original contributions

National Survey on the Effect of Oncology Drug Shortages in Clinical Practice: A Hematology Oncology Pharmacy Association Survey

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QUESTION ASKED: How are shortages in chemotherapeutics and/or supportive care agents used in cancer care affecting your institution?

SUMMARY ANSWER: Oncology pharmacists reported frequent impactful drug shortages that have interrupted cancer care delivery. Sixty-four percent of organizations experienced on average at least one or more oncology drug shortages per month. Treatment delays were common in patients with acute lymphoblastic leukemia and lymphomas because of shortages with vinca alkaloids. Supply chain strains of injectable hydrocortisone and dexamethasone and intravenous immune globulin due to the COVID-19 pandemic were also reported to have affected cancer care.

WHAT WE DID: A 36-item online survey was distributed to oncology pharmacists who were members of the Hematology/Oncology Pharmacy Association. We sought to investigate the impact of drug shortages with chemotherapy and supportive care agents routinely used in cancer care. Survey questions were focused on drug shortage impact on patient care, drug costs and resource utilization, safety implications, and effect on clinical trials.

WHAT WE FOUND: Sixty-eight US organizations participated in the survey between December 2019 and July 2020. Sixty-three percent of institutions reported one or more drug shortages per month, with a 34% increase in 2019 from 2018. Treatment delays, reduced doses, or alternative regimens were reported by 75% of respondents. The most difficult agents to obtain were vincristine, vinblastine, intravenous immunoglobulin, leucovorin, and Bacillus Calmette-Guerin.

BIAS, CONFOUNDING FACTORS: Our survey sample was limited to respondents who were members of the Hematology/Oncology Pharmacy Association, and data were submitted during an unprecedented time in history due to the COVID-19 pandemic, therefore a potential for sampling bias.

REAL-LIFE IMPLICATIONS: Drug shortages continue to impede cancer care delivery systems and present persistent challenges. Our findings highlight specific challenges during the COVID-19 pandemic. Shortages led to delays in chemotherapy and changes in treatment or omission, interrupted clinical trial accruals, and increased the risk of medication errors and adverse outcomes. Recent legislative activity continues address the multifaceted etiologies of drug shortages. But clearly, we need to improve the resiliency of the drug supply chain to serve our patients.

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abstract

PURPOSE Drug shortages are a clear and growing challenge. Prominent shortages included oncology medications and supportive care products essential for the care of patients with cancer. Oncology drug shortages often result in disruptions in the timing of chemotherapy treatments, alterations in the dose or regimen administered, or even missed doses when alternative agents are unavailable. The purpose of this survey was to characterize the impact of oncology drug shortages across the United States, including the experiences of health care organizations, resource implications, and the impact on patient safety, patient care, and clinical trials.

METHODS A 36-item online survey was distributed to membership of the Hematology/Oncology Pharmacy Association to gather information on shortages of oncology drugs (ie, all drugs essential in the care of patients with cancer, including supportive care agents).

RESULTS Sixty-eight US organizations participated in the survey between December 2019 and July 2020. Sixty-three percent of institutions reported one or more drug shortages per month, with a 34% increase in 2019 from 2018. Treatment delays, reduced doses, or alternative regimens were reported by 75% of respondents. The most difficult agents to obtain were vincristine, vinblastine, intravenous immunoglobulin, leucovorin, and Bacillus Calmette-Guerin.

CONCLUSION A survey of US oncology pharmacists indicated that oncology drug shortages occurred frequently in 2020. Shortages led to delays in chemotherapy and changes in treatment or omission, complicated clinical research, and increased risk of medication errors and adverse outcomes.

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INTRODUCTION

Drug shortages create a significant challenge for safe and effective patient care. Defined as a period of time when the realized or projected demand for the drug exceeds available supply, drug shortages occur for many acute or long-standing reasons.[1] Regardless of the specific cause, drug shortages are increasing in duration, severity, and impact on global public health.[2] In 2019, the US Food and Drug Administration (FDA) reported a total of 51 new drug shortages, in addition to 76 ongoing tracked shortages from subsequent years. In total, 575 potential shortage issues were reported by 109 different manufacturers for the calendar year 2019.[3] The number of new shortages per year has decreased from a record high in 2012 through mitigation efforts by regulators and manufacturers, but shall continue to be a burden on health care institutions in future years.

