Toxicovigilance Profile in Saudi Arabia
Capacity Assessment and Proposed Framework
2026

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List of Publications

- Najla Khoja, Abdullah AlTamimi, Abeer Mohamed, Laale Alawi, Khalid Almulhim & Robin Plevin (2024). *Prevalence and characteristics of poisoning calls/cases in Saudi Arabia: a single-center experience from a tertiary care hospital*, Toxicology Communications, 8:1, 2442859, DOI: 10.1080/24734306.2024.2442859.

- Allabun, S.M., AlNasser, S.N., Khojah, N., & Zakaria, E.A. (2021*). Reducing the Number of Drug-Overdose Poisoning Cases by Applying Modern Smart-Phone Apps Technology to the Saudi Healthcare System***.** International Journal of Research in Health Sciences, 9(1), 01-08. DOI: 10.5530/ijrhs.9.1.1.

- *Guidelines For Establishing a Poison Center.* Geneva: World Health Organization; (2020). License: CC BY-NC-SA 3.0 IGO. Khojah, N. (Reviewer of the book content).

- AlNasser, S.N., Khojah, N., & AlQahtani, S.A. (2019). *Assessment of drug and poison information centers in Saudi Arabia*. Toxicology Communications, 3(1), 43-46. DOI: 10.1080/24734306.2019.1624410.

- AlTamimi, A., Malhis, N.K., Khojah, N.M., Manea, S.A., AlTamimi, A., & AlShammary, S.A. (2017). *Antidote Availability in Saudi Arabia Hospitals in the Riyadh Province*. Basic & Clinical Pharmacology & Toxicology. DOI: 10.1111/bcpt.12897.

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Abbreviations

AAPCC	The American Association of Poison Control Centers
AAR	After-Action Reviews
ACMT	American College of Medical Toxicology
ADI	Admissible Daily Intake
AI	Artificial Intelligence
AL	Aluminum
AMR	Antimicrobial Resistance
AR	Action Plan-Reviews
As	Arsenic
ASPR	Administration for Strategic Preparedness and Response
ATSDR	Agency for Toxic Substances and Disease Registry
CBRN	Chemical, Biological, Radiological, and Nuclear
Cd	Cadmium
CDC	Center of Disease and Control
CDR	Crude Death Rate
CLP	Classification, Labelling and Packaging
CNPHI	Canadian Network for Public Health Intelligence
Co	Cobalt
CO	Carbon Monoxide
COMAH	Control of Major Accident Hazards
CoP	Collaborations Community of Practice
COVID-19	Coronavirus Disease 2019
Cr	Chromium
CSSPI	Canadian Surveillance System for Poison Information
DHIS	Digital Health Information System
DRR	Disaster Risk Reduction
DPIC	Poison and Drug Information Centers
EAPCCT	European Association of Poison Centers and Clinical Toxicologists
EBS	Event-Based Surveillance
EHR	Electronic Health Records
EMR	Eastern Mediterranean Region
EMS	Emergency Medical Services
Eu	Europium
EWRS	Early Warning Response System
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FTEs	Full Time Equivalents
GBD	Global Burden of Diseases
GCC	Gulf Cooperation Council
GDP	Gross Domestic Product
GHE	Global Health Estimates
GHO	Global Health Observatory
GHS	Globally Harmonized System of Classification and Labelling of Chemicals

H1N1	Type-1 Hemagglutinin and Type-1 Neuraminidase Proteins Influenza Virus
HCF	Healthcare Facility
HEOF	Health Emergency Operations Facility
HESN	Health Electronic Surveillance Network
HHS	Health and Human Services
Hf	Hafnium
HIPAA	Health Insurance Portability and Accountability Act
HIS	Health Information Systems
IBM	International Business Machines Corporation
ICD	International Classification of Diseases
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
IHR	International Health Regulations
ISO	International Risk Governance Center
IRGC	International Organization for Standardization
JCI	Joint Commission International
JEE	Joint External Evaluation
KACARE	King Abdullah City for Atomic and Renewable Energy
KFMC-PCC	King Fahad Medical City's Poison Control Department
KSA	Kingdom of Saudi Arabia
MAL	Maximum Allowable Limit
MMWR	Morbidity and Mortality Weekly Report
Mo	Molybdenum
MOU	Memorandum of Understanding
MoH	Ministry of Health
NCDs	Non-Communicable Diseases
NDPIC	National Drug & Poison Information Center
NPDS	National Poison Data System
NFPs	National Focal Points
NHS	National Health Services
NIOSH	National Institute for Occupational Safety and Health
NNDSS	National Notifiable Diseases Surveillance System
NPIS	National Poisons Information Service
NRRC	Nuclear and Radiological Regulatory Commission
NSAIDs	Nonsteroidal Anti-Inflammatory Drugs
NSTESS	National Saudi Toxic Exposure Surveillance System
Ni	Nickel
NTP	National Transformation System 2020
OECD	Organization for Economic Cooperation and Development
OTARR	Online Toxicology Analysis Requests and Results
PAHPA	Pandemic and All-Hazards Preparedness Act
PHE	Public Health England
PHA	Public Health Authority
PHEIC	Public Health Emergency of International Concern
PHS	Public Health Scotland
PHI	Protected Health Information

PPP	Purchasing Power Parity
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSS	Poisoning Severity Score
RASCHEM	Rapid Alert System for Chemicals
RED-Cap	Research Electronic Data Capture
RCE	Radiation, Chemicals and Environmental Hazards Directorate
Sb	Antimony
SCHS	Saudi Council for Health Specialties
SD	Standard Deviation
SDGs	Sustainable Development Goals
SFDA	Saudi Drug and Food Authority
SNTESS	Saudi National Toxic Exposure Surveillance System
SOPs	Standard Operating Procedures
SPI	Specialist in Poison Information
SPSS	Statistical Package for the Social Sciences
Tb	Terbium
TESS	Toxic Exposure Surveillance System
Tox-IC	Toxicology Investigator's Consortium
UFI	Unique Formula Identifier
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
UK	United Kingdom
UKHSA	United Kingdom Health Security Agency
UKPID	National Poison Information Database
UKTIS	United Kingdom Teratology Information Service
VRPs	Vision Realization Systems
UNDRR	United Nations Office for Disaster Risk Reduction
USA	United States of America
WHO	World Health Organization
WONDER	Wide-ranging Online Data for Epidemiologic Research
Yb	Ytterbium

Thesis Abstract

This thesis, titled "Toxicovigilance Profile in Saudi Arabia: Capacity Assessment and Proposed Framework," addresses the pressing need for a comprehensive toxicovigilance system in the Kingdom of Saudi Arabia (KSA) to combat the high prevalence of poisoning cases. Despite alarming statistics on unintentional poisoning, the country lacks a centralized data collection system and a national poison control center. The research aims to assess the magnitude and prevalence of poisoning incidents, identify contributing factors, and develop evidence-based recommendations for establishing a Saudi Toxicovigilance System, also referred to as a Saudi National Toxic Exposure Surveillance System (SNTESS).

The literature review in the thesis highlights global poisoning trends and emphasizes the limited toxicovigilance infrastructure within the Eastern Mediterranean Region (EMR), which includes KSA. It reveals significant data gaps, particularly in rural areas, and underscores the reliance on retrospective studies rather than proactive surveillance. Moreover, the thesis explores the conceptual framework of toxicovigilance, comparing international practices and identifying best practices suitable for adaptation in the context of the Saudi healthcare system.

Subsequent chapters detail similar toxicovigilance efforts in KSA, including a gap analysis of existing resources and the roles of governmental agencies. Additionally, a comparative review of toxicovigilance practices in three leading countries (the USA, the UK, and Canada) is presented. Based on this review, a strategic plan is proposed for establishing the Saudi Toxicovigilance System, outlining governance, data management, and operational tactics. Risk assessment methodologies are introduced to enhance the concept of toxicovigilance.

The thesis concludes with specific recommendations for improving current toxicovigilance efforts, including the establishment of a national poison control center, targeted public health interventions to protect vulnerable populations, the formation of a

poison control center association, and the implementation of a One Health approach for global health security. Collectively, these efforts aim to foster a stewardship program for the surveillance of toxic hazards, ultimately enhancing public health outcomes in KSA.

Finally, the thesis includes a pilot case that utilizes a toxic exposure surveillance system in a single poison control center in one region of KSA. The data from that center were published in December 2024 in the article titled "Prevalence and Characteristics of Poisoning Calls/Cases in KSA: A Single-Center Experience from a Tertiary Care Hospital" to support the thesis theory.

Chapter 1: Introduction

1.1 Thesis Question and Problem Statement

To date, there has been a lack of comprehensive research assessing the prevalence, severity, and overall burden of poisoning cases in KSA. Addressing this gap is essential to evaluate the need for establishing SNTESS. Therefore, the research question of this thesis is: What is the toxicovigilance profile in KSA?

To answer this question, the burden of poisoning cases in KSA must be addressed first. Globally, according to 2016 World Health Organization (WHO) statistics, the global average mortality rate attributed to unintentional poisoning per 100,000 population is 1.45. However, this rate was two to three times higher in several countries within the EMR, such as Somalia, Sudan, and Yemen (Figure 1-1) (1), (2), (3). Despite this, there is limited evidence that describes the overall magnitude of poisoning and toxicology problems experienced in EMR countries, KSA in particular (4). Although regional investigations and studies focusing on specific age groups or types of poisoning exist, the available data remain insufficient to the scope of the present research. This limitation is further compounded by the limited number of Poison Control Centers (PCCs) across KSA (3), and other EMR countries, a concern consistently highlighted in WHO reports (5).

Moreover, the absence of a toxicovigilance system in KSA represents a significant challenge to effective data collection (3), (4), (6). Consequently, most documented poisoning cases mentioned in literature are derived from retrospective studies rather than active surveillance within a robust national toxicovigilance system. (7). By transitioning to a more proactive centralized system, KSA could significantly enhance its capacity to identify, investigate, and respond to evolving toxicological threats in real time. This can ultimately contribute to improved patient outcomes, targeted prevention strategies, and evidence-based toxicological policy development in the country (6).

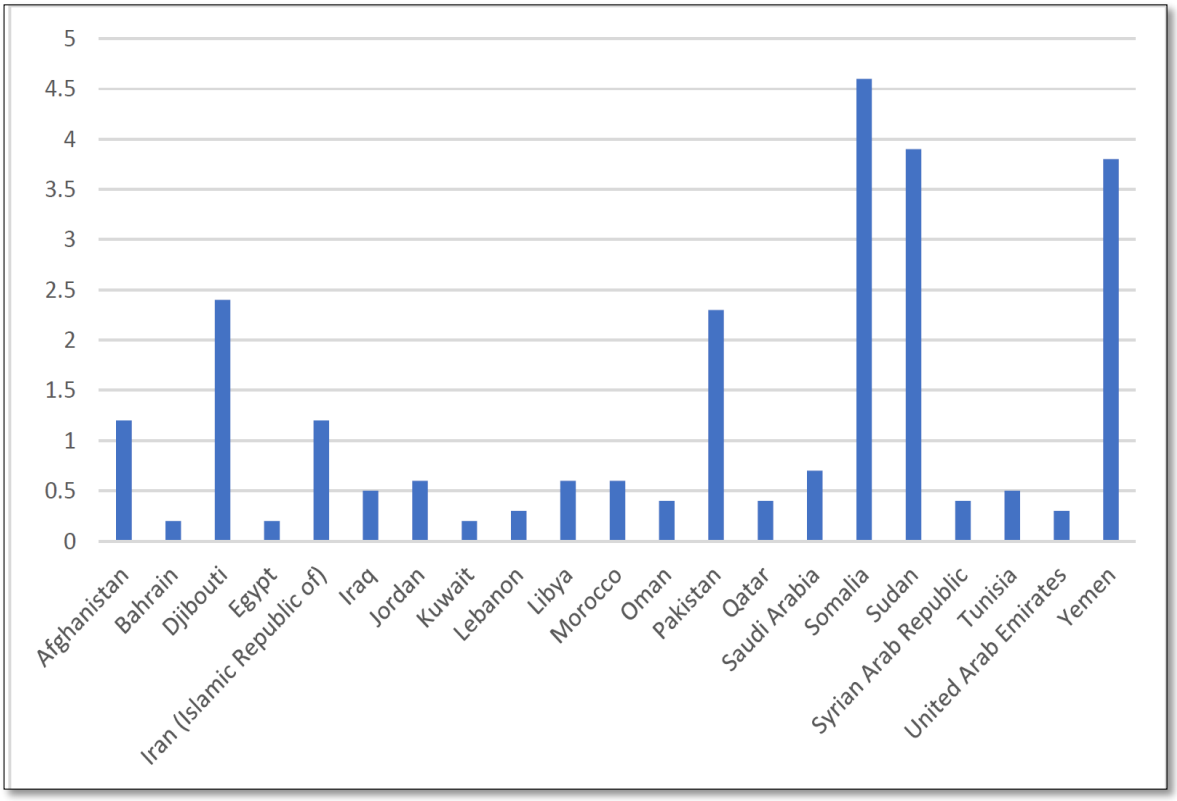

Figure 1-1: Mortality rate attributed to unintentional poisoning (per 100,000population) in EMR countries

1.2 Thesis Objectives

This thesis has three primary research objectives (Figures 1-2):

Objective 1: To assess the prevalence of poisoning cases in KSA through a pilot study (Chapter 2).

Objective 2: To assess the magnitude and patterns of poisoning cases in KSA (Chapter 3 through literature evaluation).

Objective 3: To evaluate the need for and feasibility of establishing a SNTESS in KSA, and this include:

- Review existing similar toxicovigilance systems in KSA (Chapter 4) and other countries to identify best practices (Chapter 5).

- Develop a comprehensive understanding of Toxicovigilance in general (Chapter 6).
- Develop a proposal framework for SNTESS (Chapter 7)
- Suggest recommendations that support the implementation of SNTESS (Chapter 8).

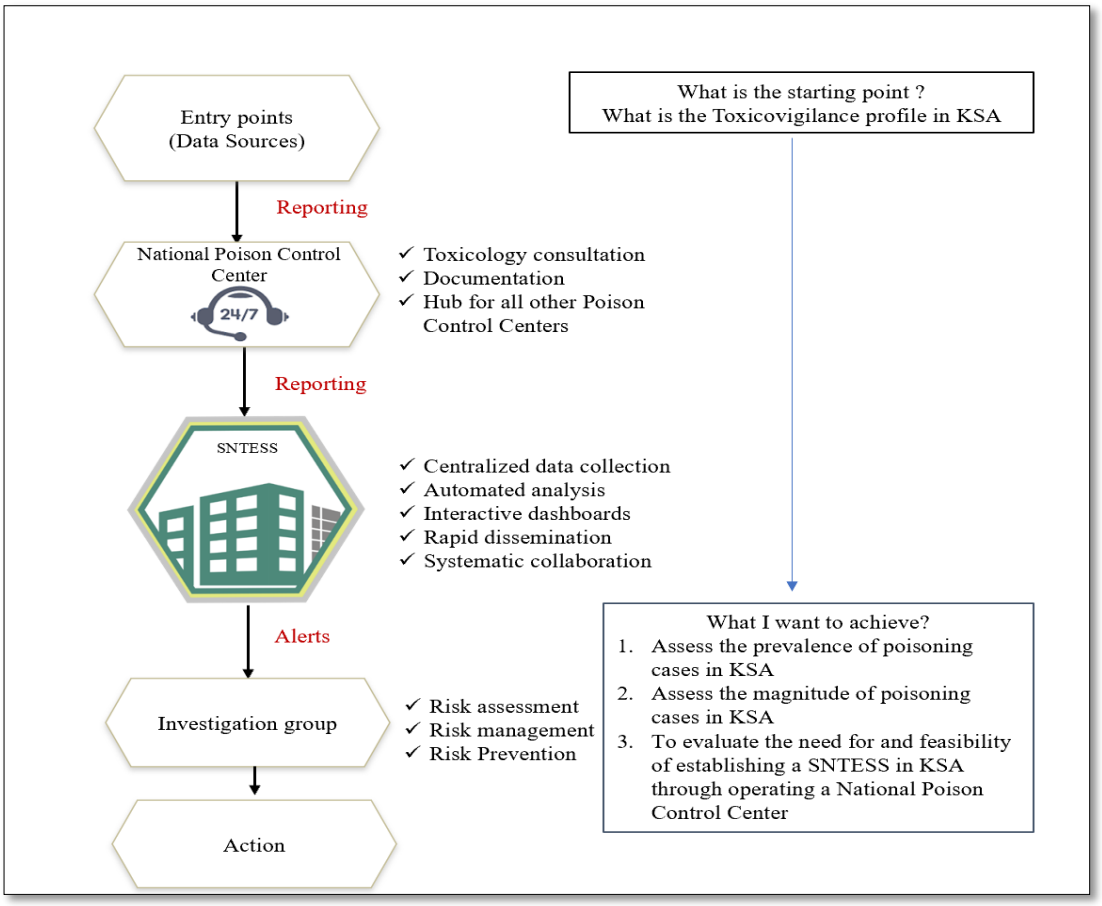

Figure 1-2: Summary of aims

1.3 Thesis Scope

This thesis examines toxicovigilance in KSA through a conceptual exploration of its evaluation process, with emphasis on poisoning and toxic exposure as public health concerns. It does not encompass experimental or laboratory-based toxicity studies.

1.4 Definition of Terms

Biological Hazard (Biohazard): Biohazard is a threat that can adversely affect human health, including waste, microorganisms, viruses, or toxins from biological sources (8).

Chemical Hazard: Chemical hazards are substances that pose risks to health and safety upon exposure, including chemicals classified as toxic, mutagenic, and carcinogenic, often encountered in laboratory settings (9).

Crisis: Crisis is an urgent situation in which the health status within the region is adversely affected. It includes localized outbreaks (e.g., an infectious disease) that has a reasonable possibility of spreading rapidly to nearby territories (10).

Disaster: Disaster is a sudden, large-scale, disruptive event of acute onset which can lead to significant physical, social, psychological, and environmental harm (11).

Emergency: Emergency is an urgent medical situation that requires immediate attention (10).

Hazardous: A hazardous substance may pose physical or health risks, in usable or waste form . It is deemed hazardous if it is flammable, corrosive, toxic, or reactive. Furthermore, substances are also classified as hazardous if they are explicitly listed by regulatory bodies (12).

Mass Casualty: Mass Casualty is an incident/event in which essential services (e.g., healthcare) are overwhelmed by the number and severity of casualties (13).

Nuclear Hazard: A nuclear hazard can arise from accidents at nuclear power plants, the spread of nuclear weapons, or the mishandling and disposal of radioactive materials (14).

One Health: One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals, and ecosystems. It recognizes the

health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent. The approach mobilizes multiple sectors, disciplines, and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for healthy food, water, energy, and air, acting on climate change and contributing to sustainable development (15).

Poison: Poison is a substance that, for humans and their non-pathogenic biological environment, is either an electromagnetic or corpuscular radiation, or a non-infectious chemical agent. It is typically no larger than a small particle and can produce direct or indirect adverse effects when generated internally or after contact, penetration, or absorption by a living organism in sufficiently high doses (16).

Poisoning: Poisoning is exposure to poison irrespective of the route of exposure. Exposures can include self-harm, environmental exposure, and chemicals found in homes or workplaces. Even typical exploratory behavior by toddlers and children can lead to poisoning incidents. Additionally, food poisoning, bites or stings from venomous animals also fall within the scope of poisoning (17).

Public Health Surveillance: Public Health Surveillance is the ongoing systematic collection, analysis, and interpretation of data, closely integrated with the timely dissemination to those responsible for preventing and controlling disease and injury (18).

Radiological Hazard: Radiation is the emission of energy as electromagnetic waves or moving subatomic particles, originating from natural radioactive materials in soil, water, air, and the human body. Exposure can occur from natural sources like radon, planned activities such as medical procedures, or accidents. It can be classified as external, which may involve contamination of skin or clothing, or internal, resulting from inhalation or ingestion. The potential harm depends on the radiation dose: higher doses increase risk of adverse health effects, whilst lower doses or prolonged exposure generally pose a reduced risk, as the body can often repair damage over time (19).

Resilience: Resilience is the capacity of a system, community, or society that faces risks to effectively resist, absorb, accommodate, adapt to, transform, and recover from the impacts of an emergency. This process should be timely and efficient, involving the preservation and restoration of essential structures and functions through effective risk management (20). National resilience is not an absolute but a characteristic of countries that determines how well they can recover from shocks, and how they can adapt to adversity in short- or long-term conditions (21).

Risk Assessment: Risk Assessment is a methodical approach to evaluate the health effects resulting from population or individual exposure (22). It is a critical component of effective risk management, and it should be applied comprehensively to identify, analyze, and evaluate all potential risks facing an organization or a community, except for those specifically categorized as threats. This broad approach ensures that the risk assessment process captures a wide range of risks, including natural disasters, disease outbreaks, food contamination, or chemical or radio-nuclear spills.

Toxicovigilance: Toxicovigilance was first defined by the WHO International Program on Chemical Safety as the active process of identifying and evaluating toxic risks in a community and assessing measures taken to reduce or eliminate them, particularly through the analysis of Poison Control Center enquiries to detect hazardous agents and vulnerable populations (23). The WHO further describes toxicovigilance as a collaborative activity involving poison centers, laboratories, public health authorities, and regulatory agencies, with its scope adapted to national resources and its response scaled to the magnitude of risk. More broadly, toxicovigilance combining toxicology and surveillance refers to the monitoring of acute and chronic toxic effects in humans from environmental or substances to enable early warning, prevention, and risk management (24), (25).

Threats: A Threat is an event that could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt

remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time (26).

Toxic Substances: Toxic Substances are substances that can cause harm to living organisms when organisms are exposed to them or when they are used inappropriately. They can be found in the environment, the workplace, and houses (27).

Venom: Venom is a complex mixture of proteins, peptides, and other substances that has evolved to help animals kill or subdue their prey or defend themselves from predators. It can enter the living organism through a bite, sting, or other means. Its effects on the exposed organism vary depending on the composition of the venom (28).

Chapter 2: King Fahad Medical City's PCC -A Pilot Study of Toxicovigilance

2.1 Pilot Study Rationale

The lack of a toxicovigilance system in KSA for the collection of poisoning data is a structural weakness in toxicovigilance capabilities. This limits the ability to accurately measure the actual burden of poisoning and delays identification of emerging trends in acute poisoning situations such as foodborne intoxication, medication overdoses, envenomation, and exposure to household or industrial chemicals that can present life-threatening incidents and require urgent clinical attention (3), (4). In the absence of real-time and/or systematically integrated reporting, toxicological events exist and are divided across entities for which there is no real-time or consistent information available; due to which this information is delayed when it relates to the identification of population-level risk and hinders early warnings and preventative action. Moreover, failure to centralize data limits identification of the at-risk groups most likely to be disproportionately exposed to toxic exposures.

A national toxicovigilance system could therefore not only act as a "data center", a passive place to gather data but in fact be an active platform that could analyze and support policy by identifying at-risk groups, prioritizing interventions, and informing regulation and education policy. Toxicovigilance in that sense is, not only a technical requirement and policy tool but also stands to revolutionize the approach to the management of poisoning in Saudi healthcare sector. Establishing a national toxicovigilance system would require proof that poisoning is a serious and under-recognized public health issue in KSA. It needs to go beyond isolated organizational reports to include national data on incidence, substance categories, clinical outcomes, and demographic patterns. Data in many nations is produced through public health surveillance agencies such as the Centers for Disease Control and Prevention (CDC) in the USA and through professional organizations

including the American Association of Poison Control Centers (AAPCC) with yearly poisoning trend reports (29) .

While studies carried out in KSA have provided important insights into the prevalence and characteristics of poisoning, such examinations are intrinsically limited in scope, methodology, and data sources, encompassing emergency department records, toxicology lab results, as well as ad hoc call registries of many organizations. Thus, although informative, the current evidence is still lacking to guide national policy or systemic-level interventions. Fragmentation of poisoning data across organizations severely limits aggregation, comparability, and longitudinal analysis, as well as rendering it less useful for toxicovigilance and prevention. Building national toxicovigilance capacity will start with pragmatic and evidence-generating pilot studies of use in a single high-volume tertiary institution, and within this backdrop, the current study represents the first-prudential step for an impactful pilot program in this phase of the study.

Unlike an attempt to achieve the nationwide system in an inbuilt state if methodology lacks validated and demonstrated feasibility, a pilot project provides the foundation to develop, validate, and optimize the data collection methods with controlled and reproducible testing. King Fahad Medical City (KFMC) was the institutionally chosen because of a variety of organizational features that made this a convenient setting for study. Given, as a referral center recognized throughout the country as a national center, KFMC has a heterogeneous clinical and high-volume poisoning case load from across the country, offering a rich and representative data background. The presence of existing clinical infrastructure, specialist staffing, and organizational capacity further reinforce the systematic implementation of structured toxicovigilance protocol. The results from this pilot study are designed not only to characterize the epidemiological profile of poisoning at KFMC, but also to provide evidence to support the national system vision within SNTESS as a proof-of-concept model. This is exactly why a national poison control center within SNTESS is not just complementary, but absolutely the cornerstone of its operations. National poison control centers perform operational functions and provide means of data collection, clinical decision support, risk communication, and public health

preparedness in the context of chemical, biological, radiological and nuclear (CBRN) threats and other all-hazards emergencies (30). At the moment, KSA does not have a full ability to identify abnormal exposure patterns, issue early warning alerts or coordinate large-scale poisoning interventions (7).

2.2 Pilot Study Scope and Aim

This study focuses on poisoning cases reported to the KFMC-PCC, as a single PCC at a tertiary care hospital in Riyadh, KSA, over a defined study period. The analysis is limited to cases documented in the center computerized data system and therefore does not include unreported cases or those managed at the community level. In addition, the scope of this study excludes experimental or laboratory-based toxicology research and does not assess long-term outcomes beyond the acute clinical setting. The study aims to describe the demographic and epidemiological characteristics of poisoning cases as well as the electronic documentation system.

2.3 Pilot Study Questions

What is the epidemiological profile of acute poisoning exposures at KFMC-PCC (incidence, implicated substances, affected populations, and clinical outcomes), and to what extent does this centralized poison-control profile justify scaling the system nationally?

2.4 Method

A retrospective investigation was conducted to review all cases of acute poisoning obtained from January 2013 to June 2021 to describe the prevalence and pattern among toxic exposures at KFMC-PCC. Data review was based on records obtained from the poison-call system; a computerized data system designed at the PCC. This data system is used to record all poison related inquiries received through the call center in a standardized electronic form. Data extracted included age, sex, year of exposure, type of exposure

a(classified as pharmaceuticals and non-pharmaceuticals), exposure location, route, and number of substances. Cases covered from 2013-2018 included one tertiary hospital, whilst cases from 2018-2021 covered 3 hospitals (inclusion of 2 secondary hospitals) belonging to the same cluster. Ethical approval was obtained from the Institutional Review Board prior to commencement (IRB Log Number: 20-690E).

2.5 Source of Data

Data was extracted from KFMC-PCC, one of the very first PCCs in the country (see Appendix 1 for the center flyer). It operates 24/7 through a designated phone number that offers immediate clinical consultation, specialized care, and evaluation of patients exposed to poisonous or hazardous substances at bedside. It covers only the population of the second healthcare cluster in Riyadh, KSA. This cluster includes one tertiary care hospital (KFMC), two secondary care hospitals; Prince Mohammed Bin Abdulaziz Hospital and Al Yamamah Hospital, plus 48 primary care clinics. It also serves as a major teaching site for pharmacists and emergency physicians seeking training in toxicology. In this study, the term "center" is utilized interchangeably with the term "department" as a metaphorical language commonly employed in discussions about best practices. This metaphorical usage not only permeates discussions surrounding best practices but also significantly shapes the understanding and actions

KFMC-PCC operates a computerized poison-call system that registers detailed information on each poison exposure or consultation handled by the center. This structured system, analogous to the SNTESS proposed in this thesis, enables near real-time surveillance for the detection of toxicological outbreaks and trends but not on a national level as KFMC-PCC covers only one region. Moreover, by explaining KFMC-PCC's operational model and the utility of its poison-call system, this study contributes to broader understanding of how PCC can serve as critical components of a multi-layered toxicovigilance activities. The insights gained from this center's experience may inform the development and optimization of similar systems in other PCCs settings, ultimately

strengthening the national and global capacity for real-time detection and response to emerging toxicological threats.

