Addressing Cancer Treatment Shortages in Saudi Arabia: Results of a National Survey and Expert Panel Recommendations

Aeshah A. AlAzmi, BSc, PharmD[1,2,3,4]; Wasil Jastaniah, MBBS[1,2,3]; Hani S. Alhamdan, MSc[6]; Arwa O. AlYamani, MBBS[1,2,3,7]; Waleed I. AlKhudhyr, MSc[8]; Shaker M. Abdullah, MD[1,2,3]; Mohammed AlZahrani, MD[9]; Ashraf AlSahafi, MD[10]; Tawfiq A. AlOhali, MSPS[11]; Trad Alkhelawi, PhD[12]; Yasser AlObaida, PhD[13]; Ayman Allam, PhD[14]; Hani Al-Hashmi, MD[15]; Essam Murshid, MD[16]; Fouad AlNajjar, PharmD[17]; Ashwag AlGethami, MSc[1,4]; Atika AlHarbi, PharmD[1,4]; Meteb O. AlFoheidi, MBBS[1,18]; Ahmad S. AlSaeed, MD[1,19]; Hassan Elsolh, MD[20]; Ibraheem Abosoudah, MD[21,22]; Abdulaziz Ben Obaid, MSc[6,23]; and Mohammed AlNahedh, PharmD[24]

abstract

PURPOSE Cancer treatment shortages are complex and a persistent problem worldwide. Patients with cancer are most vulnerable to drug shortages, which provides opportunities to examine the extent of the challenge(s) facing Saudi Arabia and to provide recommendations toward mitigating the impact of cancer treatment shortages on patient outcomes.

MATERIALS AND METHODS A qualitative methodologic approach was conducted in April 2019 using a validated questionnaire and structured panel discussion for data generation.

RESULTS Overall, 55 responses were received from practicing oncology health care professionals (26 pharmacists and 29 physicians). The annual average number of treated patients with cancer per institution was 640 (adults [n = 400] and pediatric [n = 240]). All respondents (100%) reported that cancer treatment shortages constitute a current problem in their center, with an average of 5 (range, 1-9) per month. The panelists recognized 2 fundamental points. First, the definition of cancer drug shortages should be standardized and recognized at the national level. Second, the current system must be improved to ensure proper and efficient use of the current resources. On that basis, the panelists developed 9 recommendations for action.

CONCLUSION Cancer drug shortage is a significant problem in all health centers in Saudi Arabia. This study presents challenges that should be addressed at the national level and essential consensus recommendations for a coordinated action developed by a panel of experts to tackle the current national problem of cancer treatment shortages. Implementing these recommendations will provide a blueprint for management of national drug shortages in general and cancer treatment shortages in particular.

INTRODUCTION

Drug shortage remains a serious and persistent concern worldwide that affects numerous types of medications across different therapeutic areas.[1-4] The emerging reports indicate that the number of drug shortages has increased to more than double from 2005 to 2008 and includes numerous classes of drugs, with oncology drugs at the top of the shortages list.[5-7] Shortages in vital chemotherapy drugs for patients with cancer have been recognized globally and considered an obstacle in all health care systems, where the causes are multifaceted and complex according to many published studies in different countries.[8-16] Nine major governmental national cancer centers provide cancer treatment to patients in Saudi Arabia: Princess Noorah Oncology Center (PNOC); King Abdulaziz Medical City-Jeddah; Oncology Center, King Abdulaziz Medical City-Riyadh (RD); King Faisal Specialist Hospital and Research Centre-Jeddah and RD; King Fahd Specialist Hospital-Dammam; King Fahd Medical City-RD; Prince Sultan Medical Military City-RD; King Saud Medical City-RD; and King Abdullah Medical City-Makkah.

The Kingdom of Saudi Arabia is a high-income society, yet the national drug market is not immune to drug shortages, so health care providers face shortages of vital cancer treatments, including critical supportive care and inexpensive chemotherapeutic drugs. Local published data cites specific causes that include problems with manufacturing quality, the limited role of regulatory bodies, unreliable sources of raw materials, different formulary systems among hospitals, overdependence on imported international patent drugs, increased demand for certain types of

CONTEXT

Key Objective
What is the major challenge for chemotherapeutic drug shortages in Saudi Arabia?

Knowledge Generated
Saudi Arabia is a high-income country, yet the national drug market is not immune to drug shortages in general and cancer treatment drug shortages in particular. We highlighted four main topics covering the experience of practicing oncology pharmacists and oncology physicians, the impact of chemotherapy drug shortages on patient outcomes, and the ethical dilemma that oncology pharmacists and physicians faces while dealing with shortages. A structured stakeholder panel discussion and validated questionnaire were used as the main methods for data generation.

