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Data Infrastructure for a Poisoning Registry with Designing Data Elements and a Minimum Data Set

Azam Sabahi [1], Farkhondeh Asadi [2,*], Shahin Shadnia [3], Reza Rabiei [2] and Azamossadat Hosseini [2]

[1] Assistant Professor of Health Information Management, Department of Health Information Technology, Ferdows School of Health and Allied Medical Sciences, Birjand University of Medical Sciences, Birjand, Iran
[2] Department of Health Information Technology and Management, School of Allied Medical Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[3] Department of Clinical Toxicology, Toxicological Research Center, Loghman Hakim Hospital, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

[*] *Corresponding author*: Department of Health Information Technology and Management, School of Allied Medical Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran. Email: asadifar@sbmu.ac.ir

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Abstract

Background: The prevalence of poisoning is on the rise in Iran. A poisoning registry is a key source of information about poisoning patterns used for decision-making and healthcare provision, and a minimum dataset (MDS) is a prerequisite for developing a registry.
Objectives: This study aimed to design a MDS for a poisoning registry.
Methods: This applied study was conducted in 2021. A poisoning MDS was developed with a four-stage process: (1) conducting a systematic review of the Web of Science, Scopus, PubMed, and EMBASE, (2) examining poisoning-related websites and online forms, (3) classification of data elements in separate meetings with three toxicology specialists, and (4) validating data elements using the two-stage Delphi technique. A researcher-made checklist was employed for this purpose. The content validity of the checklist was examined based on the opinions of five health information management and medical informatics experts with respect to the topic of the study. Its test-retest reliability was also confirmed with the recruitment of 25 experts (r = 0.8).
Results: Overall, 368 data elements were identified from the articles and forms, of which 358 were confirmed via the two-stage Delphi technique and classified into administrative (n = 88) and clinical data elements (n = 270).
Conclusions: The creation of a poisoning registry requires identifying the information needs of healthcare centers, and an integrated and comprehensive framework should be developed to meet these needs. To this end, a MDS contains the essential data elements that form a framework for integrated and standard data collection.

Keywords: Minimum Data Set, Common Data Elements, Registries, Data Systems, Poisoning

1. Background

Annually, more than 1 million people worldwide suffer from different poisoning-related problems, ranging from mild to severe diseases, which require admission to the intensive care unit (ICU) (1). Poisoning is still a major public health concern due to its prevalence, severity, risk of mortality, disability, and hospitalization costs (2). The annual prevalence of poisoning varies from 0.02 to 0.93% in different countries, and it usually occurs in people aged 20 - 30 years (3). The World Health Organization (WHO) estimates that poisoning will lead to the loss of 10.7 million years of healthy life globally (4). In the UK, 26,000 people are admitted to the emergency department annually due to poisoning. About £2 million are allocated to childhood poisoning costs in the UK National Health Service (NHS) (5).

Based on the report of the US Center for Disease Control and Prevention (CDC), poisoning is the third main method of suicide and the main cause of non-fatal self-harm injury in this country. The medical costs for this type of poisoning were estimated at more than $1.9 billion in 2015 (6).

Moreover, poisoning centers in the US managed more than two million cases of poisoning in 2017, one-third of which were referred to healthcare centers. In addition, five million emergency department visits annually made in the US are due to drug poisoning, which constitutes 4% of the total work done in the emergency department (7).

Acute poisoning is defined as acute exposure (less than 24 h) to a toxic substance (8). It is one of the most prevalent causes for visiting the emergency department, threatens the health of society, and leads to considerable mortality

worldwide (9, 10). Based on the 2014 report of the American Association of Poison Control Centers, drugs cause 57% of acute poisoning cases (11). The rate of annual emergency visits related to acute poisoning widely differs around the world, varying from 0.1 to 0.7%. In Western countries, the annual rate of emergency visits due to poisoning is reported to be approximately 0.3% (8). Acute intoxication can be intentional or unintentional (12). Research indicates that intentional intoxication (ie, overdose) is mostly observed in adults, while unintentional intoxication (ie, poisoning) is mostly seen in children (13). In Australia, one-fifth of all unintentional drug intoxications and one-tenth of unintentional intoxications with other substances occurred in children under the age of four years during 2009 - 2010 (14, 15).

