebody banged on the door. I got a FedEx note on my

door handle. So I went chasing it down because it said requires signature so I knew what it was. I went chasing it down and sure enough, it was the new prescription.
[Week 10]

The lack of opportunity to interact with a clinician who could explain the mailed medication was another issue. Jerry's misconceptions about his mail-delivered constipation medication resulted in unwillingness to take it. He found the side effects listed in the package insert so “spooky” that he did not even open the medication itself.

In obtaining their prescribed medications, patients faced cost issues, such as high co-payment requirements, having to pay more because of income level, and the coverage “donut hole.” Some patients changed their insurance coverage because of the high costs. For example, pharmacy co-payments for Dee were \$200/month. She eventually switched to a health savings account. Even though the initial annual deductible was high, overall annual costs were lower because of the elimination of the monthly pharmacy co-payment. Pete's employment situation changed, resulting in uncertainty about whether he would be covered under his new employer's policy, given his pre-existing cancer condition:

Pete: And I definitely am suffering from that (depression) because I have worried about my health insurance coverage and worried about my work, job security and worried about my health.But it could really, really hit you, with getting my new coverage, you know, working my new job which I've only been there since (date), and it's been really difficult and a lot to worry about. [Week 1]

Some insurance companies placed limits on the amount of a medication patients could get and coverage for new prescriptions could be an issue when the insurance company had earlier reimbursed for another analgesic:

Pete: So I'm just like walking on eggshells waiting for my pain medicine. When I was just on the 40s, they filled that with no problem but as soon as I added the 10s to it, then they (insurance company) started playing games. They gave me a whole 30 days' worth of the 10s and they started parsing on the 40s so they gave me 15 days at a time. And I took my prescription that (nurse practitioner) wrote me for the other 15 days in to (pharmacy) Sunday and they told me that the computer wouldn't allow them to fill it yet. [Week 4]

Public assistance insurance programs limited not only the amount of a particular medication, but also the actual number of prescriptions that were covered. Long waits for authorization occurred. While waiting for authorization of an increased dose of controlled-release oxycodone from her public assistance program, Ellen's pain scores went as high as 9 on a scale of 0-10.

Finally, an infrequent, but serious, problem was obtaining a medication that was incorrectly labeled. Brian received a bottle on which “haloperidol,” was crossed out and “morphine” written on the label. After the intervention nurse advised returning it to the pharmacy for correction, the bottle was found to contain haloperidol. Chuck received a bottle of senna labeled as “docusate.” Neither Brian nor Chuck recognized the errors. The intervention

nurse caught both by noticing that the medication in the bottle was not the prescribed medication.

Discussion

This qualitative study, embedded in a RCT of the Pro-Self[®] Plus Pain Control Program, provided an in-depth examination of the day-to-day experience of cancer pain medication management from the perspectives of oncology outpatients and their family caregivers. Their perspectives make a vital contribution to knowledge about access to needed analgesics, medication safety in the oncology outpatient setting, and the sheer effort required of patients experiencing persistent cancer pain.

We interpreted pain medication management as a multi-dimensional process that began with getting a prescription and obtaining the medication itself. While seemingly straightforward on the surface, these processes took place in the context of multiple complex systems involved in cancer pain management, including the clinical, reimbursement, and regulatory systems. In getting prescriptions and obtaining the prescribed medications, patients and family caregivers served as the central point for communication and coordination among diverse clinicians, insurance resources, and pharmacy services, and as the final checkpoint for insuring medication safety. Navigating the complex web of people, services, and rules was a lengthy and tedious challenge that often resulted in frustration and anxiety, revealed in language like “beyond my comfort level,” “walking on eggshells,” and “getting edgy”. Delays in pain relief and close calls in terms of medication safety occurred.

Access to pain medications and medication safety required study participants to be knowledgeable about and able to effectively navigate the intricacies of multiple bureaucratic systems. We use the term “systems” to highlight the plurality of components in the U.S. healthcare system that study participants had to navigate, and the lack of integration among system components. While the clinical, reimbursement, and regulatory systems may comprise a more or less cohesive sector of society when viewed from a macro level, they were separate entities at the experiential level of patients and family caregivers. Our findings suggest that references to “the” healthcare system as a singular entity mask the complexity experienced by individuals who have to deal with multiple fragmented systems to access pain medications. Access to pain medications required time, patience, and a high level of system know-how. In fact, coordinating the actions of individuals in separate healthcare networks, facilitating their communication, and dealing with reimbursement and regulatory policies were key ingredients in effective and safe pain medication management.