The poison-call system is developed by KFMC's Information Technology Department. The system was tailored according to the AAPCC standards to include: date/time of call, age, call type (exposure, information), reason for call, acuity (time of exposure), number of substances, exposure site, caller site, clinical effects, decontamination, and treatment (Figure 2-1).

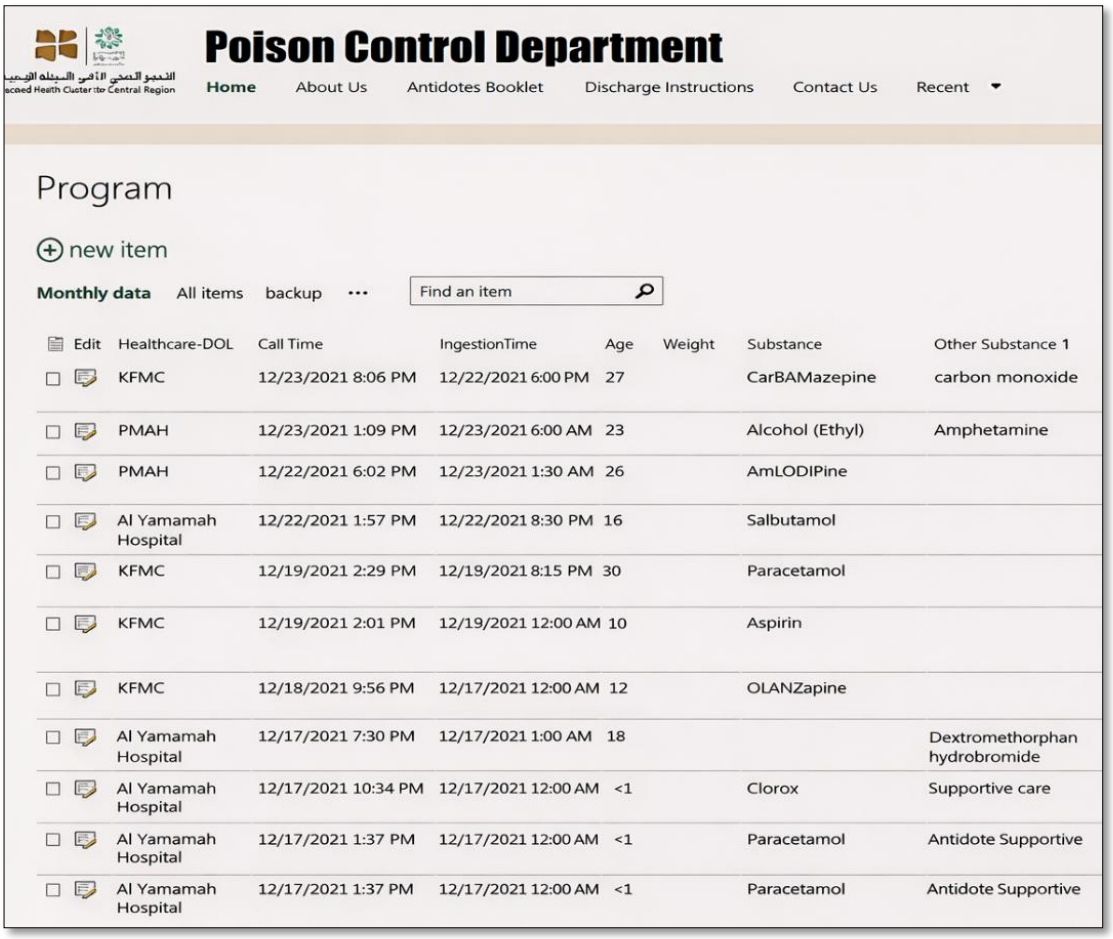

Figure 2-1: The Poison-Call System in KFMC-PCC

2.6 Data Analysis

Findings in this chapter has been published as an article in *Toxicology Communications Journal*. (see Appendix 2) (31). Data were analyzed using the Statistical Package for the Social Sciences (SPSS) 22.0 (SPSS Inc., Chicago, IL, USA). Descriptive analysis was performed to determine the frequencies (%) of the categorical variables and plotted in MS Excel, where applicable.

2.7 Results

Table 2-1 shows the characteristics of all patients stratified according to sex. Overall, more than two thirds of poisoning cases were children 5 years and below (n=1508, 69.6%) whilst elders 60 and above constitute the least number of reported cases (n=31, 1,4%). A large percentage (n=2090, 96.4%) of those exposures occurred at home. Many of those exposures were also unintentional in nature, representing 80.2% (n=1739) of all cases. Ingestion was overwhelmingly the most common route of exposure (n=2026, 93.4%) and involved a single substance (n=1980, 91.3%). Males represented 57.4% of all cases, with the highest proportion in boys aged 5 years and younger (n=916, 73.6%). The same was true for female case, with the youngest demographic being the most common group (n=592, 64.1%), although this was significantly lower than males ($p<0.001$). Furthermore, females also had a higher prevalence of intentional exposure than males (24.9% vs 12.7%; $p<0.001$). No significant differences were noted in terms of exposure location, route, and number of ingested substances in males and females.

Table 2-1: Characteristics of patients

Parameters	**All**	**Males**	**Females**	**P-Value**
N	2168	1244	924	
Age (%)				
0-5	1508 (69.6)	916 (73.6)	592 (64.1)	
6-18	227 (10.5)	110 (8.8)	117 (12.7)	
19-29	215 (9.9)	83 (6.7)	132 (14.3)	<0.001
30-59	187 (8.6)	117 (9.4)	70 (7.6)	
≥ 60	31 (1.4)	18 (1.4)	13 (1.4)	

Exposure location (%)				
Home	2090 (96.4)	1205 (96.9)	902 (97.6)	0.07
Hospital	16 (0.7)	12 (1.0)	4 (0.4)	
Outdoor	35 (1.6)	23 (1.8)	12 (1.3)	
Other	27 (1.2)	4 (0.3)	6 (0.6)	
Exposure intent (%)				
Intentional	388 (17.9)	158 (12.7)	230 (24.9)	<0.001
Unintentional	1739 (80.2)	1056 (84.5)	683 (73.9)	
Withdrawal	14 (0.6)	12 (0.9)	2 (0.2)	
Unknown	26 (1.2)	17 (1.3)	9 (0.9)	
Other	1 (0)	1 (0.0)	0	
Route (%)				
Ingestion	2026 (93.4)	1152 (92.6)	873 (94.5)	0.06
Inhalation	50 (2.3)	30 (2.4)	20 (2.2)	
Bite/sting	22 (1.0)	15 (1.2)	7 (0.8)	
Dermal	19 (0.9)	6 (0.5)	13 (1.4)	
Parenteral	15 (0.7)	14 (1.1)	3 (0.3)	
Unknown	36 (1.7)	27 (2.2)	8 (0.9)	
Exposed substances (%)	1980 (91.3)	1148 (92.3)	832 (90.0)	0.08
1	113 (5.2)	55 (4.4)	58 (6.3)	
2	38 (1.8)	19 (1.5)	19 (2.1)	
3	18 (0.8)	7 (0.7)	10 (1.1)	
>3	19 (0.9)	14 (1.1)	5 (0.5)	
Unknown				

Comparisons of demographic characteristics between children (17 years and below) and adults (18 and above) are shown in table 5. In terms of sex, a significantly higher proportion of males were children (59.5% vs 49.4%, p<0.001). Whilst home was the most common exposure location in both children and adults, adults had more outdoor exposures than children (6.0% vs 0.5%; p<0.001). Unintentional exposure was the most common intent in children (n=1621, 93.4%) whilst intentional exposure was most prevalent in adults (n=283, 65.4%) (p<0.001). Whilst ingestion was the most common route of exposure in both children and adults, inhalational exposure was significantly higher in adults than children (7.5% vs 0.9; p<0.001). Lastly, adults were significantly more likely

to be exposed to multiple (2 or more) substances than children ($p<0.001$), although single substance exposure remains to be more prevalent. The rest of the differences are shown in Table 2-2.

Table 2-2: Exposure differences in children and adults

Parameters	Children	Adults	P-Value
N	1735	433	
Sex (%)			
Males	1033 (59.5)	214 (49.4)	<0.001
Females	702 (40.5)	219 (50.6)	
Exposure location (%)			
Home	1716 (98.9)	392 (90.5)	
Hospital	7 (0.4)	9 (2.0)	<0.001
Outdoor	9 (0.5)	26 (6.0)	
Other	3 (0.2)	6 (1.5)	
Exposure intent (%)			
Intentional	105 (6.1)	283 (65.4)	
Unintentional	1621 (93.4)	118 (27.3)	<0.001
Withdrawal	0	14 (3.2)	
Unknown	8 (0.5)	18 (4.2)	
Other	1 (0.1)	0	
Route (%)			
Ingestion	1670 (96.2)	359 (82.9)	
Inhalation	16 (0.9)	32 (7.5)	
Bite/sting	14 (0.8)	9 (2.0)	<0.001
Dermal	17 (1.0)	1 (0.2)	
Parenteral	5 (0.3)	10 (2.4)	
Unknown	15 (0.8)	21 (4.9)	
Exposed substances (%)			
1	1626 (93.7)	357 (82.5)	
2	64 (3.7)	47 (10.9)	<0.001
3	24 (1.4)	13 (3.1)	
>3	11 (0.6)	6 (1.4)	
Unknown	9 (0.5)	10 (2.2)	

Figure 2-2 below shows the number of cases documented per year, highlighting a substantial increase in cases from 2019 representing a quarter of all cases recorded (n=539, 24.9%). Whilst the frequency of poison cases decreased in the years 2020 and 2021, the number of cases recorded was still higher than any of the previous years starting 2013 to 2018.

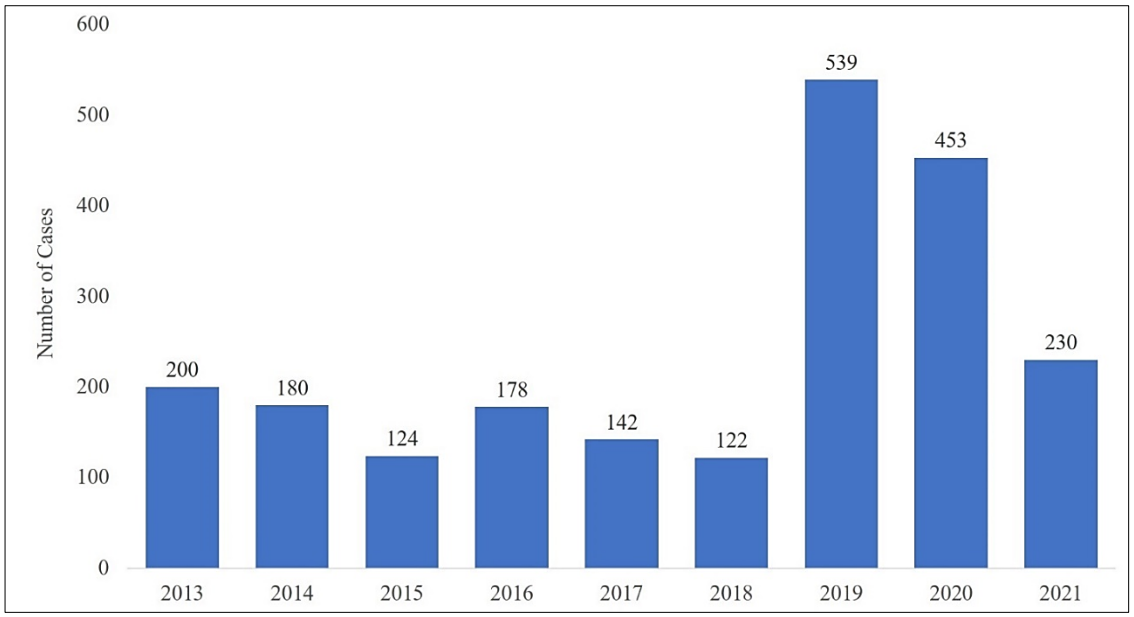

Figure 2-2: Number of registered cases per year

Lastly, most poisoning cases were due to pharmaceuticals (n=1485, 68.5%). The top 3 most frequent substance classes were analgesics (n=397, 18.3%), household cleaning substances (n=216, 10%) and hormones and hormone antagonists (n=151, 7%) (Figure 2-3).

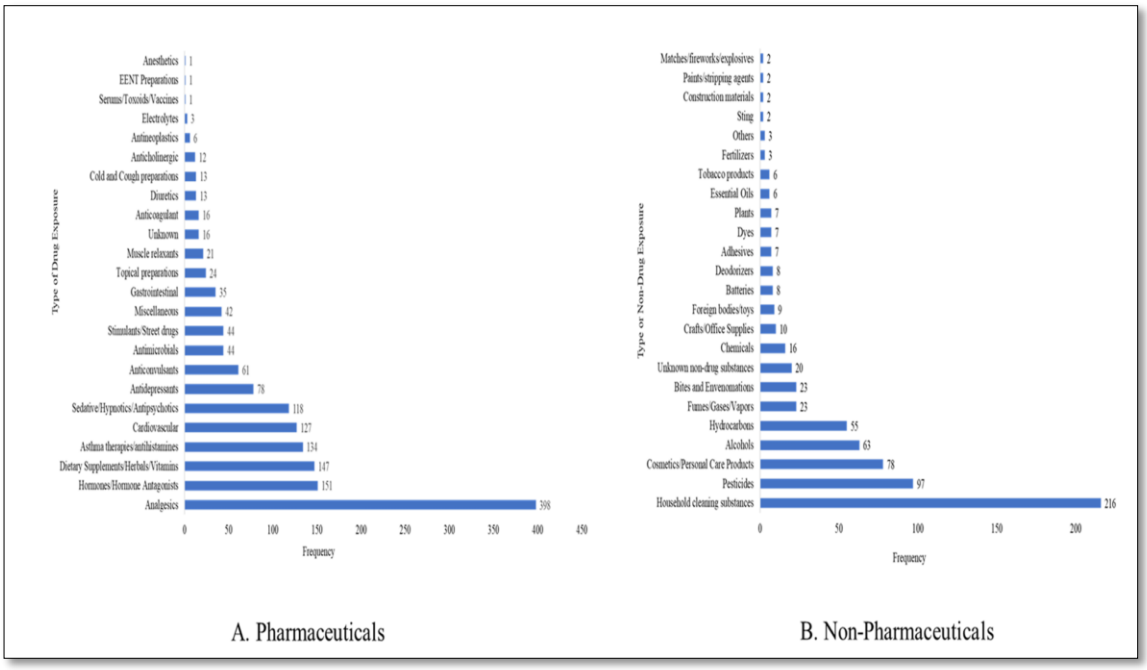

Figure 2-3: Type of exposure substance (A. Pharmaceuticals and B. Non-Pharmaceuticals)

*EENT: Eye, Ear, Nose, and Throat

2.8 Discussion

This study described the pattern of exposure and poisoning cases as experienced in KFMC-PCC. Most referrals were for unintentional pediatric exposures, most commonly to pharmaceuticals, like other studies conducted elsewhere (32), (33). This can be explained by children's curiosity to explore surroundings and their hand-to-mouth behavior, occasionally resulting in exposure to toxic substances. Furthermore, some medicines and household products resemble candies. Most of those products do not come in child-resistant packaging and are haphazardly stored in places that can be easily accessed by children. A combination of public and parental educational awareness for prevention, along with regulatory processes to maximize medication storage and formulation safety, could be effective in reducing the burden of poisoning (34), (35), (36). The present findings correspond to previous observations showing that children are at higher risk of exposure to poisonous substances (32), (33). Worth noting is that 2168 cases

over a period of 8.5 years is relatively small compared to similar developing nations such as Malaysia (N=39088 poison exposure calls from 2006-2015) (37), Egypt (N=9713 cases from 2017-2021) [22] and Iran (N=5777 cases from 2015-2019), all of which are also single-center studies. The relatively smaller number of cases can be partially attributed to the smaller population covered the by the pilot data relative to the other studies mentioned, and the lack of public awareness that such facilities exist since the hotline is not available to the public to reduce inappropriate ER and hospital visits (38), (39). This opens an opportunity to increase publicity of the PCC so it can better serve individuals and populations at higher risk of poisoning.

In this pilot data, male predominance was found among the pediatric age group. In the adult category, 50.4% of patients were male and 49.6% were female, similar to the study conducted by Moazzam et al. (40), with a male-to-female ratio of 1.01:1. In a more recent epidemiologic multi-center study conducted in emergency rooms (N=1470 patients) over a 12-month period, a substantial majority of subjects included were also males (77%) and young adults aged 18-24 years (71.0%) (41).

Other notable findings in the present study indicated that pharmaceuticals were the most common poisoning substances (68.5%), followed by household cleaning substances (10.0%), cosmetics/personal care products (3.6%), and alcohols (2.9%). Analgesics is the single biggest subclass of pharmaceuticals attributed to poisoning and this is line with a recent review stating that pharmaceuticals acting on the nervous system (e.g., antipsychotics, antidepressants, and analgesics) is the overwhelming type of pharmaceutical toxicity worldwide (35). The findings also reflect previous observations whereby poisoning caused by analgesics is very common in adult cases and is likely due to the easy accessibility, over prescription, dependence, and the high prevalence of self-medication practices in KSA (42), (43). Drug labelling with special warnings such as “keep out of reach of children” in native language is just one way to prevent unintentional ingestion in children and whilst this requires good pharmacist practice, it does not remove the requirement for good parental supervision, proper storage and discard of medications (44).

PCCs were historically regarded as sources of information about the management of pediatric poisonings and for less severe exposure. Currently, the expansion of PCC services encompasses a wide range of additional functions. Poison control staff play an important role in poison prevention, especially with preschool and elementary (36). Accidental poisoning, especially in children, can be prevented by enhancing awareness among families about the proper storage and handling of pharmaceuticals, household products and any other substances that can cause harm to the human body. Better legislation is needed to enforce improved safety measures for dangerous pharmaceuticals and chemicals (e.g., child-resistant containers), and introduce restrictions on sales of pesticides. Appropriate counselling centers should be established for addiction and drug abuse.

Finally, there is evidence that the availability of a poison control service can provide epidemiologic information and guidance on the management of the poisoned patient in a timely manner for the public and for healthcare professionals will aid in saving lives and decreasing healthcare costs (45). The CDC is one benchmark, where based on PCC data obtained from 2022, it showed that unintentional poisoning is the number one cause of death in the USA for ages 1-44 years, followed closely by motor vehicle accidents. In KSA, however, the important role of PCCs under the MoH has not yet been achieved, hence the limited published data that reflecting the true magnitude of poisoning as a public health problem. There is also a gap when it comes to the availability of credentialled toxicologists or specialists in poison information (SPI) under any specialty except consultant emergency medicine. Good collaboration between stakeholders is needed to progress poisoning services in KSA.

Implementation of a robust computerized system that connects all PCCs, facilitating nationwide coordination and data sharing, would be a considerable improvement for toxicovigilance in KSA. This system would ensure seamless communication and data exchange between centers at a national level. To effectively handle and analyze data, it is recommended to register poisoned patients using diagnostic codes. Additionally,

establishing a standardized mechanism for notifying poisoning incidents is crucial and should be circulated among all relevant entities. Furthermore, collaboration with manufacturing companies and laboratories is crucial in proactively gathering comprehensive information about their products. This approach enables better anticipation and evaluation of both short- and long-term consequences and effects of chemicals. By involving these stakeholders, the ability to effectively assess and mitigate the risks associated with exposures can be enhanced.

The findings are limited by the inherent disadvantages of a retrospective design. As such, other variables such length of hospital stay, treatment interventions, follow-up and patient outcomes are not fully included in the data captured. Future investigations at the multicenter level (primary, secondary, and tertiary care centers) to establish a national PCC database that will shed light on these factors are necessary to provide the bigger picture of the incidence and management of acute poisoning cases and exposure management in KSA. Nevertheless, the findings are scientifically valid and adds useful data to the limited existing literature on the overall toxicovigilance information in the country and support the need to establish a nationwide toxicovigilance PCC system.

Standardization in handling toxicology data is recommended to address various gaps, including guidance in cases of antidote shortage. This will elevate healthcare services to a new level of optimal care, ensuring the efficient management and treatment of toxic exposures. Meanwhile, poison centers and toxicology expertise are needed nationally as well as heightened awareness of its role in management and prevention. In this chapter, the PCC is described as a system for toxicology services that have been developed based on international standards. As poisoning is a real health issue of global importance, the availability of a toxicovigilance system specific for each country is necessary to determine the existing risks of poisoning in the community and to take the appropriate elimination measures.

2.9 Conclusion

Only a fraction of poisoning cases in KSA are currently being documented. The available data revealed that most poisoning incidents occur in domestic settings, with children under five years of age representing the most frequently affected group. These findings suggest that, due to the absence of a toxicovigilance system, the true incidence of poisoning, particularly domestic poisoning, may be substantially underestimated.

The results underscore the need for increased public health awareness and coordinated multisectoral engagement to improve poisoning prevention and reporting. Furthermore, despite identified areas for improvement, including more consistent documentation of clinical outcomes, the KFMC-PCC demonstrates the feasibility of serving as a pilot model for other healthcare organizations. Expanding this pilot approach to include emerging PCCs nationwide would enable more accurate estimation of poisoning prevalence across KSA. Such expansion would also support the development of a comprehensive national database of toxic substances like the (SNTESS), providing critical evidence for policymakers to design targeted prevention strategies and public awareness campaigns.

Chapter 3: Literature Review – Poisoning Cases in KSA

3.1 Epidemiological Findings of Poisoning Cases in KSA

This subsection presents the magnitude and patterns of poisoning cases in KSA based on literature evaluation, with a focus on key epidemiological characteristics, including location, age, and gender.

3.1.1 Study Questions

This scoping review aimed to address the following questions:

1. What are the geographic patterns of poisoning cases across different regions of KSA?
2. How do poisoning cases vary by age, gender, and severity?
3. What types of toxic agents are most involved in different populations and regions of KSA?

3.1.2 Study Design

A scoping review methodology was adopted and reported in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines to identify, map, and summarize the existing epidemiological literature on poisoning in KSA. This approach was selected because the available evidence is heterogeneous in terms of study design, populations, settings, and reported outcomes. Unlike a systematic review, which addresses narrowly defined questions and often includes quantitative synthesis, a scoping review allows for a broad examination of evidence, identification of research gaps, and clarification of key concepts relevant to toxicovigilance in KSA.

The scoping literature review began with a literature search conducted in PubMed on September 10, 2024. PubMed was selected as the primary database due to its

comprehensive coverage of peer-reviewed biomedical and public health literature, including epidemiological research related to poisoning, toxicology, and toxicovigilance. The database's use of controlled vocabulary (MeSH terms) and advanced search functionality enhances the sensitivity, transparency, and reproducibility of the search strategy.

The search strategy employed combinations of keywords and Boolean operators as follows:

"Saudi Arabia" AND "poisoning"
"Saudi Arabia" AND "poisoning" AND "epidemiology"
A narrative synthesis approach was used to analyze and present the findings. This approach was considered appropriate due to variability in study methodologies, outcome measures, and reporting formats across the included articles, which precluded quantitative pooling or meta-analysis. Narrative synthesis enabled structured comparison of study characteristics, populations, and key findings while maintaining alignment with the review objectives and supporting the identification of evidence gaps relevant to the development of SNTESS.

3.1.2.1 Eligibility Criteria

Inclusion criteria:

- English-language articles
- Published between 1981 and 2024
- Full-text availability
- Conducted in KSA
- Reported epidemiological data on poisoning (e.g., age, gender, location, severity, or outcomes)
- Sample size sufficient to reflect the impact of poisoning.

Exclusion criteria:

- Studies outside KSA

- Articles without epidemiological data
- Case reports with very small samples
- Studies lacking methodological validity
- Conference abstracts, editorials, and commentaries

3.1.2.2 Article Selection

The research yielded 134 articles; 87 were excluded following title and abstract screening, leaving 47 articles eligible for full-text review (Figure 3-1) summarized the articles selection process.

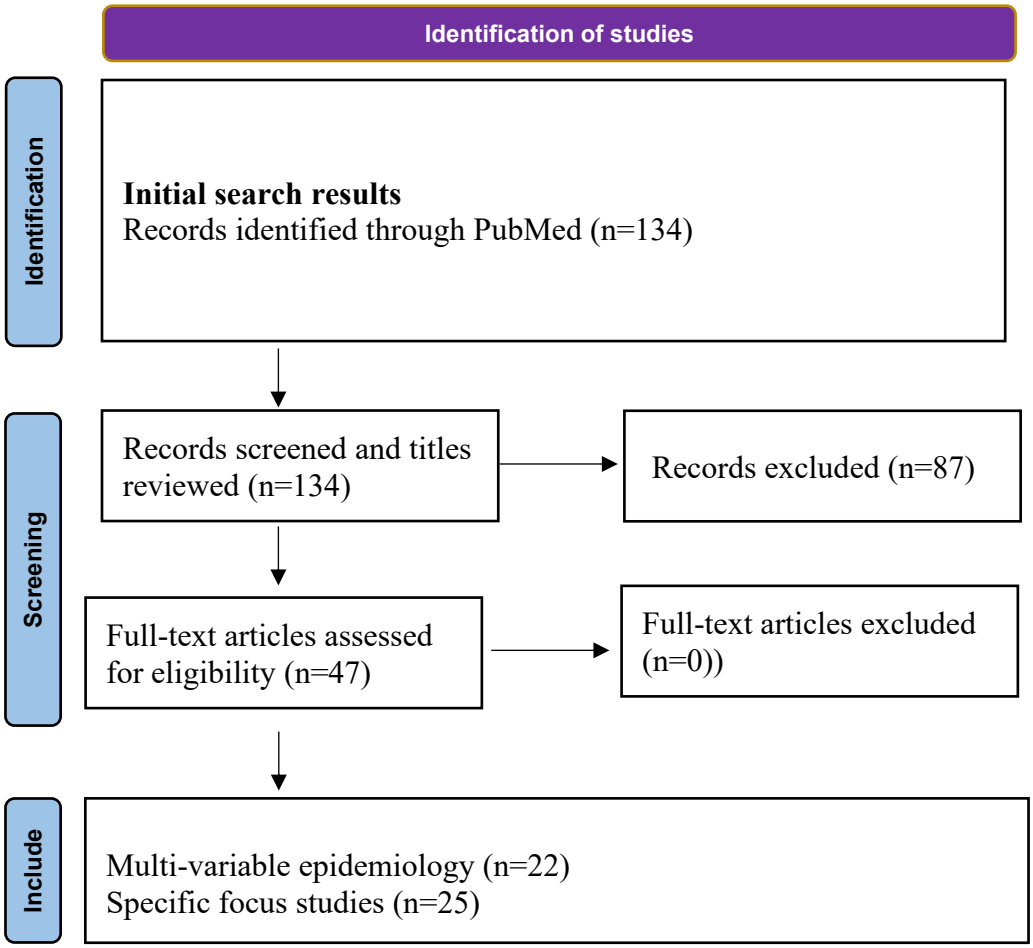

Figure 3-1: Overview of article selection

3.1.3 Study Results

3.1.3.1 Location

Although KSA is divided into thirteen administrative regions (Figure 3-2) (46), most studies originated from major urban centers (Riyadh, Jeddah, Makkah, and Dammam) due to higher population density, stronger healthcare infrastructure, and the presence of major universities (46). Consequently, poisoning patterns in rural areas remain underrepresented (47). A summary of studies analyzing the magnitude of poisoning by location in KSA is provided in Table 3-1.