Relevance
Nine possible solutions were discussed, with provided recommendations to mitigate the impact of cancer treatment shortages on patient outcomes and quality of life.

medication, lack of early warning systems, notable differences in drug regulation between hospitals, and a poor supply chain management system.[17-20]

When cancer treatment is in short supply, health care providers struggle to interact and/or intervene. Shortages in cancer treatment are a burden to all health care systems which have almost become the norm in daily health care practice. Physicians are expected to provide the highest quality of care with the best available treatment option. Pharmacists, in particular, often interact with countless patients and health care providers. They are in the front line dealing with all sorts of issues including drug shortages. Furthermore, shortage in terms of a single chemotherapy drug may raise concern for unplanned changes to the plan of treatment, leading to delay in treatment, the use of less effective alternative drugs, use of inadequate drug dosing, and/or cancellation of the treatment plan—all of which can negatively affect patient safety and treatment outcomes. Beyond the clinical outcomes, dealing with chemotherapy shortages increases the economic burden on health care system, forcing health care professionals (pharmacists, physicians, nurses, and other staff) to devote their clinical time toward allocating alternative solutions instead of the clinical care setting.[18,19]

A few studies have investigated the causes of drug shortages in the Kingdom of Saudi Arabia.[17-20] However, none of those has been systematically conducted to investigate and analyze possible nationwide solutions for managing cancer treatment shortages or addressing their impact on patient outcomes. Managing cancer therapy shortages has led oncology health care professionals to deal with the ethical dilemma of how to treat and distribute therapy fairly. There is limited information available on the proper ethical framework in such circumstances.[21]

The impact of shortages on patients with cancer is evident worldwide.[22-30] Unfortunately, we do not have data at the national level to investigate the impact of chemotherapy shortages on patient outcomes. Although oncology health care professionals are the ones having to face the challenge of managing clinical complications and difficulties that develop from shortages of life-saving chemotherapeutics drugs, patients eventually will be greatly affected: their treatment plans could be delayed, deferred, or cancelled, which potentially affects their chances of surviving cancer. The main goal of this study is to provide recommendations to improve patient outcomes by increasing patient access to the best available, affordable, and appropriate drug therapies. We hypothesized that, if shortages in cancer therapy drugs persist, then the quality of our cancer therapy would decrease while treatment of related toxicity would increase. The Saudi Arabian health care system is subsidized by some substantial investment in light of Saudi Vision 2030.[31] To maintain quality of care, ensuring proper and efficient use of the current resources should be our main focus. Of note, we cannot copy other international solutions, because we do not share the same system or health care setting. Therefore, we adopted a qualitative approach to explore and identify the challenges at the national level and then provide recommendations on how to mitigate cancer treatment shortages.

MATERIAL AND METHODS

A qualitative analysis using a validated questionnaire and structured stakeholder panel discussion for the sake of data generation was conducted to achieve the objective of this study.

Questionnaire

On April 24, 2019, the PNOC convened a workshop under the annual Patient Safety Forum in Jeddah to discuss the challenges and possible solutions on how to address cancer treatment drug shortages in Saudi Arabia. Before the workshop, the authors created an electronic questionnaire based on previously published studies to examine the magnitude of the problem, the health care professionals' experiences when cancer drugs are in short supply, and the impact on patient treatment outcomes at the national level.[32,33] The questionnaire was distributed

5 days before the workshop to members of various scientific oncology societies: Saudi Oncology Pharmacy Assembly, Saudi Oncology Society, Saudi Society of Blood and Marrow Transplant, and the Saudi Arabian Pediatric Hematology Oncology Society group. These societies represent oncology physicians and oncology pharmacists in Saudi Arabia.

There were 4 main topics with 9 anonymous questions aimed at exploring perspective, experience, and impact of chemotherapy drug shortages. The 4 main topics covered the experience of practicing oncology pharmacists and oncology physicians, the impact of chemotherapy drug shortages on patient outcomes, and the ethical dilemma that oncology pharmacists and physicians face when dealing with such shortages. The questions addressed the estimated annual number of patients with cancer treated at each institution and if chemotherapy drug shortages were a current and ongoing problem (if the answer was yes, participants were then asked the following questions: how often was cancer treatment in short supply, what was the estimated number of chemotherapy drugs currently in shortage, what were the actions taken to cope with such cancer treatment shortage, what was the estimated time spent to find a proper solution, how often were health care providers informed about such shortages, and what were the observed patient outcomes secondary to shortages as well as the ethical dilemmas faced during these shortages).

Workshop Expert Panel Discussion

The workshop featured an expert panel that were recruited via phone call or e-mail invitation who were then grouped on the basis of their professional roles using the following criteria: national authorities, including the Saudi Food and Drug Authority (SFDA) and the National Unified Procurement Company (NUPCO); pharmaceutical companies (including national and international manufacturers, pharmaceutical wholesalers, and medicine supply chain); oncology health care professionals who are professionally involved in developing solutions to the problem (pharmacists, physicians, nurses); hospital management and administration (presidents and chairmen of major national oncology centers and pharmacy directors); and president, vice president, or board member of each national scientific oncology society (Saudi Oncology Society, Saudi Arabian Pediatric Hematology Oncology Association, Saudi Oncology Pharmacy Assembly, and Saudi Scientific Society of Blood and Marrow Transplantation).

The workshop was conducted over 4 hours and included 3 main sessions to foster dialogue between the panelists and participants. The discussion points were generated after conducting an extensive literature review of studies addressing the same problem. The points were piloted and subsequently refined, covering the following main points: understanding the national status of cancer drug shortages, the impact on practice, and possible solutions and recommendations. To facilitate the panel discussion, breakdown points were distributed before the workshop on the basis of the panel members' professional grouping, and all panelists received detailed information on the workshop's design and intended purpose. The panel discussions and recommendations were audiorecorded, transcribed verbatim, and analyzed by 2 authors before the paper was reviewed and analyzed by all authors. The reliability of the text was checked for any inaccurate transcription. To increase the overall credibility of the possible solutions and discussion findings, data triangulation was performed.