The number of medication safety issues discovered in this qualitative analysis, including communication breakdowns and provision of the wrong medication, raises significant concern. These issues must be addressed in outpatient oncology settings, as they have been with inpatient settings (37,38). Further research is needed to determine how often near misses and medication errors occur in outpatient oncology. Several near-misses were “caught” by discerning patients and/or alert intervention nurses. Had they not participated in this study, patients and family caregivers would have served as the final checkpoint for insuring medication safety. How many near misses go undetected is unknown, as is how

many medication errors occur in outpatient cancer pain management when patients do not have the benefit of regular in-home contact with a nurse. The preponderance of medication safety work has focused on acute care settings (37,38,39) and transitions from one setting to another (40,41). Although the medication safety literature alludes to the importance of patient and family caregiver involvement (37,41), their role is seriously understudied. Increased attention to pain medication safety in oncology outpatient settings is vital, given the complexity of managing multiple analgesics. The anticipated increase in the number of older individuals with cancer and the fact that older cancer patients are likely to have multiple chronic pain conditions make attention to safety in outpatient pain medication management even more pressing.

The sheer effort required in getting prescriptions and obtaining medications is reminiscent of Corbin and Strauss' (42) classic work on the "unending work and care" of chronic illness management. Getting prescriptions and obtaining pain medications in the oncology outpatient setting required significant effort by patients already experiencing multiple cancer-related challenges, including stress, worry, many medical appointments, pain, fatigue, and other symptoms. To our knowledge, symptom management interventions have not taken into account the effort required of patients to implement the intervention and how these efforts affect outcomes. Future research on pain and symptom management needs to acknowledge the work required of patients in the context of today's health systems and seek to better understand the effects of navigating system-level barriers on patient symptoms, such as pain and fatigue.

Our qualitative results suggest that system-level barriers to cancer pain management, described some 20 years ago (43), are not resolved. The effect of increasing specialization, increasing compartmentalization of healthcare into local services and regional referral centers, ongoing initiatives for reducing medication costs, and increased scrutiny of medications at high risk for abuse were clearly evident in study participants' narrative accounts. Moreover, two extremes of system-level challenges were evident. On one hand, barriers to access resulted in insufficient medication and delays in pain relief. On the other hand, diligent pain management efforts by multiple clinicians in multiple settings resulted in an over-supply of pain medications for some patients and raised issues related to communication, coordination, and safety.

Current efforts to reform the U.S. health care system provide a once-in-a-generation opportunity to resolve previous, seemingly intractable system issues, taking into account patient and family caregiver perspectives as mandated by the Patient-Centered Outcomes Research Institute (44-46). Not only is the current healthcare system fragmented, it was in considerable flux while this study was underway and will continue to be so for the foreseeable future. During the study, the Prescription Drug Act of 2003 was in its initial years of implementation and the Affordable Care Act of 2010 was passed. While our study was not designed to explore the effect of these new laws on pain medication management, the new laws do increase access to needed medications and provide opportunities to create a more integrated healthcare system for the future.

Worldwide, the World Health Organization initiative entitled “Innovative Care for Chronic Conditions” (47), including cancer, provides building blocks for better integration of health care organizations, communities, policies, and patients. Expanding upon the Chronic Care Model (48), these building blocks are designed to promote active participation in care by patients and families. Exemplars of integrated systems that support patient self-management demonstrate the potential benefits. Thus, the health systems experienced by participants in this study are not the health systems of the future. However, patient and family caregiver responsibilities for navigating health systems and the effort required to do so are unlikely to change. This study underscores the need to consider patient and family caregiver perspectives when designing the health systems of the future.

Limitations

This qualitative study in a RCT has limitations inherent in its design. For example, our unobtrusive data collection strategies, designed to prevent confounding of the intervention, meant that participant comments that a trained qualitative interviewer might have followed up on were not explored in depth. Despite this limitation, the data resulting from intervention nurses' interactions with study participants were rich and extensive. In addition, the U.S. health care system is currently in flux, as noted above, raising questions about potential historical effects on the generalizability of our findings. Nevertheless, our findings indicate the importance of designing systems that facilitate effective and safe pain medication management by oncology outpatients and family caregivers.

Summary and Conclusion

An important contextual condition for pain medication management by oncology outpatients and their family caregivers is the complexity and lack of coordination among the multiple clinical, reimbursement, and regulatory systems involved in cancer pain management. Getting prescriptions and obtaining the prescribed medications were two pain medication management processes particularly affected by this context. Study participants gave voice to issues that have not received sufficient attention, including access to needed analgesics, pain medication safety in outpatient settings, and the effort required of individuals with cancer and their family caregivers. These issues require attention in future research and healthcare reform initiatives.

