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Pharmacology Section

Medicine Crisis Indicators in the Pharmaceutical System of Iran: A Descriptive Strategic Analysis

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ABSTRACT

Introduction: Iran is one of the countries that frequently encounters natural disasters. Providing and delivering medicine and initiating treatment for the injured in the early stages of disasters and crisis play a significant role in reducing pain, fatal injuries, and increasing the chances of recovery and survival for the injured individuals.

Aim: To design a model for drug management during crises and hazards in Iran.

Materials and Methods: This descriptive study was conducted from October 2019 to November 2020 at Department of Health Services Management, Islamic Azad University, Tehran, Iran. The opinions of 30 health and drug experts from the Food and Drug Administration and the Ministry of Health in Iran were considered in developing the initial conceptual model. Subsequently, a questionnaire was designed, and its validity and reliability were confirmed. The questionnaire evaluated seven parameters, including supply chain, policy-making, organisation, guidance and leadership, crisis instances, planning, and education. These parameters were scored on a Likert scale from 1 to 5. The total number of respondents was 403. Direct or reverse encoding was applied depending on the nature of the positive or negative questions. Data analysis was performed using Statistical Package for Social Sciences (SPSS) version 21.0 and Analysis of Moment Structures (AMOS) version 22 software. Descriptive statistical analysis was performed to develop the final model for drug management during crises and hazards.

Results: The results highlighted the importance of factors such as supply chain, policy-making, organisation, guidance and leadership, crisis instances, planning, and education in influencing drug management during crises and disasters. These findings were based on the perspectives of intermediate and senior managers in the medicine supply and distribution system in Iran.

Conclusion: The model presented in the present study presents and emphasises the crucial factors that impact drug management during crises and disasters.

Keywords: Emergencies, Hazards, Management, Natural disasters

INTRODUCTION

Health services play an essential role in saving lives during natural and man-made hazards and often have a significant impact on the health of those affected [1]. The long-term implications of natural hazards are acknowledged by well known international organisations, such as the United Nations [2]. Previous research has shown the importance of accessibility measures following a natural hazard [3]. Natural hazards can have severe impacts on human lives, the economy, and ecosystems [4]. They are dynamic and unpredictable, posing a threat to socio-economic development [5]. In this regard, due to concentrated and growing populations, urban areas can become hotspots for natural hazard risks [6]. Iran is one of the top seven countries in the world that is exposed to many hazards, crises, and problems.

A crisis is an event that occurs naturally or as a result of human activities and imposes hardship on human society to such an extent that fundamental and extraordinary measures are needed to resolve it. Currently, the main weaknesses in crisis management include a lack of coordination and cooperation among organisations, a lack of comprehensive and barrier rules and regulations, the dispersion of existing laws and regulations, and limited financial resources [7]. Comprehensive crisis management involves the planning, performance and execution of actions by governmental, non governmental, and public organisations. Its aim is to recognise and reduce the level of risk (risk management) and effectively manage response operations and the rehabilitation of affected areas (crisis management) [8].

Compiling a list of medicines required in crisis-affected areas is one of the essential requirements for drug management during a crisis. The composition of this list may vary depending on the type of hazard. For instance, different types of medications may be needed in the case of chemical, nuclear, flood, storm, and earthquake accidents. Examples of specific needs include pneumonia and sepsis cases reported after floods, microbial contamination of wounds following earthquakes, and the requirement for psychiatric medications after traumatic disasters. The priority of taking drugs changes after the first 72 hours following the occurrence of the crisis [9].

While previous studies have been conducted on various aspects of crises in Iran [1,9], no study has specifically focused on developing a model for drug management in crises and disasters within the country. Each of these studies has approached crises from different perspectives, and none has presented a comprehensive model of drug management that can identify the factors influencing the country's response to crises.

Considering that Iran has experienced numerous crises and hazards and is in a high-risk geographical position from different dimensions, designing a suitable model can help society minimise economic, human, and social damages when faced with hazards.