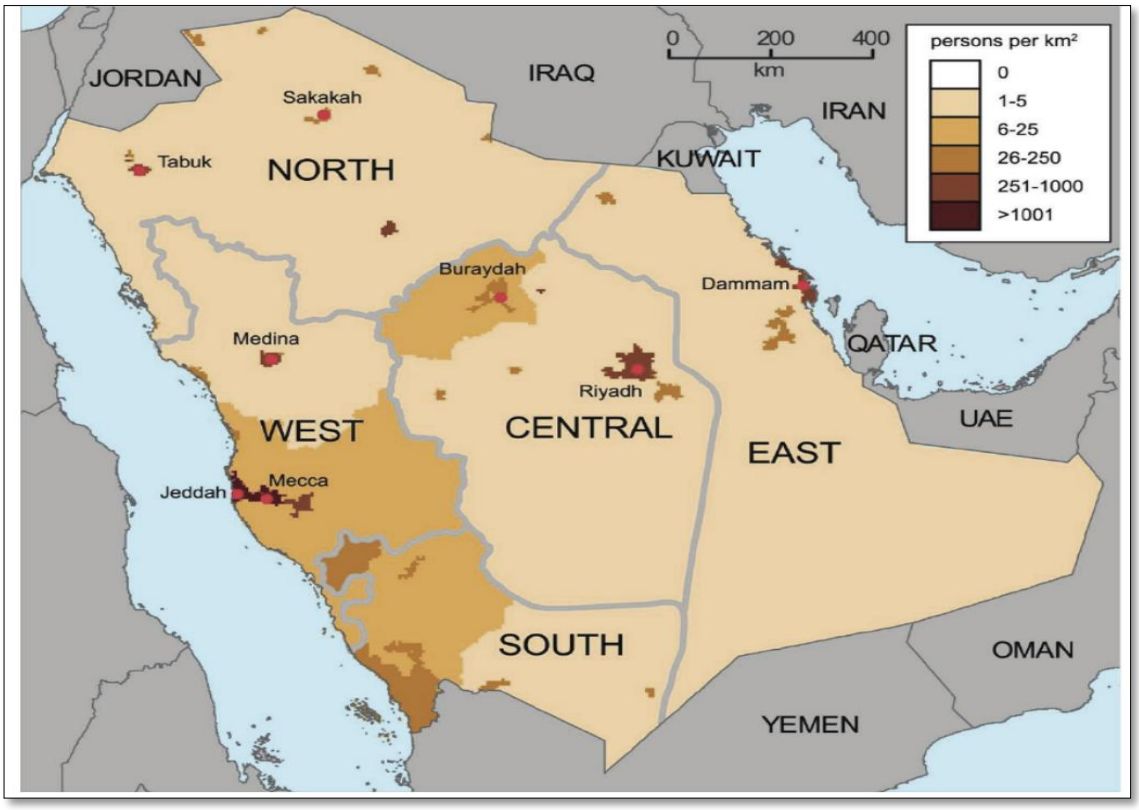

Figure 3-2: Population density map of KSA

One of the earliest studies was conducted in Riyadh in 1983 and examined 178 cases of accidental home poisoning in children under 7 years over 14 months. The highest prevalence occurred among children aged 1–5 years. Drugs accounted for 52% of cases

and household products for 46%, particularly kerosene (46). Preventive recommendations included child-resistant containers, restricting over-the-counter drug sales, a national registry, and PCCs (48).

In Jeddah, a retrospective review of 994 chemical poisoning cases found that 54.6% involved males and 56.6% involved children under 5 years of age. Most cases were accidental (77.3%) and resulted from ingestion (77.4%), with detergents being the most common agents (36.0%), followed by disinfectants and insecticides (49) . Another Jeddah-based study reported that females accounted for 54.3% of cases; children under 12 comprised 44.2%, and 1–5 years was the most affected age group. Drug overdose accounted for 92.2%, with analgesics and NSAIDs most common (20.4%). Intentional poisoning constituted 26.4%, particularly among females aged 12–35 years (46).

In Makkah, a study during the COVID-19 pandemic reported 122 pediatric cases under 12 years of age, with 59% males. Common agents included carbamazepine and risperidone, with 38.5% mild, 31.1% moderate, and 30.3% severe toxicity; 34.4% required intubation (50).

In the Eastern Province, 1,812 suspected poisoning-related deaths were reported, with 353 (19.5%) confirmed as drug-related. Most were accidental (56.4%) and male (92.6%), with ethanol responsible for 49% of cases (51).

In Najran, most poisonings were accidental and involved therapeutic drugs, cleaners, or alcohol, with a low fatality rate (1.2%) mainly in those aged ≥35 years (52). In Al-Qassim, poisoning involved medications (47%), food (32%), and chemicals (21%), with 96% occurring at home (53); pesticides accounted for 24.7% in an earlier study (40). In the Northern region, 3,009 pediatric chemical poisonings were reported, predominantly in children aged 1–5 years (76.4%), with solvents (20.4%) and disinfectants (22.7%) as common agents (33). In the Southern region, 22 deliberate self-poisoning cases over four years were reported, mainly involving paracetamol (54). By location, cultural and recreational practices such as desert camping and the use of braziers (kanun), hookah, gas

heaters, and charcoal fires, contribute to increased risks of carbon monoxide exposure (55).

Table 3-1: Summary of KSA articles showing the variability of poisoning in relation to location

	Author	Year	Title	Location
1.	Alanazi et al. (56)	2015	Hospital Performance Indicators and Their Associated Factors in Acute Child Poisoning at a Single Poison Center, Central Saudi Arabia	Riyadh
2.	Alghafees et al. (57)	2022	Poisoning-related emergency department visits: the experience of a Saudi high-volume toxicology center	Riyadh
3.	Al-Mousa et al. (4)	2021	Medical toxicology experience: Poisoning consultations cases registry in Saudi Ministry of Health	Multicenter
4.	Almutairi et al. (58)	2023	Pediatric poisoning deaths in Saudi Arabia: A systematic review	Multicenter
5.	Alnasser et al. (50)	2022	Drug and Chemical Poisoning Patterns in Makkah Region, Saudi Arabia	Makkah
6.	Alnasser et al. (53)	2020	Pattern of food, drug and chemical poisoning in Qassim region, Saudi Arabia from January 2017 to December 2017	Al-Qassim
7.	Alruwaili et al. (59)	2019	An epidemiological snapshot of toxicological exposure in children 12 years of age and younger in Riyadh	Riyadh

8.	Alshahrani et al. (33)	2023	Epidemiological Trends of Acute Chemical Poisoning among Children over a Recent Three-Year Period in Saudi Arabia	Northern Region
9.	Alwafi et al. (46)	2023	A Methodological Review of Drug-Related Toxicological Studies in Saudi Arabia	Multicenter
10.	Alzahrani et al. (49)	2017	Five-year epidemiological trends for chemical poisoning in Jeddah, Saudi Arabia	Jeddah
11.	Asiri et al. (54)	2019	Deliberate self-poisoning in the Southern region of Saudi Arabia	Southern Region
12.	Bakhaidar et al. (60)	2015	Pattern of drug overdose and chemical poisoning among patients attending an emergency department, western Saudi Arabia.	Western Region
13.	Mahdi, et al. (48)	1983	Epidemiology of Accidental Home Poisoning in Riyadh (Saudi Arabia)	Riyadh
14.	Moazzam et al. (40)	2009	Pattern of acute poisoning in Al-Qassim region: a surveillance report from Saudi Arabia, 1999-2003.	Al-Qassim
15.	Ragab et al. (61)	2015	Poisoning-Related Fatalities in Eastern Province-Saudi Arabia	Eastern Region
16.	Wahba et al. (52)	2021	Incidence and profile of acute intoxication among adult population in Najran, Saudi Arabia: A retrospective thesis	Najran

3.1.3.2 Age, Gender, and Severity

Children under five years old are at a high risk of accidental ingestion of common household substances, such as cleaning agents, pesticides, medications, and drugs, largely due to low caregiver awareness (46). Whilst most of these cases are asymptomatic, it remains a leading cause of ER visits among children (7), (59), (62). In adults, the most prevalent poisoning cases vary by age; individuals aged 15 to 35 are more likely to experience drug and medication overdoses, whereas those aged ≥ 35 years are more prone to alcohol poisoning (52). Additionally, the risks differ significantly based on whether the poisoning was intentional or accidental. In intentional cases, drugs and chemicals are the most common toxins, with males at a higher risk of fatal outcomes than females. In accidental poisonings, there is evidence that heavy metals and pesticides can be ingested from seemingly harmless sources like fruits, vegetables, or locally made cosmetics (62), (63).

Although many patients are asymptomatic, common symptoms include altered unconsciousness, vomiting, abdominal pain, dizziness, sweating, tachycardia, headaches, and chest pain (57). Despite these lesser side effects, frequently abused substances like alcohol and cannabis significantly elevate the risk of successful suicide attempts, which, whilst not directly caused by the poisons, still result in fatal outcomes, and should be regarded as equally serious (64). Most studies examining various poison types indicate that the age group at highest risk is from 1 to 5 years, with a predominance of males (33). In cases of alcohol poisoning, males aged 19 to 49 years are at highest risk (65), (66). Most incidents involving animal toxins occurred in rural agricultural areas [80%] during spring and summer nights, primarily affecting males aged 25 to 44 years (67). For medication overdoses, the most common age group was 15 to 25 years, whilst cases involving household chemicals predominantly involve young children aged 6 years and under (64), (68). Studies reporting high-risk age groups, gender distribution, and other demographic characteristics are summarized in Table 3-2. Studies reporting sample size and impact of poisoning are summarized in Table 3-3.

Table 3-2: Summary of studies that included analysis of highest risk age range, gender, and/or other characteristics

	Author	Year	Location	Poisoning Type	Age Range	Sample Size	Most Common Age	Highest Risk Gender	Other Characteristics
1.	Alghafees et al. (57)	2022	Riyadh	All	Children & Adults	n = 1,505	0-18 years	N/A	Medical history included neuropsychiatric disorders in 10.4% of adults and 7.5% of children
2.	Alhaidan et al. (63)	2022	Multicenter	Alcohol Poisoning	Adults	n = 250	19-30 years	Male	N/A
3.	Al-Mousa et al. (4)	2021	Multicenter	All	Children & Adults	n = 20,513	0-6 years (78%)	Male (54.6%)	Occupants of Riyadh City (40.9%)
4.	Alnasser. (50)	2021	Makkah	Drugs and Medications Household Chemicals	Children & Adults	n = 1,216	Drugs: 15-25 years (67%) Chemicals: Under 5s (60%)	Male (65%)	N/A

5.	Alnasser et al. (53)	2020	Qassim Region	Food Poisoning	Children & Adults	n = 81	20-49 years	Female (65%)	City residents
6.	Alruwaili et al. (59)	2019	Riyadh	All	Children	n = 1,035	23-42 months (2-4 years)	Male	46.6% of cases occurred between 6 pm and 12 am 28% occurred between 12 am and 8 am
7.	Al-Sadoon et al. (69)	2021	Multicentre	Animal Toxins	Children & Adults	n = 14,679	25-44 years	Male (80%)	Most occurred during the night
8.	Eskandrani et al. (68)	2022	Multicenter	Alcohol Poisoning	Adults	n = 9	19-49 years	Male	Social events/gatherings Oldest patient (49) had the worst outcome
9.	Mahmoud et al. (70)	2021	Eastern Province	All	Adults	N/A	31-40 years	Male (85.3%)	Non-Saudi Nationals (76%)
10.	Mahmoud, Al-Mazroua & Afify (71)	2021	Centre-Eastern Province	Household Chemicals	Children & Adults	n = 2,430	0-5 years	N/A	N/A

11.	Pico et al. (72)	2018	Multicentre	Household Chemicals	N/A	N/A	Children - due to lower admissible daily intake (ADI)	N/A	N/A
12.	Wahba et al. (52)	2021	Najran	Alcohol Poisoning Drugs and Medications Household Chemicals	Adults	n = 852	15-25 years (53.9%)	Female (53.5%)	The majority occurred in the summer months

Table 3-3: Summary of poison research articles that includes sample size and impact in KSA

	Author	Location & Year	Poisoning Type	Age Range	Sample Size	Impact - None (0)	Impact - Mild (1)	Impact - Moderate (2)	Impact – Severe (3)	Impact - Fatal (4)
1.	Alghafees et al. (57)	Riyadh 2022	All	Children & Adults	n = 1,505	N/A	No differentiation n = 1,412 93.8%		n = 82 5.5%	n = 7 0.5%
2.	Alhaidan et al. (63)	Multicenter 2022	Alcohol Poisoning	Adults	n = 250	N/A	n = 150 60%	n = 50 20%	N/A	n = 1 0.4%
3.	Al-Mousa et al. (4)	Multicenter 2021	All	Children & Adults	n = 20,513	n = 12,723 62%	n = 6,278 30.6%	n = 1,013 8%	n = 124 0.6%	N/A
4.	Alnasser. (50)	Makkah 2022	Drugs & Household Chemicals	Children & Adults	n = 1,216	N/A	85-95%	5%	N/A	N=122 0.50%
5.	Alnasser et al. (53)	Qassim 2020	Food Poisoning	Children & Adults	n = 81	N/A	N/A	Required medication n = 116 44%		N/A
6.	Alruwaili et al. (59)	Riyadh 2019	All	Children	n = 1,035	N/A	n = 797 77%	n = 149 14.4%	n = 70 6.8%	n = 2 0.2%
7.	Al-Sadoon et al. (69)	Multicenter 2021	Animal Toxins	Children & Adults	n = 14,679	N/A	n = 497 3.38%	n = 11,010 75%	n = 3,172 21.6%	n = 36 0.24%

8.	Eskandrani et al. (68)	Multicenter 2022	Alcohol Poisoning	Adults	n = 9	N/A	N/A	n = 8 89%	n = 1 11%	N/A
9.	Madmoud, Al-Mazroua & Afify (71)	Center-Eastern Province 2021	Household Chemicals	Children & Adults	n = 2,430	Disinfectant n = 283 57% Hand sanitizer n = 65 78.3%	Disinfectant n = 118 23.7%	Disinfectant n = 89 18% Hand sanitizer n = 18 21.6%	Disinfectant n = 6 1.2%	N/A
10.	Wahba et al. (52)	Najran 2021	Alcohol Poisoning Drugs Household Chemicals	Adults	n = 852	N/A	n = 109 12.8%	No differentiation between admission & ICU n = 733 86%		n = 10 1.2%

3.1.4 Discussion

The poisoning epidemiology in KSA is strongly shaped by geographic, demographic, and sociocultural factors. Urban centers dominate available evidence, which may reflect better reporting rather than higher true incidence. Rural underrepresentation suggests possible surveillance gaps and unmet public health needs. The consistent vulnerability of young children highlights persistent household safety challenges, including unsafe storage and limited caregiver awareness. The high proportion of accidental exposures suggests that many cases are preventable through education and regulatory measures.

Gender differences likely reflect behavioral and occupational patterns, with males more exposed to substances such as alcohol, industrial chemicals, and animal toxins. The emergence of intentional poisoning among young females, particularly in urban areas, suggests a growing mental health dimension that requires integrated psychosocial interventions. The presence of region-specific risks (e.g., pesticides in agricultural areas, carbon monoxide in desert camping, alcohol in urban males) underscores the need for regionally tailored prevention strategies rather than a single national approach.

3.1.5 Conclusion

Poisoning patterns in KSA vary significantly by location, age, and gender, underscoring the need for a coordinated SNTESS. The high vulnerability of children below five to accidental poisoning highlights the importance of real-time exposure reporting and early warning mechanisms. Similarly, the increasing burden of drug overdoses, alcohol-related toxicity, and intentional self-harm among adolescents and adults supports the inclusion of intentionality indicators and substance-specific monitoring within the framework.

The predominance of urban-based data and the limited availability of rural poisoning information reveal critical surveillance gaps. These findings directly inform the SNTESS by emphasizing the need for nationwide data integration, including mandatory reporting from rural healthcare facilities and PCCs, to ensure equitable surveillance coverage across regions.

Furthermore, the epidemiological trends support the integration of preventive and response components within SNTESS, including strengthened PCC infrastructure, targeted public education campaigns, improved safe storage regulations, and expanded national reporting mechanisms. Together, these elements position SNTESS as a data-driven framework designed to reduce poisoning-related morbidity and mortality in KSA through timely detection, prevention, and policy-informed intervention.

3.2 Trends of Poisoning Cases in KSA

3.2.1 Study Questions

This narrative review aimed to address the following questions:

1. What are the most prevalent types of poisoning reported in KSA?
2. What are the major risk factors and vulnerable populations associated with each poisoning type?
3. What are the reported health outcomes and fatality rates associated with different poisons?
4. What gaps exist in reporting and prevention for poisoning in KSA?

3.2.2 Study Design

This narrative review was structured and reported with reference to PRISMA principles to ensure transparency in the identification, screening, and selection of studies addressing poisoning trends in KSA. The review was designed as a PRISMA-informed narrative review due to the heterogeneity of study designs, populations, outcomes, and reporting methods in the available literature. Each dedicated subsection presents the best available evidence on its prevalence, risk factors, adverse health outcomes, and recommended interventions, with reference to specific cities and regions within KSA, up to October 2023.

All published studies reporting poisoning in KSA were considered when available and relevant to the aims of this thesis. Observational studies and case series constituted most of the included literature. More recent publications and meta-analyses, when available,

were prioritized. Given the limited and heterogeneous nature of the literature, a formal systematic review and meta-analysis was not conducted, as this would have excluded valuable contextual and descriptive evidence and would not adequately address all clinically relevant questions related to poisoning in KSA. A structured literature search was conducted in the PubMed and MEDLINE databases to identify relevant studies. These databases use of controlled vocabulary (MeSH terms) and advanced search functionality enhances the sensitivity, transparency, and reproducibility of the search strategy.

The search strategy used combinations of keywords and Boolean operators as follows:
"Saudi Arabia" AND "poisoning"
"Saudi Arabia" AND "toxic exposure"
"Saudi Arabia" AND "drug overdose"
"Saudi Arabia" AND "chemical poisoning"
"Saudi Arabia" AND "epidemiology"

Reference lists of included articles were manually screened to identify additional relevant studies. Open-access articles were prioritized since full-text access to subscription-based articles was limited.

3.2.2.1 Eligibility Criteria

Inclusion criteria:

- Studies conducted in KSA
- Studies on any form of poisoning or toxic exposure
- Observational studies, case series, and relevant reviews
- Studies reporting prevalence, risk factors, clinical outcomes, or public health implications
- Articles published in English

Exclusion criteria:

- Studies outside KSA
- Opinion pieces, editorials, and conference abstracts without primary data

3.2.2.2 Article Selection

The search conducted yielded 884 articles, of which 429 duplicates were removed. The remaining articles (n=455) were screened and 128 were deemed eligible for full screening, of which 32 were included in the PRISMA report and 20 in the present review (Figure 3-3).

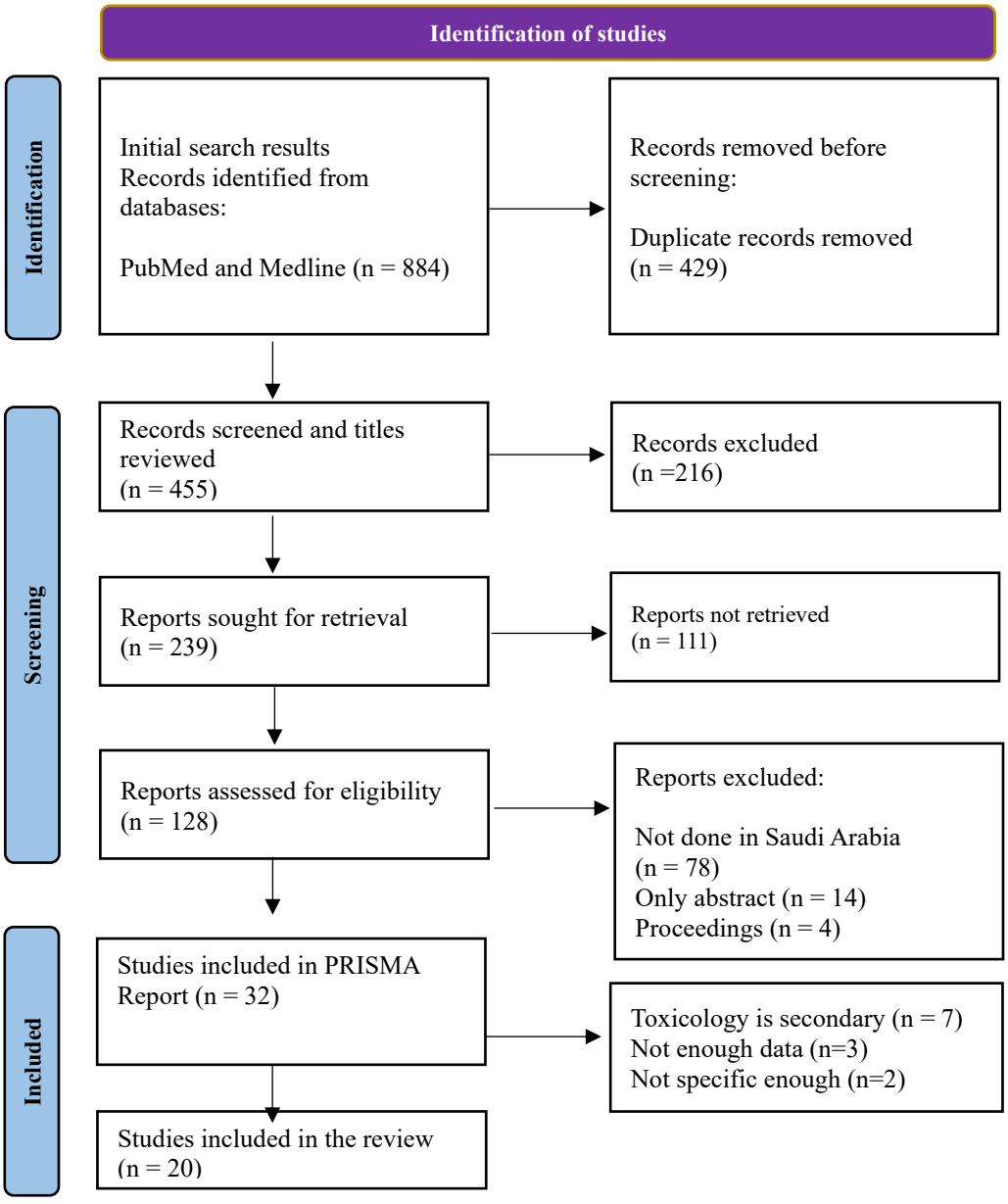

Figure 3-3: Overview of article selection

3.2.3 Study Results

3.2.3.1 Alcohol

Alcohol consumption is prohibited in KSA, therefore, locally made alcohol and derivatives are illegal and frequently cause severe side effects on an individual's health, with the contamination of home-made liquor, smuggled alcohol, and other alternatives shown to cause methanol poisoning which often leads to toxic optic neuropathy (66), (67). Methanol which is derived from wood, is a highly toxic and illegal alternative to traditional ethanol and is commonly found in KSA, where alcohol consumption is largely restricted (68). Despite no causality, there have been trends in the United States identified that link rural areas with higher levels of alcohol poisoning, particularly in adults above 35 years (73). This is consistent with alcohol abuse mortality estimates worldwide, where research has found life expectancy to be 24-28 years shorter in patients with alcohol use disorder (52), (62).

One theory from Najran found that alcohol consumption accounted for 10.6% of poisoning cases within the region, and although 86% of cases required hospitalization, and 1.2% were fatal, it is unknown whether these numbers were solely attributed to alcohol, since they were reported alongside medications and household chemicals (52). Another study focused solely on alcohol poisoning in Hail region, and found that alcohol consumption had a 0.4% fatality rate and [20%] suffered from substantial clinical symptoms such as severe abdominal pain (63).

3.2.3.2 Animal Toxins (Venoms)

KSA has densely populated interior oases and near-empty landscapes ideal for desert snakes. However, more data is required regarding the number of snake bites in rural regions, their severity, and their clinical outcomes – particularly in cases where the distance to a healthcare center is significant (69), (74). Across the kingdom, 14,678 cases of snake bites were reported between 2015 and 2018, all of which required hospital intervention. The direct fatality rate was 0.24%, with males aged 25-44 years comprising

the most common patient demographic (69). Although this area has been relatively well researched, limitations arise from the reliance on partial datasets. As a result, it remains challenging to determine whether factors such as the patient's age or the type of snake encountered pose a higher risk of fatal outcomes. The primary report highlighted snake bites, which are common in rural areas of KSA. While only 0.24% of these cases resulted in fatalities, this still accounted for 36 unnecessary deaths, and all patients required anti-venom treatment. Consequently, the recommendations include increasing education on the associated risks and implementing protective measures for the lower limbs, which are the most frequently bitten areas (69).

Scorpion sting envenomation is another significant health issue in KSA, particularly affecting children, and the elderly. Approximately 14,500 scorpion stings are reported annually, with the highest incidence recorded during summer (75).Vulnerable populations include individuals living in desert areas, such as Bedouins, though the mortality rate remains low.

3.2.3.3 Toxic Plants

A study reviewing toxic plants in KSA highlights their ecological and medicinal significance while emphasizing the health risks they pose. It notes that many local plants, such as Nerium oleander and Datura stramonium, contain toxic compounds that can harm humans and animals, necessitating public awareness and education about their dangers.

3.2.3.4 Cosmetics

A study has found that Cobalt (Co), a type of metal, exceeded the permissible limits allowed in cosmetic products, and Lead (Pb) was above the permissible limit in [22%] of samples. The study recommended to reduce the use of these products, and at the national policy level, to develop an immediate plan for ongoing testing of cosmetic products (76). In another study, the presence of heavy metals in products such as creams, shampoos, soaps, and toothpaste were found, using Inductively Coupled Plasma Mass Spectrometry (ICP-MS).

3.2.3.5 Medications

Pharmaceuticals are the leading cause of acute poisoning in Saudi Arabia, primarily due to their widespread accessibility. Analgesics, particularly paracetamol and NSAIDs, are the most frequently involved, often linked to suicide attempts, especially among females. Antipsychotics and anticonvulsants also contribute significantly to poisoning cases, with their prevalence varying by region. Additionally, other CNS-affecting drugs, as well as miscellaneous pharmaceuticals like antibiotics and antihypertensives, are occasionally implicated (77).

One of the most widely used over-the-counter medications worldwide is paracetamol (acetaminophen) (78). Primarily known for its analgesic properties, it is available without a prescription. However, it can lead to significant consequences, such as fulminant hepatitis or even death, if abused (79). This risk is particularly pronounced in children, especially those aged six or younger, based on data published in KSA. They are more susceptible to severe or fatal outcomes due to their lower body weight, which results in a lower permissible daily intake being recommended (4).

3.2.3.6 Food Poisoning

Food poisoning accounted for 32% of all poisoning cases in the Qassim region alone from January to December 2017 (53), (40). In another study conducted in the Aseer region, only [41%] of participants were found to regularly engage in positive food safety practices. Individuals under 30 years old and those without a university-level education were identified as being at the highest risk for unsafe food consumption (80). Similarly, up to 93% of students from Majmaah University held unsafe food safety beliefs, with only 44% able to identify key concerns related to raw white cheese (unpasteurized milk), and 88% unaware of the risks associated with consuming unwashed vegetables (81).