In developed countries, the most important cause of acute poisoning is the abuse of drugs available on the market. On the contrary, pesticides are the most prevalent cause of acute poisoning in developing countries (16). Based on the WHO report, about one million cases of poisoning with pesticides occur annually with severe manifestations, leading to about 20,000 deaths (17). Many cases of overdose, with a high mortality rate, occur in developing countries that face a shortage of resources (18). Moreover, more than 90% of the mortality resulting from poisoning occurs in low-to-middle-income countries (19), in which the mortality rate due to poisoning is four times higher than that of high-income countries (20). In Iran, as a developing country, statistics show that the number of poisoning cases has increased in recent decades (21-23), and poisoning has become one of the most prevalent harms related to morbidity and mortality (24). National studies suggest a rising trend of illicit drug poisoning and mortality in Iran (1, 16). Approximately two million people (about 2.7% of the population) use illicit drugs daily in Iran (25). In this country, the rate of mortality due to poisoning is eight per 1,000 patients in general wards and 109 per 1,000 patients in the ICU (16). Generally, the increasing incidence of poisoning in different countries, including Iran, can be due to a change in the lifestyle, socioeconomic behavior, cultural factors, and religious beliefs in society, as well as the easy access to many toxic agents, such as pesticides, therapeutic drugs, and other chemicals (26).

Awareness of the nature of poisoning in a region is important not only for the timely diagnosis and treatment of patients but also for awareness-raising and forming new policies for preventing poisoning (27). Therefore, the epidemiological evaluation of poisoning in different regions is essential to expand preventive strategies. Furthermore, there is a constant need for obtaining up-to-date information about poisoning to plan the reasonable use of resources and assess the public health interventions (28).

Disease registries are designed to collect and manage information about the approaches and outcomes of a population of patients to evaluate and improve care quality and safety, patient monitoring and follow-up, and facilitate new research (29). As an information management tool, the poisoning registry is an important source of information about poisoning patterns, decision-making, and healthcare provision (30). In registries, a minimum dataset (MDS) is usually utilized to facilitate the precise data analysis, decision-making, and management of disease cases (31). MDS is a standard tool for data collection that guarantees access to accurate and precise health data (32), improves the use of high-quality data, and is highly beneficial to planning, developing, monitoring, managing, and evaluating performances, disease control, and cost reduction. Moreover, the MDS enhances the accuracy and comprehensiveness of medical information and eventually leads to high-quality healthcare provision (33, 34). The development of MDS for poisoning registries can contribute to the provision of high-quality care and improvement of registration and efficiency in hospitals and clinical settings (35). For the prevention, monitoring, management, and follow-up of poisoned patients, the WHO established the INTOX International Program on Chemical Safety (IPCS) with the cooperation of more than 200 specialists in poison centers, clinical treatment units, and toxicology laboratories, in more than 75 countries. The datasets of exposure to chemicals collected by poison centers cooperating in the INTOX include demographic information, exposure information, signs and symptoms, laboratory findings, outcomes, and treatment (4). The National Poison Data System (NPDS) registry was developed in the US in 1983. In 2006, it was a database for all poison centers and the only comprehensive base for real-time poisoning monitoring in this country. In this registry, the poisoning MDS is classified into seven categories (36). Moreover, the data elements in the US TOXIC registry are divided into eight categories (37). To the best of our knowledge, the studies conducted in Iran about poisoning MDS have focused on the development of the MDS of poisoning with acidic and basic substances (38). In a study by Banaye Yazdipour et al. (35) to identify a national MDS for a poisoning registry in Iran, the MDS was divided into six main categories. Despite the identification of the poisoning MDS, the target data elements were not examined in their study. The poisoning MDS and data elements are essential to the constant collection and registration of data, and the creation of an MDS for integrated and standard data collection is the most important measure to be taken (39). Furthermore, the creation and design of an MDS and data elements are fundamental steps of establishing a registry that improves the communications between individ-

uals and organizations involved in healthcare (40).