Most susceptible to drug shortages are sterile injectable generic products, particularly those costing < $9 US dollars per dose.[2,3] This category of products contains both chemotherapeutic and supportive care agents. Shortages of critical oncology medications may lead to disruption in timing of antineoplastic treatments, alterations in dose or regimen administered, or potential missed doses.[4–7] In addition, there is a significant financial and personnel resource burden in examining therapeutic alternatives and mitigating shortages at the institutional level.[8] Given the impact of the COVID-19 pandemic on cancer care delivery, particularly with concerns with manufacturing and supply chain, we sought to characterize oncology drug shortages on resource allocation, patient safety, and clinical trials in the United States.

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METHODS

A 36-item survey was developed by the Hematology/Oncology Pharmacy Association (HOPA) Public Policy Committee members. The survey was distributed electronically using the online survey software SurveyMonkey (San Mateo, CA). Pharmacy professionals caring for oncology patients were the primary target of the survey.

The electronic survey invitation described the purpose of the survey and provided a web link to the survey. The invitation stated participation in the survey was voluntary and data would be reported in aggregate. Participants were directed to complete one survey per institution, reflecting the collective feedback from oncology pharmacists, oncology nurses, purchasing staff, and others routinely involved in managing drug shortages. Data collection began on December 9, 2019, and closed on July 1, 2020.

The demographic and facility data collected for the survey included the communication method the participant was informed about the survey, the participant's patient care role, the facility type, the geographic location of the facility, the total number of parenteral chemotherapy doses administered per month, and whether the facility administered inpatient chemotherapy, had an infusion center, or had an outpatient pharmacy.

In this survey, drug shortage was defined as a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when providers must use an alternative agent. All chemotherapy and supportive care drugs were included in the scope of the survey. The survey included questions regarding the frequency new drug shortages per month, the need to dose reduce or use an alternative regimen, and the percentage of total drug shortages that were oncology drugs. Additional questions addressed resource implications of drug shortages assessing whether the institution incurred increased costs, full-time equivalent hours devoted to drug shortages, reimbursement issues for brand name drug alternatives for generics in short supply, and whether institutions purchased drugs from the gray market defined as a supply channel that is unofficial, unauthorized, or unintended by the original manufacturer. The medication safety impact of drug shortages was assessed by asking participants questions regarding medication errors and adverse patient outcomes because of drug shortages.

The survey included questions to assess the impact on patient care on the basis of the approach for standard therapies known to be in short supply at the time of the survey. One additional question was included regarding management of patients requiring intravenous immune globulin (IVIG) as this was a timely drug shortage that could affect patients with cancer. Questions were also asked to assess the impact of drug shortages on clinical trials.

RESULTS

A total of 68 membership institutions participated in the survey, and facility characteristics are seen on Table 1. The majority of facilities represented community hospitals (43%) and academic medical centers (38%). All survey participants were pharmacists and members of HOPA. Ninety-eight percent of participants have an onsite infusion center with 84% of sites administering inpatient chemotherapy and 87% providing outpatient pharmacy services. Fifty-two percent (n = 37) of survey participants reported that at least 1,000 doses of chemotherapy were administered each month at their site.

Impact on Patient Care

A majority of survey respondents (64%) reported experiencing on average at least one or more oncology drug

TABLE 1. Survey Demographics—Participating Facility Characteristics (N = 68)

Characteristic	No. (%) of Respondents
Facility type	
Community hospital	29 (43)
Academic medical center	27 (40)
Community retail/specialty pharmacy	11 (16)
Other[a]	1 (1)
Geography	
East North Central (IL, IN, MI, OH, WI)	14 (21)
South Atlantic (DE, FL, GA, MD, NC, SC, VA, WV, DC)	13 (19)
Middle Atlantic (NJ, NY, PA)	7 (10)
East South Central (AL, KY, MS, TN)	7 (10)
Pacific (AK, CA, HI, OR, WA)	7 (10)
West North (IA, KS, MN, MO, NE, ND, SD)	6 (9)
West South (AR, LA, OK, TX)	5 (7)
Mountain (AZ, CO, ID, NM, UT, NV, WY)	5 (7)
New England (CT, MA, NH, RI, VT)	3 (4)
Other[b]	1 (1)
No. of chemotherapy (parenteral) doses per month	
< 100	1 (1)
100-499	19 (28)
500-999	12 (18)
1,000-4,999	23 (34)
≥ 5,000	12 (18)
Administration of inpatient chemotherapy	57 (84)
Facility has outpatient pharmacy	59 (87)

[a]Other facility types referenced—physician practice, community ambulatory infusion centers, private infusion center, and nonacademic multisite health system.