In a previous study conducted by the same authors, deficiencies in drug distribution and necessary healthcare practices during disasters in Iran and selected countries were identified. The study discussed the consequences of mismanagement during crises [10]. Building on these findings, the present study aims to provide a specific model for managing and supporting medical assistance in hazardous and crisis situations. This model is intended to guide health policymakers and planners in improving the quality of drug delivery during natural and man-made crises.

MATERIALS AND METHODS

The present descriptive study was conducted at Islamic Azad University, Iran, from October 2019 to November 2020. The project

adhered to ethical principles and national norms and standards for conducting medical research in Iran. It was approved by the Ethics Committee of Islamic Azad University on May 25, 2019, with the code IR.IAU.TMU.REC 1398.008.

Inclusion and Exclusion criteria: All healthcare experts, including policy-makers, planners, pharmaceutical managers, and crisis management experts from the Ministry of Health and Medical Education, Food and Drug Administration, Medical Universities, Pharmaceutical Production and Distribution Companies, Iran Red Crescent, and other relevant organisations in Iran were invited to participate. Those who were willing to participate were included in the study, while those who were not willing were excluded.

Study Procedure

The initial questionnaire was designed based on a comparative study and literature review [10]. The questionnaire, using the Likert scale, was developed and its reliability and validity were investigated. The validity of the questionnaire was confirmed based on expert opinions. The reliability of the questionnaire was analysed using Cronbach's alpha, which yielded a value of 0.87, indicating a desirable level of reliability.

Exploratory factor analysis was conducted to extract meaningful factors based on the expert responses to the questionnaire items. The adequacy of the completed questionnaire responses was assessed. The results of the exploratory factor analysis were used to investigate the overall adequacy of the questionnaire and to assess the conformity between the results and the conceptual model.

Confirmatory factor analysis was performed based on the conceptual model proposed in the study. Appropriate statistical indicators such as Root Mean Square Error (RMSE), Goodness of Fit Index (GFI), and Chi-square were used to assess the adequacy of the conceptual model. The correlation status between the domains of the conceptual model and the overall index was determined, and the correlation coefficients between the items of each domain and the factors introduced in the proposed conceptual model were reported.

Descriptive analysis of the questionnaire items, based on the domains of the questionnaire, was conducted after analysing the expert opinions and qualitative surveys. The questionnaire, consisting of 40 items and seven domains, was finalised and distributed to experts for data collection. Finally, 403 participants completed the questionnaire.

Exploratory factor analysis was conducted to explore the underlying structural dimensions of the questionnaire and assess its adequacy in providing meaningful and acceptable dimensions. This analysis was based on the covariance matrix or correlation matrix of the questionnaire items. The goal of exploratory factor analysis is to identify hidden variables that can be extracted from the linear composition of the questionnaire domain scores and determine their statistical significance.

First, it was necessary to demonstrate that the correlation matrix between items was suitable for factor analysis. This confirms the presence of unobservable variables that can be extracted from the questionnaire responses and are statistically significant. This is referred to as the "after" factor analysis. Subsequently, other significant unseen variables can be extracted from the questionnaire, and a sufficient number of unseen variables are determined based on conventional thresholds to explain the frequency matrix of observations. This approach helps reveal the existence of the unseen dimensions (domains) within the questionnaire and identifies the important and influential dimensions in order of importance and impact.

To assess the adequacy of the questionnaire and the presence of hidden variables, the Kaiser-Meyer-Olkin (KMO) index and Bartlett's test were utilised. The appropriate KMO index, typically above 0.6, indicates the acceptability of hidden variables within the questionnaire. It signifies that the questionnaire can be categorised into most areas or domains. Similarly, Bartlett's test was used to determine the adequacy of the questionnaire in providing statistically significant domains. If the p-value of Bartlett's test is significant, it suggests that the questionnaire is suitable for factor analysis. Therefore, Bartlett's test was employed to investigate the significance of hidden domains within the questionnaire.

The responses to the 40 items of the questionnaire were inserted into the exploratory factor analysis model. The model was tested using the main components of the initial exploratory factor analysis. The adequacy of the data for factor analysis was assessed using the Bartlett and KMO tests. Through orthogonal and non orthogonal rotation, the items related to the seven domains of the drug management questionnaire in a crisis were identified.