3.2.3.7 Heavy Metals

Although it is rare, there is evidence of arsenic poisoning related to rice consumption in KSA (82). (72). On the other hand, date fruits, which although contain beneficial minerals,

also pose a risk to health due to certain varieties containing high levels of toxic metals such as Aluminum (Al), Arsenic (As), Chromium (Cr), Pb, Cadmium (Cd), and Antimony (Sb), with Pb being the primary concern across all varieties available in KSA (Table 3-4) (83).

Table 3-4: Concentration of toxic heavy metals in different type of dates (mg/kg) compared to the Maximum Allowable Limit (MAL)

Metals	S Mabroum (Al-Karj)	S Normal (Al-Karj)	Rashadya (Al-Qaseem)	Barny (Al-Madina)	Eklas (Al-Hasaa)	Safawy (Al-Madina)	Kadary (Al-Qaseem)	MAL
Al	1.141 E	5.513 C	5.099 C	7.047 B	15.202 A	4.151 D	0.923 E	N/A
As	0.095 D	0.109 CD	0.079 E	0.078 E	0.584 A	0.132 B	0.121 BC	0.1
Cr	0.070 B	0.442 C	0.508 A	0.031 C	0.071 B	0.085 B	0.045 C	2.3
Pb	2.859 C	0.493 D	50.28 A	0.479 D	9.417 B	0.665 D	1.206 D	0.3
Cd	0.159 B	0.203 A	0.025 E	0.004 F	0.084 D	0.027 E	0.131 C	0.3
Sb	0.046 B	0.017 E	0.032 D	0.073 A	0.038 C	0.040 C	0.044 B	N/A

In another study, heavy metal pollution has also been documented within soil samples around Ras Tanura, with Cd, Molybdenum (Mo), Europium (Eu), Hafnium (Hf), Terbium (Tb), and Ytterbium (Yb) at levels higher than the global average, with values high enough to justify a classification of significant pollution (84).

3.2.3.8 Household and Industrial Chemicals

Historically, most chemical poisoning cases in KSA come from household detergents, with males aged under five at the highest risk (49). However, industrial chemicals, pesticides, and metals have also been found in above-permissible levels in the most common tobacco brands in circulation within KSA, which affects smokers and those

around them – with a 95% risk of cancer over their lifetime (85). Unfortunately, pesticides and other household and industrial chemicals are responsible for the majority of poisoning cases in KSA (53), (40). One study investigated the presence of pesticides on fruit produce in the country, and found that in 80% of cases had levels above the admissible daily intake (ADI) value for adults (72). Since the ADI for children is lower than adults, they are likely to be disproportionately affected by this.

3.2.3.9 Substance Abuse

A 2024 study revealed that the most common patterns of substance abuse in KSA can be divided into two categories: traditionally abused drugs (e.g., Captagon, khat, heroin, ethanol, and cannabis) and substances that have emerged in recent years (e.g., methamphetamine "Shabu," pregabalin, and benzodiazepines) (86). This highlights the necessity of thorough data collection for evidence-based policymaking. Substance abuse is likely under-reported because of the lack of an integrated Health Information Systems (HIS) between hospitals in KSA (87). Moreover, heroin and cocaine addicts are often hesitant to seek medical care since it is considered a crime (66). In a review of postmortem cases in Jeddah between 2008 and 2018, 97 deaths recorded were attributed to a heroin overdose, representing 2% of all cases, with the 21-30 years identified as the highest risk age category (54).

Substance abuse can involve recreational drugs as well as the misuse of medications. Given that the prevalence of drug and medication overdoses varies between age groups, a multi-faceted approach should be adopted to address the needs of the 0-6 age group and the 15-35 age group separately. For the younger group, it is essential to educate parents about the importance of keeping all drugs and medicines securely locked away and recognizing what constitutes an emergency visit in the event of an overdose. For the 15-35 age group, there should be an increased emphasis on raising awareness of the long-term impacts of substance abuse, along with the establishment of support groups for those struggling with addiction (71), (4).

3.2.4 Discussion

This review highlights the multifaceted nature of toxicological risks in KSA and underscores the need for SNTESS, targeted prevention strategies, and strengthened regulatory frameworks. Alcohol poisoning remains primarily an adult health concern, particularly among individuals aged 19–49 years (68), (41). The association between alcohol abuse and suicide attempts reinforces the need for improved public awareness campaigns and mental health integration within poisoning prevention strategies. Enhanced documentation of outbreaks and strengthened monitoring within public health networks are essential to ensure timely detection and response to alcohol-related harms.

Envenomation, particularly scorpion stings, represents another persistent public health concern in KSA since limited availability of comprehensive epidemiological and autopsy data restricts the understanding of mortality patterns and clinical progression (75). Further research is needed to improve case documentation, clarify fatality mechanisms, and strengthen management protocols, especially in high-risk regions. The risks associated with poisonous plants and herbal remedies highlight the importance of balancing traditional practices with evidence-based safety evaluations (88). Increased research into the toxicological profiles, safety, and efficacy of these plants is necessary to mitigate potential harm while preserving culturally significant practices. Similarly, contamination risks such as heavy metals in cosmetics—underscore the need for stricter regulatory oversight and routine monitoring of raw materials to protect public health (89).

For medication-related poisoning, although regulatory measures and clinical interventions have been implemented, limited epidemiological data restricts accurate assessment of severity and burden (90). This gap emphasizes the need for improved reporting systems and integration of medication error surveillance within toxicovigilance frameworks.

Food safety deficiencies across KSA further highlight the importance of comprehensive education programs (80). Developing structured educational interventions within schools and for individuals involved in food preparation at home could significantly reduce preventable poisoning incidents. Such programs should include measurable evaluation

mechanisms to assess effectiveness and sustainability. Environmental toxic exposures require additional investigation. Understanding the long-term public health implications of environmental pollutants is essential for risk assessment and preventive regulation.

Children aged 0–6 years represent the most vulnerable group in cases involving household and industrial chemical exposures (57). Preventive strategies should prioritize accurate product labeling, child-resistant packaging, parental education, and enforcement of safe storage practices. These measures are critical to reducing preventable childhood poisonings.

The evolving landscape of drug abuse in KSA presents additional surveillance challenges. Cultural and security considerations further limit the availability of recent epidemiological data, leaving the true magnitude of substance use disorders uncertain (86), (91). Therefore, innovative toxicovigilance approaches are warranted. Integrating social media analytics, artificial intelligence, computational linguistics, graph theory, and agent-based modeling into surveillance systems may offer novel insights into emerging drug trends and behavioral patterns, enabling earlier intervention. Overall, the findings reveal significant surveillance gaps across multiple toxicological domains, reinforcing the need for a comprehensive, integrated toxicovigilance system capable of capturing diverse exposure types, populations, and emerging threats. Based on the information gathered regarding prevalence, magnitude, and recommendations for each specific type of poison or toxin, a summary has been compiled (Table 3-5).

Table 3-5: Summary of findings relating to prevalence, magnitude, and recommendations

Poison/Toxin	Prevalence	Magnitude	Recommendations
Alcohol	*Circa.10.6% of cases High risk: 19-49 years	0.4-1.2% fatality rate	1. Improve public education 2. Improve documentation of outbreaks 3. Increase monitoring among public health networks

Animal Toxins	Circa. 36% per year High risk: 25-44 years	0.24% fatality rate	1. Increased public education about whom to contact for seeking medical advice and how to report in case of animal bites and venom poisoning
Cosmetics	Circa. 22% of samples	Unknown	1. Reduce use of cosmetic products from unknown or unregulated brands 2. Develop a policy plan for ongoing testing of cosmetic products
Drugs & Medications	Circa. 60% of cases High risk: 15-25 years	Unknown	1. Parent education program including safe storage 2. Education program on impacts of substance abuse 3. Support groups for addiction
Food Poisoning	Circa. 32% of cases High risk: 18-30 years	Unknown	1. Increased public education about whom to contact for seeking medical advice and how to report in case of food poisoning
Heavy Metals	Unknown	Unknown	1. Further research on the impact on local air quality and foods grown in contaminated soil
Household & Industrial Chemicals	Circa. 24% of cases High risk: 0-6 years	Unknown	1. Regulate proper labelling 2. Develop prevention awareness programmes promoting safe storage and restricted access
Inhalants	100% of cases	Long-term fatality rate of 95%	1. Decrease the national smoking rate 2. Regularly measure and create policies to reduce the number of toxins in tobacco products

*In the context of poisoning prevalence, "circa 3670 per year" means that approximately 3,670 cases of poisoning are reported annually within the specified population or region. The phrase "high risk: 25-44 years" indicates that individuals aged 25 to 44 years are identified as the demographic group most at risk for poisoning. This suggests that this age group experiences a higher incidence of poisoning incidents compared to other age groups. Together, this information highlights both the estimated annual prevalence of poisoning cases and the specific age range that is particularly vulnerable.

3.2.5 Conclusion

Toxicological risks in KSA are diverse, population-specific, and influenced by cultural, environmental, and behavioral factors. Adults remain at highest risk for alcohol-related poisoning, while children are particularly vulnerable to household chemical exposures, and evolving drug abuse patterns present emerging surveillance challenges. Additional concerns include envenomation, medication errors, contaminated consumer products, food safety deficiencies, and environmental pollutants.

Addressing these challenges requires a multi-sectoral approach that combines strengthened surveillance through systems such as SNTESS, enhanced public education, regulatory enforcement, targeted prevention strategies, and innovative data integration methods. Expanding toxicovigilance systems to incorporate non-traditional data sources, including social media analytics and advanced computational tools, may significantly improve early detection and response to emerging risks. Ultimately, the development of a comprehensive national toxicovigilance framework—supported by research, policy reform, and public engagement—is essential to reduce poisoning-related morbidity and mortality and to ensure equitable protection of public health across all regions and population groups.

Chapter 4: Toxicovigilance Landscape in KSA: A Gap Analysis Towards Improvement

4.1 Available Resources and Systems in KSA

This chapter examines the existing components available in KSA that fall within the scope of this thesis. Specifically, assessing the need for and feasibility of establishing the SNTESS.

4.1.1 Review Question

This review addresses the following question: To what extent do existing resources and systems in KSA collectively meet the functional requirements of SNTESS?

4.1.2 Review Design

This review adopts a current situation analysis, a descriptive and exploratory research approach that focuses on understanding existing conditions, practices, challenges, and contextual factors. The analysis was conducted using: (i) systems review, (ii) published literature, and (iii) publicly available documentation describing Saudi services and surveillance platforms with a scope like the SNTESS.

The proposed structure of SNTESS, described in the following chapter, is informed by best practices in toxicovigilance and it aims to develop a feasible, Saudi-contextualized framework for that integrates existing resources to provide near real-time surveillance and generate early actionable outputs.

One key limitation encountered during this analysis was the difficulty of conducting one-on-one questionnaires with stakeholders involved in existing systems. Despite multiple attempts to collect data through questionnaires, response rates were limited due to the

sensitive nature of the topic. Consequently, the analysis relied primarily on the authors' interpretative assessment of available evidence derived from the current situation analysis.

The current situation analysis was conducted in two phases:

Phase One: Analysis of Available Resources

This phase assessed the availability and capacity of essential resources required for the successful implementation of SNTESS including; PCCs, medical toxicologists, hotline services, and documentation systems.

Phase Two: Analysis of Similar Systems

This phase examined existing surveillance systems within governmental organizations that support decision-making in toxicological risk reporting. Examples include; HESN, OTARR, Tayaquth , and RASID.

4.1.3 Results of Phase One

4.1.3.1 PCCs in KSA

PCCs are an essential component for toxicovigilance (92), yet there are few PCCs in KSA (7). Whilst some service organizations in the country are making commendable efforts to achieve excellence in operating PCCs, these efforts remain fragmented (3). For example, the PCCs within the MoH operates independently from the PCCs in other government hospitals (3), which makes it difficult to establish the necessary functions for the toxicovigilance process.

The major obstacle regarding the availability of PCCs is the confusion surrounding their scope in KSA. Laboratories, forensic centers, and clinical centers are all referred to as PCCs, which makes it-extremely difficult to demonstrate the gaps through published data. One PCC in KSA is identified as the national PCC, or the National Drug & Poison Information Center (NDPIC) within the Saudi Food and Drug Authority (SFDA). The SFDA is responsible for regulating the safety and efficacy of drugs, medical devices, and

food products in the KSA. Consequently, the scope of the NDPIC is primarily focused on drug-related information and it operates exclusively through an electronic, non–two-way interactive platform (64). However, this modality is not suitable for managing acute cases and is insufficient to support an active toxicovigilance system. Moreover, NDPIC services are available only from Saturday to Wednesday during official working hours, which limits accessibility for individuals seeking assistance outside these periods (65).

In another study, results showed that KSA has five PCCs listed in the 2017-2019 WHO directory (93). Despite that, the study indicates that none of these centers provides the comprehensive services expected from PCCs (7). However, the study notes that there is one center designed to fulfill a comprehensive role, which belongs to KFMC. This center was not explicitly named in the article, as it stated the information anonymously (7).

4.1.3.2 Medical Toxicologists Availability in KSA

Healthcare in KSA is structured across multiple sectors, including hospitals belonging to the MoH, Military Hospitals (Saudi Arabian National Guard and the Ministry of Defense and Aviation), Specialized Referral Hospitals, and private for-profit hospitals noting that the MoH is responsible for regulating the healthcare system and providing healthcare services across the country (94). This approach aims to provide a comprehensive range of medical services to the population, addressing various healthcare needs through both public and private entities. As of 2017, the number of hospitals in the KSA was 487 (95). Although, there has been an increase in hospital facilities, with a total of 497 hospitals and 72,981 hospital beds (2.2 per 1,000 capita) reported in 2022 (96), it remains challenging to determine how well these facilities cover the geographical distribution across the country, and more importantly how the data of exposures can be shared especially toxicology data.

On the other hand, there are no articles that estimate the number of medical toxicologists available in the country. One study pointed out that none of the surveyed centers included in that article had an onsite medical toxicologist, which is crucial for the effective operation of Poison and Drug Information Centers (DPIC) and PCCs (Table 4-1) (7).

Overall, there is a general shortage of approximately 15,000 doctors in the country particularly in rural areas (94). Saudi Vision 2030 aims to address this workforce gap by enhancing the healthcare workforce, particularly in the field of toxicology. The goal is to strengthen the capacity to effectively manage poisoning cases and improve overall public health outcomes (97).

Table 4-1: Assessing staff availability in some Saudi Arabia's PCCs

Center	Number of staff	Staff qualifications	Availability of a medical toxicologist in the team
1	4	Pharmacists with Masters in Pharmacology and Toxicology	Not available
2	2	Pharmacists with Masters in Pharmacology and Toxicology	Not available
3	1	Pharmacist	Not available
4	2	PharmD and Pharmacy Residents	Not available
5[a]	5	Pharmacists	Not available
6	1	PharmD	Not available
7	2	Pharmacists and Clinical Pharmacists	Not available
8	9	Pharmacists with Masters in Pharmacology and Toxicology	Not available
9	3	Clinical Pharmacists	Not available
10	2	Pharmacists with Masters in Pharmacology and Toxicology	Not available
11	1	Pharmacist	Not available
12[a]	3	Clinical Pharmacists	Not available
13[b]	2	Clinical Pharmacists	Not available
14	1	Pharmacist	Not available

[a]DPIC with WHO designation as poison control center.
[b]This center defers all poisoning cases to a poison control center (WHO designated) available only within their health care institution.

Moreover, general healthcare providers often lack adequate training in toxicology. Consequently, the shortage of medical and clinical toxicologists poses serious challenges to the effective management of poisoning cases. This shortage arises from several factors, including a limited number of specialized training programs, increasing demand for toxicology expertise due to rising incidents of poisoning from pharmaceuticals and illicit substances, and structural limitations within the healthcare system that hinder the recognition of toxicology as a distinct medical specialty. In addition, retention challenges persist, as trained toxicologists may seek better opportunities abroad or in other medical fields, further exacerbating the gap in expertise (74). The implications of this shortage are substantial, directly affecting the effectiveness and intended outcomes of toxicovigilance system.

4.1.3.3 Toxicology Documentation System in KSA

Although all related service organizations in KSA are making significant efforts to maintain most health reports electronically, there is still a strong reliance on paper forms (87). The importance of a SNTESS has been recognized under the context of non-communicable diseases (NCDs) in the Saudi Vision 2030 transformation plan and its strategic objectives (98). This includes the establishment of a shared portal for reporting, a shared health signal database, and a regional monitoring and health assessment support group, which will-ultimately contribute to creating a national chemical terrorism defense system (99). In general, health data reports can be found on three main official sites: the MoH, the General Authority of Statistics, and the National Platform for Data.

Data collection of toxic exposures is collected either from the emergency rooms' registry system, and/ or from public health offices. Healthcare practitioners fill a special form from MoH (Appendix 3) to report any poisoning case. This stage is called "case reporting", the forms then are collected by the public health officer from the authorized department within the health facility or hospital. After that, the public health officer will report to the General Public Health Authority (PHA), a step referred to as "case notification." The PHA team then investigates and gathers the necessary data from other systems (such as laboratory and death registry systems) to complete the investigation, especially if an outbreak is suspected. These steps can be time-consuming due to lack of Electronic Health Records (EHR) integration with other systems. This gap has been emphasized by numerous authors (100), (101), (47). As a result, data collection in most poisoning published studies in KSA has been conducted manually (102), (103). which makes it difficult to establish the necessary functions for the toxicovigilance process.

4.1.3.4 Health Help Hotline in KSA

The 937 hotline is a 24/7 service in KSA, it was established in 2010 by the MoH, provide free access to health information for the public and healthcare professionals (104). The hotline addresses all health inquiries, including poisoning cases. It is staffed by trained healthcare practitioners including clinical pharmacists, with medical toxicologists

available for support. Its goal is to improve health outcomes quickly and effectively by preventing unnecessary hospital visits. Additionally, ongoing efforts are being made to enhance their documentation processes, transitioning from manual systems to electronic systems for greater efficiency (105). In 2024, a study highlighted the existence of a toxicology database (The Ministry of Health Toxicology Call Center Database). The system relies on collecting data over the phone to gather information from the caller, either public or healthcare practitioners (3). Another study explored the medical toxicology practice in KSA and mentioned a case registry program that collects data through the forensic laboratory poison centers across the country, but did not clarify whether the call registry is the same as the one mentioned in the previous study or not (4).

The MoH releases the number of deaths reported in its hospitals due to poisoning and other causes through the statistical yearbook. However, there is no compilation of data from other non-MoH hospitals. The reliability of the latest mortality data is questionable, as nearly one-third of hospital deaths are classified as symptoms, signs, or abnormal findings rather than being assigned to specific disease groups (Figure 4-1) (99). These limitations ultimately hinder the establishment of essential functions required for an effective toxicovigilance process.

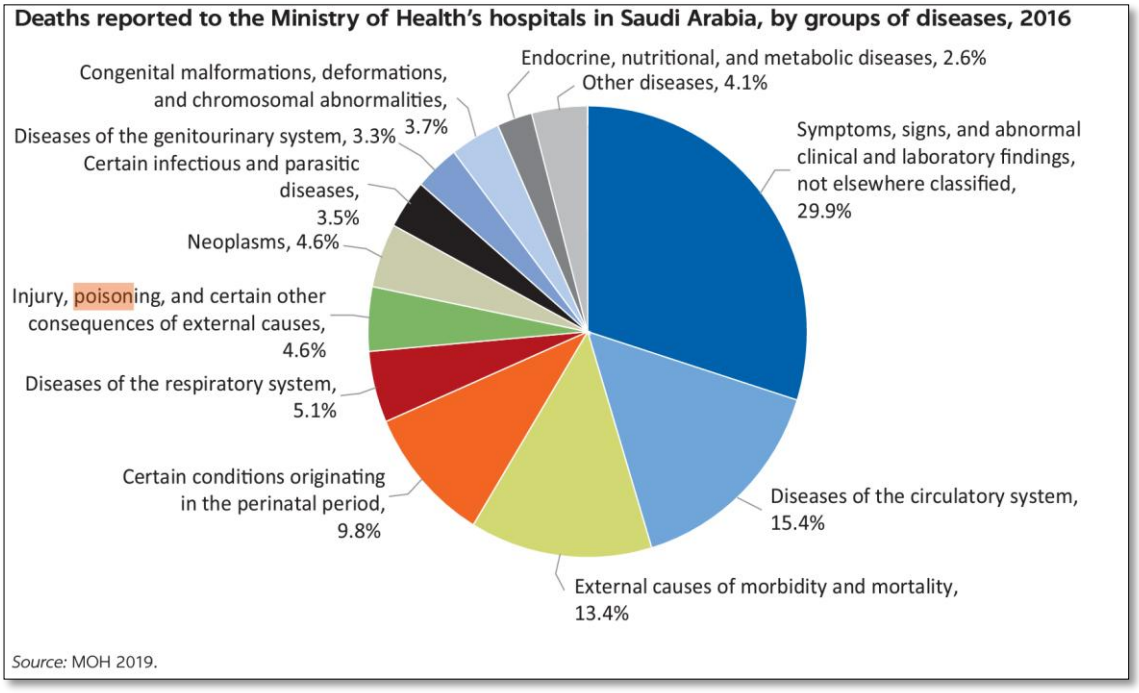

Figure 4-1: Published mortality data from the MoH 2016 report

4.1.4 Results of Phase Two

4.1.4.1 Health Electronic Surveillance Network (HESN)

HESN is a surveillance system that was initially developed by the International Business Machines Corporation and used in Canada for the first time under the name of "Panorama." KSA was granted the license to operate it under the name of HESN in 2012 (106). HESN is a web-based electronic health solution that was implemented to accommodate all Saudi public health plans to better detect, respond, prevent, and control diseases and injuries in addition to monitoring the population's health status, thus, empowering decision makers to lead and manage more effectively by providing timely, useful, high-quality data (107). It provides public health data including epidemic outbreaks, vaccinations, and immunizations (108). HESN is expected to aid the country's public health services in combating bioterrorism, health threats, and facilitating other health programs (e.g., immunization and general health research) (107).

However, the actual reporting pathway within HESN (Figure 4-2) (107), reveals important limitations. HESN is used exclusively within hospitals affiliated with MoH, which restricts its coverage and limits its representation as a truly surveillance system. This limitation is particularly relevant in the context of toxicovigilance, as effective surveillance requires comprehensive, cross-sectoral data integration beyond MoH facilities alone.

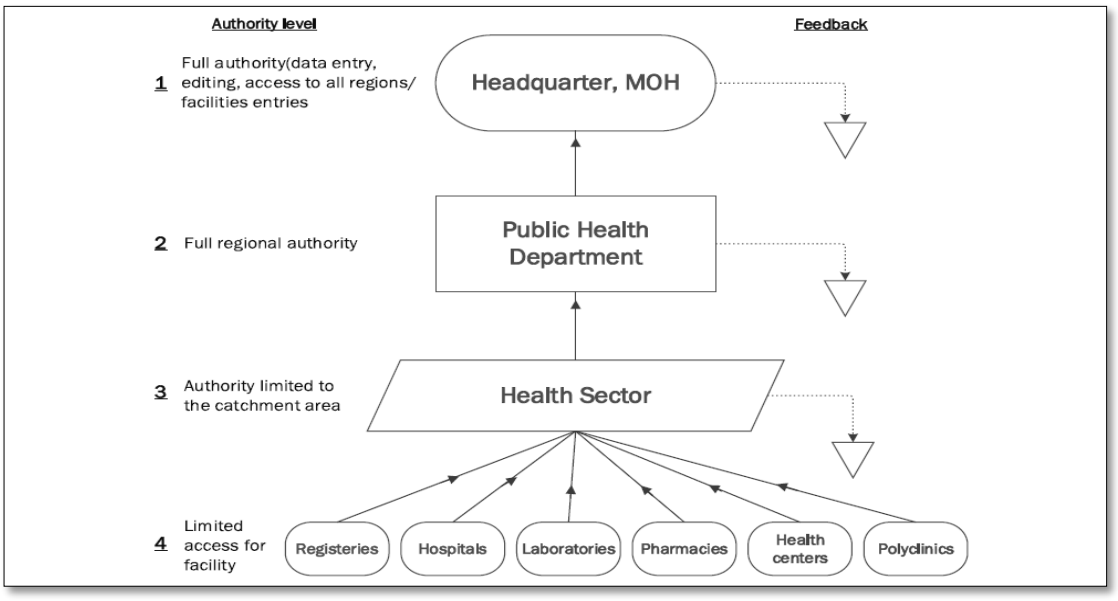

Figure 4-2: HESN flowchart of information with regards to the authority and feedback process

4.1.4.2 Online Toxicology Analysis Requests and Results (OTARR)

An online system was developed to standardize labor policies across poison control laboratories within the MoH. This system aims to track lab specimens and results within the labs therefore it covers only exposure cases (109). It provides users with complete and accurate information whilst automating the registration and documentation of all procedures for specimens. The system ensures smooth, secure, and precise reporting of analysis outcomes and offers access to a unified database of integrated toxins and psychotropic substances which can be an additional component to toxicovigilance System.

4.1.4.3 National Vigilance System “Tayaquth”

A National Pharmacovigilance System which was established by the SFDA in March 2009 (110). It has implemented initiatives to improve pharmacovigilance and post marketing surveillance (111), (112). The Pharmacovigilance service enables health practitioners, organizations, and individuals to report various issues, including; side effects, pharmacological errors, cosmetic products side effects, drug shortage, quality defects in pharmaceuticals, food poisoning, and defects in medical devices and supplies (113). It is open to health practitioners, companies, health organizations, pharmacies, and community members. Pharmacovigilance activities can be an add on to toxicovigilance activities but it does not replace it.

4.1.4.4 RASID by Saudi Standards, Metrology and Quality Organization

RASID is an Arabic term meaning “capture.” It is an integrated system operated by the Saudi Standards, Metrology and Quality Organization, a national governmental entity. RASID is designed to facilitate the collection and sharing of information related to incidents involving consumer products that may pose risks to health and safety. The system focuses on monitoring and analyzing complaints related to non-medical and non-nutritional products, generating recommendations, and enhancing consumer awareness of associated hazards. In addition, RASID supports the issuance of early national alerts regarding product-related incidents, contributing to proactive consumer protection and risk mitigation (114).

4.1.5 Discussion

The analysis identifies several existing resources and systems that could contribute to the operation of the proposed SNTESS, and highlights the need for sustained collaboration between healthcare providers and regulatory bodies to enhance patient safety and protect public health, particularly with respect to toxicological risks such as poisoning. Among the resources reviewed, the MoH Health Hotline and its call registry system is the only entity whose mandate closely aligns with the objectives of the proposed SNTESS,

positioning it as a key contributor to successful implementation. Although the system does not currently provide real-time surveillance, it demonstrates greater potential for adaptation and enhancement.

The existence of only a small number of PCCs, coupled with their independent operation across different healthcare sectors, undermines the establishment of a coordinated SNTESS framework. Fragmentation restricts data sharing, standardization of practices, and the ability to generate comprehensive national insights into poisoning trends. NDPIC as the national PCC represents an important organizational effort; however, its positioning within the SFDA inherently shapes its scope and functionality. As the SFDA's mandate focuses primarily on product regulation, the NDPIC's emphasis on drug-related information reflects this regulatory orientation rather than a clinical or public health mandate.

Among available systems analysis; Tayaquth, operated by the SFDA, is primarily focused on post-marketing surveillance, while HESN under MoH functions as a broader public health surveillance system rather than a dedicated toxicological platform. OTARR under MoH is specifically designed for toxicology-related lab specimens, whereas RASID mainly targets non-consumable product surveillance.