[b]Facility with multiple sites throughout the United States.

shortages per month. In this portion of the survey, 27 different antineoplastic or supportive care agents were provided by membership as having a drug shortage. The most difficult medications to obtain (Fig 1) included vincristine, vinblastine, IVIG, leucovorin, and Bacillus Calmette-Guerin (BCG). Notably, 75 percent of institutions reported having to delay treatments, reduce doses, or use alternative treatment regimens based upon oncology drug shortages. The most frequently reported drug shortages with chemotherapy medications are listed on Table 2. Treatment delays were most commonly reported in the treatment of patients with acute lymphoblastic leukemia (ALL; 44%), lymphomas (40%), bladder (21%), multiple myeloma (16%), and chronic lymphocytic leukemia (14%). The most frequently reported supportive care agents used in cancer populations are reported in Table 3. Survey respondents noted impactful shortages in antimicrobials used in treatment and prophylactic strategies, antiemetics, and immunosuppressants. Seventy-three percent of institutions reported challenges in procurement of IVIG. These challenges associated with IVIG led to the following impact on patient care—dose reduction of IVIG for treatment (61%), institutions creating restrictions (58%), and deferred IVIG for a later treatment (52%). Eight institutions reported having to obtain IVIG from another institution.

Drug Costs and Resource Utilization

Approximately 64% of institutions reported that they incurred increased costs from oncology drug shortages. In markets where supplies are scarce or in short supply, gray markets evolve to sell shortage products at higher costs. Notably, only seven institutions reported purchasing oncology drug products from the gray market with most reporting at least 25% more in drug costs associated with these agents. Participants (n = 29) reported their facilities dedicating 1,000 or more personnel-hours to managing drug shortages; this equates to at least 0.5 full-time equivalent staff resource unit, or 20 hours/wk. A majority of respondents (92%) did not receive additional full-time equivalent hours to manage drug shortages.

Safety Implications

The use of alternative agents in situations in which drug shortages exist can lead to medication errors. Near-miss medication errors (ie, errors that did not reach the patient) were reported in 4% (n = 3) of survey participants. These included dose-conversion errors between intravenous and oral etoposide as well as incorrect electronic medical record builds that led to confusion regarding preparation and administration. Six-percent of responders did report a medication error because of shortages.

Impact on Clinical Trials

In our survey, 13% (n = 9) of institutions reported that drug shortages did affect clinical trials at their site. Specifically, responders stated that these shortages led to patients being unable to be enrolled on trial (n = 6), additional trial documentation and communication with the institutional review board (n = 5), and delayed trial approval or activation (n = 2). One respondent reported an increase in accrual for a BCG-containing clinical trial, given the global issue of BCG shortage outside of trial.

DISCUSSION

For nearly a decade, health care systems in the United States have struggled with the number of prescription drug shortages that continue to plague health systems and cancer providers.[5] A significant percentage of drug shortages continue to be sterile injectables, including chemotherapy, anesthesia, and other acute drugs. The primary causes of these shortages are because of shortage of raw material, natural disasters, and manufacturing issues not limited to economic discontinuations and delays.[5,9,10] These shortages may negatively affect patient outcomes and pose a risk to patient safety, leaving health care providers pivoting to ration or access alternative medication for life-saving therapies.