RESULTS

Questionnaire (magnitude of the problem and impact on patient outcomes)

There were 55 respondents in total (26 practicing oncology pharmacists and 29 practicing oncology physicians) from cancer centers around the kingdom. The estimated average number of patients treated per institution was 640 (400 adult and 240 pediatric patients per year). All respondents answered yes when asked if a shortage of cancer therapy is a current and/or ongoing problem. When asked, "How often does your hospital pharmacy experience chemotherapy/cancer treatment shortages," the most frequent response was monthly (34%), followed by occasionally (31%), weekly (24%), and daily (11%). The average number of chemotherapy drugs currently in shortage was estimated at 5 (range, 1-9).

Responses from oncology pharmacists. When asked, "What action did you take to manage and cope with chemotherapy shortages," it was of special interest to find that approximately 35% of pharmacists stated that they never discussed it with the prescriber to allocate or suggest an alternative treatment approach, because they had not the time to deal with such issue (Fig 1, details of actions taken by oncology pharmacists to cope with chemotherapy shortages).

The majority (89%) of pharmacists found that managing drug shortages is extremely time consuming, with their weekly time spent away from direct patient care, averaging ≥ 5 hours for 66% of respondents. Of those, 30% reported > 10 hours per week spent on dealing with cancer treatment shortages (Fig 2, weekly time spent by oncology pharmacist away from direct patient care dealing with drug shortages).

Responses from oncology physicians. When asked, "What action did you take to manage and cope with cancer treatment shortages," 48% of respondents said that "they always look for alternative medications after conducting multidisciplinary discussion." However, 7% of respondents reported delaying or cancelling the chemotherapy treatment plan if no alternative exists until the availability of the drug in shortage; 7% said that they asked their patients if it would be possible to bring his/her own cancer medication
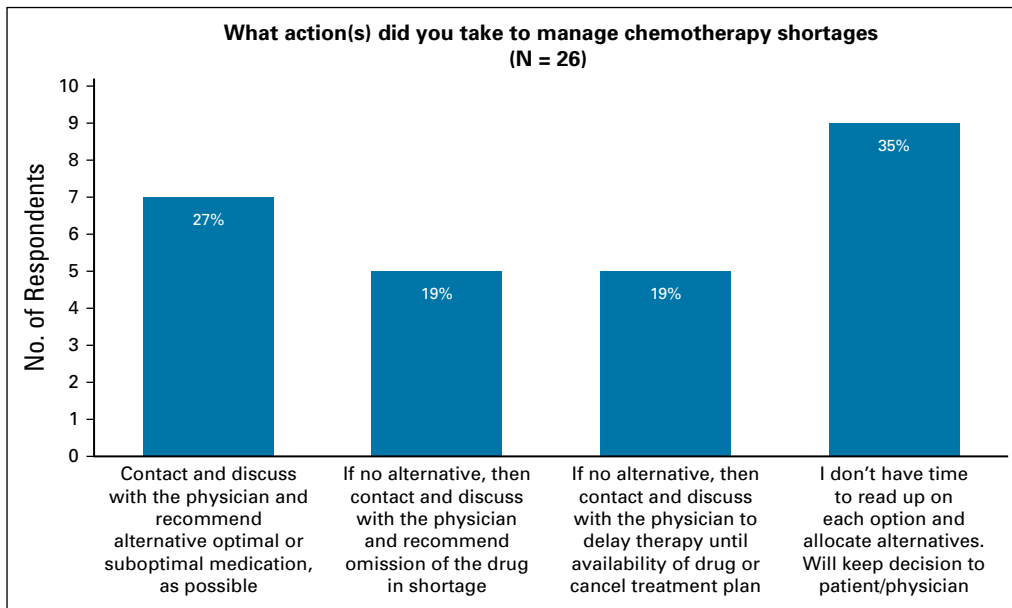
FIG 1. Oncology pharmacists' experience: action taken to manage chemotherapy shortages.

that is in shortage; and 38% said that they transferred their patient to another national/international institution that had a supply of the needed medication for cancer treatment (Fig 3, details of actions taken by oncology physicians to cope with chemotherapy shortages).

Impact on patient outcomes. When asked about the "patient outcomes caused by cancer treatment shortages and using alternative approaches," 33% of all respondents said that patient satisfaction decreased and/or patients lost trust and faith in the institution, 31% experienced increased

FIG 2. Weekly time spent by oncology pharmacists away from direct patient care dealing with drug shortages (N = 26).