The purpose of rotation is to identify the domains from the main questions obtained from exploratory factor analysis. This helps to distinguish and attribute each question to a specific factor derived from the exploratory factor analysis. The aim is to minimise ambiguity in the allocation of questions to factors. The high coefficients of the questions within a specific domain indicate their strong association with that factor.

Since the domains in the present questionnaire are related and correlated with each other, both orthogonal and non orthogonal rotations were employed. Orthogonal rotation presents factors that are independent and not related to each other, which may not fully accordance with the theoretical structure of the questionnaire. On the other hand, non-orthogonal rotation allows for correlated factors, which is more consistent with the theoretical framework of the questionnaire. For example, the planning and organising domain may have a significant correlation with the guidance and leadership domain, and non-orthogonal rotation takes this into account during statistical calculations. However, orthogonal rotation assumes that all factors are independent.

Both orthogonal and non-orthogonal rotations were used in the analysis of the questionnaire. Varimax with Kaiser Normalisation method was used for orthogonal rotation, while Promax with Kaiser Normalisation was used for non-orthogonal rotation.

The data adequacy for factor analysis was assessed using Bartlett and KMO tests. The results indicated that the implementation of factor analysis was acceptable, as Bartlett's test was significant. The KMO index was above the threshold of 0.6 (specifically, it was 0.844), confirming the presence of a significant unseen factor in the questionnaire. Atleast one meaningful factor could be extracted from the linear combination of the 40 items in the final questionnaire.

The final questionnaire consisted of seven domains, with the following number of questions in each domain: supply chain (9 questions), policy making (4 questions), organisation (6 questions), guidance and leadership (6 questions), crisis instances (6 questions), planning (4 questions), and education (5 questions) [Table/Fig-1,2]. Respondents provided their answers based on the Likert scale, ranging from strongly agree to strongly disagree.

No.	Area	Number of items*
1.	Supply chain	9 questions
2.	Policy-making	4 questions
3.	Organisation	6 questions
4.	Guidance and leadership	6 questions
5.	Crisis instances	6 questions
6.	Planning	4 questions
7.	Education	5 questions

[Table/Fig-1]: Areas and number of items in the questionnaire.
*: the number of questions relevant to each content

STATISTICAL ANALYSIS

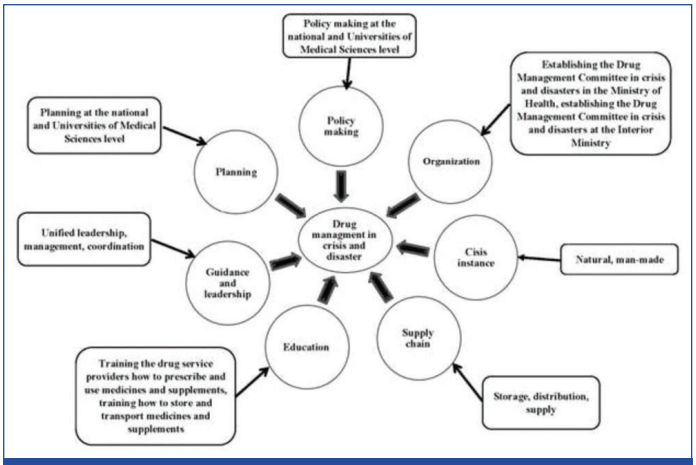
Descriptive statistics were used, and the data were analysed using SPSS version 21 and AMOS version 22.

RESULTS

Primary model: The conceptual model of the research was proposed based on studies and experts' opinions [Table/Fig-3].