Moreover, effective toxicovigilance requires the consolidation of public health data generated across multiple programs and departments under a single coordinating authority. Such integration would enable the application of standardized surveillance criteria and facilitate the production of unified national reports. In this context, PHA, formerly known as the Saudi Center for Disease Prevention and Control (Weqaya), plays a central role in disease prevention, surveillance, and emergency preparedness. However, despite its mandate encompassing both communicable and non-communicable diseases, there remains a notable lack of publicly available data related to toxicological risk surveillance. Although a 2021 publication referenced plans to establish a national system and database for monitoring and evaluating non-communicable diseases, there is currently

no published evidence describing an operational toxicovigilance system or reporting on the prevalence and burden of poisoning in KSA.

4.1.6. Conclusion

To support the above analysis, a summary table (Table 4-2) is included to outline existing toxicovigilance systems and resources in KSA, identify their functional gaps, and highlight how these deficiencies undermine national toxicovigilance capacity. The corresponding solutions and implementation framework are presented in a parallel table in Chapter 7.

Table 4-2: Summary of phase two analysis

Existing resources and systems in KSA	Current role	Key gaps identified	How this undermines national toxicovigilance
PCCs	Poison treatment advice and documentation	Fragmented; unclear PCC scope/definition; no national integration	No unified validation and surveillance "hub;" inconsistent data; delay in national trend detection
Medical Toxicologists workforce	Clinical care, Emergency management	Unknown national toxicologist capacity	Cannot grantee a national coverage
Documentation systems	Case reporting pathway from emergency rooms	Multi-stage, not real-time; limited interoperability with EHR	Delayed detection of clusters/outbreaks; weak early warning
MoH Health Hotline	Public/ professional advice	Not poisoning help-dedicated; uncertain linkage to other registries; data not validated as national data	Incomplete data; delayed escalation; limited analytic outputs

MoH HESN	Public health surveillance platform for health practitioners	Primarily communicable disease-focused; reporting not real-time; partial adoption; training	Cannot function as unified surveillance; weak signal detection for novel hazards
MoH OTARR	Lab specimen tracking/ results	Tracks specimens not cases; excludes non-tested exposures	Misses a large proportion of poison exposures
SFDA "Tayaquth"	Online reporting for adverse drug reactions, food poisoning, devices	Form-based, not real-time surveillance	Limited use inconsistent national dataset
RASID By Saudi Standards, Metrology and Quality Organization	Product incident alerting	Limited info; reportedly inactive	Lost opportunity for consumer-product hazard signals

Chapter 5: Toxicovigilance Landscape Outside KSA

5.1 History and Revolution of Toxicovigilance

In the 19th century, Orfila, the French forensic toxicologist, introduced the importance of systematic data collection from animal and human poisoning, thereby transforming medical toxicology from a discipline focused primarily on the management of poisoned patients into one grounded in structured data generation and analysis (25). As the field evolved, risk assessment emerged as another central function, contributing to improvements in population safety through the identification and mitigation of hazards in homes, workplaces, and the environment. However, although risk identification is a necessary first step, it remains constrained by insufficient data on human exposures, underscoring the need for more comprehensive toxicological epidemiological studies (115).

Toxicovigilance therefore represents a critical evolution within toxicology and should be regarded as a complementary approach to traditional risk assessment. Its primary objective is the collection of medically validated data in a standardized and structured format that enables aggregation of individual case reports for national and global risk assessment. In this context, data mining from large databases, such as those maintained by PCCs, plays a key role by enabling the early detection of emerging risks and the generation of alerts for public health authorities (116).

5.2 Worldwide Implementation of Toxicovigilance

Very few structured toxicovigilance systems have been set up worldwide (25). France (toxicovigilance) and the US (toxic-surveillance) both have comprehensive national systems for documenting, analyzing, and responding to toxicological risks, while Canada operates a toxicovigilance network primarily focused on intelligence sharing and

situational awareness rather than centralized surveillance (117). Furthermore, the WHO classifies unintentional poisoning as a global public health concern and identifies the establishment of PCCs as a priority (92). Currently, approximately 348 PCCs exist worldwide, covering only 47% of WHO member states, with the largest gaps in the African, Western Pacific, and Eastern Mediterranean regions (118). These regions simultaneously rank 1st, 4th, and 3rd, respectively, for the highest deaths per 100,000 population from unintentional poisoning (Figure 5-1) (118), indicating a mismatch between disease burden and surveillance capacity.

In 2021, approximately 59,000 people globally (range: 32,000–90,000) died from unintentional poisoning, representing a decrease of over 4,000 deaths since 2000 and a 25% reduction in the crude death rate (CDR) from 1.0 (range: 0.8–1.5) per 100,000 population in 2000 to 0.7 (range: 0.4–1.1) per 100,000 in 2021 (SDG indicator 3.9.3). Despite this decline, substantial regional variation persists. The highest CDR in 2021 was observed in the African region at 1.2 (range: 0.7–2.2) per 100,000, followed closely by the Western Pacific region at just under 1.2 (range: 0.5–1.7) per 100,000. Although the European region experienced nearly a two-thirds reduction in CDR between 2000 and 2021, slight increases were reported in the Americas and Western Pacific regions, demonstrating that temporal trends are not uniform (119).

Significant demographic disparities were also evident. Men had a mortality rate 68% higher than women, with male-to-female ratios of 2.3 in the Americas and 2.6 in Europe, compared with 1.4 in Africa. Individuals under 5 years of age and those aged 65 years accounted for nearly 40% of unintentional poisoning deaths in 2021 (119).

Taken together, these data indicate that while global poisoning mortality is declining, it remains unevenly distributed across regions and demographic groups, and its surveillance infrastructure is most limited where the burden is highest. For the EMR, this combination of elevated risk and limited toxicovigilance capacity underscores the need for systematic national data collection to accurately assess prevalence, monitor trends, identify high-risk populations, evaluate outcomes, and support the development of SNTESS.

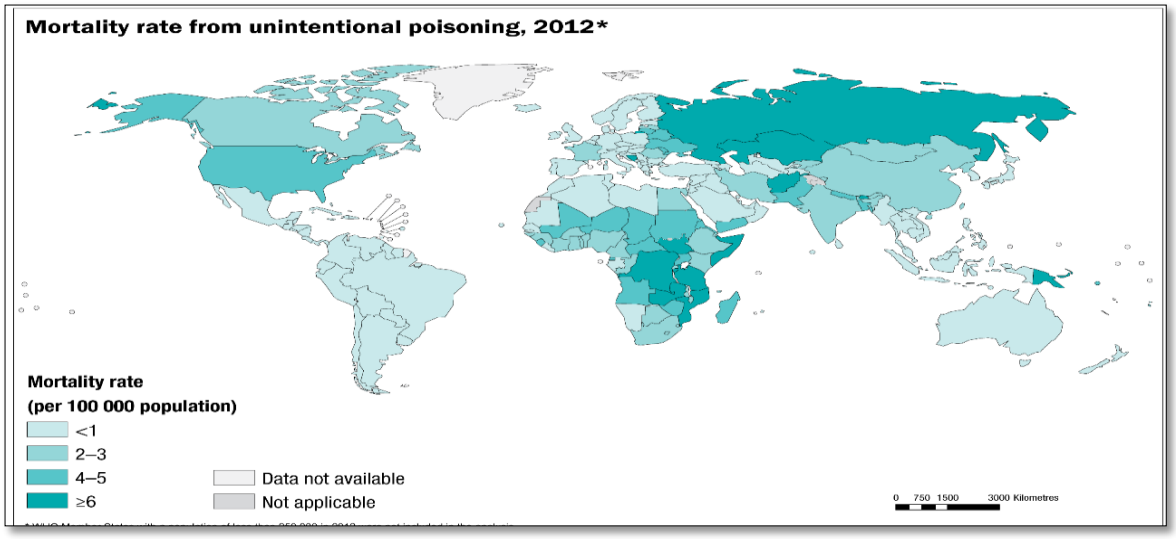

Figure 5-1: Worldwide mortality rates per 100,000 from unintentional poisoning

The WHO 2019 statistics revealed around 1.5 deaths per 100,000 from unintentional poisoning. It also had the lowest suicide mortality rate, least total alcohol per capita consumption, and 4th in the prevalence of tobacco smoking (Table 5-1) (2).

Table 5-1: WHO EMR countries: statistics relating to poisoning and mortality

WHO Sustainable Development Goals (SDGs) Indicator	**WHO EMR Countries' Outcome**	**WHO EMR countries Ranking (/6) ***
Mortality rate from unintentional poisoning (per 100,000 population)	1.5	4th
Suicide mortality rate (per 100,000 population)	3.9	1st
Total alcohol per capita (≥15 years of age) consumption (liters)	0.6	1st
Prevalence of tobacco smoking among persons aged 15 years and older	18.1%	4th

* The term "WHO EMR countries Ranking (/6)" refers to a ranking system for countries within the EMR. The "/6" indicates six categories or criteria used for ranking. A higher ranking (one is highest) might suggest better health outcomes or more effective health systems, whilst a lower ranking could indicate challenges in healthcare delivery or higher disease prevalence.

5.2.1 Review Question

This review addresses the following question: How do established toxicovigilance systems in the UK, USA and Canada operate in terms of governance, reporting mechanisms, and integration with public health systems, and what best practices and transferable components can be identified to inform the development of a national toxicovigilance system?

Although many countries could offer relevant insights, these three were selected for specific reasons. First, each has a well-established and operational toxicovigilance or toxic-surveillance system with documented governance structures, reporting mechanisms, and public health integration (120). Second, all three are members of the Organization for Economic Cooperation and Development (OECD), reflecting comparable levels of economic development, organizational capacity, and healthcare infrastructure (121). Third, these countries share broadly similar administrative and regulatory traditions, including strong public health agencies, established legal frameworks for surveillance, and mature data systems, which enhances the relevance of their experiences for adaptation to other centralized healthcare systems (122). Examining toxicovigilance models in advanced economies therefore provides a useful reference point for identifying best practices and transferable system components.

5.2.2 Review Design

This review adopts a comparative analysis as a method. It is typically conducted using a structured narrative review of publicly available policy documents, government reports, peer-reviewed literature, and official websites of national PCC and public health agencies in the USA, UK, and Canada. Key domains examined included governance and legal frameworks, system architecture, data sources and reporting mechanisms, integration with public health emergency response, workforce and training, and system outputs such as alerts, reports, and public communications. Information was extracted and synthesized

thematically to identify common elements, best practices, and structural differences across systems, with attention to their potential applicability to the Saudi context.

This selection also has important limitations. Focusing exclusively on high-income OECD countries may bias the analysis toward resource-intensive models that are not directly transferable to middle-income or resource-constrained settings. It also excludes examples from regions with high poisoning burdens but weaker surveillance infrastructures, such as parts of Africa, Asia, and the Eastern Mediterranean, where toxicovigilance challenges and innovations may differ substantially. As a result, the findings may overemphasize organizational and technological solutions while underrepresenting community-based, low-cost, or decentralized approaches to toxicovigilance.

5.2.3 Results

5.2.3.1 US

Poisoning is a significant problem in the US and the leading cause of unintentional injury and death, surpassing motor vehicle accidents (123). In 2019, the 55 PCCs provided telephone guidance for over 2.1 million human poison exposures (124). Poisoning is also one of the most common causes of emergency room visits in the US, with around 1.1 million visits from 2008 to 2011 alone due to drug poisoning (125). This trend is consistent across different states, where studies have demonstrated the increasing impact of poisonings. In 2023, across all ages, there were 623 poison exposures reported per 100,000 population, the highest incidence occurring in children 2 years and below (5,330 per 100,000 population) (126). Between 2019 and 2024, pain medications were the most frequent causes of pediatric fatalities reported to PCCs, followed by fumes, gases, and vapors such as carbon monoxide (126).

Currently, the 55 PCCs in the US collectively serve all states (29). All PCCs use a nationwide toll-free number (800-222-1222) for calls, established and managed by the AAPCC (30). Approximately 70% of calls come through this nationwide number (127).

The PCCs collect specific data points and transmit them every 4.72 minutes to the National Poison Data System (NPDS) (29).

The Toxic Exposure Surveillance System (TESS) was established in 1985 following a successful two-year pilot, under the umbrella of the CDC. TESS is a uniform data set of cases from PCCs across the USA, with standardized categories of information including patient data, caller, exposure, substance, clinical toxicity, treatment, and medical outcome (128). By 2003, the system had 36.2 million recorded cases, prompting the CDC to establish a national chemical terrorism surveillance system. This initiative involved collecting real-time toxicovigilance reports to a centralized database, enhancing the ability to respond to public health threats. A near real-time toxicovigilance system, using both general and specific approaches, was systematically integrated with the TESS, further increasing the potential of poison center data for early identification of public health threats (129).

In 2006, the CDC collaborated with the AAPCC to create the NPDS, which replaced TESS as the nationwide poison center data repository and surveillance system (130). During the transition, the NPDS preserved data from 1985 to the present day, and improved the accessibility of data through online publications, enhancing data analysis and increasing data transmission (131). Regarding the process of poison cases recording in NPDS, each call placed to a PCC records demographic and clinical information about the exposed individual. This information must be chosen from among the NPDS database which allow for coding of up to 131 different clinical effects (signs, symptoms, or laboratory abnormalities), decontamination, and management options available, all of which are predetermined and encoded on the server, with the exposure products classified according to POISINDEX™ codes (132). In addition, exposure incidents play a crucial role in detecting outbreaks related to chemical, biological, radiological, and nuclear substances. To facilitate this, all PCCs maintain electronic medical records. Alerts are then sent to an NPDS surveillance team which is responsible for monitoring and responding to the

signals, and subsequently collaborating with CDC to investigate outbreaks and data trends (Figure 5-2) (130).

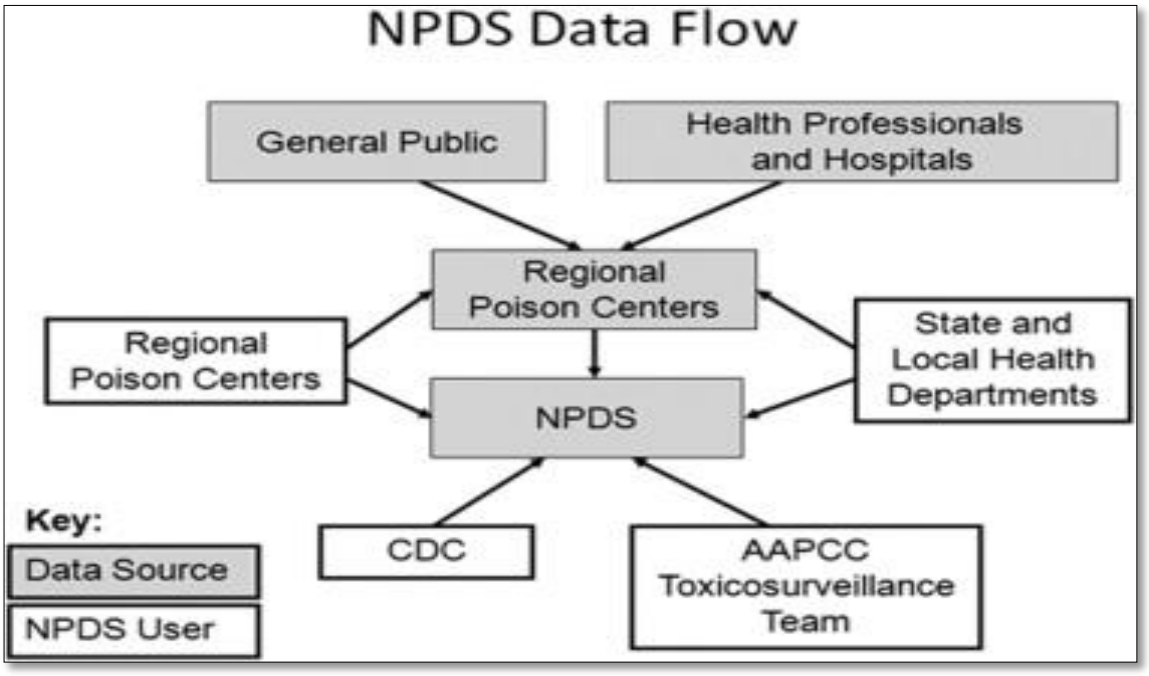

Figure 5-2: Illustration of data flow for NPDS users

During public health emergencies, data gathered from NPDS has proven invaluable in identifying potential cases, tracking their temporal and spatial distribution, and characterizing illness symptoms and severity (133). Additional measures such as creating more specific substance codes and geospatial mapping of caller/case sites, can be implemented when necessary to enhance surveillance during these events (134), (135). For instance, tracking salmonella outbreak due to contaminated peanut butter/paste (133), monitoring levamisole-contaminated cocaine (136), and tracking exposures to oil, dispersants, and contaminated seafood in the aftermath of the Deepwater Horizon oil spill (137,138).

One notable advantage of the NPDS is capturing cases that may not be seen at healthcare facilities. The Florida Poison Information Center Network, for instance, contributed 94%

of illness reports collected in Florida's public health surveillance system during the Deepwater Horizon oil spill, whilst only 6% were derived from emergency room chief complaint data (139). As such, the integration of PCCs data, collected through the NPDS, is essential in detecting and monitoring incidents and outbreaks involving toxic substances, enhancing the ability of public health services to enact an effective response, supported by ongoing surveillance during crisis situations. The NPDS in the USA is operated by the AAPCC. And reports to the Department of Health and Human Services (HHS) includes well-known divisions such as CCD and the Food and Drug Administration (FDA) (140).

In 2008, the American College of Medical Toxicology (ACMT) created the Toxicology Investigator's Consortium (ToxIC), a broad national network for research and collaboration between medical toxicologists. ToxIC's members established the ToxIC Registry, which includes cases evaluated or managed by members in their practices in hospital or clinical environments, including treatment decisions and research questions to be considered (141). Nevertheless, the primary purpose of the ToxIC Registry is promoting subsequent clinical research.

5.2.3.2 Canada

Toxicovigilance Canada, a pan-Canadian system that aggregates, analyzes, and interprets data from five PCCs {Atlantic Canada Poison Centre (ACPC-NS), Centre anti-poison du Québec (QC), Ontario Poison Centre (ON), Poison and Drug Information Service in Alberta (AB), and the Drug and Poison Information Centre in British Columbia (BC)} to provide near real-time surveillance and national statistics on poisonings, chemical intoxications, and adverse drug reactions (Figure 5-3) (142). Hosted by the Canadian Network for Public Health Intelligence, this secure scientific informatics and bio-surveillance platform is owned and operated by the Public Health Agency of Canada. The surveillance system is guided by a committee that includes representatives from PCCs, provincial and federal governments (120). In 2013, the 5 PCCs were unified to establish the Canadian Surveillance System for Poison Information (CSSPI). Contributors to this

assessment included Health Canada, the Canadian Association of Poison Control Centers, provincial/territorial Health Partners, academic organizations, and non-governmental organizations. This resulted in the 2014 launch of the CSSPI initiative to enhance the timely detection of toxic exposure events of public health concern and to generate statistics based on poison center information to inform prevention, treatment, and harm reduction (117). In 2015, a virtual Canadian Poison Control Community of Practice was established on the Canadian Network for Public Health Intelligence (CNPHI), a robust public health informatics platform (117). This platform facilitates multidisciplinary and jurisdictional collaboration between PCCs, public health, health security, regulatory, non-governmental organization, and academic partners. All Canadian PCCs follow the NPDS coding guidelines published by the AAPCC (143). In 2020, Canada's PCCs managed 215,589 cases; more than one-third involved a child aged 5 or under and the most common substances were medications for pain relief (analgesics) and household cleaning products, such as bleach (144).

Whilst all components within Toxicovigilance Canada are currently under varying stages of development, value is already being recognized from the enhanced information exchange, trust, and collaboration on a common goal. For example, in the fiscal year 2019-20, Health Canada engaged partners and stakeholders to refine the common vision and conduct regional focus groups across the country (145). In March 2023, Health Canada has launched a new toll-free number, 1-844 POISON-X, or 1-844-764-7669, in collaboration with the Canadian PCCs, to make it easier for Canadian residents to access critical medical advice for poisonings (144).

In the context of natural disasters or industrial accidents, toxicovigilance provide timely data that guide response strategies. For instance, during the COVID-19 pandemic, the integration of toxicovigilance helped identify toxic exposures related to sanitation and personal protective equipment (146). Furthermore, Canadian public health agencies use toxicovigilance to track chemical exposures, thereby developing policies for prevention

and promoting a proactive approach to mitigating the health effects of toxic exposures in vulnerable populations (147).

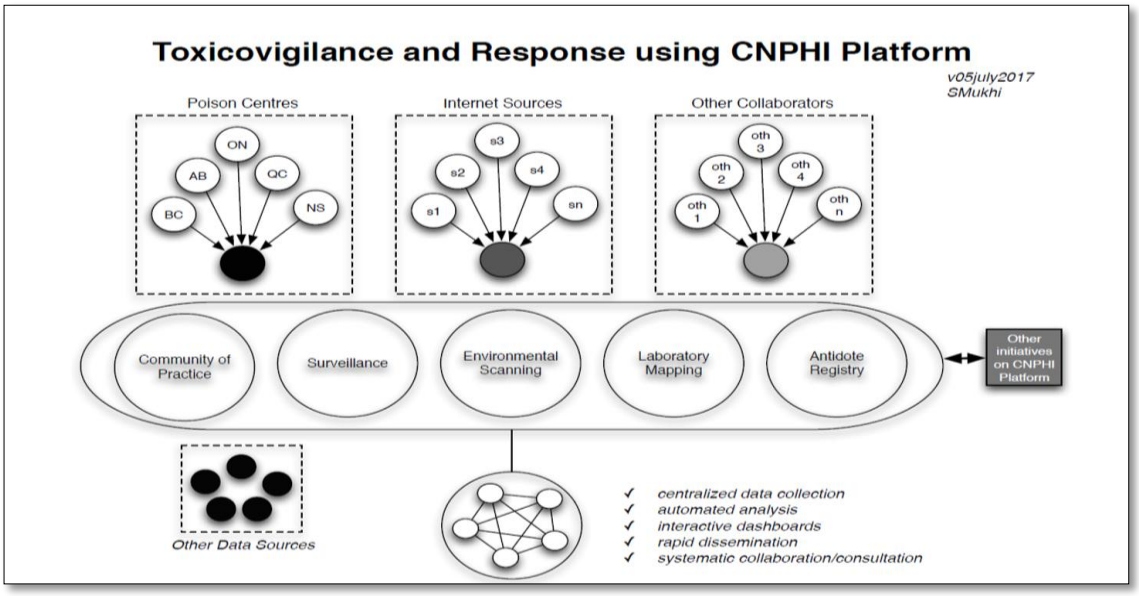

Figure 5-3: Illustration of data flow for CNPHI users

*Atlantic Canada Poison Centre (NS), Centre anti-poison du Québec (QC), Ontario Poison Centre (ON), Poison and Drug Information Service in Alberta (AB), and the Drug and Poison Information Centre in British Columbia (BC)
*Sn=1-5 Internet sources
*oth= Other collaborations
* CNPHI=Canadian Network for Public Health Intelligence

5.2.3.3 UK

Severe poisoning is quite common in the UK. In 2019 there were 4,393 registered deaths attributed to drug poisoning in England and Wales, 1,264 in Scotland and 191 in Northern Ireland (148). In 2022 the most viewed products in the National Poisons Information Service (NPIS) data source "TOXBASE" was: paracetamol, followed by ibuprofen and sertraline (149). NPIS was established in 1963, commissioned by Public Health England (PHE) (150). Commissioned to provide 24-hour free information and advice to the UK National Health Services (NHS) healthcare professionals, the NPIS supports clinicians to manage patients with suspected poisoning. This information is provided primarily via TOXBASE, an online information database (also available as an app) that can be accessed

both on- and offline (151), (152). Additionally, the NPIS also covers the UK Teratology Information Service (UKTIS) the national source of information and advice about exposure to drugs and chemicals during pregnancy (153). The 4 NPIS units are currently based within NHS teaching hospitals ,2 in England and one each in Scotland and Wales. Birmingham, Cardiff, and Newcastle participate in a 24-hour national telephone enquiry Rota; the Edinburgh unit receives telephone enquiries during working hours only as its focus is on the editing of TOXBASE (154). For public inquiries, the UK has a non-emergency hotline, -NHS 111- for (England, Scotland, and Wales). This is a telephone and online service provided free by the NHS for all health inquires (155). (148).

In summary, poisoning cases from the public will be assessed through NHS helpline services only while cases from healthcare professionals will be assessed through either the NHS helpline or directly through NPIS helpline for more complex cases. All helplines are using TOXBASE as an information database. Furthermore, TOXBASE saves all searches that are made through their login system, to capture all poisoning cases. In cases of chemical poisoning cases, the NPIS liaise with the UK Health Security Agency (UKHSA) Radiation, Chemicals and Environmental Hazards Directorate (RCE) and Public Health Scotland (PHS) for providing best advice possible to patients and ensuring efficient use of resources (Figure 5-4) (154), (148), (156).

The framework for responding to public health emergencies due to chemicals in the UK is built on a solid legislative foundation, including significant laws such as the Health and Safety at Work Act and the Control of Major Accident Hazards Regulations. These regulations define the responsibilities of various stakeholders in ensuring safety and effective emergency response. PHE plays a crucial role in this framework by assessing chemical risks, providing guidance, and coordinating responses among different agencies (156). On the other hand, there is the UK Poisons Information Database (UKPID), for collation of data and surveillance of the patterns of enquiries received. Details of all telephone enquiries made since 2007 are held within UKPID, making it an invaluable resource for studying the patterns of poisoning in the UK (157). In summary,

TOXBASE is the poisons information resources database while, UKPID is the UK poison information reservoir of data (158).

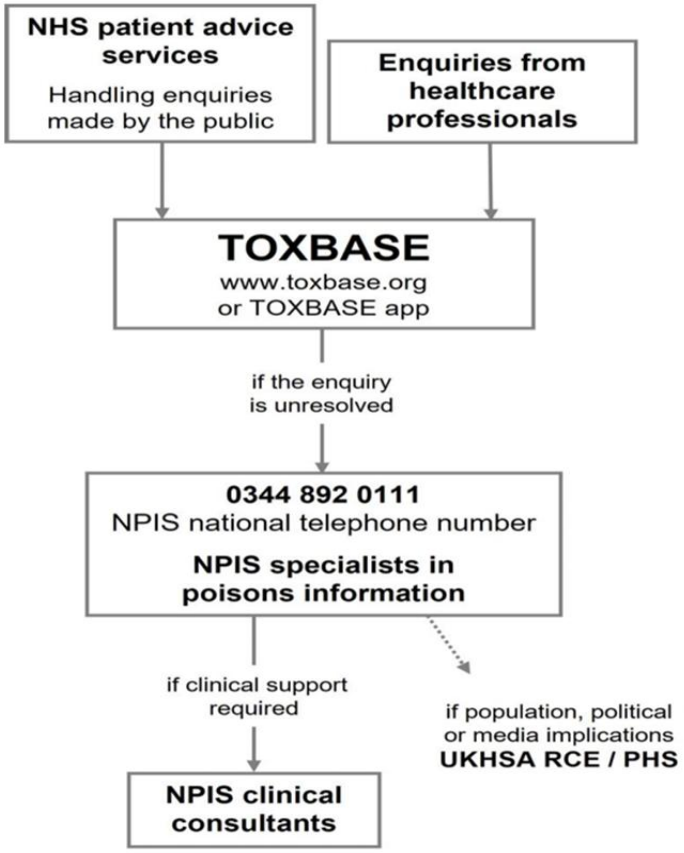

Figure 5-4: How poison inquiries are managed by the NPIS

Moreover, if the UKPID has shown a pattern of poisoning including self-harm, accidental exposures, medication errors, and drug misuse, this is recorded in the National Postmortem Toxicology Database, managed by the Office for Health Improvement and Disparities of the Department of Health and Social Care (159). Therefore, in case of public health emergencies, UKPID plays an important role especially in early detection of threats. For example, the UK has established an emergency preparedness system that includes risk assessment, incident management protocols, and collaboration among local health authorities and national agencies to handle potential cross-border threats.