patient and drug monitoring (laboratory or clinically) with/without subsequent prolonged hospitalization as a consequence of drug shortages, 18% of patients experienced treatment failure or relapse secondary to using alternative treatment approaches or delayed therapy because of shortages as evidenced by disease evaluation, 11% experienced care cancellations, 5% had readmission secondary to adverse events with/without subsequent prolonged hospitalization, and 2% of respondents reported death as an outcome as evidenced by root cause analysis that cited the cause as most probably secondary to delay in therapy or use of suboptimal drugs (Fig 4, the impact of cancer treatment shortages on patients).
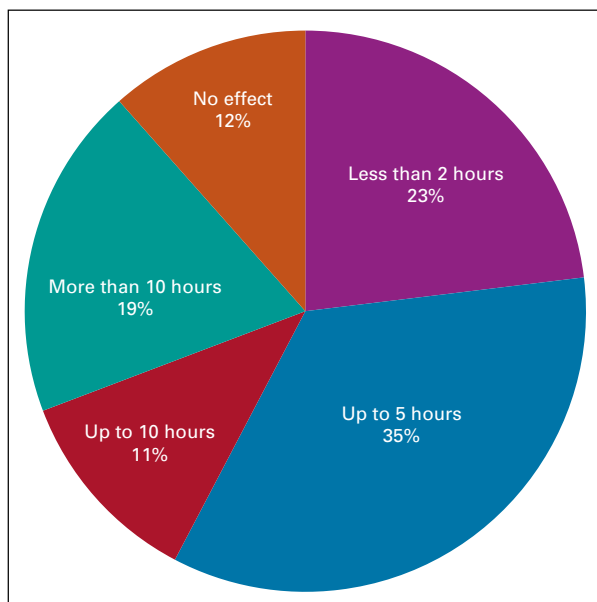
A father of a 6-year-old boy with refractory relapsed neuroblastoma shared his experience with drug shortages as his son started on palliative therapy with a 5-day course of intravenous irinotecan and oral temozolomide every 4 weeks. The son is receiving his treatment at PNOC-Jeddah though he lives in the south of Saudi Arabia (> 700 km from Jeddah). The father provided his story in Arabic, which we translated to English as the following: "I came today for the scheduled treatment for my son and, upon arrival, I was informed that oral chemotherapy had been canceled because the medicine used to treat it was not available. I will not be able to reschedule chemotherapy so far; I live far away from Jeddah. I am concerned, as this drug is important for my son to be treated, because the chance of survival is low and there is no other alternative available as his doctor told me. After 3 days: The pharmacist called me and told me that the oral chemotherapy is available now; unfortunately, they will skip the current chemo cycle and reschedule the treatment for other week."
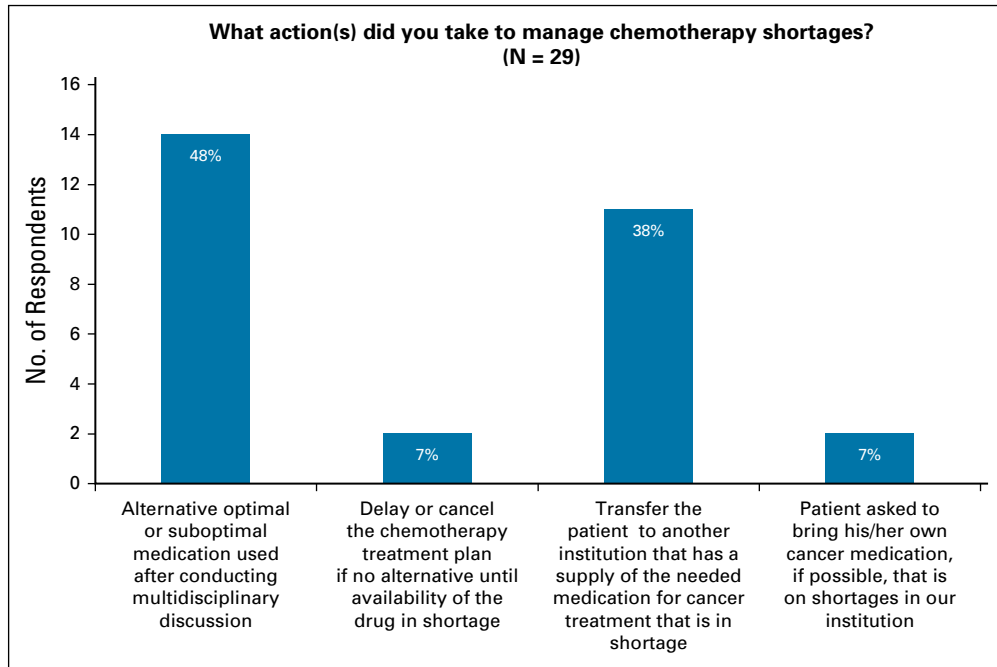
FIG 3. Oncology physicians' experience: action taken to manage chemotherapy shortages.

When we asked the oncology pharmacist's opinion, the pharmacist said, "the dose of temozolomide for this child is 60 mg. Unfortunately, we neither have a suspension dosage form nor a formula for extemporaneous preparation. The most suitable dosage form is [a] 20-mg capsule, which often [is] not available due to short supply."

Ethical dilemma. When asked, "What ethical principles guide you in your decision-making process when the supply of an effective drug is insufficient to meet the demand," 55% said that they would decide to treat the sickest patient first, 35% said that "curative intent should be prioritized over using the drug for palliation," 5% said "drug with approved indication should have priority over off-label drug use," and 5% said "first come, first served" would be the ethical basis of their action. (Fig 5, health care providers' ethical dilemma when dealing with chemotherapy shortage).