Area	Abbreviation	Number	Item	CVR	CVI
Supply chain	Fa1	a1	Do you agree to send medicines to the affected areas based on the priority of the need?	0.70	0.90
		a2	Do you agree with the delivery of medicines to areas affected by pharmaceutical distribution companies?	0.90	1
		a3	Do you agree with sending donor-donated medicines to affected areas?	0.60	0.85
		a4	Do you agree with the distribution of medicines in the affected areas under the supervision of the Food and Drug Administration?	0.70	0.85
		a5	Do you agree with the distribution of medicines in affected areas under the supervision of healthcare organisations?	0.60	0.90
		a6	Do you agree with the storage of medicines in affected areas under the supervision of universities of medical sciences?	0.60	0.85
		a7	Do you agree with the storage of emergency medicines needed in crises and hazards by pharmaceutical distribution companies?	0.70	0.95
		a8	Do you agree with the storage of drugs used in chemical, biological and nuclear attacks by medical universities?	0.50	0.80
		a9	Do you agree with the storage of drugs used in chemical, biological and nuclear attacks by the armed forces?	0.60	0.90
Policy-making	Fa2	b1	Do you agree with drug management in crisis and hazards at the national level?	1	1
		b2	Do you agree with drug management in crisis and hazards at the pole level?	0.9	0.95
		b3	Do you agree with the Food and Drug Organisations approval of the quality of medicines sent to areas affected by crisis and hazards?	0.8	0.90
		b4	Do you agree with drug management in crises and hazards by the university of medical sciences?	0.5	0.95
Organisation	Fa3	c1	Do you agree with preparing the list of medicines needed in a variety of crises and hazards?	1	1
		c2	Do you agree with establishment of the Drug Management Committee in crisis and hazards under the supervision of ministry of the interior?	0.6	1
		c3	Do you agree with the establishment of the Drug Management Committee in crisis and hazards under supervision of the ministry of health?	0.7	1
		c4	Do you agree with the "residency in Iran, living in the region, during crisis and hazards", to be covered free of charge?	0.7	1
		c5	Do you agree with financing of medicines in crisis and hazards from government credits?	0.5	1
		c6	Do you agree with financing medicines in crises and hazards by receiving franchisees from the victims?	1	1
Guidance and leadership	Fa4	d1	Do you agree with estimating the amount of the emergency medicines in crisis zones by the Food and Drug Department of The Regional University of Medical Sciences?	1	1
		d2	Do you agree with estimating the amount of the emergency medicines in crisis zones by the Red Crescent Organisation?	0.80	0.95
		d3	Do you agree with estimating the amount of the emergency medicines in crisis zones by NGOs?	0.60	0.85
		d4	Do you agree with the guidance of pharmaceutical assistance to the affected area by NGOs?	0.50	0.85
		d5	Do you agree with the guidance of pharmaceutical assistance to the affected area by Food and Drug Organisation?	0.60	0.80
		d6	Do you agree with the guidance of pharmaceutical assistance to the affected area by the Red Crescent Organisation?	0.90	0.95
Crisis instances	Fa5	e1	Do you agree that earthquake is one crisis instance that affects drug management in crisis and hazards?	0.90	1
		e2	Do you agree that flood is one crisis instance that affects drug management in crisis and hazards?	0.60	0.85
		e3	Do you agree that war is one crisis instance that affects drug management in crisis and hazards?	0.50	0.85
		e4	Do you agree that economic sanction is one crisis instance that affects drug management in crisis and hazards?	0.50	0.80
		e5	Do you agree that chemical attack is one crisis instance that affects drug management in crisis and hazards?	0.70	0.90
		e6	Do you agree that biological attack is one crisis instance that affects drug management in crisis and hazards?	0.80	0.95
Planning	Fa6	f1	Do you agree with drug management planning in the national level?	1	1
		f2	Do you agree with drug management planning in the at regional pole level?	0.90	0.95
		f3	Do you agree with drug management planning at the universities of medical sciences national?	0.80	0.90
		f4	Do you agree with prioritising the medicines needed before the crises and hazards?	0.50	0.95
Education	Fa7	h1	Do you agree with training the conditions for transporting medicines to affected areas?	0.70	0.80
		h2	Do you agree with teaching how to shelving medicines in pre-crisis and hazard in distribution companies?	1	1
		h3	Do you agree with teaching how to shelving medicines in pre-crisis and hazard in pharmacies?	0.90	0.90
		h4	Do you agree with teaching the public about the conditions of keeping over-the-counter medicines before crisis and hazards?	0.90	0.95
		h5	Do you agree with teaching the general public how to use over-the-counter medications before crises and disasters?	0.80	0.95