2. Objectives

The present study aimed to identify an MDS and data elements for a poisoning registry in Iran.

3. Methods

This applied study was conducted in 2021. A poisoning MDS was developed via a four-stage process: (1) systematic review, (2) a review of websites and institutes related to poisoning, (3) classification of data elements, and (4) validation of data elements using the two-stage Delphi method.

3.1. Systematic Review

A systematic review was conducted by searching Web of Science, Scopus, PubMed, and EMBASE databases using the following keywords:

(1) Keywords related to the MDS concepts:

Minimum Data Set, **Dataset**, **Common Data Elements**, Data Elements, Data Recording, Data Utilization, Common Data, **Data Collection**, National Data Set, Core Data Set

(2) Keywords related to the registry:

Register*, **Database***, **Database Management System***, **Information System***, **Data System***, Data Management, **Information Management**, Surveillance System

(3) Keywords related to poisoning:

Poison*, Toxic*, Intoxic*, Noxious, **Poisons**

The MeSH term keywords are shown in boldface.

The keywords of the first group were retrieved in all the fields, while those of the second and third groups were retrieved in the titles and abstracts.

The articles were screened without time limitation up to May 8, 2019. The keywords and references of the articles identified in the preliminary search were reviewed to identify additional keywords and other relevant items. The titles and abstracts of the articles were screened by two reviewers to identify those in line with the research objectives. One of the reviewers performed the preliminary search of the databases. Then, the full text of the articles was assessed based on the inclusion and exclusion criteria. Administrative data and clinical data were extracted by a structured table format.

3.2. A Review of Websites and Institutes Related to Poisoning

The data elements extracted from websites, online forms, and articles about poisoning were examined to remove the duplicates.

3.3. Classification of the Data Elements

The data elements were classified based on various data element classifications presented in the articles. Subsequently, the classification applied to the data elements was determined in separate meetings with three toxicology specialists.

3.4. Validation of the Data Elements Using the Delphi Technique

The data elements were validated using the two-stage Delphi technique. A researcher-made checklist developed based on the obtained data elements was employed for this purpose. The content validity of the checklist was examined based on the opinions of five health information management and medical informatics experts with regard to the topic of the study. The test-retest reliability of the checklist was also confirmed by recruiting 25 participants ($r = 0.80$). The questions in each section had two options of “agree” and "disagree". For each question, space was also provided for mentioning the reasons and providing comments.

The scores of collected checklists were calculated in the first Delphi stage, and the expert consensus acceptable range (ie, scores > 75%) was taken into account. All the questions with a score of > 75% achieved expert consensus, all the questions with a score of 50 - 75% entered the second Delphi stage and the questions with a score of < 50% were eliminated in the first Delphi stage. As such, another checklist was designed for the second Delphi stage to apply the comments and modifications. This checklist was structurally similar to the previous one, with the difference that the row for suggesting data elements was removed in the second stage. Each Delphi stage lasted four weeks. Both checklists were handed to the experts in person.

Participants in this study included clinical toxicologists ($n = 10$), pharmacologists ($n = 5$), emergency medicine specialists ($n = 5$), health information management specialists ($n = 5$), 11 of them were between five to 10 and 14 of them had more than 10 years of work experience.

4. Results

4.1. Systematic Review and a Survey of the Poisoning Institutions and Websites

In the preliminary examination of the four databases, 6,208 articles were retrieved and inputted to EndNote. Finally, 34 articles were selected after the removal of duplicates or irrelevant cases based on title, abstract, and full-text screening. The search strategy is depicted in Figure 1.