Panel Discussion (national challenges and recommendations)

Twenty-three key health care professional representatives from different national sectors with different specialties and major stakeholders were recruited for the workshop discussion. Six participants represented national authorities, oncology associations, and wholesale distributors; 5 participants represented pharmaceutical companies and the supply chain; 3 represented oncology centers and pharmaceutical department leadership; 3 represented oncology pharmacists; 3 represented oncologists; and 3 represented oncology nurses (Table 1).

Challenges. The panelists discussed a number of factors affecting national access to cancer treatment drugs, which

were summarized into 8 main points: (1) The local manufacturers cover less than a quarter of the local demand, because the majority of pharmaceutical products are imported. (2) The current deployed pharmaceutical procurement strategy is focused on the product price and gives little weight to the quality of the product. (3) Different tender procurement processes exist among Saudi hospitals with different budget allocations. (4) There is a lack of well-structured supply chain management system throughout the kingdom. (5) A lengthy review and approval process by the SFDA for pharmaceutical products that have already gained approval by international drug authority bodies, such as the US Food and Drug Administration and European Medicines Agency, could only further delay the availability of drugs and give a chance for an unmonitored product procurement process. (6) A lack of a well-defined unified communicating system that oversees the availability of stock nationwide exists. There is an urgent need for a collaborative, well-structured functioning network and alert reporting system that connects national institutions and provides an up-to-date status of drug supply, because the majority of these suppliers do not consistently inform institutions if and when their stock will arrive. (7) There is lack of an early warning system for anticipated drug shortage notifications from suppliers to the SFDA and then from the SFDA to national health institutions. (8) There is a lack of evidence-based policy at the national level to address ethical dilemmas while dealing with drug shortage.

Recommendations. The panelists discussed several strategies, as well as the different roles of stakeholders in
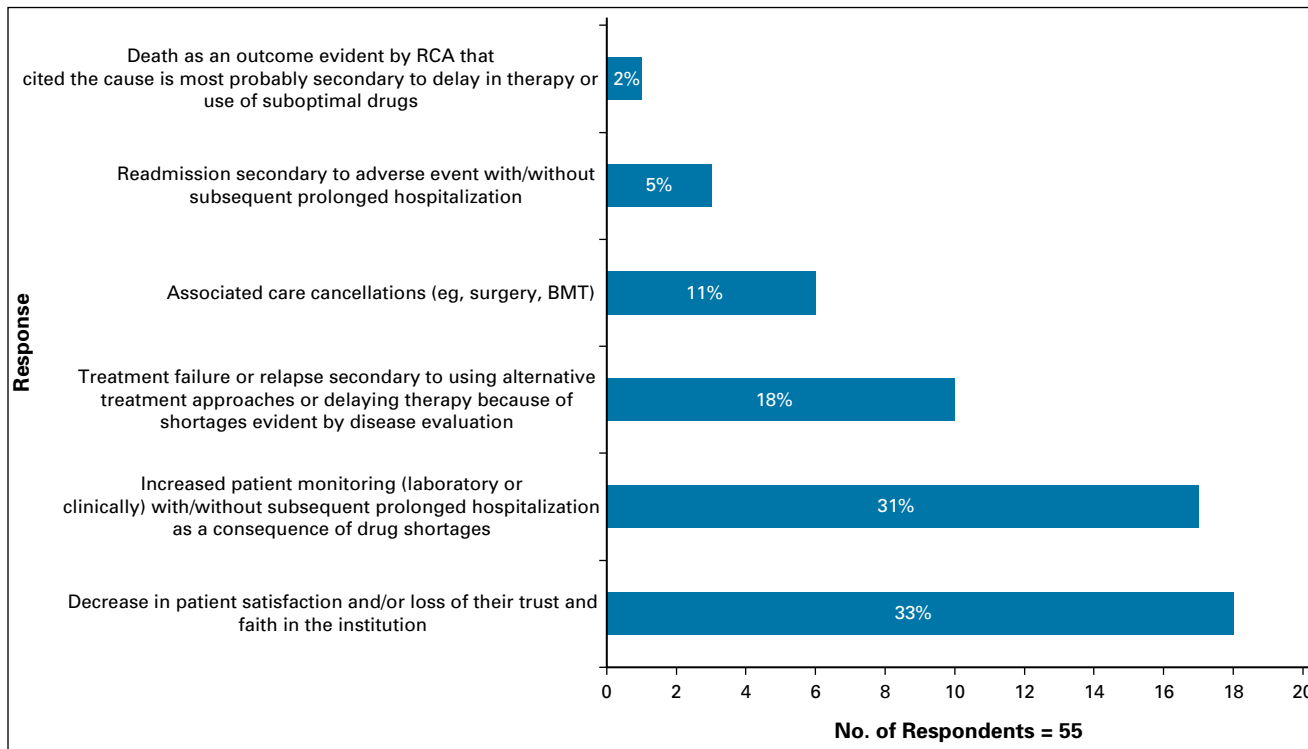
FIG 4. The impact of cancer treatment shortages on patient care outcome. BMT, bone marrow transplantation; RCA, root cause analysis.

addressing the current challenges, and proposed in the end the following 9 actionable recommendations:

First, the panelists recommended defining "cancer treatment shortage at the national level," because we do not have a uniform and specific definition of drug shortages in Saudi Arabia, in contrast to other international agencies.[34-37] The SFDA commissioner stated that the

SFDA defines drug shortages as "when the demand exceeds the drug supply," a definition that will be applied to all types of drug shortages, including cancer treatment.