In critical populations such as patients with cancer, drug shortages can create a strain on the health care system. The rate of drug shortages has slowed, however, but a large number are still active and pose a threat to patient care. In total 1,744 drug shortages have occurred in the United States since 2011, and 57% of medications involved are sterile injectable medications used in hospital or acute care settings.[11] Of particular interest in this data set is the continued annual increase of chemotherapy drug shortages between 2016 and 2020. Once a drug shortage is identified in a care delivery system, a cascading strategic planning event occurs to help mitigate the drug shortage. Drug shortage management activities are undertaken immediately, which focused on communicating with suppliers, identifying alternative agents in the market, providing education to facility personnel on alternative agents, developing or modifying policies or clinical guidelines, and updating electronic and medication administration systems.[12] Given health care strains over the past 2 years due to the COVID-19 pandemic, administrative activity associated with mitigating drug shortages is challenging.

Threats to the pharmaceutical supply chain as well as the international surge of patients requiring intensive care admission and treatments led to impactful shortages. Hospitals reported numerous shortages in medications that could affect cancer care, which included albuterol inhalers (60%), sedatives and anesthetic agents (58%), corticosteroids (34%), cardiovascular agents (24%), and investigational agents (24%).[13] As Table 3 indicates, the authors identified several supportive care medications commonly used in cancer care that also experienced drug shortages. Specifically, injectable steroids such as hydrocortisone and dexamethasone as well as intravenous opioids (eg, fentanyl/hydromorphone/morphine) were reported by HOPA survey participants to have drug shortages.

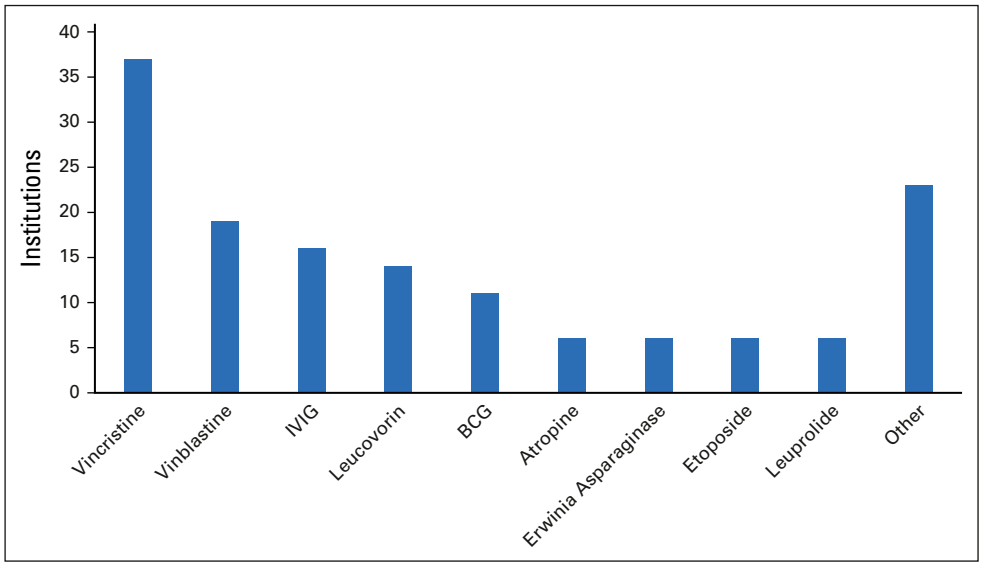

FIG 1. Most difficult to obtain: chemotherapy and supportive care agents (n = 53). Institution participants were asked to identify three most difficult drugs to obtain. Other medications include bleomycin (n = 2), famotidine (n = 2), fluoruracil (n = 2), sodium bicarbonate (n = 2), tacrolimus (n = 2), aprepitant (n = 1), carboplatin (n = 1), doxorubicin (n = 1), gemcitabine (n = 1), fludarabine (n = 1), granisetron (n = 1), ibrutinib (n = 1), intravenous temozolomide (n = 1), nelarabine (n = 1), paclitaxel (n = 1), thiotepa (n = 1), vinorelbine (n = 1), and ranitidine (n = 1). BCG, Bacillus Calmette-Guerin; IVIG, intravenous immune globulin.

Unfortunately, the impacts of drug shortages not only affect supportive care but also the backbone cancer treatments of some regimens as well.