Additionally, the UK participates in European alert systems like the Early Warning Response System (EWRS) and the Rapid Alert System for Chemicals (RASCHEM) (133, 134).

These systems enhance communication and coordination during toxicological incidents. Regular training exercises are conducted to keep public health officials and emergency responders well-prepared for potential crises. Lastly, effective public communication strategies are in place to ensure that the public is informed about risks and safety measures during chemical emergencies. This comprehensive framework aims to facilitate a timely and coordinated response, ultimately protecting public health in the face of chemical threats (160).

Finally, Table 5-2 shows a summary of the toxicovigilance systems in the three countries discussed above. This table provides key insights into each country's approach, highlighting their hotlines, the number of available PCCs, the toxicovigilance systems used, and their governance structures in managing toxic exposures and ensuring public health safety.

Table 5-2: Summary of the toxicovigilance systems in US, UK, and Canada

Country	Hotline	PCC	Toxicovigilance System	Managed by	Governance	Report to	Platform
USA	800-222-1222	55	National Poison Data System (NPDS) Formally TESS	AAPCC	Health and Human Services (HHS)	NPDs Annual reports provided to: CDC and WHO	Web-POISON-CONTROL For public and healthcare
UK	NHS 111	4	UK Poisons Information Database (UKPID)	The National Poisons Information Service (NPIS)	Public Health England (PHE)	NPIS Annual reports provided to: UK Health Security Agency (UKHSA) Radiation, Chemicals and Environmental Hazards Directorate (RCE); Public Health Scotland (PHS); The Office for Health Improvement and Disparities of the Department of Health and Social Care; The Rapid Alert System for Chemicals (RASCHEM); WHO	TOXBASE Only for healthcare
Canada	1-844 POISON-X	5	Canadian Surveillance System for Poison Information (CSSPI)	The Canadian Association of Poison Centers and Clinical Toxicologists (CAPCCT)	The Canadian Network for Public Health Intelligence (CNPHI)	Pan-Canadian Poison Centers Annual Report provided to: injury prevention agency (Parachute); Public Health Agency of Canada (PHAC) and Health Canada (HC) and WHO	Toxicovigilance Canada Platform Only for healthcare

5.2.4 Discussion and Conclusion

Lessons that should be applied from US/Canada/UK Toxicovigilance Systems:

1. **Centralized Data Collection Systems:** A unified national database (USA's NPDS, Canada's CSSPI, UK's UKPID) that aggregates data from all PCCs in real-time to ensure consistency and comparability
2. **Accessible Emergency Hotlines:** A single, easy-to-remember toll-free number with 24/7 availability for public access
3. **Multi-Stakeholder Collaboration:** Partnerships between PCC, government health agencies, academic organizations, and non-governmental organizations
4. **Real-Time Surveillance Capabilities:** A near real-time data transmission (USA: every 4.72 minutes) to enable early detection of outbreaks and public health threats with automated alert systems to notify surveillance teams of unusual patterns
5. **Standardized Coding Systems:** Internationally recognized coding guidelines (Canadian PCCs follow AAPCC's NPDS coding guidelines)
6. **Integration with Public Health Infrastructure:** Toxicovigilance systems connection with broader public health emergency response frameworks (USA: CDC/FDA, Canada: Public Health Agency, UK: UKHSA)
7. **Capture Cases Beyond Healthcare Facilities:** All poisoning exposure cases not presenting to emergency departments must be captured through the toxicovigilance system.
8. **Research and Quality Improvement Networks:** A platform for toxicologists to collaborate on research (USA's ToxIC Registry). This will establish communities of practice for knowledge sharing (Canada's virtual Community of Practice).
9. **Flexible System Enhancement During Emergencies:** Ability to scale up surveillance during disasters (COVID-19, oil spills, chemical incidents)
10. **Legal and Regulatory Framework:** A clear legislative foundation defining stakeholder responsibilities and ensure regulatory support for data sharing and emergency response coordination

11. **Public Communication Strategy:** An effective communication channels to inform the public about risks and safety measures and to provide accessible information resources for both professionals and the public

The purpose of this summary is to outline the proposed framework for establishing SNTESS.

5.3 Alignment of Toxicovigilance with International Frameworks

The International Health Regulations 2005 (IHR), governed by the WHO and mandated since 2005 across 196 countries, provides a framework that defines the obligations of countries in managing public health events that may cross borders (161). The IHR include the requirements for countries to develop and maintain 13 core capacities as outlined in Articles 5 and 13, along with Annex 1 of the IHR (2005) (162). The 13 core capacities (Table 5-3) have been identified as essential for the detection, assessment, notification, reporting of, and response to events that may pose a public health risk or emergency at the national or international level. Using these regulations, the WHO can subsequently seek confirmation of events it identifies through consolidated surveillance and reporting efforts from the affected countries. Prioritizing real-time surveillance and reporting as a national mandate improves preparedness and response capabilities, fosters international collaboration, and enhances global health security. Therefore, the WHO's Global Health Security Index assesses countries' health security capabilities, evaluating their preparedness to prevent, detect, and respond to infectious disease threats and health emergencies.

Table 5-3: Core capacities as outlined in the IHR (2005)

C1	Legislation and Financing
C2	IHR Coordination and National IHR Focal Point Functions
C3	Zoonotic Events and the Human-Animal Interface

C4	Food Safety
C5	Laboratory
C6	Surveillance
C7	Human Resources
C8	National Health Emergency Framework
C9	Health Service Provision
C10	Risk Communication
C11	Points of Entry
C12	Chemical Events
C13	Radiation Emergencies

An excellent illustration of this process, is the COVID-19 pandemic outbreak (163). Upon notification of the outbreak, the WHO organized a 15-member IHR emergency committee in January 2020 to discuss whether the evidence to date indicated a Public Health Emergency of International Concern (PHEIC). As a result, a suite of recommendations was issued, including notifying all countries of COVID-19 as a PHEIC. This designation enabled countries with less developed public health infrastructures to prepare effectively (164). Furthermore, the IHR ensures that the surveillance and response capacities for countries meet certain functional and technical criteria, with a set timeframe in which to meet these standards (165). Through these predefined roles, processes, and capacities, poisons centers contribute to national capacities for implementation of the IHR by improving capabilities relating to surveillance, preparedness, and response to public health events (166). However, despite the clear requirements, the capability of least-developed countries to fully comply with the IHR is lacking and several improvement measures to increase effectiveness, and address the regional inequalities caused by cross-border incidents are necessary (167).

Furthermore, to prevent countries from applying internal bias to their current IHR compliance rating, WHO published an IHR companion document, the Joint External

Evaluation (JEE) tool, which is now in its third edition (168). Through four sections and sub-criterion (Table 5-4) (169), the JEE supports countries to comply with their annual reporting mandates, alongside the IHR Monitoring and Evaluation Framework and States Parties Annual Reporting tools. Recommended by the IHR review committee, JEEs provide a more thorough reporting mechanism to self-assessments, by including options for peer reviews, domestic and independent reports.

Table 5-4: Rating sections of the JEE tool

Prevent	
P1	Legal Instruments
P2	Financing
P3	IHR Coordination, National IHR Focal Point, Functions & Advocacy
P4	Antimicrobial Resistance
P5	Zoonotic Disease
P6	Food Safety
P7	Biosafety and Biosecurity
P8	Immunization
Detect	
D1	National Laboratory System
D2	Surveillance
D3	Human Resources
Respond	
R1	Health Emergency Management
R2	Linking Public Health and Security Authorities
R3	Health Services Provision
R4	Infection Prevention and Control
R5	Risk Communication and Community Engagement
IHR Related Hazards	
PoE	Points of Entry and Border Health

CE	Chemical Events
RE	Radiation Emergencies

Each criterion is rated on a scale from one to five, with one being the lowest score and five the highest. Generally, a score of one indicates a lack of knowledge, planning, or mapping, suggesting-that the country has a low level of evidence regarding its ability to meet that objective. In contrast, a score of five signifies full implementation according to the target, close monitoring, adequate budgeting, and reliable reporting (168). One mechanism that serves as an enabler is the IHR National Focal Points (NFPs). NFPs are responsible for notifying the WHO of potential events that may constitute public health emergencies of international concern, such as outbreaks of novel infectious diseases (170). Ideally, the designated NFP would be a poison control center, as it has up-to-date information, provides surveillance and reporting, and is available 24/7 in accordance with the requirements.

Although implemented only in 2016, the JEE has become a pivotal tool for enhancing the reporting of IHR compliance. This gained particular interest in the period following the COVID-19 pandemic, as researchers have viewed JEE reports as real-world examples based on the data available and reported during the pandemic. Through this analysis, it was found that the region with the lowest JEE score was Africa at 38.4%, followed by South-East Asia at 47.8% and the Eastern Mediterranean at 58.9%. In contrast, the highest scoring regions were the Americas at 90.1%, Europe at 74.1%, and the Western Pacific at 59%. Overall, the average IHR score worldwide was 50%, with the highest scores in the 'detect' category, followed by prevent and respond. (171). In the EMR countries, which includes KSA, the JEE assessment indicated that capacities ranged from 1 to 4, with a cumulative mean of 3 suggesting that, on average, the country has a relatively good level of capacity (172). Areas of greatest concern included alignment with antimicrobial resistance, biosecurity, and biosafety indicators (173).

In recognition of the above, WHO is actively engaged in assisting countries within the region to implement and enhance their national health information systems. This assistance typically involves conducting thorough assessments of the health information systems, formulating strategies for national health information systems, and enhancing the country's capabilities in areas such as death certification and analysis, International Statistical Classification of Diseases and Related Health Problems (ICD-10) coding, and the utilization of the Digital Health Information Systems System (DHIS) platforms. These efforts are aimed at improving the accuracy and efficiency of routine data reporting, thus enabling improved accessibility and reliability of key data (174).

The WHO's Global Health Estimates (GHE) which provide the latest available data on death and disability globally, by region and country, and by age, sex and cause, track poisoning using standard codes, under the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10). The previous version ICD-10 indicators include X40-X49 for cases of accidental poisoning, X60-X69 for intentional self-poisoning, X85-X90 for assault by chemicals and toxins, and Y10-Y19 for poisoning by undetermined intent. Within each range there are numerous categories and sub-categories, with those for accidental poisoning listed as an example in Table 5-5 (175)

Table 5-5: ICD-10 codes relevant to accidental poisoning

X40		Accidental poisoning by and exposure to nonopioid analgesics, antipyretics and antirheumatics
X41		Accidental poisoning by and exposure to antiepileptic, sedative-hypnotic, anti-parkinsonism, and psychotropic drugs, not elsewhere classified
X42		Accidental poisoning by and exposure to narcotics and hallucinogens, not elsewhere classified
X43		Accidental poisoning by and exposure to other drugs acting on the autonomic nervous system

X44		Accidental poisoning by and exposure to other and unspecified drugs, medicaments and biological substances
X45		Accidental poisoning by and exposure to alcohol
X46		Accidental poisoning by and exposure to organic solvents and halogenated hydrocarbons and their vapors
X47		Accidental poisoning by and exposure to carbon monoxide and other gases and vapors
	X470	Accidental poisoning by and exposure to carbon monoxide from combustion engine exhaust
	X471	Accidental poisoning by and exposure to carbon monoxide from utility gas
	X472	Accidental poisoning by and exposure to carbon monoxide from other domestic fuels
	X473	Accidental poisoning by and exposure to carbon monoxide from other sources
	X474	Accidental poisoning by and exposure to carbon monoxide from unspecified sources
	X478	Accidental poisoning by and exposure to other specified gases and vapors
	X479	Accidental poisoning by and exposure to unspecified gases and vapors
X48		Accidental poisoning by and exposure to pesticides
X49		Accidental poisoning by and exposure to other and unspecified chemicals and noxious substances

In addition to the ICD-10 codes, WHO also considers wider trends for accidental and intentional poisoning such as mortality, disability-adjusted life years, suicide, homicide, and associated risk factors including socioeconomic, demographic, and environmental. WHO uses these indicators to monitor progress, identify high-risk populations, and inform policies and interventions to address the global burden of poisoning and other concerns. This has also been addressed by the SDGs which were adopted by all the UN member states as a universal call to action to end poverty, protect the planet and ensure that all people enjoy peace and prosperity by 2030. Conceptualized in 2012, agreed in 2015, and enacted in 2016, there are 17 SDGs with 169 associated targets (176).

SDG3 is titled ‘Good health and wellbeing’ with the focus on ensuring healthy lives and promoting well-being for individuals of all ages. SDG3 comprises 13 targets, with each target being linked to at least one WHO indicator. With a total of 26 indicators, SDG3 has the largest number of proposed indicators among the 17 SDGs (detailed below in Table 5-6) (177) .

Table 5-6: SDG3 targets for improving health and well-being

3.1	Maternal mortality By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births
3.2	Neonatal and child mortality By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births
3.3	Infectious diseases By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases
3.4	Noncommunicable diseases By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being
3.5	Substance abuse Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol
3.6	Road traffic By 2020, halve the number of global deaths and injuries from road traffic accidents
3.7	Sexual and reproductive health By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and systems.
3.8	Universal health coverage

	Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all
3.9	Environmental health By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination
Resources of implementation for the targets above	
3.A	Tobacco control Strengthen the implementation of the World Health Organization Framework Convention on Tobacco Control in all countries, as appropriate
3.B	Medicines and vaccines Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all
3.C	Health financing and workforce Substantially increase health financing and the recruitment, development, training, and retention of the health workforce in developing countries, especially in least developed countries and small island developing States
3.D	Emergency preparedness Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks

Chapter 6: Conceptual Understanding of Toxicovigilance

6.1 Introduction

Toxicovigilance system and public health surveillance both report, analyze, generate actions, and monitor health risks (Figure 6-1). The toxicovigilance system focuses on toxicological risks, while public health surveillance addresses other emerging notifiable and reportable diseases, including both communicable and non-communicable conditions (23). The process of toxicovigilance signifies a transformation in public health surveillance, providing a more targeted focus on toxicological risks (Table 6-1).

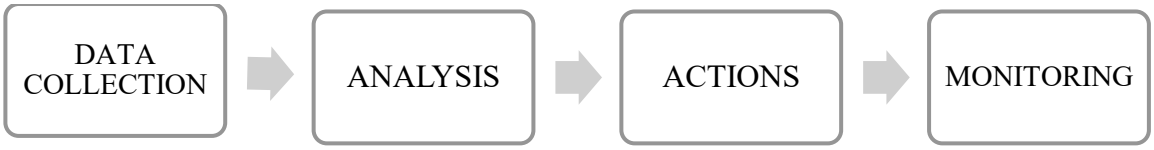

Figure 6-1: Four main basic activities of toxicovigilance

Although there are many other types of surveillance, for example hazardous surveillance, sentinel surveillance, post-marketing surveillance, adverse drug reaction surveillance, and occupational health surveillance, the underlying process remains consistent. These surveillance types and others can be categorized, based on the source of information, into two main approaches: indicator-based and event-based (14).

Table 6-1: Transforming public health surveillance into toxicovigilance system summary

FROM	TO
Reactive	Proactive
Single-hazard	All-hazard
Disease focus	Toxic exposures focus
Single agency	Whole-of-society
Separate responsibility	Shared responsibility of health systems
Response-focus	Risk management focus
Planning for	Planning with

6.1.1 Type of Toxicovigilance Based on Sources of Data

Event-Based Surveillance (EBS) involves the collection, monitoring, evaluation, and analysis of predominantly unstructured information from a wide range of formal and informal sources to detect signals of potential public health threats (178). EBS is not limited to predefined case definitions and does not rely solely on confirmed cases; rather, it captures early signals, reports, and other indications of emerging, unusual, or infrequent events that may represent an acute risk to human health. As such, EBS functions as a core component (not only) of early warning and response systems, enabling the rapid detection of hazards that fall outside routine reporting structures (14).

Indicator-Based Surveillance (IBS) refers to the routine collection and analysis of structured health data guided by predefined indicators, which may align with any national health statistical systems (14). IBS encompasses all structured data organized for the purpose of human health monitoring and risk assessment (14). IBS typically supports the ongoing assessment of trends, burden, and patterns of known health risks across local, national, and international levels (178).Together, EBS and IBS (Table 6-2) (14), provide complementary approaches for detecting and monitoring incidents or hazards that may threaten human health (179).

Table 6-2: Differences between EBS and IBS

Characteristics	EBS	IBS
Objectives	Detect health events that can pose a serious risk to public health and outbreaks	Monitors health trends over time using specific indicators
Scope	Can capture both known and unknown health events affecting humans and animals	Focuses on monitoring of known diseases over longer time periods and can provide more detailed information on trends and patterns
Data Type	Unstructured	Structured
Data sources	• Health providers reports • Nontraditional sources, news media, publicly accessible social media, and other online sources	• Relies on routine collection of data based on predefined health indicators (e.g., incidence rates, vaccination coverage)
Outputs	Early warning signals of new emerging and re-emerging threats to public health	Indicators or measures related to health issue
Examples (not exhaustive)	• Metal Toxicity • Food Poisoning -Botulism • Chemical, Biological, Radiological and Nuclear Events • Illicit drug cases • Occupational health events • Hazardous events • Post-Marketing • Adverse Drug Reactions • Emerging and re-emerging diseases like COVID-19 epidemics	• Syndromic surveillance • Health Registries • Laboratory data • Epidemiological surveillance • Sentinel events surveillance • Surveys and research studies

Statistical Calculation	Mainly Qualitative, often involving real-time reporting and alerts	Mainly Quantitative, using statistical methods to analyze trends and patterns, for example: To analyze (Hourly call volume) = Baseline + 3 SD* anomaly
Timeframe	Short-term; focuses on immediate events	Long-term; assesses trends over extended periods
Disadvantage	• Need more investigations to complete one case which can lead to delay in detection of public health threats	• It may not capture all relevant data, leading to incomplete or biased information • Structured not adaptable

*Baseline: This is the average call volume during a typical period (e.g., the average number of calls per hour over a defined timeframe).
*SD (Standard Deviation): This measures the amount of variation or dispersion in the call volume data Baseline + 3 SD: This means that if the call volume exceeds the baseline by three standard deviations, it is considered an anomaly. This threshold is often used to identify significant increases in call volume, which might indicate a public health event (e.g., disease outbreak) (92).

Another type of data that is important to mention here is reportable and notifiable disease data. In the US, for instance, the National Notifiable Diseases Surveillance System (NNDSS), operated by the CDC, provides a national framework for the surveillance of notifiable and reportable diseases. Under NNDSS, notifiable diseases are those for which data are voluntarily reported by state and territorial health authorities to the CDC when predefined criteria, such as severity, transmissibility, or public health importance, are met (180). Whereas reportable diseases require mandatory notification (180). The CDC monitors hundreds of notifiable and reportable conditions at the national level, and the list is updated annually as surveillance priorities evolve (181). Each U.S. state establishes its own regulations and procedures specifying which diseases and conditions must be reported and the timelines for reporting. The distinctions between notifiable and reportable diseases are summarized in Table 6-3 (181).

Table 6-3: Reportable and notifiable disease differences

Reportable Diseases and Conditions	Notifiable Diseases and Conditions
Each region or territory sets local laws and rules for which diseases and conditions must be reported	The Council of each region and territorial epidemiologists identify the list of notifiable diseases
Healthcare professionals, laboratories, and other providers must inform public health departments when a person is diagnosed	Regions voluntarily inform public health departments when a person meets certain criteria to become a case
Public health departments collect information about the person and how they became ill	Case records do not contain personally identifiable information
This information is used to locate the source of an outbreak and prevent spread	Public health departments use data to monitor, measure, and alert individual communities or the nation to outbreaks and other public health threats

In KSA, a comparable legal foundation for NNDSS exists. Under the Law of Practicing Healthcare Professions (Article 11 of the Health Profession Regulation): *the Minister of Health is authorized to designate diseases that must be reported, the authorities to be notified, and the procedures to be followed. Accordingly, healthcare practitioners are legally required to notify health authorities when they examine a patient suspected of having a designated infectious disease* (182). In line with this mandate, the MoH requires healthcare practitioners and laboratory service providers to report and notify specified diseases to the PHA. The list of MoH notifiable and reportable diseases can be found in Appendix 4.

In summary, this law can serve as a formal, legally grounded mandate for reporting in establishing the proposed SNTESS, particularly since the MoH has listed some toxicology-related events under its notifiable and reportable diseases list. Hence, the MoH uses the terms reportable and notifiable diseases interchangeably, which is acceptable because notifiable diseases can include reportable diseases but may also encompass

conditions that require reporting and monitoring for surveillance purposes, even if reporting is not legally mandated. Moreover, SNTESS proposes to include both IBS and EBS as sources of data because both sources can include toxicology-related events

6.1.2 Type of Toxicovigilance Based on Reporting Approaches (Passive/Active)

Passive and active surveillance represent operational approaches in reporting data that can be applied within IBS and EBS. Passive reporting refers to routine reporting in which data are generated through regular clinical, laboratory, or administrative processes and subsequently submitted for public health purposes (183). However, passive reporting is vulnerable to underreporting, inconsistent case definitions, fragmented data sources, reporting delays, and selection bias, and registries may be slow to update and resource-intensive to maintain (184).

Active reporting, by contrast, involves the deliberate and proactive collection of data from predefined sources, populations, or sites for specific public health objectives (183). A common example of how a single surveillance type can incorporate different operational approaches is sentinel surveillance (185). Although sentinel surveillance is primarily classified as IBS, it may operate through both passive and active data collection. In this model, selected healthcare providers, clinics, or hospitals are designated to systematically report predefined health events. Such systems can provide timely and sensitive detection of trends and emerging risks, particularly in high-risk populations or for conditions requiring early warning, such as influenza or acute flaccid paralysis. However, because sentinel systems intentionally focus on specific subsets of the population, their findings may not be representative of the general population and must therefore be interpreted within the context of their design and whether the data were passively reported or actively collected, particularly during specific events or outbreaks.

In summary, these reporting approaches are explained to emphasize that, within the proposed framework of SNTESS, both reporting approaches are mandatory and complementary to each other. If a toxicological incident is reported, all relevant data sources and types of exposure—whether reported passively or actively, and whether

occurring as single cases or outbreak events—should be considered. The MoH Notifiable and Reportable Disease list and its categories should serve as the framework guiding reporting mandates. This reporting taxonomy is described in Figure 6-2.

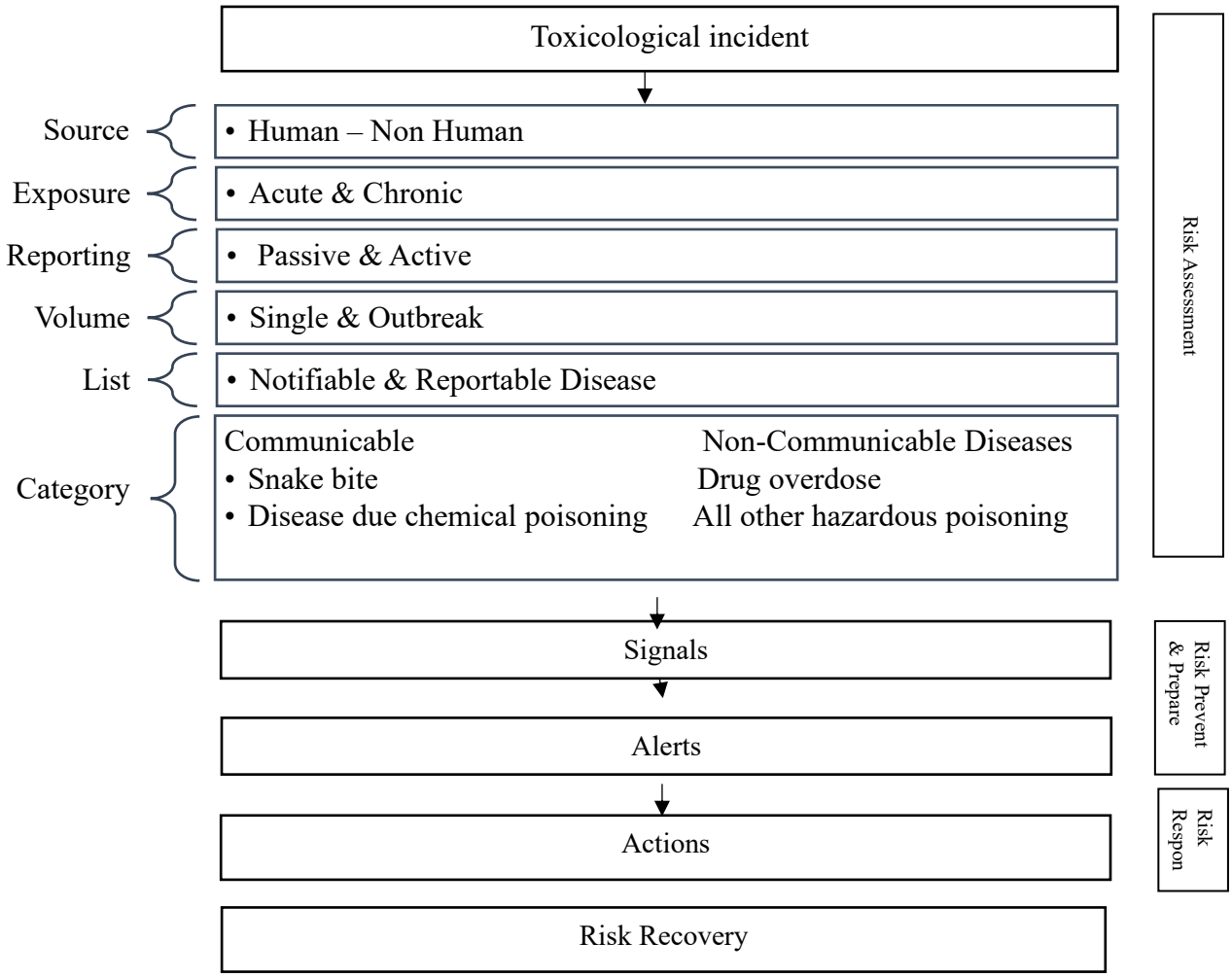

Figure 6-2: Summary of operational models within Toxicovigilance

6.1.3 Type of Toxicovigilance Based on Risk Management Framework

Risk assessment is crucial for analyzing emerging events and for strengthening national resilience. It determines how well countries can resist, absorb, respond to, and recover from shocks, and adapt to changing conditions in both the short and long term (158). The risk management framework comprises five interconnected phases (The resilience cycle): risk anticipation and assessment, prevention, preparation, response, and recovery (Figure 6-3). Each phase requires distinct management approaches tailored to its specific objectives.