Second, there is an urgent need to proactively establish a strategic plan to address cancer treatment shortages, with the main emphasis on the following:
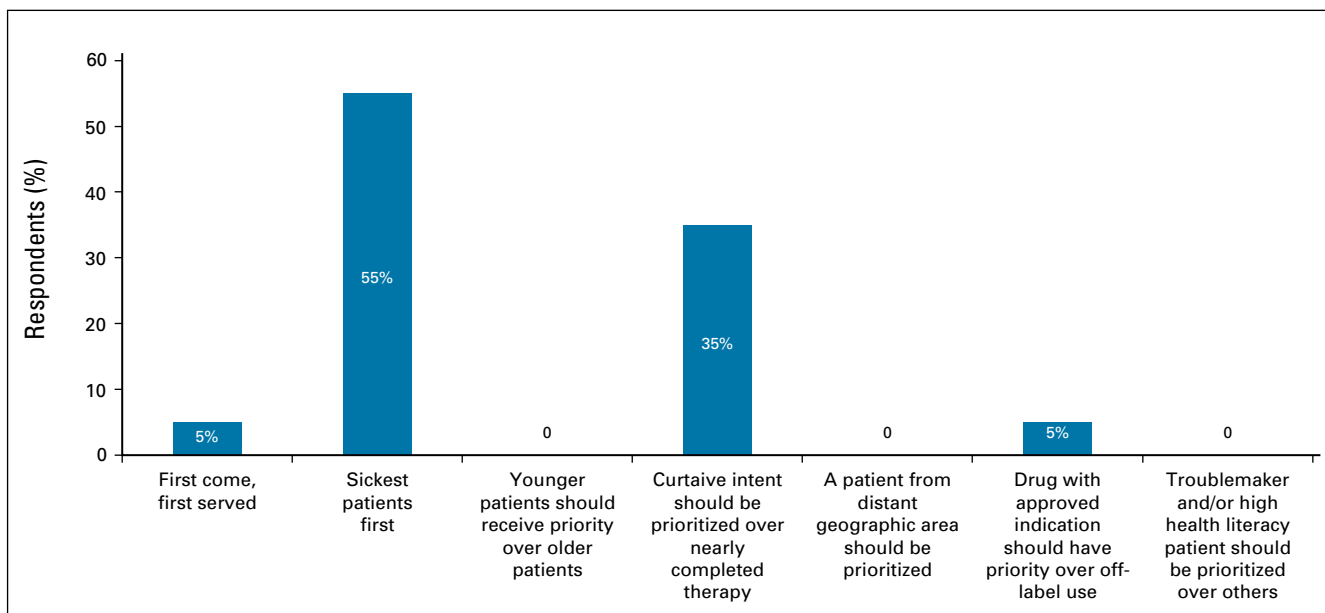

FIG 5. Health care providers' ethical dilemma when dealing with chemotherapy shortages.

TABLE 1. Summary of Challenges and Recommendations From the Expert Panel

Challenges
1) Overdependence on imported pharmaceutical products
2) Current procurement strategy that mainly focuses on the product price
3) Different tender procurement processes in every hospital, with different budget allocations
4) Poor supply chain management system
5) Lengthy review and approval process by the SFDA for already-approved pharmaceutical products
6) Lack of collaborative stock availability network and alert reporting system
7) Lack of an early warning system for anticipated drug shortage
8) Lack of evidence-based policy to address ethical dilemmas

Recommendations
1) Establish a drug shortage warning system.
2) Ensure a national safety stockpile.
3) Explore and create an innovative national clearinghouse system for cancer drug shortage database among relevant institutions.
4) Provide a value-added decision-based system.
5) Establish a dedicated cancer drug shortage oncology working group or steering oncology committee.
6) Develop a national ethical policy and framework to guide health care providers when dealing with drug shortage.
7) Create a policy that penalizes pharmaceutical companies in case of unjustified shortages.
8) Provide incentives to manufacturers that are committed to obtaining a local marketing approval (registration) and securing long-term procurement.
9) Provide support to local cancer drugs manufacturing.

Abbreviation: SFDA, Saudi Food and Drug Authority.

1. Change to the current fundamental drug regulatory system is necessary: (a) Lack of reliable metrics to examine national drug shortages and issues secondary to shortages are obstacles to understanding the root of the problem and finding the optimal solutions. (b) Establish an early drug shortage warning system. Cancer drug shortages usually develop without a suitable, acceptable reporting mechanism. The SFDA commissioner indicated that a newly established electronic system (http://ade.sfda.gove.sa) is dedicated to providing a list of drugs shortages.

2. Optimize the current cancer treatment supply and ensure a national safety stockpile. Every center has a variable demand and cluster of cancer diagnoses. Shortages in terms of a single chemotherapy drug usually affect the treatment plan for several cancer diseases, and, in some cases, no alternative approach is found suitable for treatment. There is a need for NUPCO to provide cancer institutions with more than 1 drug supplier and a unified procurement process while ensuring that each institution will have the ability to choose from the provided supplier list on the basis of their demand and budget allocation.

