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Assessing oncology providers attitudes and practices toward nonformulary drugs and mapping current obstacles in Saudi Arabia

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ABSTRACT

Introduction: Formulary drug list is a continually updated list of medications routinely stocked by hospitals and other healthcare facilities and deemed effective, safe, and cost saving. Non-formulary drug (NFD) refers to medications not on the formulary, due to cost or lack of clinical data. This study aimed to examine the processing of NFD requests by oncology providers (OPs) in Saudi Arabia.

Method: A cross-sectional survey in Saudi oncology centers gathered perspectives of healthcare practitioners, mainly oncology pharmacists and physicians, on NFDs and request processes, aiming to understand variations, reasons for NFDs, and suggestions for an improved, unified NFDs request algorithm.

Result: A total of 93 physicians and pharmacists responded, 57 % were pharmacists, 43 % were physicians, and 94.6 % worked in the governmental sector. Around 31.2 % reported that it takes one week to receive a decision on their NFD request, while 28 % reported it takes two weeks to one month. Furthermore, 35.5 % of participants reported that the complete NFD process, from the initial order placement to the receipt of medications, spans a duration of 2–4 months, while 8.6 % noted a longer duration exceeding six months. The participants reported that the most common obstacles while requesting NFD were procurement delays and lengthy processing times. Additionally, 26.9 % agreed that formulary restrictions hindered medical care and 40.3 % reported delays in patient care. While 33.8 % were forced to use fewer effective options, and 22.1 % referred patients to palliative care.

Conclusion: The current practice of NFDs has negative consequences on cancer patient outcomes due to delays in patient care or the use of less effective drugs. Thus, we recommend having a national NFD access program.

1. Introduction

Formulary drugs are prescription medications determined by the Pharmacy and Therapeutics (P&T) Committee in a particular healthcare system, and the latter commits to providing its physicians with them to prescribe for their patients (Holdford and Brown n.d.). Nonformulary drugs (NFDs), on the other hand, are prescription medications that could be as effective as the formulary ones, prescribed by physicians; however, they are deemed by the P&T committee as less preferred to be included in the formulary list (Ciccarello et al. 2021). Hence, NFDs require special evaluation by the P&T committee before purchase which delays its supply (Khardaly et al. 2022).

Saudi Arabia's healthcare systems are categorized as either public, private, or non-profit healthcare systems, which are structured as medical cities, specialty, university and military hospitals, or primary care centers (Sajjad and Qureshi 2018). National Unified Procurement Company (NUPCO) is the only Saudi Arabian, governmentally owned, medical devices and pharmaceuticals supplier company that aims to improve spending efficiency and healthcare services of government hospitals (Report 2020). Nevertheless, hospitals are still obliged to

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request NFDs for special medical cases, yet, such requests are encountered with many obstacles and delays due to evaluation and audit processes to ensure cost-effectiveness and credibility of such requests (Khardaly et al. 2022). Khardaly AM et al., investigated the impact of implementing a national clinical review process for NFDs in Saudi Arabia and reported that the absence of such a process led to increased costs incurred by hospitals and the time required to accept or reject requests (Khardaly et al. 2022). There has been contradictory data about the rate of NFDs use around the world, yet, most of the studies reported approximately 10–25 % of the prescribed medications are NFDs (Radomski et al. 2016; Rodriguez-Carrero, Iglesias, and Puente 2012; Tramontina, Heineck, and Dos Santos. 2013). Hence, improving the procurement process for NFDs can lead to better healthcare outcomes and cost savings.

Cancer is estimated to be one of the primary causes of mortality globally. Despite advancements in preventing and treating certain malignancies, the cancer burden is growing. The high incidence of cancer has been attributed to a variety of lifestyle and socioeconomic risk factors (Althubiti and Nour, 2018). In Saudi Arabia, a societal transition over the past four decades has led to changes in the population's lifestyle and contributed to the rise in cancer incidence (Althubiti and Nour, 2018). The economic burden of cancer is also increasing, primarily due to the rising cost of pharmaceuticals, the most costly component of overall healthcare expenditure.(McCabe et al. 2009) However, costly interventions are not always guaranteed to be effective (McCabe et al. 2009). There is pressure on healthcare payers to decide on new products with limited information regarding their long-term efficacy and safety. When evaluating novel oncology medications, it is essential to consider value in terms of clinical outcomes relative to cost, which is part of the NFDs evaluations (Khardaly et al. 2022). In order to address this problem, and to bridge the gap in the current system by identifying the issues and proposing solutions we aim to examine the practice of oncology providers (OPs) in Saudi Arabia regarding NFDs which allow us to gain insight into the challenges faced by OPs.