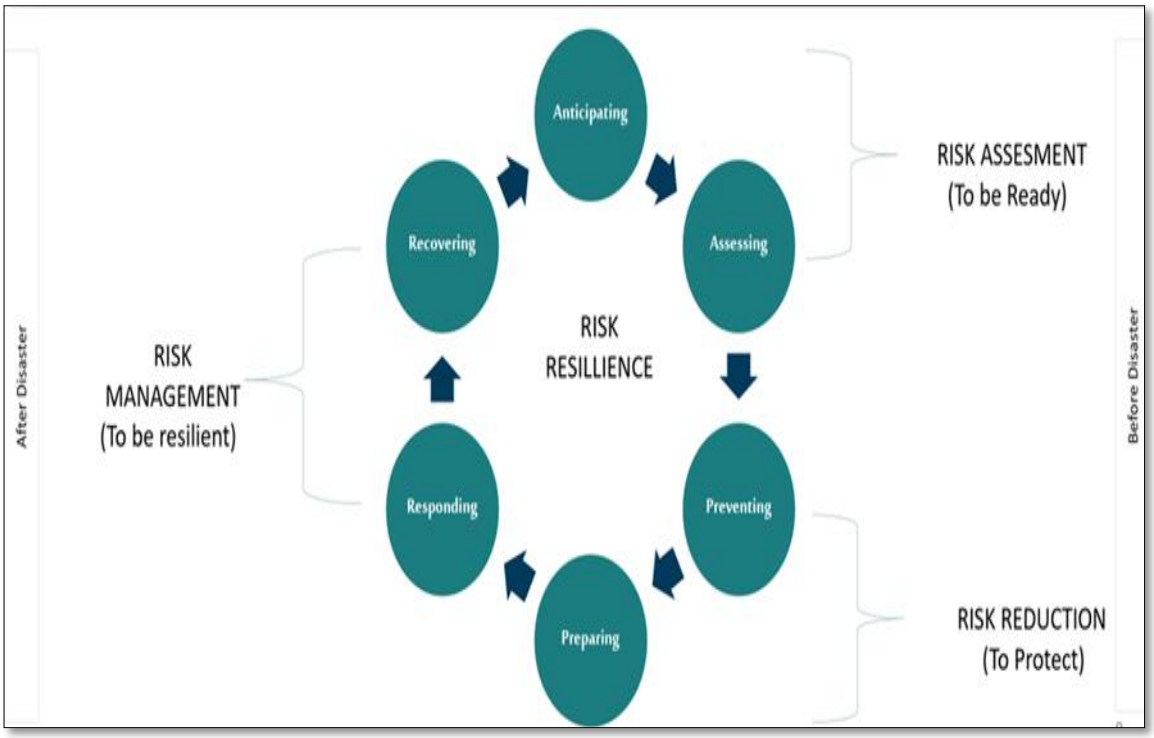

Figure 6-3: The resilience cycle

6.1.3.1 Risk Assessment

In toxicovigilance, risk assessment extends beyond conventional monitoring to include preparedness and response to hazardous materials. This process involves identifying potentially toxic substances, developing appropriate response protocols, and enabling timely interventions to manage risks associated with new or emerging hazardous materials

(186). Moreover, risk assessment relies on the same operational modules used for reporting and classifying data sources described above.

At a broader level, the assessment of toxicological risks is referred to as the "all-hazards approach" to risk assessment (187). At a more specific level, it is described as "risk assessment under toxicovigilance" (25). Essentially, this process supports risk management efforts aimed at reducing the incidence of poisoning and effectively managing both emerging and known toxicological risks (Table 6-4) (188).

Table 6-4: Examples of toxicological risks

Environmental factors such as air quality
New psychoactive substances
Gas leakage
Deaths related to poisoning

Risk Assessment method

The use of a risk matrix is a suitable method for risk assessment due to its ability to clearly visualize the relationship between the likelihood and impact of toxicological risks. It also enables structured prioritization of risks, which is essential in resource-limited settings, by identifying substances or exposure scenarios that pose the greatest threat to public health. The risk matrix integrates qualitative expert judgment with quantitative exposure data, supports stakeholder engagement through a shared and easily understood framework, and can be readily adapted to emerging chemicals and evolving exposure scenarios (115).

The methodology described below draws on established best practices in public-health risk assessment, supplemented by applied experience in national risk management within the Saudi context:

1. The first step is identifying risks, by studying the history of the risks most likely to arise (what may happen in the future is what has happened in the past).

2. Then, for each risk thought likely to arise, a risk scenario is formulated. This process typically involves distributing a questionnaire to risk owners, who in return provide their responses as 'Outcome Statement" (Table 6-5).

Table 6-5: Example of questionnaire and outcome statement

Question	Outcome Statement
What is the objective, approach, and scope of the risk assessment?	A clear idea of the objective and scope of the assessment, the resources available and the approach to be followed
What is the risk management goal and the acceptable degree of uncertainty?	A clear vision of what is needed to achieve the risk management goal
For this risk, who are the collaborating entities to your organization?	A clear list of collaborating entities and their roles in handling this risk
How often has this risk happened in the past?	A clear statement about the number of times that this risk occurred with description of the related circumstances like time of the year, pre or post incident summary
What is the strategic plan for mitigation of this risk?	A clear statement about the plan including response, prevent and prepare measures

3. After the risk scenario, a risk matrix will be created based on the risk score (A 3x3 matrix with coded risks plotted according to impact and likelihood) (Figure 6-4) (189). The choice between a 3x3 and a 5x5 risk matrix depends on the specific needs of the organization, the complexity and the level of detail provided by stakeholders for risk assessment of the risks being assessed. A 3x3 matrix may suffice for preliminary assessments, whilst a 5x5 matrix is better suited for detailed and intricate risk evaluations. Therefore, the 3x3 risk matrix is the best and the most used in public health risk assessment (190), and is therefore proposed for use within the SNTESS toxicovigilance framework:

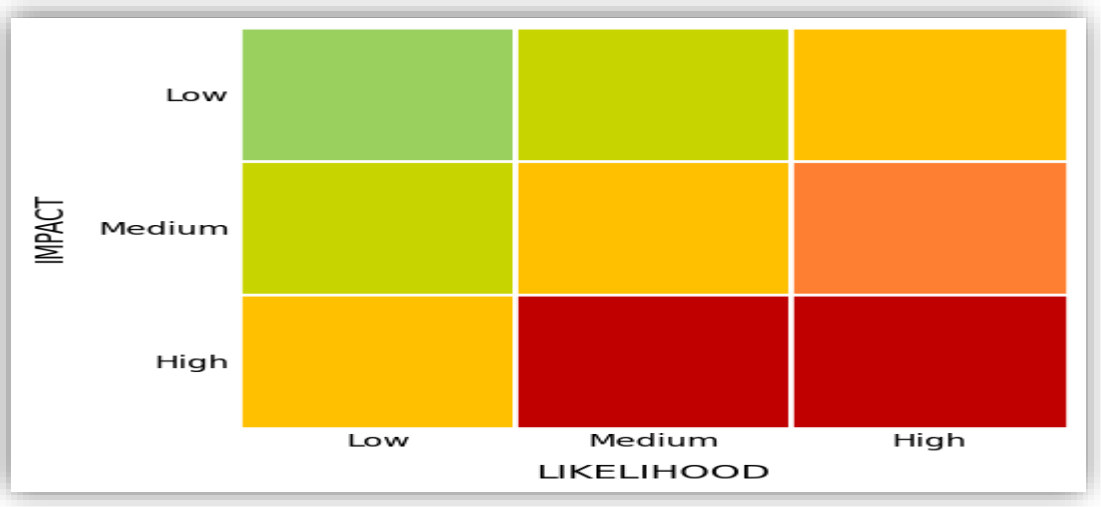

Figure 6-4: Example of a 3x3 risk matrix

4. To place risks in the risk matrix we need first to calculate risk score (Figure 6-5). Risk score is the relative impact of each risk scenario, and the likelihood of the scenario happening and they are estimated as the following:

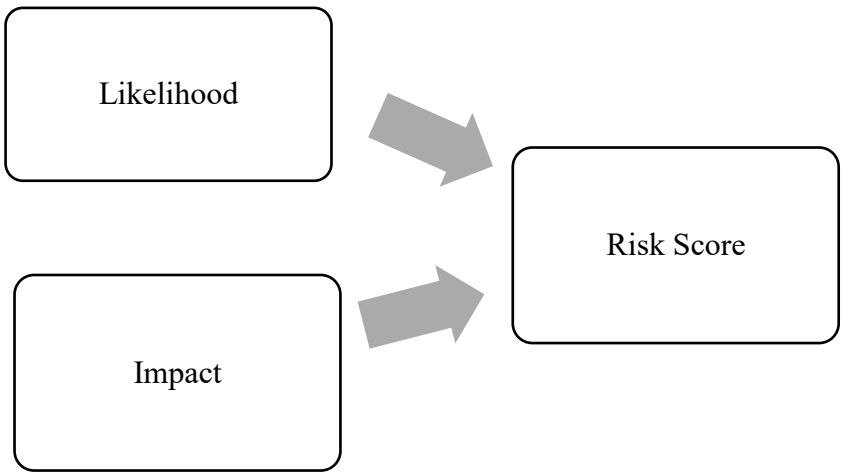

Figure 6-5: Summary of the risk score method

- The likelihood of a risk is estimated by:
  - There are three levels of likelihood (low, medium, or high) (Table 6-6) (191).
  - Finding out how often this kind of scenario has been seen in the recent past.
  - Considering known factors that would increase or decrease the likelihood of the scenario.
  - Considering expert opinion.
  - Considering any preventive measures.

Table 6-6: Description of the likelihood of a risk

Low Likelihood	Medium Likelihood	High Likelihood
Not likely to occur in the next 6 months season	May occur in the next 6 months	More likely than not to occur in the next 6 months
There are very few reliable indicators that the event will occur	Some background factors increase the likelihood of the event occurring	Several background factors increase the likelihood of the event occurring
No significant background factors increasing the likelihood	Some reliable indicators (including expert opinion) that the event will occur, but some counter indicators	There are reliable indicators (including expert opinion) that the event will occur
Measures in place are likely to prevent the event from occurring	Measures in place may reduce the impact but are unlikely to prevent the event from occurring	Measures in place may not reduce the impact and are unlikely to prevent the event from occurring

The impact of a risk is estimated by:

- There are three levels of impact (Table 6-7) (191). It is called impact score
- To calculate the impact score, the severity should be estimated by %, it is called severity score.
- Severity score: measure the impact of the hazard across five domains:

I. Human Health: Metrics include mortality rates, emergency medical service transports, and emergency department visits.

II. Health Care Services: Assess the supply and demand for outpatient services, hospital beds, and mental health services.

III. Inpatient Health Care Facility Infrastructure: Consider factors like personnel availability, facility utilities (water, electricity), and patient care capabilities.

IV. Community Impact: Evaluate disruptions in water supply, sanitation, public utilities, and population displacement.

V. Public Health Service readiness: Analyze personnel availability, surveillance needs, and mass care requirements.

Table 6-7: Impact score estimation

Severity score	Impact Score 1	Impact Score 2	Impact Score 3
Human Health Impact	Minimal Impact – Little to no change from the baseline (e.g., 0-5% change)	Moderate Impact – Noticeable change but manageable (e.g., 6-20% change)	Significant Impact – Major change that disrupts normal operations (e.g., more than 21 % change)
Health Care Service Impact			
Inpatient Health Care			
Facility Infrastructure			

As the relative likelihood and impact of risks become clearer during the process, the risks can be ranked, allowing low-ranking risks to be moved to a 'reserve risk' list (190). The main risks that warrant attention from senior individuals (ministers) will be ranked in the top 6, while remaining risks will be under inspection for any changes during the quarterly review of the risk matrix.

5. Risk Cards (Appendix 5) will be created to record information on each risk based on the responses to the questionnaire. Each risk will be assigned a specific code to facilitate the creation of the Risk Register (191).

6.1.3.2 Risk Prevent & Prepare

Risk prevention, also referred to as risk minimization, includes actions aimed at preventing or reducing the probability and severity of harm associated with exposure to health products, consumer products, or environmental agents (22). The prevent and prepare phase is a continuous process that runs in parallel with risk assessment and focuses on ensuring the effectiveness of mitigation measures. Increasing public and governmental awareness is a critical component of risk prevention, as awareness programs strengthen community resilience by promoting risk-aware behaviors and empowering individuals and organizations to take proactive protective actions (192).

Within the toxicovigilance framework, PCCs serve as the primary operational mechanism through which these prevention and preparedness functions are delivered. This includes delivering education and advice to the public and healthcare professionals, collaborating with stakeholders to improve product safety and restrict access to hazardous substances, and strengthening coordination among toxicology services, regulatory bodies, and research organizations to implement effective preventive measures (193).

6.1.3.3 Risk Response

Risk response focuses on managing identified risks through the implementation of actions aimed at reducing their likelihood or severity, while considering scientific, economic, social, cultural, ethical, political, and legal factors (22). Effective risk response relies on multidisciplinary health risk management strategies involving toxicologists, epidemiologists, regulatory authorities, and public health practitioners to identify causal agents, exposure sources, affected populations, and appropriate mitigation measures, thereby enabling timely and effective interventions (120). National disaster response planning is a critical component of preparedness, encompassing natural, technological, and human-caused disasters, and enabling coordinated, scalable, and flexible responses to protect population safety and resilience (194). In KSA, emergency response is coordinated through a Lead Government Ministry working with the national command center, with roles potentially shifting between response and recovery phases depending on the nature and scale of the emergency, requiring careful coordination to ensure continuity and effectiveness (195).

Emergency response operates across escalating levels of severity, ranging from localized incidents requiring limited central involvement to large-scale emergencies necessitating full central government direction, with flexibility, simplicity, and integration of lessons learned being essential for effective management (110), (196), (197). Emergency responders and physicians play a critical role in monitoring and surveillance, prioritizing time-sensitive interventions, early risk assessment, and coordinated care supported by regional toxicology networks to optimize patient outcomes and resource use (188). Effective risk response is further dependent on timely, transparent, and two-way risk communication to ensure accurate information exchange among authorities, responders, and the public, thereby supporting trust and effective emergency management (193).

6.1.3.4 Risk Recovery

The recovery phase begins once a toxic exposure event is stabilized and focuses on rebuilding, restoring, and rehabilitating affected communities. Transition from response to recovery depends on the nature of the event and is guided by situation reports that provide evidence for shifting coordination and ensuring sustained support for affected populations (198).

Recovery from chemical or nuclear exposures is a critical stage in toxicovigilance and frequently leads to long-term health programs and policy reform. The Bhopal gas tragedy illustrates the importance of comprehensive recovery efforts, where immediate medical response was followed by long-term healthcare, compensation mechanisms, environmental remediation, community rehabilitation, and strengthened industrial safety regulations, highlighting the need for integrated recovery strategies addressing health, legal, environmental, and regulatory dimensions (199).

6.2 Conclusion

This chapter established a conceptual and operational foundation for toxicovigilance, covering EBS and IBS as complementary data frameworks, passive and active reporting approaches, and the risk management cycle encompassing assessment, prevention, preparedness, response, and recovery. Together, these components underscore the need for a nationally coordinated toxicovigilance system capable of integrating diverse data sources and responding to both known and emerging toxicological risks. This foundation directly informs the design of the proposed SNTESS framework, presented in the following chapter.

Chapter 7: Establishing a Saudi National Toxic Exposure Surveillance System (SNTESS): A Proposed Framework

7.1 Introduction

Drawing upon international toxicovigilance experience and informed by identified national system gaps, this chapter presents the proposed SNTESS. The framework is strategically aligned with relevant international standards and emergency management models to address documented deficiencies in surveillance integration, responsiveness, and national coordination (Figure 7-1).

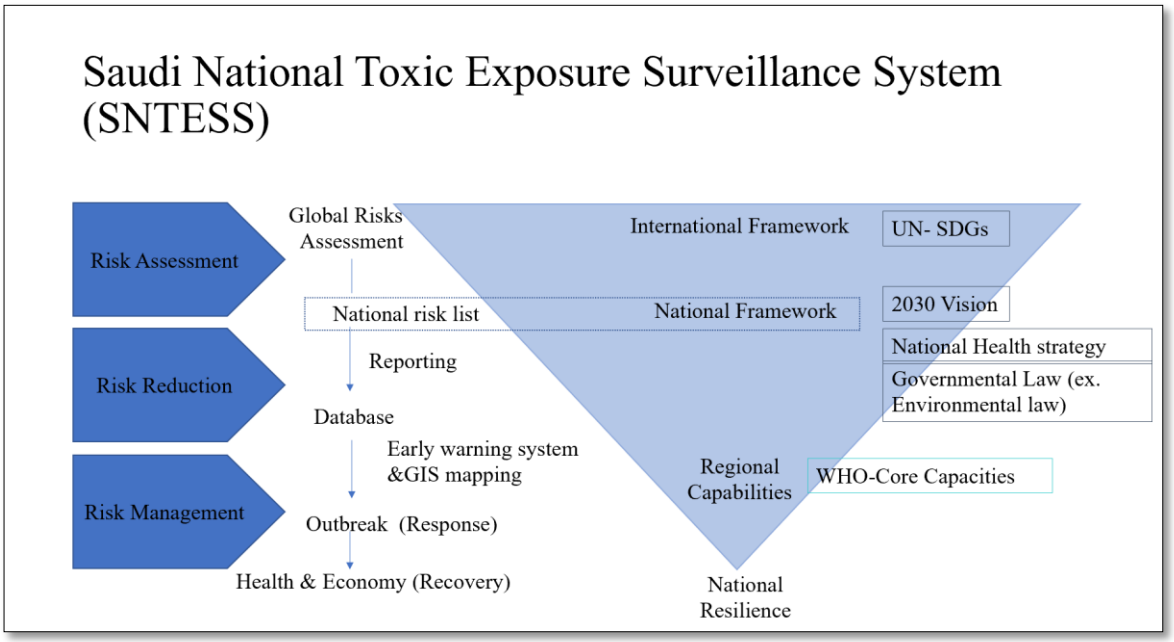

Figure7-1: Strategic framework for SNTESS

7.2 Objectives of the Framework

1. To create a nationally coordinated toxicovigilance system that incorporates KSA's current regulatory, surveillance, and poison control infrastructure.
2. To use evidence-based procedures and unified case definitions to standardize the identification, reporting, and categorization of toxic exposure cases.
3. To improve early warning and quick response capabilities by using GIS mapping, predictive analytics, and real-time surveillance tools.
4. To improve the nation's toxicology workforce by implementing the SNTESS operational model's defined professional roles, credentialing, and organized training.
5. To lower the morbidity and mortality associated with poisoning by promoting prompt clinical intervention, methodical case follow-up, and outcome monitoring.
6. To coordinate national toxicovigilance initiatives with national priorities like Vision 2030 and the National Health Strategy, as well as international frameworks like the UN Sustainable Development Goals (SDGs) and WHO core capacities.
7. To produce actionable epidemiological intelligence by publishing national toxic exposure reports, dashboard reporting, and routine data analysis.
8. To encourage multi-sectoral cooperation between the PHA, MoH, academic institutions, regulatory agencies, and regional health authorities to advance a whole-of-society approach. Specify governance and roles across national stakeholders (who does what, when, and how).

7.3 Methods and Rationale for the Framework Development

The proposed SNTESS framework is developed using a requirements-driven design informed by two primary analytical foundations (Table 7-1):

- Gap analysis findings done in Chapter 4, which identified key systemic deficiencies, including fragmentation, delayed reporting, absence of 24/7 validation, inconsistent coding practices, limited interoperability, and the lack of unified national outputs.

- Evidence synthesis from best practices in other countries done in Chapter 5.

Table 7-1: Gap-to-solution framework for SNTESS

Gap Analysis (Ch4)	SNTESS Design and Operationalization (Best-practice–based solution and how it is implemented from Ch 5)	Lead / Accountable Body	Output / Deliverable
Fragmented PCC services, unclear PCC scope and definition, no national integration, lack of 24/7 clinical validation and systematic follow up	Establishment of a national PCC by the implementation of a hub-and-spoke PCC, defining escalation pathways, and establishing a continuous SPI workflow with toxicologist oversight	PHA + MoH+ National PCC	Unified national PCC network; standardized operating model
Unknown national toxicologists and SPIs capacity	Implementation of a national toxicology workforce by the development and credentialing toxicology training programs, formalizing SPI roles, and integrating toxicology consultation pathways into SNTESS	MoH + Academic partners + National PCC	Sustainable toxicology workforce, improved care, and surveillance capacity
Reporting is slow, paper-based, multi-stage, and not near real time; limited EHR interoperability	Introduction of an electronic system to capture toxicology cases from all sources to enable near real-time reporting by digitizing reporting processes, integrating ED and hotline forms, and implementing automated alert thresholds	MoH + National PCC	Faster reporting, reduced data loss, and improved timeliness
Hotline 937 is not poison-dedicated; weak linkage to	Establishing a dedicated poison helpline by the integration to the national PCC	MoH + National PCC	24/7 validated poison cases,

registries; data not validated or positioned as providing national coverage			and national coverage
HESN is a disease focused reporting system, not fit for toxic exposures, partial adoption and limited training	Adding a dedicated toxic exposure module for reporting by the integration with other similar surveillance systems	MoH + PHA	Functional toxic exposure reporting within national infrastructure
Laboratory systems capture specimens rather than cases, non-tested exposures excluded	Enabling lab-to-case linkage by expanding laboratory systems (e.g. OTARR) to capture exposure cases, and assigning unique case identifiers	National PCC + Laboratory Network	Complete case records, and strengthened agent identification
Data duplication across MoH, SFDA, and other platforms	Implementing a national data governance framework through MOUs and SLAs that define data ownership and sharing responsibilities	PHA	Reduced duplication; single source of truth
Absence of routine national toxicovigilance outputs from various resources (e.g. RASID)	Establish a dedicated analytics and reporting function within SNTESS by developing dashboards and publishing monthly bulletins and an annual national toxic exposure report	National PCC + PHA	Actionable intelligence; system accountability
Limited early warning signals, weak detection of outbreaks and CBRN-related signals	Deployment of an EWRS with defined thresholds and escalation pathways by applying predictive analytics across all data sources	National PCC + PHA	Early detection alerts; faster public health response

7.4 Result: The SNTESS Framework

Based on the findings presented in the previous table, the proposed framework suggests that SNTESS operates through a hub-and-spoke model (see Appendix 6 the Toxicovigilance Brochure). This can be achieved by prioritizing integration of existing assets (e.g., existing PCCs, hotline services, laboratory outputs, and regulatory signals) through a phased implementation pathway explained in upcoming section.

To operationalize this framework, several interconnected components must first be established. These components are organized into four categories: foundational components, encompassing governance and scope; operational components, including case definition, framework requirements, and the implementation pathway; management components, comprising data management and performance management; and finally, an application component addressing the role of SNTESS in public health emergencies. Each category builds upon the preceding one, forming a coherent and progressive framework for national toxicovigilance.

7.4.1 Identifying Governance

The first step in developing the framework is identifying stakeholders and their roles. Good governance generally has three main components: policy, procedures, and compliance. They work in a complementary manner to define the "what," the "how," and the "why" that guide the operations and decision-making within an organization, promoting transparency, accountability, and the achievement of desired outcomes (200).

According to the Saudi Council of Ministers Cabinet Resolution No. 200 dated 6/19/1424 AH about the Organization of PHA and its duties, stated that "*The authority aims to protect and promote public health, prevent exposure to diseases (communicable and non-communicable), raise public preparedness to respond to public health emergencies, and organize efforts among relevant authorities, in accordance with the relevant regulatory*

texts". Accordingly, public health surveillance can be achieved by including a registry for diseases communicable and non-communicable, investigating risk and toxicological events, studying the perceived health burden and managing them at the national, regional, and international levels (201). Therefore, it is concluded that the proposed SNTESS is within the responsibility of the PHA. In this regard, the *KSA Public Health Surveillance Technical Guidelines* published by the MoH was used as backbone reference in the implementation pathway below (202).

7.4.2 Identifying Scope

The scope of SNTESS encompasses several critical areas related to toxic substances, including all possible toxins: medications, toxic plants, venomous exposures, food poisoning, as well as mass poisoning and disaster responses. These areas were chosen because they provide valuable data on human exposure (Table 7-2) (22), (193), (203).

Table 7-2: Some of the most valuable human exposure data (what we need to survey in the SNTESS)

Valuable human exposure data	**Examples**
Therapeutic and health products	Pharmaceuticals, Natural Health Products
Consumer products	Detergent, Electronic Cigarettes
Pesticides	Insecticides, Herbicides, Fungicides, And Rodenticides (Insecticides like Organophosphates)
Controlled substances	Opioids, Illicit Drugs
Environmental, occupational / industrial exposures	CO, Toxic Metals
Marine Toxins	Cnidaria phylum (jellyfish), Mollusca (octopus, squid, and snails), and Echinodermata (sea stars, urchins)

Food	Foodborne illness (such as foodborne botulism)
Substances of concern for intentional harm	Substances used in criminal acts and terrorism (such as Chlorine Gas)
Mass poisoning	CBRN exposures

Finally, the foundational toxicological principle, 'The dose makes the poison,' means that almost any substance ingested in large quantities can be toxic (193). Therefore, risk assessment of potential hazards of various substances is crucial for effective monitoring.

7.4.3 Case Definition

Developing effective case definitions is a crucial step in establishing SNTESS framework. Below are the key steps for creating a robust case definition (202):

1. Articulating the purpose and focus of the surveillance system: Determine whether it will target specific types of toxic exposures (e.g., chemical spills, environmental contamination) or have a broader scope.
2. Identifying relevant exposure pathways: Thoroughly examine the potential routes of toxic exposure, such as inhalation, ingestion, or dermal contact.
3. Establishing clinical criteria: Determine the specific signs, symptoms, and health effects that would indicate a potential toxic exposure case. This may involve consulting with medical experts and reviewing existing literature on the known health impacts of various toxins.
4. Determining the case definition level: The case definition level can be defined as follows (202):
    - **Confirmed:** Cases with definitive evidence of exposure and corresponding clinical symptoms. It is based on clinical and epidemiological information.
    - **Probable:** Cases with high likelihood based on clinical symptoms and exposure history but lacking laboratory confirmation. It is based on clinical and epidemiological information.

- **Possible:** Cases with some evidence of exposure and clinical symptoms but not enough to meet the criteria for confirmed or probable. It is based on clinical information only.

5. Case Detection: All cases in the SNTESS should be detected as "exposure cases" rather than "calls" because a single call can involve multiple cases (203). A case is considered closed when no further follow-up or recommendations are necessary, or when no additional information is available. To ensure the most accurate medical outcomes and data integrity, all cases are followed up systematically (202). Most cases are closed within a few hours of the initial contact to the PCC; however, complex cases—such as those involving hospitalized patients or fatalities—may remain open for months while data are collected to ensure data integrity and the most accurate recording of medical outcomes (203).

7.4.4 Identifying Framework Requirements

First, data sources: It is essential to integrate the various data resources in KSA identified in Chapter 4 together to ensure comprehensive national coverage. Collaboration with PCCs provides crucial insights into case management and treatment outcomes (204).

Second, national PCC: It is essential to integrate all existing PCCs and/or designate one national center. Standard operating criteria for a national PCC are outlined in Appendix 7, based on the self-assessment checklist for minimum and optimum standards prepared by the Working Group on Quality & Accreditation of Poisons Centers of the European Association of Poisons Centers and Clinical Toxicologists (EAPCCT) in 2011, as well as the AAPCC accreditation criteria of PCCs (29), (205).

Third, personnel: It includes public health specialists, epidemiologists, and toxicologists. Since SNTESS relies heavily on PCC staff, a comprehensive review of their roles is provided below.

PCC personnel include trained SPIs, medical toxicologists, and medical secretaries, all of whom are trained to provide rapid risk assessment, clinical guidance, education, and research support. Adequate staffing levels, continuous training, and effective workload planning are essential to ensure sustained coverage, particularly during periods of peak demand and regional surges (10), (87). Training programs for PCC specialists and public health surveillance professionals vary significantly in their focus areas, skill sets, practical experiences, and objectives. Training for poison control specialists emphasizes toxicology, clinical assessment, emergency response, pharmacology, communication, case management, and regulatory knowledge. This training includes classroom instruction, simulations, clinical rotations, and certification courses. See Appendix 8 for an example of the SPI training curriculum.

In contrast, public health surveillance training focuses on epidemiology, data collection and analysis, biostatistics, informatics, public health policy, communication, and outbreak investigation. This program involves academic coursework, workshops, field training, simulation exercises, and continuing education. As a result, PCC specialists acquire clinical and emergency response skills, while public health professionals develop expertise in data analysis and statistics. These training differences ensure that each role is adequately prepared to tackle specific health threats, highlighting the significance of specialized education in enhancing public health outcomes.