3. Explore and create an innovated national database clearinghouse. The database system at clearinghouse should be able to communicate, track, and trace the drug supply status as well as facilitate a nationwide exchange and sharing of medications among institutions. To that end, effort should be made to adopt the medication exchange and sharing network program, which is a national voluntary group that creates a simple program to cope with drug shortages, to be overseen by national regulatory bodies (NUPCO and/or SFDA)[38].

The SFDA commissioner shared that a new initiative from the SFDA to tackle the drug shortage problem in addition to other issues has been set up. This initiative is the Drug Track and Trace System for pharmaceutical products. This system aims to enhance the role of the SFDA in protecting society and guaranteeing the safety of all drugs by knowing their origin, starting from the manufacturing phase until consumption. The application of this new system (https://rsd.sfda.gov.sa), with the collaboration of all health care providers, will play a major role in overcoming the drug shortage problem in general as well as the chemotherapy shortage issue in particular.

4. Provide a value-added decision-making system through the SFDA. Representatives of pharmaceutical companies shared their experiences on reporting the shortages to SFDA, even though there was no specific well-structured feedback. The panelists suggested to the SFDA commissioner to develop a structured feedback system for companies with required effective action plans, while companies should forecast the supply status at least 6-12 months in advance.

5. Establishing and allocating structured dedicated and multidisciplinary nationwide oncology working group or steering oncology committee to (a) develop a national cancer treatment plan that unifies drug formulary with the creation of an "essential oncology medication list" that should never be in shortage; (b) create a potential alternative treatment approach and national cancer treatment guidelines and share these with all concerned oncology centers, oncology scientific societies, SFDA, and NUPCO; and (c) establish a clear national framework and policy for actionable procedures relating to cancer drug shortages.

6. Develop an evidence-based national ethical policy and framework to guide health care providers when dealing with drugs in short supply. This calls for setting up a dedicated committee or task force to deal with this problem, aiming to establish a patient advocacy oncology group to work closely with oncology scientific societies to track and follow up on the effect of shortages (or use of alternative drugs in case of shortages) on patient treatment outcomes.

7. Create a policy for penalizing pharmaceutical companies if they do not comply with the national policy or, in the case of unjustified shortages, mandate all foreign imported companies to provide their products with

package inserts in English. Some imported medications come with a product package insert in a foreign language, which was reported as an added burden and cause for drug shortages, because it delayed the SFDA approval process and so delayed the care. NUPCO and SFDA should take the lead in mandating that non-Arabic/non-English–speaking imported product companies translate their pharmaceutical product package inserts into English to enhance the quality of evaluation and ensure the safety of our patients.

8. Provide incentives to those manufacturers that are committed to obtaining a local marketing approval (registration) and secure long-term procurement. For oncology drugs that historically faced shortages in the past 3-5 years, provide incentives to committed manufacturers to obtain a local marketing approval (registration) and secure long-term procurement by pricing those "molecules" with appropriate prices that justify the investment. From the procurement system's perspective, this will allow for purchasing from multiple suppliers to mitigate the risks from shortage in molecules that are already known to have such shortage issues.

9. SFDA and NUPCO should provide their full support to local cancer drug manufacturing to reduce overdependence on imported drugs.

DISCUSSION

The panelists developed a comprehensive blueprint of actionable recommendations for mitigating and managing national cancer treatment shortages. The main goal is to ensure that all patients with cancer have timely access to cancer treatment (chemotherapeutics and supportive care agents). The consensus recommendations emphasize that cancer treatment shortage is a current and ongoing problem that affects health care systems and ultimately affects patient outcomes in a negative way. These recommendations mainly focus on cancer treatment shortages and accessibility, but they also are applicable to national drug shortages in general. Implementing these recommendations will be most effective when used as part of an integrated and collaborative framework. Furthermore, these recommendations might improve aspects of the drug shortage problem by sharing the national drug stockpile between institutions and determining an "essential oncology medication list" (recommendation 5a) that should never be in shortage.

These recommendations aim to improve the current national drug system by increasing the awareness of cancer treatment shortages. This approach requires its adoption and implementation by national institutions and drug authority bodies so as to improve and manage the current drug shortages and prevent forthcoming problems.

Strengths and limitations of this study are as follows: Qualitative research was performed, because it allowed for in-depth assessment and systemically outline the challenges facing to access cancer treatment. This paper focused on obtaining expert opinions from practicing oncology health care professionals and authorities across Saudi Arabia through both a panel and a validated questionnaire to assess the cause and impact of cancer treatment shortages and providing actionable solutions to these problems. We used qualitative descriptive methodology, which can be applied easily to the oncology clinical practice. There was a small sample size of the participants in the questionnaire, because we did not include oncology nurses.