Two forms about INTOX IPCS were extracted from the WHO website, two forms from the American College of Medical Toxicology (ACMT) website, and three forms about

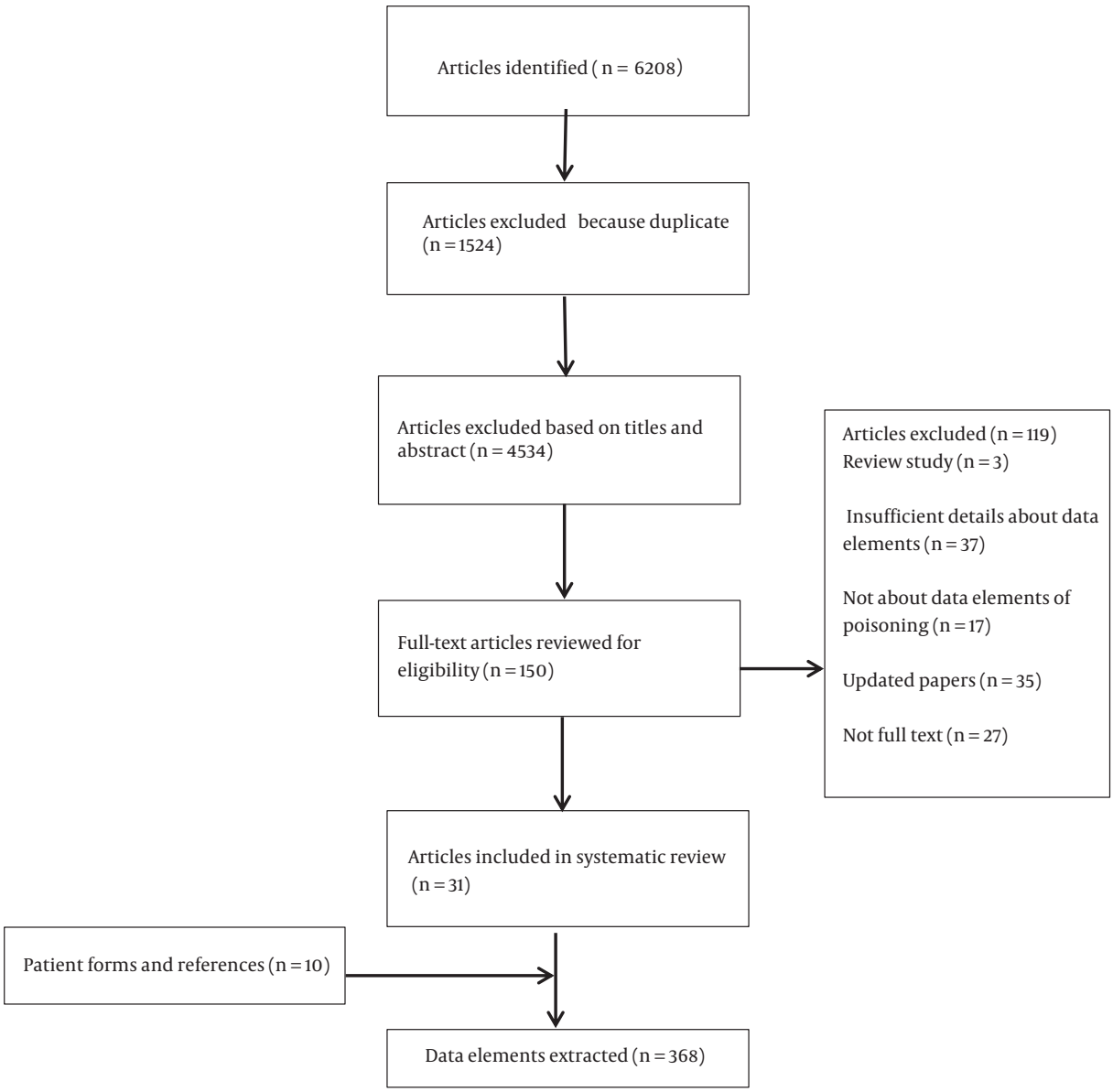

Figure 1. Systematic review flowchart

poisoning from the websites of the ministries of health in different countries, including Iran, Japan, and Australia. Overall, 368 data elements were identified in the articles and forms. Figure 1 displays the details of these cases.

4.2. Classification of the Data Elements

Nine sections were determined in meetings with three clinical toxicology experts, which were then classified into administrative data and clinical data. Administrative data included 110 data elements in the following sections: characteristics of the healthcare center, general patient data, admission data, and discharge data. Clinical data included 258 data elements in the following sections: the data of exposure, clinical observations, treatment plans, laboratory results on admission, and radiographic findings.