[Table/Fig-2]: The questionnaire and Content Validity Relative Coefficient (CVR) and Content Validity Index (CVI).
CVR: Content validity ratio; CVI: Content validity index; Fa1: Supply chain (a1-a9); Fa2: Policymaking (b1-b4); Fa3: Organisation (c1-c6); Fa4: Guidance and leadership (d1-d6); Fa5: Crisis instances (e1-e6); Fa6: planning (f1-f4); Fa7: Education (h1-h5)

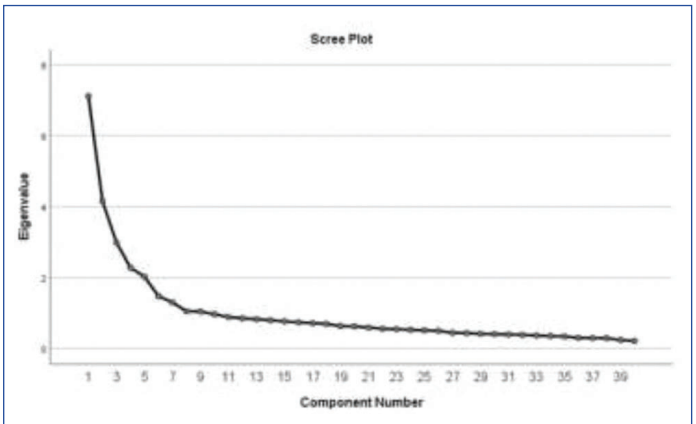


[Table/Fig-3]: Conceptual model derived from the experts' point of view.

Initial pattern retest: The areas included supply chain with 9 items (a1-a9), policy-making with 4 items (b1-b4), organisation with 6 items (c1-c6), guidance and leadership with 6 items (d1-d6), crisis instances with 6 items (e1-e6), planning with 4 items (f1-f4), and education with 5 items (h1-h5). There were 403 respondents, and the answers to each item were scored from 1 to 5 using a Likert scale. Direct or reverse encoding was applied depending on the type of positive or negative question.

CVR and CVI: The relative coefficient of Content Validity (CVR) and Content Validity Index (CVI) for items in each domain were reported based on the proposed conceptual model of the study. These indicators were collected based on expert opinions. Each item was ranked and scored according to its value and relevance. All items in the final questionnaire demonstrated appropriate CVR above 0.8, indicating their acceptable presence in the questionnaire [Table/Fig-2].

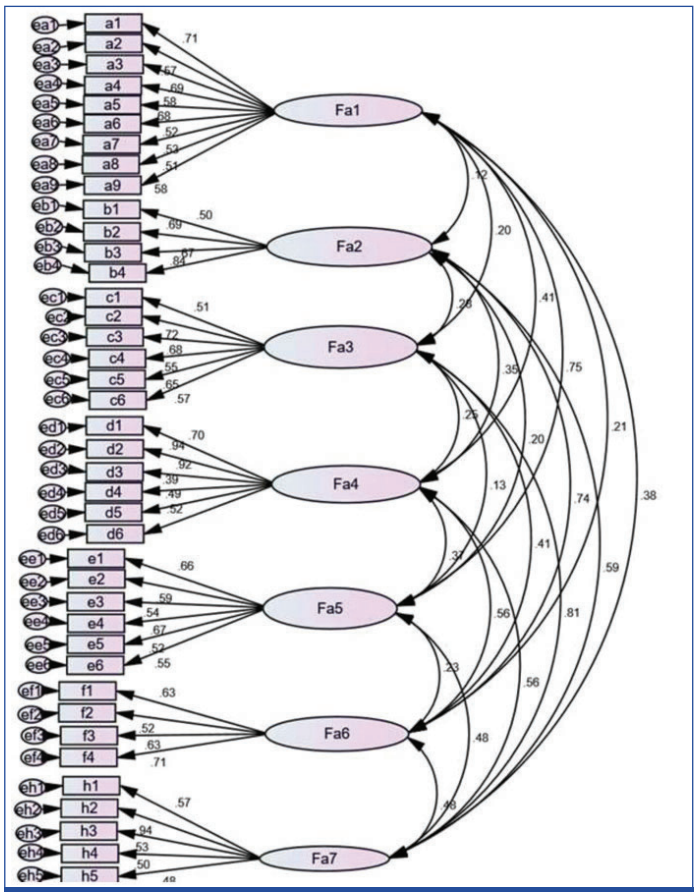
To determine the number of appropriate and adequate domains for factor analysis, [Table/Fig-4] was plotted. It was observed that beyond the 7th factor, the contribution of factors was negligible in explaining the variance of the entire questionnaire. Therefore, the use of seven domains was deemed sufficient and appropriate.