AFFILIATIONS

[1]Princess Noorah Oncology Center, King Abdulaziz Medical City, Ministry of National Guard Health Affairs, Jeddah, Kingdom of Saudi Arabia

[2]King Saud Bin Abdulaziz University for Health Sciences, Jeddah, Kingdom of Saudi Arabia

[3]King Abdullah International Medical Research Center, Kingdom of Saudi Arabia

[4]Department of Clinical Pharmacy, Pharmaceutical Care Services, King Abdulaziz Medical City, Ministry of National Guard Health Affairs, Jeddah, Kingdom of Saudi Arabia

[5]Department of Pediatrics, Faculty of Medicine, Umm AlQura University, Makkah, Kingdom of Saudi Arabia

[6]Pharmaceutical Care Services Department, King Abdulaziz Medical City, Ministry of National Guard Health Affairs, Jeddah, Kingdom of Saudi Arabia

[7]Oncology Quality & Patient Safety, Princess Noorah Oncology Center, King Abdulaziz Medical City, Ministry of National Guard Health Affairs, Jeddah, Kingdom of Saudi Arabia

[8]Saudi Food and Drug Authority, Riyadh, Kingdom of Saudi Arabia

[9]Medical Services, Ministry of National Guard Health Affairs, Western Region, Kingdom of Saudi Arabia

[10]Clinical Services, Ministry of National Guard Health Affairs, Western Region, Kingdom of Saudi Arabia

[11]National Unified Procurement Company, Riyadh, Kingdom of Saudi Arabia

[12]Policy & Market Access in Gulf Cooperation Council, Amgen, Kingdom of Saudi Arabia

[13]Sudair Pharma, Riyadh, Kingdom of Saudi Arabia

[14]Roche, Riyadh, Kingdom of Saudi Arabia

[15]Oncology Center, King Fahad Specialist Hospital, Dammam, Kingdom of Saudi Arabia

[16]Department of Medical/Radiation Oncology, Prince Sultan Medical Military City, Riyadh, Kingdom of Saudi Arabia

[17]Pharmaceutical Care Services Department, Comprehensive Cancer Center, King Fahad Medical City, Riyadh, Kingdom of Saudi Arabia

[18]Saudi Oncology Society, Riyadh, Kingdom of Saudi Arabia

[19]Saudi Scientific Society of Blood and Marrow Transplantation, Riyadh, Kingdom of Saudi Arabia

[20]Medical Affairs, King Faisal Specialist Hospital & Research Center, Riyadh, Kingdom of Saudi Arabia
[21]King Faisal Specialist Hospital & Research Center, Jeddah, Kingdom of Saudi Arabia
[22]Saudi Arabian Pediatric Hematology Oncology Society, Riyadh, Kingdom of Saudi Arabia
[23]Saudi Oncology Pharmacy Assembly, Riyadh, Kingdom of Saudi Arabia
[24]Department of Pharmaceutical Care, Oncology Pharmacy Services, King Faisal Specialist Hospital & Research Center, Riyadh, Kingdom of Saudi Arabia

CORRESPONDING AUTHOR

Aeshah AlAzmi, PharmD, FISQua, Ministry of National Guard Health Affairs, King Abdulaziz Medical City (KAMC)-6255, Princess Noorah Oncology Center, Pharmaceutical Care Services Department, Jeddah 21423, Saudi Arabia 9515; Twitter: @AeshahAlAzmi; e-mail: aeshah.alazmi@gmail.com.

AUTHOR CONTRIBUTIONS

Conception and design: Aeshah A. AlAzmi, Wasil A. Jastaniah, Hani S. Alhamdan, Arwa O. Yamani, Shaker M. Abdullah, Mohammed AlZahrani, Ashraf AlSahafi, Tawfiq A. AlOhali, Trad Alkhelawi, Essam Murshid, Ashwag AlGethami, Atika AlHarbi, Meteb O. AlFoheidi, Ahmad S. AlSaeed, Hasan Elsolh, Ibraheem Abosoudah, Abdulaziz Ben Obaid, Mohammed AlNahedh

Collection and assembly of data: Aeshah A. AlAzmi, Wasil A. Jastaniah, Hani S. Alhamdan, Arwa O. Yamani, Waleed I. AlKhudhyr, Shaker M. Abdullah, Ashraf AlSahafi, Tawfiq A. AlOhali, Fouad AlNajjar, Ashwag AlGethami, Hasan Elsolh

Data analysis and interpretation: Aeshah A. AlAzmi, Wasil A. Jastaniah, Arwa O. Yamani, Ashraf AlSahafi, Tawfiq A. AlOhali, Yasser AlObaida, Ayman Allam, Hani AlHashmi, Essam Murshid, Fouad AlNajjar

Provision of study material or patients: Arwa O. Yamani, Shaker M. Abdullah, Mohammed AlZahrani, Yasser AlObaida, Essam Murshid, Hasan Elsolh

Administrative support: Aeshah A. AlAzmi, Hani S. Alhamdan, Arwa O. Yamani, Shaker M. Abdullah, Ibraheem Abosoudah, Abdulaziz Ben Obaid

Manuscript writing: All authors

Final approval of manuscript: All authors

Agree to be accountable for all aspects of the work: All authors

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Trad Alkhelaiwi
Employment: Amgen, AstraZeneca
Stock and Other Ownership Interests: Amgen

Yasser AlObaida
Employment: Sudair Pharma
Leadership: Sudair Pharma (Inst)

Ahmad S. Alsaeed
Honoraria: Amgen
Consulting or Advisory Role: Amgen
Speakers' Bureau: Amgen
Travel, Accommodations, Expenses: Roche, Abbvie, Amgen

Ibraheem Abosoudah
Speakers' Bureau: Apothecom Gilead
Travel, Accommodations, Expenses: Amgen

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