2. Method

2.1. Objectives

A cross-sectional online survey was conducted among oncology pharmacists and physicians in Saudi Arabia, with the aim of obtaining their perspectives on NFDs and the associated request process. The survey sought to identify any variations in the request process across different hospitals and determine the reasons behind rejections of such requests. Additionally, OPs were surveyed to gather insights on potential improvements to the requesting process, with the goal of developing a comprehensive algorithm for a unified NFDs request process. The research project, under the reference number E-22–7249, has received approval from the Institutional Review Board (IRB) at King Saud University.

2.2. Sample Size

Previous research has indicated that approximately most of hospitals in the region have ordered NFDs for oncology purposes at least once per year (Khardaly et al. 2022). In considering this, we estimated that at least 95 % of hospitals would have a demand for non-formulary requests and requested NFD regarding by OPs. To obtain a desired precision level of 5 % with a 95 % confidence interval while take into account a population size of 300 oncology-classified healthcare professionals registered with the Saudi Commission for Health Specialties (SCFHS). It was determined that 59 OPs were required for recruitment in our study. Convenience sampling was utilized to identify participants for this study. The inclusion criteria for the study require that participants must be OPs, specifically pharmacists or physicians.

2.3. Data collection

To study the prevalence of NFDs use among OPs and their perspectives on NFDs, a rigorously validated survey was designed. The questionnaire was developed specifically to cover all pertinent obstacles associated with NFDs usage. The final version of the questionnaire included 30 concise questions covering a variety of topics, including demographics, NFDs practices, and the existence of NFDs-related departmental policies. In addition, the questionnaire was designed to assess the underlying causes and barriers that influence NFDs utilization, as well as their potential impact on healthcare outcomes. Participants' perceptions about the timeliness and accessibility of NFDs were assessed using a Likert scale. Six questions covered NFD reviews, receipt of non-formulary medications, formulary comprehensiveness, interference with medical care, formulary restrictions, and ease of NFD requests. Higher scores (4–5) indicated positive perceptions, while lower scores (1–3) indicated negative perceptions. This scoring method allowed for quantitative evaluation of participants' attitudes and experiences regarding NFDs in a healthcare setting.

2.4. Statistical analysis

Descriptive statistics were employed to analyze the data obtained from the research sample. Continuous variables were described using descriptive measures such as means, standard deviations (SDs), medians, and ranges. The proportions of categorical variables were used to characterize them. The utilization of NFDs was analyzed and compared across a range of demographic variables, including age, gender, marital status, hospital department, and duration of employment. Chi-square tests were used to analyze categorical data, while t-tests were used to compare continuous variables whose distributions were close to normal. When the normality assumptions were not met, nonparametric Mann-Whitney U tests were used. $p < 0.05$ was specified as the statistical significance threshold. The statistical analysis was performed using version 28 of SPSS.

3. Results

A total of 93 participants filled out the questionnaire. The mean age of the participants was found to be 39 ± 8 years, with an average of 12 ± 8 years of professional experience, key demographic characteristics in (Table 1). Most participants were male (69 %) and Saudi nationals (73 %). Pharmacists with licenses accounted for 57 % of participants, whereas 43 % were registered physicians. Twenty-eight percent of participants completed a fellowship in oncology, 19.4 % possessed an MSc, and 18.3 % had completed a specialized oncology residency. The remaining participants held credentials such as MBBS, MD, PhD, PharmD, or residency in internal medicine. The majority of participants (94,6%) were government employees. Participants worked at several oncology institutions in Saudi Arabia. All participants from various hospitals reported placing at least one NFDs request for an oncology medication in their respective healthcare institutions.