4.3. Validation of the Data Elements Using the Delphi Technique

In total, 12 out of 368 final data elements included in the Delphi survey were removed (score < 50%), and 323 data elements were confirmed (score > 75%) in the first

stage. Then, 33 data elements (score 50 - 75%) with 31 suggested data elements (n = 64 in total) entered the second Delphi stage. Of these, 35 cases were confirmed in the second stage. Thus, 358 data elements were finally confirmed and classified into the following sections: (A) administrative data: general data (n = 45), admission data (n = 35), and discharge data (n = 8); (B) clinical data: data of exposure (n = 73), clinical observations (n = 22), treatment plans (n = 121), toxicology analytical results (n = 19), laboratory results on admission (n = 29), and radiographic findings (n = 6). Tables 1 and 2 and Appendices 1 and 2 present the classification of the data elements.

5. Discussion

In this study, databases, poisoning websites, and online forms were searched to determine the MDS required for a poisoning registry. After individual sessions with experts, the MDS for a poisoning registry was created using the Delphi technique and collecting the opinions of experts (clinical toxicologists, pharmacists, emergency medicine specialists, and health information management experts). Based on the findings, 358 data elements were identified and divided into two classes of administrative data (general, admission, and discharge data) and clinical data (data of exposure, clinical observation, treatment plans, toxicology analytical results, laboratory results on admission, and radiographic findings).

In the INTOX data management system of the WHO, poisoning data collected by poison control centers include demographic information, exposure information, signs and symptoms, laboratory findings, outcomes, and treatment (41). Most sections of the present classification are based on the INTOX system, where the patient's height and weight are the data elements of the demographic data section. In the present study, however, the patient's height and weight were classified into admission data for a more precise evaluation of the patient on admission.

The American College of Medical Toxicology has created an international registry of poisoned patients called the Toxicology Investigators Consortium. It is a tool for clinical toxicology studies for furthering cooperation, education, and research among specialists for the global management of human poisoning with the final goal of improving patient care. The data elements of this registry are classified into patient demographic information, exposure information, symptoms and clinical findings, vital signs, physical examination findings, laboratory test results, treatment plans, and medical outcomes (42). In this registry, the race data element belongs to the demographic information category.

Table 1. Administrative Data Category for Minimum Data Set for the Poisoning Registry

Data Sections	Number of Data Elements	First Round of Delphi				Second Round of Delphi				Final Number of Data Elements
		< 50%	50 - 75%	75% <	Rejected Data Elements	Suggested Data Elements or Data Section	< 50%	50 - 75%	75% <	Rejected Data Elements	
Medical center information	2	2	0	0	Medical care name, medical care type	None	0	0	0	None	0
General data	48	4	0	44	Patient's email address, religion, race, ethnicity	Mobile number of the patient	0	0	1	None	45
Admission data	45	0	11	34	None	History of poisoning with toxic substances	11	0	1	Date of poisoning, time of poisoning, date of hospitalization, patients code, type of insurance, mode of arrival (ambulance, non-ambulance), source of referral (emergency department, outpatient/clinic, direct reference), physical examination findings	35
Discharge data	15	0	7	8	None	None	7	0	0	Date and time of discharge, length of hospital stay, type of hospital (public hospital, private hospital), types of the used services (emergency department, intensive care unit, others)	8