[Table/Fig-4]: Share chart of each factor in total frequency.

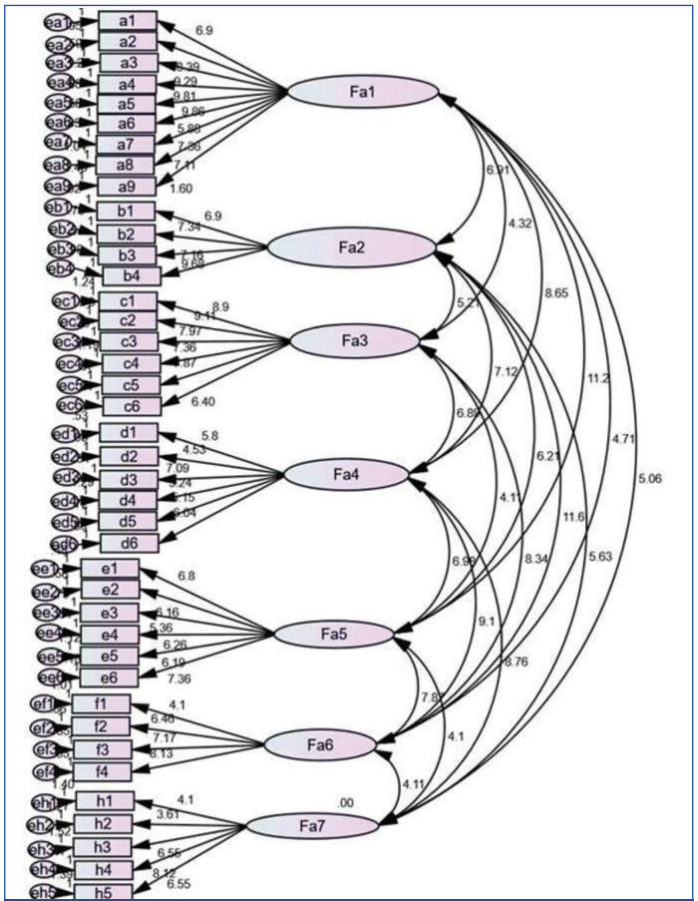
To investigate the relationship between each factor in the model, the standard regression coefficients of factors affecting the model were estimated using confirmatory factor analysis, in accordance with the proposed conceptual model. The relationship between the domains of drug management in a crisis and the standardised regression coefficients of each item in each area were also obtained.

In [Table/Fig-5], the findings of the first-order confirmatory factor analysis model for the conceptual model are shown. High correlations were observed between the 'policy-making' and 'planning' domains, with a correlation coefficient of 0.74, and between the 'supply chain' and 'crisis instances' domains, with a correlation coefficient of 0.75. The highest correlation was found between the 'training' and 'organising' domains, with a correlation coefficient of 0.81.



[Table/Fig-5]: Confirmatory factor analysis of factors and items in crisis and hazards based on standardised coefficients.

In [Table/Fig-6], the findings of the second-order confirmatory factor analysis for the conceptual model are presented. The 'supply chain' domain had the highest correlation coefficient of 0.78, indicating its importance in drug management in a crisis. The



[Table/Fig-6]: Confirmatory factor analysis of factors and items based on significant coefficients.