A significant proportion of participants (67.7 %) believed that access to medication is influenced by factors related to the institution. Table 2 presents the findings regarding various aspects related to NFDs requests, as perceived by the study participants. The most commonly reported reasons for requesting NFDs were the recent approval of the medication (72 %), the medication being the patient's last choice (53.8 %), or the only choice (40.9 %). The majority of participants (81.7 %) believed that physicians were commonly responsible for submitting NFDs requests and most of the participants (92.5 %) believed that clinical pharmacists were the ones responsible for reviewing NFDs requests. Participants identified various entities and individuals as commonly responsible for approving NFDs requests, including the Cancer Therapeutic Subcommittee (48.4 %), oncology clinical pharmacists (46.2 %), and oncology section heads (32.3 %). Regarding the role of the P&T committee in

Table 1
Characteristics of participants (N = 93).

	Mean	SD	N	%
Age	39	8		
Years of experience	12	8		
Gender	Female		24	25.8 %
	Male		69	74.2 %
Nationality	Non-Saudi		20	21.5 %
	Saudi		73	78.5 %
Job title	Registered Pharmacist		53	57.0 %
	Registered Physician		40	43.0 %
Highest level of education	Internal medicine residency		1	1.1 %
	MBBS		4	4.3 %
	MD		3	3.2 %
	MSc		18	19.4 %
	PhD		4	4.3 %
	Specialized fellowship in oncology		26	28.0 %
	Specialized residency in oncology		17	18.3 %
	Other		20	21.5 %
Current practice	Governmental sector		88	94.6 %
	Private sector		5	5.4 %
Hospital	Al-Habib hospital/Private sector		1	1.1 %
	King Abdulaziz specialist hospital/ Mecca region		3	3.2 %
	King Fahad hospital/Eastern region		4	4.3 %
	King Fahad medical city/Riyadh region		20	21.5 %
	King Faisal specialist hospital/ Riyadh region		8	8.6 %
	King Khalid university hospital/ Riyadh region		11	11.8 %
	Maternity and children hospital/ Mecca region		1	1.1 %
	National blood and cancer center/ Private sector		1	1.1 %
	National guard hospital/Riyadh region		10	10.8 %
	Prince Abdulaziz bin Musaad hospital/Northern Borders region		1	1.1 %
	Prince Faisal bin bandar center for pediatric oncology/Al Qassim region		2	2.2 %
	Prince Sultan military hospital/ Riyadh region		4	4.3 %
	Security forces hospital/Riyadh region		1	1.1 %
	Other hospitals		26	28.0 %

Table 2
Attitude and practice of NFDs in hospital in Saudi Arabia.

	N	%
What affects your access to the medication?		
Institution related factors	63	67.7 %
Patient related factors	42	45.2 %
Product related factors	46	49.5 %
Payers related factors	38	40.9 %
Other	1	1.1 %
What is the most common reason for requesting NFDs?		
Patient last choice	50	53.8 %
Patient only choice	38	40.9 %
Medication is not SFDA registered	27	29.0 %
Medication is old and removed from formulary	16	17.2 %
Medication is recently approved	67	72.0 %
Medication is too expensive	26	28.0 %
Limited number of patients that needs this medication	40	43.0 %
Who is commonly responsible of submitting NFDs requests?		
Pharmacist	16	17.2 %
Physician	76	81.7 %
Both	1	1.1 %
Who is commonly responsible of reviewing NFDs requests?		
Clinical Pharmacist	86	92.5 %
Physician	6	6.5 %
Both	1	1.1 %
Who is commonly responsible of approving NFDs requests?		
Pharmacist	23	24.7 %
Physician	15	16.1 %
Oncology section head	30	32.3 %
Oncology clinical pharmacist	43	46.2 %
Cancer therapeutic subcommittee	45	48.4 %
Head of clinical services	25	26.9 %
others	4	4.3 %
What's the role of the P&T committee in NFDs requests in your institution?		
Monitoring the trend of non-formulary requests	20	21.5 %
Reviewing non-formulary requests	43	46.2 %
They don't have any role	25	26.9 %
Other	5	5.4 %
On average, how long does it take you to receive a decision on your NFDs request?		
1 week	29	31.2 %
2 weeks	15	16.1 %
2 weeks − 1 month	26	28.0 %
more than 1 month	23	24.7 %
How long does it usually take for NFDs requested to be received?		
1–2 months	20	21.5 %
2 weeks − 1 month	8	8.6 %
2–4 months	33	35.5 %
4–6 months	24	25.8 %
more than 6 months	8	8.6 %
Is there a separate budget in your department for NFDs?		
I don't know	38	40.9 %
No	25	26.9 %
Yes	30	32.3 %
If yes, what's the maximum budget you have for each request?		
100 k SR	8	8.6 %
200 k SR	4	4.3 %
50 k SR	1	1.1 %
I don't know	60	64.5 %
More than 200 k	4	4.3 %
Not responded	16	17.2 %