Table 2. Clinical Data Category for Minimum Data Set for the Poisoning Registry

Data Sections	Number of Data Elements	First Round of Delphi					Second Round of Delphi				Final Number of Data Elements
		< 50%	50 - 75%	75% <	Rejected Data Elements	Suggested Data Elements or Data Section	< 50%	50 - 75%	75% <	Rejected Data Elements	
Exposure data											
Reason for encounter	17	0	4	13	None	None	0	0	4	None	17
Type of encounter	4	0	0	4	None	None	0	0	0	None	4
Risk assessment of poisoning	5	5	0	0	Risk assessment of poisoning (no, minimal, moderate, high, critical)	None	0	0	0	None	0
Initial severity	5	0	5	0	None	None	5	0	0	Initial severity (none, minor, moderate, sever, fatal)	0
Final severity	5	0	5	0	None	None	5	0	0	Final severity (none, minor, moderate, sever, fatal)	0
Route of exposure	16	1	0	15	Placental	None	0	0	0	None	15
Activity during exposure	1	0	0	1	None	None	0	0	0	None	1
Date and time of exposure	1	0	0	1	None	None	0	0	0	None	1
Exposure agent	36	0	1	35	None	None	1	0	0	Riot agent/radiological	35
Clinical observation data											
Signs and symptoms	17	0	0	17	None	None	0	0	0	None	17
Vital signs	5	0	0	5	None	None	0	0	0	None	5
Treatment plan data											
Decontamination	15	0	0	15	None	None	0	0	0	None	15
Antidote	33	0	0	33	None	None	0	0	0	None	33
Chelators	10	0	0	10	None	None	0	0	0	None	10
Antivenom	4	0	0	4	None	Botulism antitoxin, rabies immune globulin	0	0	2	None	6
Pharmacologic support	15	0	0	15	None	None	0	0	0	None	15
Elimination	7	0	0	7	None	None	0	0	0	None	7
None-pharmacologic support	25	0	0	25	None	Surgeries (esophagectomy, colon interposition, gastric pull-up, buginage, jejunostomy feeding, laparotomy, gastrotomy, tracheostomy)	0	0	8	None	33
Duration of treatment (days, weeks)	1	0	0	1	None		0	0	0	None	1
Frequency of treatment (per day, per week)	1	0	0	1	None	None	0	0	0	None	1
29	0	0	29	None	None	0	0	0	None	29	
6	0	0	6	None	None	0	0	0	None	6	
0	0	0	0		Suggested data section: analytical result (n = 19)	0	0	19	None	19	

In the present study, on the other hand, the experts deemed this data element unnecessary, which might have been due to the lack of racial diversity in Iran. Moreover, the ethnicity and religion data elements were deemed unnecessary. To contact the patients, the patient's email address was removed due to the access of only some patients to the Internet, and the patient's cell phone number was recommended due to the widespread use of cellphones. In the TOXIC registry, the findings of physical examination belong to the MDS. Nevertheless, this data element, along with the date and time of poisoning, time of admission, patient code, state at arrival, type of insurance, and reference were deemed unnecessary by the experts and removed in the present study. Apparently, some of these data items are not in line with the goals of the registry and can also be obtained from the hospital information system. Moreover, a large volume of data would lead to confusion and waste of time, based on the definition of the MDS that encompasses the most essential data elements (43).

Another registry in the US is the National Poison Data System (NPDS) managing more than 390,000 pharmaceutical, chemical, and household products (37). The MDS of this database includes the patient's demographic information, exposure information, symptoms and clinical findings, physical examination findings, laboratory test results, treatment plans, and medical outcomes (42). The classification of the data elements in this registry is similar to that of the TOXIC registry, but the vital signs data element is not included in the former. It is essential to control patients' vital signs, especially in acute poisoning, and can help doctors with timely decision-making and taking the necessary measures, thereby saving patients' lives (44). Consequently, these data elements can be beneficial in the poisoning registry, and the experts in this study agreed with its inclusion. In Israel, the Israel Poison Information Center (IPIC) is a valuable national resource for collecting and monitoring poisoning exposure cases and can be employed as a real-time monitoring system. This database contains information about chemical and pharmaceutical products, and its data elements are classified into the patient's demographic information, exposure information, clinical severity of exposure, laboratory test results, treatment plans, and medical outcomes (45). In the exposure data section of the present study, the experts did not agree with data elements of poisoning risk assessment and exposure severity, and thus these elements were removed from this section. It seems that the type, cause, route, and duration of exposure can meet the specialists' information needs in this section. None of the reviewed registries mentioned the activity at the time of exposure data element in the exposure data section, whereas These data elements can be used in planning and policy-making to prevent poisoning related to the activity at the time of exposure (35).