'policy-making', 'planning', and 'education' domains followed with correlation coefficients of 0.66, 0.58, and 0.54, respectively. The 'crisis instances' domain had the lowest rating, with a regression coefficient of 0.28.

The final conceptual model of drug management in a crisis and hazards remained the same as the initial model [Table/Fig-3].

DISCUSSION

In the present study, the supply chain was identified as the most important factor to consider. The supply chain plays a crucial role in crisis situations, regardless of their cause. Okeagu CN et al., emphasised the need for effective management of the supply chain, addressing any gaps and finding ways to resolve them during times of crisis [11]. In a pandemic crisis like Coronavirus Disease-2019 (COVID-19), countries worldwide faced unpredicted problems where shortages in the supply chain could have a significant negative impact on people's lives [12]. While it may not be possible to fully prepare and prevent supply shortages for every hazard, planning and effective management can help mitigate the impact of crises [13]. Bastani P et al., highlighted that resource wastage is a critical factor that affects the supply chain during disasters, and this issue can be exacerbated by weak management [14].

Another important factor in the model is policy making during a crisis. Planning for crises and implementing predictive protocols plays a crucial role in policy making, as it improves the response of authorities during a crisis [15]. A review by Adivar B and Selin Selen E highlighted that developed countries tend to have more planning and preparedness for disasters [16]. Confronting previous disasters can positively impact policy making, preparedness, and response during crises [17]. Policy makers should receive training to make effective decisions during a crisis, gaining sufficient knowledge about the factors influencing crises and disasters to take cost-effective actions [18]. During the initial wave of the COVID-19 pandemic in Italy, policy alignment in government actions was deemed essential to overcome the crisis and mitigate regional problems [15]. However, it is important to note that while predictive planning and preparedness before a disaster can improve response outcomes, there are multiple factors influencing each case, and preplanning does not guarantee a successful response [19].

Senior managers play a crucial role in providing financial support for planning, promoting teamwork, and fully supporting teams to effectively overcome a crisis [20]. In their study on crisis management, Thürmer JL et al., indicated that even well-organised and committed teams may not always successfully act during a crisis. They suggested that simple plans, such as collective implementation intentions, can help overcome this challenge [21].

Several factors influence how healthcare personnel react in a crisis, including their knowledge, obligations, work environment, and the nature of the disaster itself [22]. Education of personnel involved in crises is an undeniable factor in effectively handling such situations [23,24]. A study by Aghaei MH et al., reported that education was helpful for military nurses in managing crises [23]. Education and previous experience not only benefit the personnel involved but also play a critical role in reducing the damages caused by disasters for the general population [25]. While plans during a disaster can never be successful to help everyone, educating people before disasters can help reduce the intensity of damage and casualties [26].

Taking prompt actions during crises and hazards significantly influences the loss of lives and mitigates destructive effects. In the healthcare sector, especially in the field of medicine, rapid access and supply of medications are crucial for saving lives. Pharmaceutical distribution companies, whether public or private, are responsible for drug distribution in Iran. Given that Iran is a relatively a vast country, ensuring rapid drug delivery and effective management is of utmost importance. In the present research, by using exploratory factor analysis, seven factors affecting drug management were identified in terms of their importance: supply chain, policy-making, organisation, guidance and leadership, crisis instances, planning, and education.

The present study highlights the components and areas that affect rapid access to medicine during crises and hazards, with a logical, appropriate, and equitable distribution approach. Implementing the findings of this study can be beneficial in preventing shortages or absence of pharmaceutical items during critical situations.

Limitation(s)

The most significant limitation of the present research was the difficulty in accessing experts and the limited availability of information sources on the subject of drug management in crises and disasters in the country's health system. This limitation arose due to the novelty of designing such a model, which resulted in a scarcity of relevant data and expertise.

CONCLUSION(S)

The results of the present study highlight the significance of factors such as the supply chain, policy-making, organisation, guidance and leadership, crisis instances, planning, and education in effectively managing drug distribution during crises and disasters. The present study presents a model that is applicable for health policymakers and planners, aiming to improve community health and enhance the quality of drug delivery during both natural and man-made crises.

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