NFDs requests, 46.2 % of participants believed it had a role, while 26.9 % believed otherwise. Regarding the entire time period for NFDs to be processed participants believed it takes 2–4 months (35.5 %), 4–6 months (25.8 %), and 1–2 months (21.5 %), while the time frame for key opinion leaders to decide on NFDs requests, participants believed it takes one week (31.2 %), 2 weeks to 1 month (28 %), and more than a month (24.7 %). A significant proportion of participants (40.9 %) were uncertain about the existence of a separate budget for NFDs in their departments, while 32.3 % believed such a budget existed. Most participants (64.5 %) were unaware of the maximum budget for a single NFDs request, while 8.6 % believed it is 100,000 Saudi Riyals (SR).

Based on Fig. 1, the mean attitude score of all participants' perceptions regarding the timeliness and accessibility of NFDs was 23.6 ± 5.5. The identified obstacles, determining factors for acceptance/rejection, and consequences faced by participants in relation to NFDs requests were presented in (Table 3). The majority of participants (75.3 %) identified delay in procurement time as a significant obstacle, followed by excessive processing time (65.6 %) and prolonged evaluation time (28 %). Regarding the factors influencing the acceptance or rejection of NFDs requests, 62.4 % of participants highlighted expensive medication, availability of alternatives in the formulary (50.5 %), unavailability in NUPCO (46.2 %), and lack of registration with the Saudi Food and Drug Authority (SFDA) (43 %) as key determinants. Participants reported that inability to obtain NFDs led to delays in patient care (66.7 %), the use of less effective medication (55.9 %), and/or referral to palliative care services. Eighty percent of participants supported the algorithm detailed in Fig. 2 for the evaluation and processing of NFDs. Surveyed participants provided valuable feedback regarding the algorithm for NFDs requests for oncology medication, highlighting areas for improvement. One prominent concern expressed by participants was the lengthy nature of the process and the perceived excessive involvement of the medical directors. To address this, participants suggested to limit the role of the medical directors in initial approval of physician requests, with subsequent steps including purchasing process to be handled by the pharmacy directors, clinical pharmacists, and Cancer subcommittee. The results of a comparative examination of the practice scores of various groups based on age, gender, nationality, job title, years of experience, highest degree, current work practice, and hospital affiliation. The results revealed significant differences in attitude scores by

1. In your opinion, are NFDs reviewed in a timely manner?
2. In your opinion, are non-formulary medications received in a timely manner?
3. In your opinion, do formulary lists in your institution include all essential medications by definition by WHO?
4. In your opinion, does your institution's formulary interfere with your ability to provide the best medical care?
5. In your opinion, are there too many formulary restrictions at your facility?
6. In your opinion, is the process of requesting NFDs easily attainable?

Fig. 1. Survey questions was used to obtain participants perceptions on timeliness and accessibility of NFDs. Note: Participants were asked to rate their agreement or disagreement with each statement on a Likert scale ranging from Strongly Disagree (1) to Strongly Agree (5).

Table 3
Obstacles and outcome of requesting of NFDs.

	N	%
In your opinion what obstacles do you face requesting NFDs?		
Evaluation time is too long	26	28.0 %
Processing time is too long	61	65.6 %
Delay in procurement time	70	75.3 %
Other	2	2.2 %
What are the factors that determine rejection and acceptance of NFDs requests		
Expensive medication	58	62.4 %
Unavailability in NUPCO	43	46.2 %
Available alternatives in formulary	47	50.5 %
SFDA registration	40	43.0 %
Limited supply	33	35.5 %
Lack of strong evidence	31	33.3 %
Other	2	2.2 %
In the most recent incident, what was the effect your patient faced in result of the inability to get access to the rejected NFDs?		
No effect at all	2	2.2 %
Delay in patient care	62	66.7 %
Use of less effective medication	52	55.9 %
Refer to palliative care service	34	36.6 %
Other	4	4.3 %

nationality (p-value = 0.032), education level (p-value = 0.032), and hospital group (p-value = 0.003) as shown in Table 4.