In our survey, respondents reported significant challenges in obtaining vinca alkaloids. The vincristine shortage has gained international attention, particularly in lieu of the impact in the treatment of pediatric ALL.[14] The etiology of this shortage was due to quality control issue in the production line forcing Pfizer to temporarily close production.[15] Forty-percent of survey participants reported chemotherapy delays in patients with ALL and non-Hodgkin lymphoma (HL) at their institution. Vinblastine has also experienced shortages over the past year. Fresenius Kabi, the sole supplier of vinblastine, reported short-term manufacturing delay. The lack of vinblastine has been particularly challenging for clinicians who treat patients with classic HL, who often receive doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD) as the frontline treatment. Our survey revealed that some patients received treatment with

TABLE 2. Frequently Reported Oncology Drug Shortages (n = 52)

Drug	Experienced Shortage (%)	Minimal Delay (< 7 days in procuring agent; %)	Major Delay (> 7 days in procuring agent; %)
Epirubicin	90	5	0
Flutamide	90	10	0
Decitabine (IV)	82	9	5
Mechlorethamine	82	5	0
Melphalan (IV)	81	13	5
Dactinomycin	79	12	4
Pentostatin	76	5	9
Fludarabine	74	9	13
Degarelix	72	5	9
Carmustine	71	5	10
Paclitaxel	68	25	4
Dacarbazine	67	21	8

Abbreviation: IV, intravenous.

TABLE 3. Frequently Reported Supportive Care Agents in Oncology Practice Drug Shortages (n = 47)

Drug	Experienced Shortage (%)	Minimal Delay (< 7 days in procuring agent; %)	Major Delay (> 7 days in procuring agent; %)
Hydrocortisone	83	6	6
Promethazine	79	6	11
Mycophenolate sodium	76	12	12
Metronidazole (IV)	74	0	11
Metoclopramide	72	6	11
Ganciclovir	70	15	5
Fluconazole	70	20	5
Mycophenolate mofetil	67	17	11
Ondansetron (IV)	62	14	5
Dexamethasone (IV)	62	27	8
Tacrolimus (PO)	60	0	20
Prochlorperazine	52	14	10
Acyclovir (IV)	50	25	8

Abbreviations: IV, intravenous; PO, orally.

vinblastine omitted, substitution with vincristine (if available), or received bleomycin, doxorubicin, cyclophosphamide, vincristine, procarbazine, and prednisone, which is associated with more toxicities. Since the time of our survey completion and analysis, dacarbazine continues to be on shortage because of manufacturing delays, which further challenges the treatment landscape of HL.[16] The omission of dacarbazine in ABVD in an open-label, randomized noninferiority trial was stopped early because of increased progression of disease.[17] Given the current shortage, clinicians are contemplating the use of escalated bleomycin, doxorubicin, cyclophosphamide, vincristine, procarbazine, and prednisone, replacing dacarbazine with procarbazine and using the doxorubicin, bleomycin, vinblastine, procarbazine, and prednisone regimen, or replacing dacarbazine with cyclophosphamide.[18,19] Transitions to alternative regimens can lead to increased patient toxicity as well significantly disrupt cancer care delivery, considering ABVD is the most common frontline treatment for National Comprehensive Cancer Network institutions.[20]

Challenges with procurement of IVIG were reported by 73% of institutions and affected patient care. This drug shortage is frequently associated with manufacturing issues.[21] However, additional factors such as increased demand, requirement of plasma donors, and drug exportation add the complexity of IVIG supply chain. The demand for immunoglobulin products continues to grow by 8% annually. Despite numerous manufacturers who produce 15 currently available products, having to invest into new or expanding plasma collection facilities because of increased demand has been challenging. The United States is the largest contributor to the global supply in plasma and in 2019, produced approximately 40 million liters of source plasma in more than 50 million collections.[22] The impact of the COVID-19 pandemic on plasma collection strained donor pools. Our survey respondents indicated dose reductions of IVIG and institutional restrictions to address the IVIG shortages. Given periodic IVIG shortages, institutions should consider IVIG stewardship programs that increase national guideline adherence, decrease infections and antibiotic usage, and mitigate overutilization.[23,24]