Furthermore, the data element of the cause of exposure was classified into intentional, unintentional, adverse drug reaction, others, and unknown. In the present study, this classification is presented more expansively, and the experts agreed upon data elements of environmental evaluation and occupational evaluation in the unintentional exposure - non-pharmaceutical section as the causes of poisoning. These data elements are included in this study probably because it is important to identify and evaluate the risk of non-pharmaceutical factors (46, 47).

The Hunter Area Toxicology Service (HAST) database was developed to collect information on poisoning cases in Australia. This database collects the following MDS: demographic information, exposure information, presentation information, history, clinical examination, psychiatric counseling, information about treatment, outcome, discharge, and follow-up information (48). The MDS classification in the present study is greatly similar to the HAST. Contrary to other registries, the HAST contains the patient's history. In the present study, the experts agreed with this data element and its sub-items. As the medical history is significant for the preliminary management of poisoned patients (49), it is better to include this data element in the poisoning registry.

In all reviewed registries, a separate section is allocated to the medical outcome data. In the present study, medical outcomes, was classified into the discharge data section. In this section, the data on discharge time and date, length of hospital stay, type of hospital, and the service used were deemed unnecessary by the experts. The collection of unnecessary data in information systems and registries leads to data redundancy, and a failure to send the necessary data can reduce the quality of collected data (50).

In addition, all the reviewed registries contained the data element of treatment, which is in line with the results of the present study. In most of these registries, treatment is categorized into the following sections: decontamination, antidote, chelators, antivenom, pharmacologic support, elimination, and none-pharmacologic support.

In this study, botulism antitoxin and rabies immune globulin data elements were suggested for the antivenom-related therapeutic section based on expert consensus. Since botulism is a health and treatment emergency (51), and rabies is a prevalent disease in Iran that can introduce poison into the body (52), their treatment methods are of special importance. Moreover, the experts suggested the types of common surgeries in poisoning in the section of treatment methods.

The data section of the toxicology analytical results was recommended and agreed upon by the experts due to its significance in treatment evaluation and quick pa-

tient management (53). In a study by Banaye Yazdipour et al. (35) to identify a national MDS for a poisoning registry in Iran, the MDS was divided into six main categories: demographic and communication data, diagnostic data, and medical history, clinical data, treatment data, biobank, and discharge data.

In this study, biobank data was suggested and agreed upon by the experts in the second stage of the Delphi technique. Although the use of biobanks will help treatment, research, and educational activities (54), there are still challenges such as ethical constructions (informed consent model, sample ownership, veto right, and biobank sustainability). Additionally, the complexity and diversity of biobanking practices cause hazards, advantages, and responsibilities that are not well identified or resolved (55).

In the present study, the comments and evaluations used for finalizing the dataset were obtained from the experts only in Tehran, the most populous city of Iran. However, the MDS developed in the present study can be updated by the experts of other cities to develop a poisoning registry.

The WHO emphasizes that data should be available in order to contribute to the development of healthcare systems (43). Accordingly, future studies are recommended to investigate the accessibility of data using focus group discussions. Finally, it is suggested to specify the mandatory and optional datasets after developing a poisoning registry.

5.1. Conclusions

With regard to the prevalence of poisoning in Iran, the use of a poisoning registry seems to be necessary for the management of poisoning cases. The first step for creating a poisoning registry is to identify the information needs of healthcare centers. Therefore, it is essential to develop an integrated and comprehensive framework that takes into account the information needs of all the stakeholders. An MDS contains the essential data elements that form a framework for integrated and standard data collection and satisfaction of the stakeholders' information needs. It is also a prerequisite for developing registries, including poisoning registries.

Supplementary Material

Supplementary material(s) is available here [To read supplementary materials, please refer to the journal website and open PDF/HTML].

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Footnotes

Authors' Contribution: A.S. and F.A. worked on defining appropriate search terms, A.S., F.A., SH. SH., R.R., and A.H. worked on data extraction, and analysis. A.S. and F.A performed the searches in the electronic databases. A.S. and F.A. collected and analyzed checklists. Also, all the authors wrote, read, and approved the final manuscript.

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