4. Discussion

This study is the first to our knowledge to assess OPs attitudes and practices regarding NFDs in Saudi Arabia. The study revealed a negative perception of OPs regarding NFDs practices in Saudi Arabia, which they believed that such practices led to undesirable consequences on cancer patients' outcomes. The negative perception mainly generated from the prolonged time NFDs request takes to be processed and accepted by decision makers and then be provided for oncology patients. On the other hand, two thirds of the participants reported that recent approval of oncology medications was the main trigger to request NFDs, furthermore, the majority of participants reported that physicians alone were responsible for submitting NFDs requests, which justify the prolonged time of processing the NFDs requests to assure that such requests were not incentivized by manufacturers sponsored studies or conferences.(Shepherd 2019) Such concerns of conflicts of interests among physicians requesting NFDs are legitimate and have been discussed in the literature and assigning different OPs or committees to review such requests are mandatory.(Robertson, Rose, and Kesselheim 2012; Tungaraza and Poole 2007).

The majority of participants reported that restrictions on obtaining NFDs led to poor prognosis of patients, de-escalation to less effective medication, and/or referral to palliative care services, yet more than 50 % of the participants reported that such restrictions are due to the availability of alternatives in the formulary. This brings doubt about the association concluded by the participants between poor prognosis of patients and restrictions on obtaining NFDs. This actually could link poor prognosis of patients to other confounding factors such as the patients' low adherence to the available alternative drugs in the formulary or negative perception about their efficacy.(Brown et al. 2016; Shrank et al. 2011) Also, the request could be driven by a belief in the efficacy of new therapies. In addition, it usually takes at least 12 months from the date that the department's request for formulary addition until formulary stock is available which leads to negative perception. Furthermore,

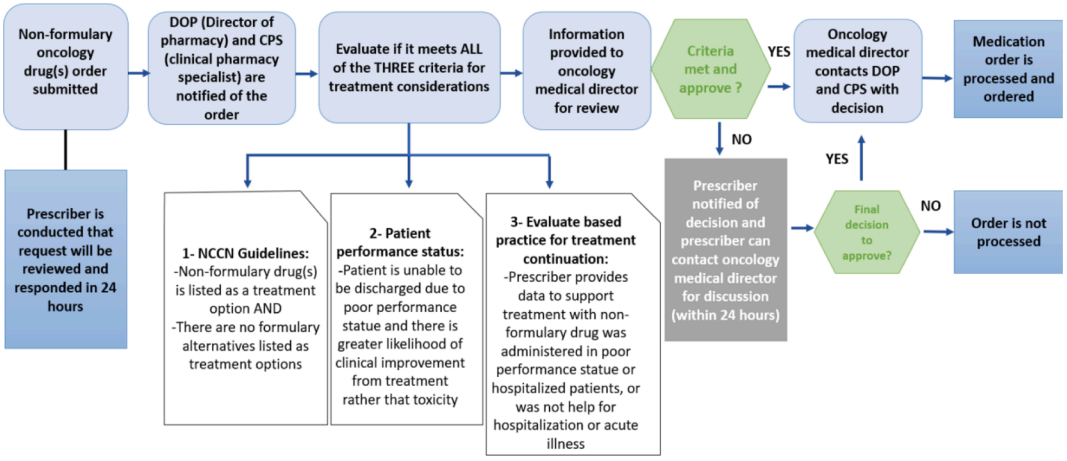

Fig. 2. Suggested algorithm for ordering non-formulary drugs.

Table 4
Comparison between the groups attitude score.