Numerous challenges have disrupted accruals to oncology clinical trials over the past 2 years, given the COVID-19 pandemic. The inability to screen patients based upon reduced personnel or infrastructure closures, reduced capacity to comply with protocol-mandated tumor biopsies, and inability to comply with protocol-specific procedures have been identified as challenges.[25] In our survey, nine institutions (13%) surveyed reported that drug shortages affected clinical trial enrollment at their facility. This was less than a prior assessment of our membership on drug shortages affecting clinical trials in 2013, which reported that 44% of institutions were affected.[7] This observation could be a result of the significant disruptions in cancer care, specifically in delay in cancer diagnosis as well as receipt of treatment. A retrospective analysis of approximately six million Medicare fee-for-services claims during our membership survey period demonstrated a 30% decrease in change of chemotherapy administration compared with 2019.[26] Weekly enrollments of the National Cancer Institute–sponsored trials (January 2020-January 2021) have exhibited signs of recovery.[27] Given the steep declines in cancer screening associated with the COVID-19 pandemic, the emergence of more patients with advanced cancer cases could affect immediate and future drug shortages.

To our knowledge, this is the only survey that represents a national assessment of oncology drug shortages during the COVID-19 pandemic. As Table 1 demonstrates, our data represent a variety of practice settings and include

responses throughout the United States. Drug shortage assessments are often limited as responses represent a snapshot in time. For example, since our survey dissemination, drug shortages of azacitidine (injection), asparaginase erwinia, dacarbazine, nanoparticle albumin-bound paclitaxel (nab-paclitaxel), tocilizumab, tretinoin, and several others have been reported.[11,28] The current shortage of nab-paclitaxel is dramatically affecting cancer care in pancreatic cancer. Patients who are in need for immediate therapies are being told about limited supply and temporary allocations. Also, some patients are unable to enroll into certain clinical trials unless the institution has a minimum of two cycles of nab-paclitaxel. In centers authorized to administer chimeric antigen receptor T-cell (CAR-T) therapies, the emergence of tocilizumab shortage since August 2021 has led to significant challenges in scheduling patients for potentially life-saving treatments. The positive tocilizumab data in the treatment of patients with COVID-19 presented in the RECOVERY trial in addition to the Delta variant surge in August/September 2021 led to an unforeseen demand for this therapy, despite its vital use for managing cytokine release syndrome following CAR-T therapies. Given the FDA Risk Evaluation and Mitigation Strategies program requires CAR-T centers to have a minimum of two doses of tocilizumab for each patient undergoing CAR-T, this shortage has led to delay in therapies.[29]

Drug shortages continue to impede cancer care delivery systems and presents serious challenges globally. The unprecedented events associated with the COVID-19 pandemic led to many challenges in drug procurement. Manufacturing issues are often discussed as the etiology of many shortages. Given an estimated 73% of raw ingredients for FDA-registered drugs originate in foreign countries, particularly China and India, the US health care continues to be susceptible to future shortages.[30] We recommend economic incentives to manufacturers to increase capacity for sterile injectable drugs to assure a consistent oncology drug supply and improve transparency for supply chain sourcing. The etiology of shortages are multifactorial, but clearly action needs to occur to address this persistent issue.

Recent congressional proposals, such as S.2595, the Drug Shortage Prevention and Quality Improvement Act (117th Congress), and S.2723, the Mitigating Emergency Drug Shortages Act (116th Congress), have attempted to improve this continued problem for patients and clinicians.[31,32] Components of the Mitigating Emergency Drug Shortages Act that include (1) prioritization of drug applications and inspections, (2) manufacturer reporting requirements that include full disclosure of problems, and (3) manufacturer planning requirements were included into the Coronavirus Aid, Relief, and Economic Security Act, which was signed into law on March 27, 2020.[33] In a response to the Coronavirus Aid, Relief, and Economic Security act, The National Academies of Sciences, Engineering, and Medicine created a committee charged with evaluating the dependence on critical drugs manufactured outside the United States. Their findings and recommendations to improve the resiliency of the drug supply chain are to be released in March 2022.[34] With proper oversight and effective communication between health care professionals, manufacturers, patient advocacy organizations, and government agencies, drug shortages can be managed in a safer, more transparent fashion, or avoided altogether. Individuals with cancer should not shoulder the burden of drug shortages.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

National Survey on the Effect of Oncology Drug Shortages in Clinical Practice: A Hematology Oncology Pharmacy Association Survey

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