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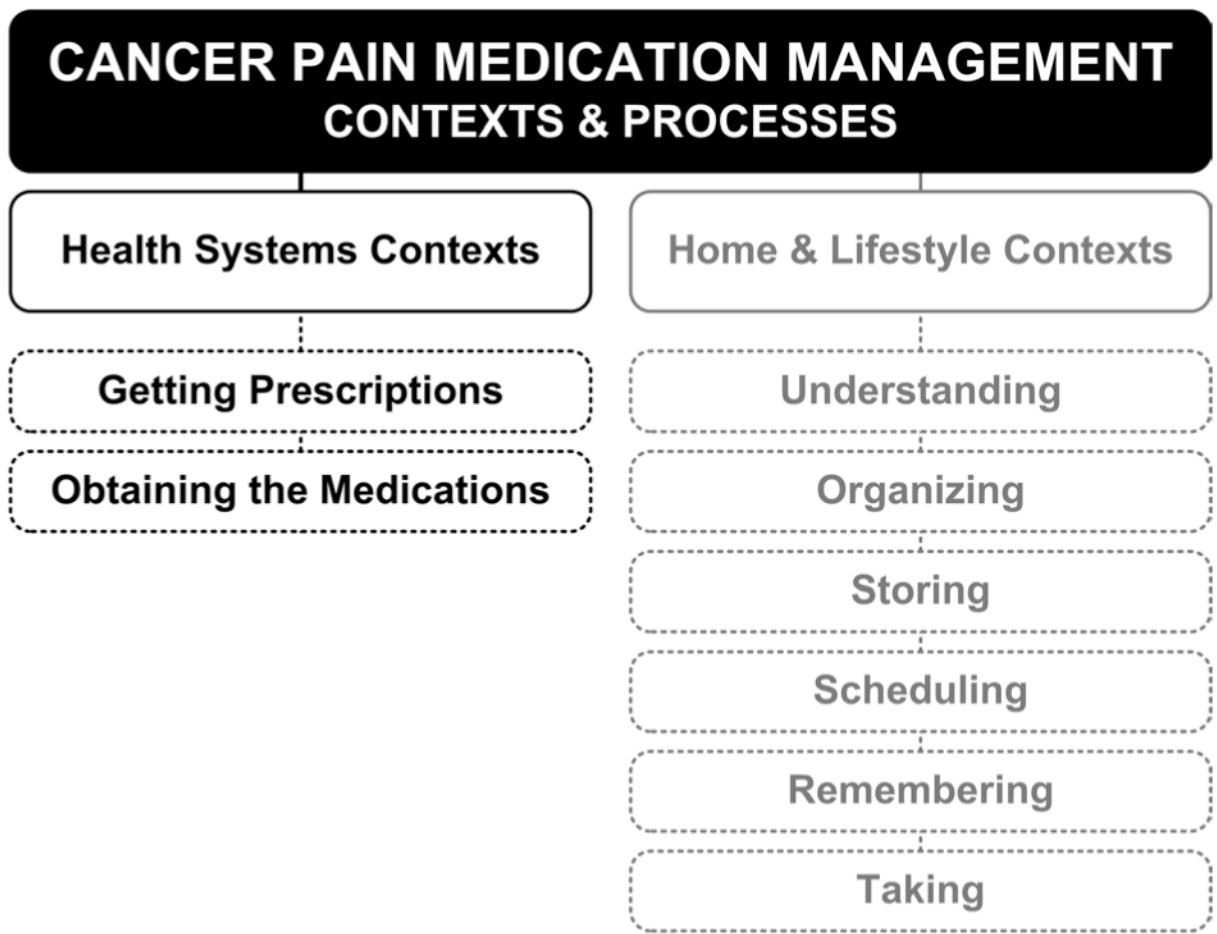


Figure 1.
Pain medication management contexts and processes.

Table 1

Sample Characteristics.

Characteristic	Patients (<i>n</i> = 42)	Family Caregivers (<i>n</i> = 20)
Age (years) Mean ± SD	64.0 ± 10.9	63.2 ± 7.5
Education (years) Mean ± SD	15.7 ± 2.8	15.3 ± 1.9
KPS* Score Mean ± SD	69.5 ± 11.8	
Gender <i>n</i> (%)		
Male	25 (59.5)	6 (30)
Female	17 (40.5)	14 (70)
Currently working for pay <i>n</i> (%)	8 (19)	7 (35.0)
Race/Ethnicity <i>n</i> (%)		
Asian	1 (2.4)	1 (5.0)
Black	6 (14.3)	1 (5.0)
White	31 (73.8)	16 (80)
Mixed	1 (2.4)	--
Other	2 (4.8)	1 (5.0)
Hispanic/Latino	1 (2.4)	--
Type of Cancer <i>n</i> (%)		
Breast	14 (33.3)	
Lung	6 (14.3)	
Prostate	17 (40.5)	
Other	5 (11.9)	
Current Treatment <i>n</i> (%)		
Radiation therapy	6 (14.3)	
Chemotherapy	25 (59.5)	
Hormonal therapy	15 (35.7)	

* KPS = Karnofsky Performance Status