Variable		N	Attitude score		
			Mean	St. Deviation	Sig.
Age	28–35	32	23.5	5.7	0.81**
	36–40	26	24.2	5.3	
	41–50	29	23.5	5.4	
	51–65	6	21.8	6.8	
Gender	Male	69	24.1	5.8	0.166*
	Female	24	22.3	4.5	
Nationality	Non-Saudi	20	21.3	5.41	0.032*
	Saudi	73	24.2	5.44	
Job title	Registered Pharmacist	53	23.2	5.2	0.426*
	Registered Physician	40	24.17	5.8	
Years of experience	1–5	24	24.1	5.7	0.114**
	11–15	18	25.7	6.1	
	16–30	28	22.5	4.1	
	31–35	1	13		
	6–10	22	23.4	6	
Highest level of education	Internal medicine residency	1	30		0.032**
	MBBS	4	27.75	5.12	
	MD	3	19	3	
	MSc	18	21.4	4.6	
	Other	20	25.5	5.8	
	PhD	4	21	1.4	
	Specialized fellowship in oncology	26	23.9	5.7	
	Specialized residency in oncology	17	23.1	5.1	
Current practice	Governmental sector	88	23.4	5.5	0.193*
	Private sector	5	26.8	5.7	
The hospital	Al-Habib hospital/ Private sector	1	29		0.003**
	King Abdulaziz specialist hospital/Mecca region	3	22	8.7	
	King Fahad hospital/ Eastern region	4	19	3.5	
	King Fahad medical city/ Riyadh region	20	23.05	3.94	
	King Faisal specialist hospital/Riyadh region	8	22	5.75	
	King Khalid university hospital/Riyadh region	11	24.09	4.7	
	Maternity and children hospital/Mecca region	1	25		
	National blood and cancer center/Private sector	1	35		
	National guard hospital/ Riyadh region	10	28.1	6.62	
	Other	26	21.03	4.19	
	Prince Abdulaziz bin Musaad hospital/ Northern Borders region	1	28		
	Prince Faisal bin bandar center for pediatric oncology/Al Qassim region	2	25.5	3.53	
	Prince sultan military hospital/Riyadh region	4	25.75	4.2	
	Security forces hospital/ Riyadh region	1	30		

* Independent *t* test.
** One way ANOVA.

this research collected the general feedback regarding the practice of non-formulaic requests in Saudi Arabia. Participants emphasized the importance of physicians providing a summary of evidence supporting the requested medications, including establishing cutoffs for determining the cost-effectiveness and clinical benefit, such as considering parameters like progression-free survival (PFS) and overall survival (OS). They also emphasized the potential for conducting the entire process online and organizing frequent committee meetings to streamline the process. Another key aspect highlighted by participants was the significance of cooperation from manufacturers. They expressed that many of the issues encountered, such as delayed supply and a lack in registering medications with regulatory agencies like SFDA and NUPCO and stemmed from manufacturer-related challenges. Participants identified the need to minimize approval steps and reduce delays that hinder timely access to medications. They proposed limiting the number of approvals to the prescriber, chairman, clinical pharmacist, and head of the pharmacy, with logistical arrangements for procurement handled afterward. While acknowledging the importance of considering cost, participants emphasized that patient care should remain the top priority throughout the process.

There have been many limitations for our study including, but not limited to, almost all the participants practiced in a governmentally owned hospitals in Riyadh whose patients are mostly uninsured citizens, which limits the generalizability of their views to private hospitals, whose patients are highly likely insured and non-citizens, and to other parts of the country. The study relies on self-reported data, particularly regarding participants' experiences and perceptions of NFDs and this introduces the possibility of recall bias. The study focused exclusively on healthcare professionals' experiences with oncology NFDs. This narrow focus may overlook the broader perspectives of other stakeholders, such as patients, or administrators, who may have different insights and experiences related to NFDs in healthcare. Future research should encompass various stakeholders' perspectives, including patients and administrators, to gain a comprehensive understanding of non-formulary drugs (NFDs) in healthcare. Comparative analyses between government-owned and private hospitals can reveal valuable insights. There is ample room to optimize the NFD request process, streamlining approvals, reducing delays, and fostering collaboration with manufacturers to ensure more patient-centered care. Future studies must aim for a holistic and efficient approach to NFDs to deliver timely and effective cancer treatments. These efforts will enhance oncology healthcare practices and ultimately improve patient outcomes.

5. Conclusion

The current practice of NFDs has negative consequences on cancer patient outcomes due to delays in patient care or the use of less effective drugs. Thus, we recommend having a national NFD access program.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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