Assessing calls to PCCs can be one of the most challenging tasks due to the nature of the calls, whether they involve exposure incidents or requests for information. Additional factors include whether the call is from a member of the public (the patient or caregiver) or from emergency rooms versus other healthcare facilities. All these elements influence the type of assistance provided. SPIs are typically well-trained to handle each situation appropriately, following established call protocols and etiquette. In contrast, there are also crisis calls, where the caller may be seeking help or information related to suicidal intentions. SPIs also have very important role in conducting awareness campaigns and developing educational materials for the public (Appendix 9).

Fourth, clinical guidelines and protocols: As previously described, the PCC is one of the critical components of SNTESS framework. PCC staff must receive structured training based on established best practices, an example of which is provided in Table 7-3.

Table 7-3: Sample guiding questions for handling a poison case call

Greetings, this is the poison control center. How can I help you?
What is your name and the name of the person who was poisoned?
What phone number can we use to reach you for follow-up?
What is the age and weight of the person who was poisoned?
Do you know any information about the person's medical history?
What product, medication, or poison was the person exposed to?
At what time did the exposure or ingestion occur?
How does the person look now?
Describe any physical symptoms the person may be experiencing?
How long was the person in contact with the poisonous substance?
Was it swallowed, inhaled, absorbed through skin contact, or splashed into the eye?
How much could he/she have ingested? Was anything done for the person before the poison control center was called?
How did the exposure occur?

Moreover, PCCs must establish clear clinical guidelines and standardized protocols to ensure that staff respond consistently, safely, and in accordance with evidence-based practice across all toxicological scenarios, as exemplified in Table 7-4 (197). While workforce shortages, training gaps, and legal liability remain ongoing challenges, adherence to these guidelines is essential to sustaining the PCC's role in toxicovigilance and emergency response. To develop and maintain a skilled workforce, training should be tailored to professional roles: medical and nursing students require grounding in toxicology and therapeutic management, while pharmacy students should focus on pharmacokinetics, dosing strategies, and clinical toxicology principles. Appendix 10

presents Out-Of-Hospital Management cards as an example of pharmacist training material.

Table 7-4: Example protocol for escalating poison cases to a senior specialist or medical toxicologist based on the AAPCC

Senior Specialist	**Medical Toxicologist**
Calcium Channel Blockers Beta blockers Antidepressants Flecainide Opioids and Narcotic pain medications Antidiabetic (Sulfonylureas) Camphor Topical Blood Pressure Patches, Eye Drops, and Nasal Sprays (Clonidine and imidazolines) Antimalaria Salicylates Patient is vitally not stable Patients/ caller asked to speak with senior staff	Carbon Monoxide Hypothermia, Acidosis, Seizure Theophylline Cyanide Organophosphates Snake bites Iron Toxic Alcohols (ethylene glycol, methanol, isopropyl alcohol, and acetone) Corrosive Patient is vitally not stable, with major findings like arrhythmia, seizure pregnant women with toxic ingestion

Fifth, equipment and software programs: Achieving the required quality for the conduct of toxicovigilance processes and their outcomes is also intrinsically linked with appropriate facilities and equipment used to support the processes. Equipment like: toll free telephone lines with answering machine/voice mail recorder, fax machine, printer, photocopy machine, and scanner. Soundproof workstations with fully equipped computer terminals. They should be located, designed, constructed, adapted, and maintained to suit their intended purpose in line with the quality objectives for toxicovigilance. On the other hand there are software programs (systems) that are essential to operate the SNTESS (Table 7-5) (30), (120).

Table 7-5: Summary of systems needed to operate SNTESS

Case-log in system (case management system)
Electronic reporting system
Laboratory information system
Inventory management system
Product coding system
Internal communication system
GIS mapping system
Early warning /alert system
Data management system
Business intelligence system

For case management systems, there are many options available, but the most used ones in this field are Epi Info™ and Case Management Solutions by Microsoft. Epi Info™ is a free public domain suite of interoperable software tools designed for the global community of public health practitioners and researchers. Developed and maintained by the CDC. It provides easy data entry form and database construction, customized data entry experience, and data analyses with epidemiologic statistics, maps, and graphs. It is used for outbreak investigations, developing disease surveillance systems, as analysis and reporting components of larger systems, and in epidemiology education at schools of public health worldwide. It is compatible in multiple platforms - for Windows, Mobile, and Web & Cloud - catering to the diverse needs of public health professionals, from small-scale field studies to large-scale surveillance activities, and is freely downloadable and accessible (206). Since 1998, Epi Info has been downloaded approximately 2,000,000 times from the CDC website, reaching 180 of the 193 countries worldwide. Although there has not been a comprehensive international survey on its usage, Epi Info serves as the core surveillance systems in 27 African countries and 8 provinces in Kenya. Additionally, an Epi Info system for Acute Flaccid Paralysis (potential poliomyelitis) surveillance in India operates in 300 districts, covering 25% of the country's population (206).

While Case Management Solutions by Microsoft refer to tools and software designed to help organizations systematically manage and track individual cases or incidents, these solutions are often part of Microsoft 365 or Dynamics 365. They include various features to enhance productivity and collaboration; therefore, they are not considered free, as organizations globally must have a subscription to access Microsoft features (207).

On the other hand, there are four commercially available software programs for collecting toxicology data in the US, designed specifically for use by PCCs. These solutions are commercially licensed and must be purchased. They can be used outside US with the necessary integration and with more specialized tools for data analysis. These software programs include (30):

DotLab®: A comprehensive laboratory information management system designed for toxicology, facilitating data entry, tracking, and reporting of laboratory results to improve efficiency and accuracy in toxicological analysis. And in some PCCs it is used as the case management system.

CasePro®: A case management software tailored for PCCs, allowing for streamlined documentation, tracking of patient cases, and reporting of outcomes to enhance the management of poisoning incidents.

ToxiCALL®: A case management software specifically designed for PCCs, enabling rapid response and consultation for poisoning cases, ensuring timely and accurate information exchange between healthcare professionals and experts.

ToxSentry®: A case management software monitors and analyzes data related to toxic exposures, providing real-time insights and alerts to public health officials, thereby enhancing the capacity for effective toxicovigilance and response strategies.

7.4.5 The Implementation Pathway

The following subsections outline how SNTESS can be implemented, in alignment with the gap-to-solution analysis presented earlier in this chapter. Figure 7-2 provides a clear visual representation it its implementation steps:

Step 1 — Indicator-Based Surveillance: Harmonization protocols for data collection, analysis, quality control, and data management procedures must be established, feeding into a single national platform for all hazardous exposures.

Step 2 — Case-Based Surveillance: SNTESS requires a documented legal mandate that obligates reporting from all relevant stakeholders, establishing the regulatory foundation upon which all reporting obligations, data-sharing agreements, and inter-agency responsibilities are defined.

Step 3 — 24/7 National Poison Control Center & Database: The resulting data feeds into a single national platform for all hazardous exposures, namely the Toxicovigilance Center, through a national PCC based on established best practices.

Step 4 — Signals: Public health personnel must be designated to investigate signals and anomalies. They must understand data collection principles, apply statistical and epidemiologic methods, and participate in outbreak investigations.

Step 5 — Investigation Group: Personnel must possess essential competencies including data analysis and interpretation, investigation and response, effective communication, and proficiency in information systems and technology, enabling them to effectively support public health surveillance, investigation, and response activities.

Step 6 — Early Warning System: Signals are detected through two complementary approaches: qualitatively, based on the severity, novelty, and geographical characteristics of cases, and quantitatively, through regular statistical analysis of the database based on event frequency. Once validated, a signal is transformed into an alert, assessed for the level of threat to population health and the appropriate response measures.

Step 7 — National Command Center: The National Command Center under the MoH (as an example) is responsible for managing alerts, facilitating close integration and ensuring that decision-makers are directly involved in translating information into action. A risk assessment is conducted before escalating to the next response level.

Step 8 — Action: Required actions include emergency response, prevention awareness, and regulatory interventions. Additional actions may involve monitoring actual performance and documenting outcomes using data reports or statistical summaries.

Step 9 — Reports & International Communication: Surveillance reports are delivered at pre-determined intervals — quarterly, monthly, weekly, daily, or as needed — to national and international agencies including the WHO and UN, ensuring timely communication of emerging public health concerns in accordance with IHR obligations.

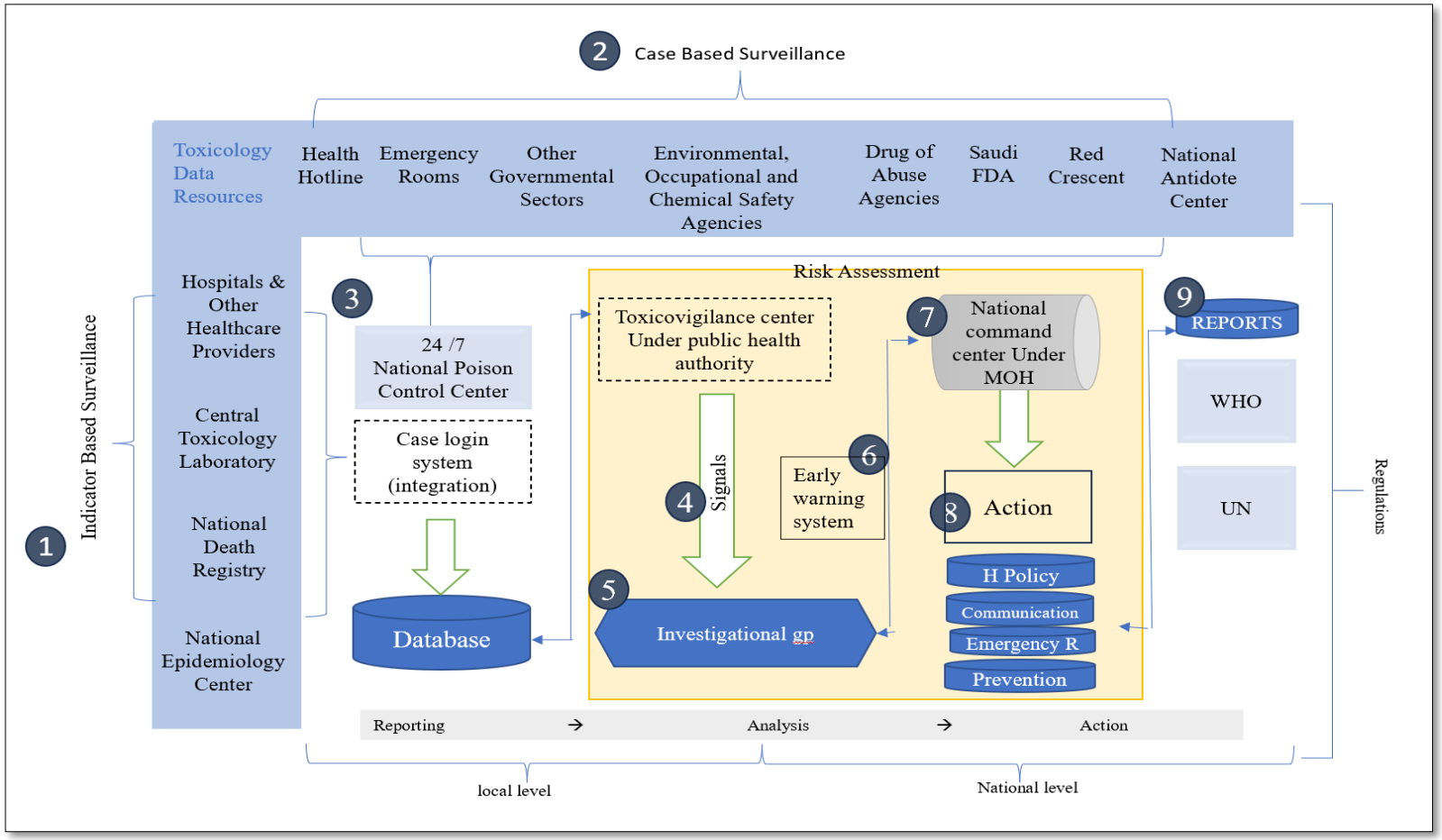

Figure 7-2: Proposed implementation pathway of SNTESS

7.4.6 Data Management

1. SNTESS data should be entered in an organized manner. This process encompasses two categories: Case Information Coding and Product Coding. Case information coding includes (Patient Information & Exposure Data, Clinical Effects, and therapies) (Appendix 11). While product coding includes the substances, information involved in the case. The data collected for each poison exposure is further categorized into four main areas. Figure 7- 3 is an example of data elements created by NPDS (212):

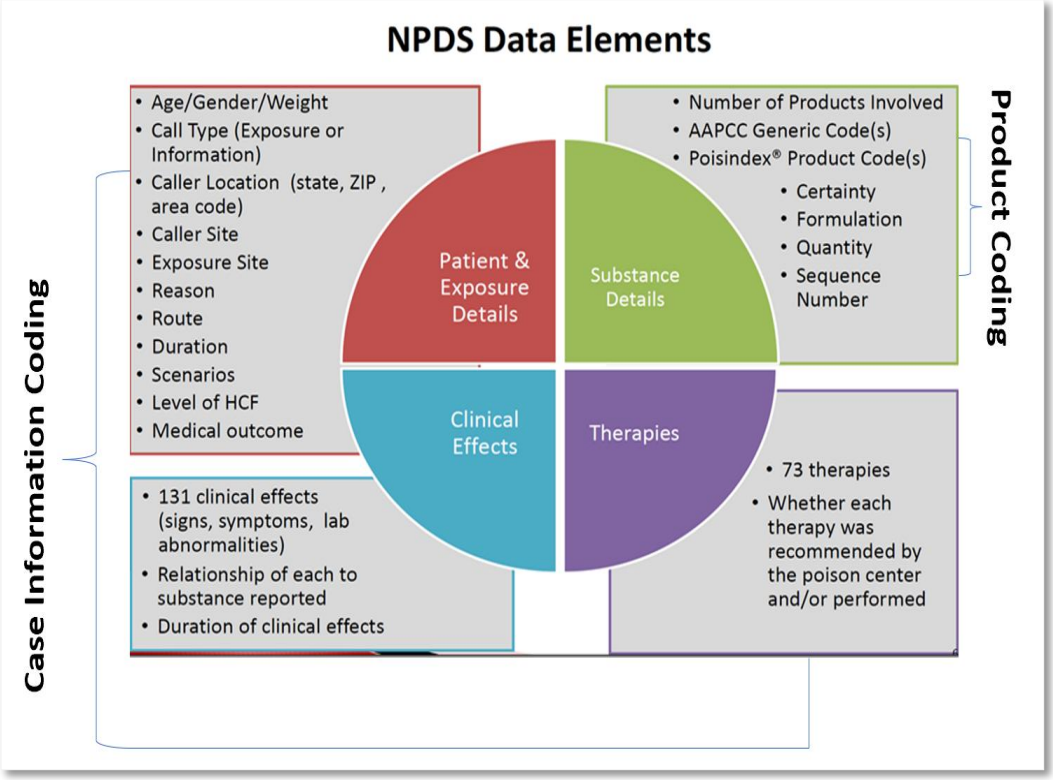

Figure 7-3: The NPDS automated data elements for a toxicology case

*HCF: healthcare facility
*Poisnindex® is a software database by "IBM Watson. Health" company

2. In SNTESS, using the Poisoning Severity Score (PSS) developed by the EAPCCT is required for standardizing incoming data. PSS is a tool used to assess the

severity of poisoning cases and helps in evaluating patient outcomes and guiding treatment decisions (213). Symptoms and signs addressed by the PSS are given in the following categories: gastrointestinal tract, respiratory system, nervous system, cardiovascular system, metabolic balance, liver, kidney, blood, muscular system, local effects on skin, local effects on eye and local effects from bites and stings (see Appendix 12). PSS is primarily intended for retrospective grading of poisoning cases collected in poisons information centers and it can also be used during telephone consultations and is applicable in clinical settings (214).

Grading is determined by the actual manifestations of toxicity rather than by the risk of poisoning. The PSS facilitates the collection of comparable data on poisoning and predictive analytics (215). It may be modified for certain kinds of poisoning. Whilst it shows some weaknesses when grading 'borderline' cases, it is nevertheless easy to use, which encourages its widespread application.

The Severity Grades are:

0 None: No symptoms or signs related to poisoning

1 Minor: Mild, transient, and spontaneously resolving symptoms

2 Moderate: Pronounced or prolonged symptoms

3 Severe: Severe or life-threatening symptoms

4 Fatal: Death

3. Another tool for standardizing incoming data in SNTESS is the AAPCC generic codes for products. AAPCC has more than 444 000 products codes, each associated with a unique 7-digit code (Figure 7-4) (216).

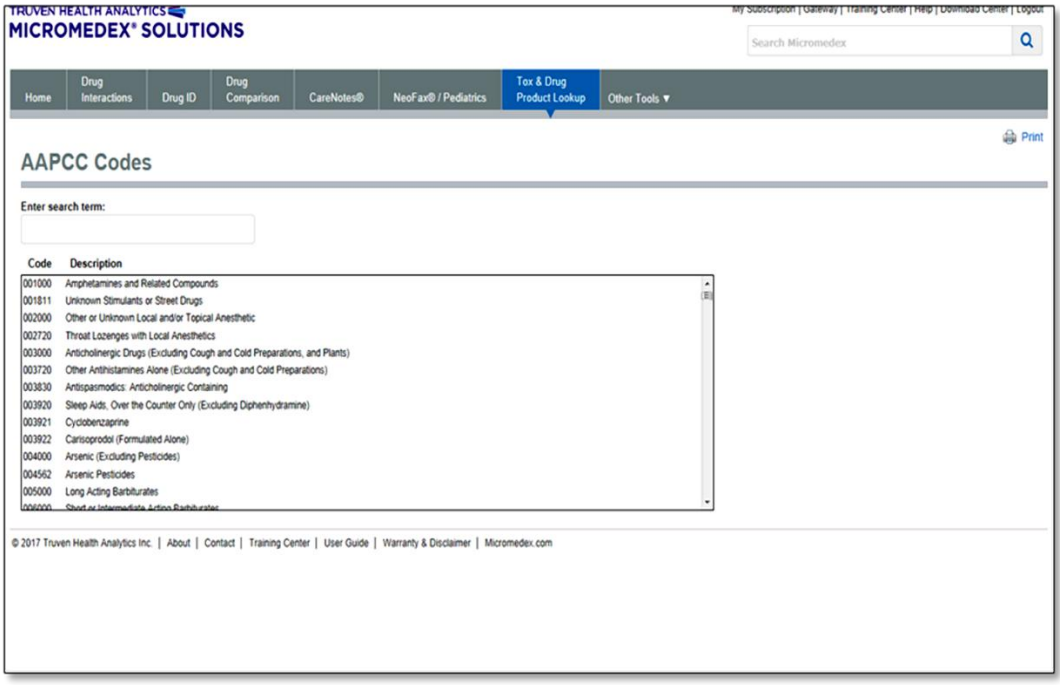

Figure 7-4: AAPCC codes

4. The most common statistical analysis will be based on the US NPDS analysis which uses automated algorithms (117), to identify anomalies based on the following (217):

   - **Call Volume:** Algorithm identifies increases in call volume to a PCC compared to a threshold based on historical data.
   - **Clinical Effect Volume**: Algorithm identifies increased reports of specific signs and symptoms compared to a threshold based on historical data.
   - **Case-Based Volume:** Algorithm identifies calls meeting prespecified criteria.

   In general, statistical methods are used to identify unusual clustering, patterns, or trends in the data. A key aspect is defining appropriate surveillance indicators and their thresholds, which can trigger signals that require public health intervention (218). For rare diseases or events, the threshold may be set at a single case, as any occurrence would necessitate action. For more common conditions, thresholds

may be based on rates over specific time periods or increases compared to baseline levels. Indicators must be clearly defined in terms of time and geographic area (e.g., cases per week per district) to effectively monitor the surveillance process and detect abnormal events or trends (219). NPDS exposure data are classified as 'numerator data' for a specific time, while the total population served by the PCC during the same timeframe serves as the 'denominator data' (202). Furthermore, statistical measures such as mean, ratio, and standard deviation are commonly used to interpret and summarize data (220).

While summary statistics on poisonings may not accurately reflect national incidence, morbidity, and mortality, this limitation can be addressed by increasing the number of poison centers submitting case histories and enhancing reporting procedures. Furthermore, these statistics are not designed to evaluate individual poison center operations, limiting their usefulness. Modifying the format of annual statistics and improving feedback of center-specific data could address these needs. The goal of statistical analysis in toxicovigilance is to use data analysis to identify signals of potential public health significance that require further investigation and response (22). Data interpretation involves qualitatively assessing the significance of detected signals or unusual patterns, considering various factors such as seasonal, geographical, and historical trends, along with clinical or biological elements like changes in severity, antimicrobial resistance, or case fatality rates. However, not all detected signals indicate genuine public health events; some may result in false alerts due to surveillance biases. For individual cases, biases can occur from improper use of case definitions, leading to false positive diagnoses that require validation through clinical or laboratory confirmation. For aggregated cases, biases may arise from incorrect denominators or shifts in healthcare utilization. Thus, identifying and addressing these potential data artifacts is a crucial first step in the validation process for unusual health events (30).

5. Data storage plays a crucial role in SNTESS. Whilst the primary function of a PCC is to offer guidance on poisoning-related matters such as diagnosis, treatment, and prevention, SNTESS should extend beyond this narrow focus. The tasks assigned to the system encompass a broader scope, necessitating a comprehensive approach to data storage. By leveraging predictive analytics, the system can analyze and interpret a wide range of toxicological data to identify patterns, trends, and potential risks. This enables proactive and timely interventions, empowering public health officials to mitigate adverse health outcomes and prevent future toxic exposures. The utilization of predictive analytics in the toxicovigilance data storage system enhances its interpretive and consequential capabilities, facilitating informed decision-making and safeguarding public health more effectively (30).

   On the other hand, data storage for the purpose of toxicovigilance may face various challenges. These include ensuring data quality and availability, integrating diverse data sources, addressing data privacy and security concerns, developing, and validating accurate models, achieving interpretability and understandability of predictions, and managing resource constraints. Overcoming these challenges requires robust data management processes, compliance with privacy regulations, expertise in modeling and domain knowledge, investment in resources, and collaboration among stakeholders. By addressing these issues, the toxicovigilance system can harness the power of predictive analytics to proactively protect public health (25).

7.4.7 Performance Measurement

In SNTESS, performance measurement and validation is crucial to ensure these systems operate optimally, several key attributes must be considered. Each attribute significantly influences the overall effectiveness of the surveillance system, affecting its capacity to deliver accurate, timely, and actionable information (222). This section will explore the attributes and features (Table 7-6) (202), to enhance understanding of how they contribute to the success of toxicovigilance.

Table 7-6: Surveillance system attributes

Surveillance System Attributes	Question it Answers
Validity and reliability	How useful is the system in accomplishing its objectives?
Flexibility	How quickly can the system adapt to changes?
Predictive value positive	How many of the reported cases meet the case definition?
Representativeness	How good is the system at representing the population under surveillance?
Sensitivity	How well does it capture the intended cases?
Stability	Does the surveillance system work well? Does it break down often?
Data quality	How reliable are the available data? How complete and accurate are data fields in the reports received by the system?
Timeliness	How quickly are reports received?
Simplicity	How easy is the system's operation?
Acceptability	How willing are stakeholders to participate in and use the system?

Validity and reliability

Ensuring the validity and reliability of data is of paramount importance in any toxicovigilance system. Regardless of the data source, a meticulous validation process is essential. This validation process must be primarily grounded in toxicological expertise to reliably establish causal links between clinical presentations due to poisoning and documented individual exposures, and all available data on the toxic potential of the suspected causative chemical (25). Validation, in this context, not only means verifying the completeness and accuracy of the available data to avoid drawing misleading

conclusions due to missing key information, but also thoroughly analyzing the final diagnosis of the clinical adverse event under investigation. This assessment requires carefully matching the available clinical, analytical, and biological data with other potential medical diagnoses, the patient's exposure characteristics, and the toxicological plausibility of the suspected causal relationship. By upholding these rigorous validation standards, toxicovigilance can provide reliable and actionable insights to support public health interventions, clinical management, and the development of effective prevention and mitigation strategies (25).

Flexibility

The flexibility of a public health surveillance system can be assessed by its capacity to adapt to evolving information needs or operational changes with minimal additional resources in terms of time, personnel, or allocated funds. Indicators of this flexibility include the system's ability to transform case definitions, adopt new technologies, incorporate emerging health-related events, and onboard new reporting sources or funding streams. Furthermore, the system's integration with other surveillance systems is enhanced using standardized data formats, such as electronic data interchange, which facilitates seamless information sharing and coordinated responses to public health threats (6).

Predictive value positive

Predictive Value Positive (PVP) is the percentage of recorded cases that truly have the health-related event under surveillance. Evaluating the performance of a surveillance system involves assessing its sensitivity and PVP. It is crucial to achieve PVP alongside sensitivity to meet the goals of public health surveillance. Validating reported cases is the primary concern when evaluating PVP (223). Moreover, PVP impacts resource utilization at two levels:

1. Case Recognition Level: PVP affects the resources used for investigating reported cases.

2. Outbreak Identification Level: Evaluating PVP involves reviewing personnel activity reports, travel records, and telephone logs. External data (e.g., medical records) is also necessary to validate cases.

Data sources for PVP calculation include medical records, registries, and death certificates. Multiple measurements are required to sufficiently evaluate PVP, using data fields from various sources for specific health events (223). A low PVP means non-cases may be investigated, and false outbreaks (pseudo-outbreaks) may be identified, leading to unnecessary interventions and distress. A high PVP reduces misallocated resources and false-positive reports. PVP is influenced by the sensitivity and specificity of case definitions and the prevalence of the event (Figure 7-5) (223).

Predictive Value Positive (PVP)

- **Definition**: PVP measures the proportion of true positive cases among all positive reports from a surveillance system. It indicates how accurately the system identifies actual cases.
- **Formula**:

$$\text{PVP} = \frac{\text{True Positives}}{\text{True Positives} + \text{False Positives}} \times 100$$

- **Purpose**: PVP assesses the reliability of the surveillance system in identifying health-related events, highlighting the effectiveness of case detection.

Figure 7-5: Understanding PVP: An overview and calculation method

Representativeness

A public health surveillance system is representative if it accurately describes the health-related event and its distribution in the population by time, place, and person. Evaluating representativeness involves comparing reported event characteristics to actual events, considering (224):

- Population characteristics (age, socioeconomic status, healthcare access, geographic location)
- Clinical course and behavior of the disease
- Predominant medical approaches
- Multiple data sources (e.g., mortality rates, incidence data, laboratory reports)

Sensitivity

Sensitivity is the percentage of diseases or health-related events that the surveillance system successfully identifies. It includes the ability to detect outbreaks and variations in the number of cases over time. Factors influencing the measurement of sensitivity in public health surveillance include (224):

- Population Characteristics: The diversity of diseases or health-related events within the population under surveillance.
- Medical Care and Reporting: The role of medical care, laboratory testing, and organizations responsible for reporting cases.
- Healthcare Workers' Skills: The diagnostic skills of healthcare workers and the sensitivity of screening and diagnostic tests (case definitions).
- Notification: How effectively the system is informed about cases.

The sensitivity of a surveillance system depends on the extent to which these conditions are met and the resources available for assessment. The focus is on accurately categorizing reported cases to evaluate the proportion of cases identified within the surveillance population. When evaluating these sources, it is important to consider how adding or removing a data source would affect overall surveillance outcomes (224).

Stability and Utility

A public health surveillance system with reasonably constant sensitivity can still be useful for monitoring trends, even if it does not have high sensitivity. However, questions about

sensitivity arise when there are changes in the occurrence of the health-related event being monitored. Several factors can cause changes in sensitivity, including:

- Increased awareness of a health-related event
- Availability of new diagnostic tests
- Changes in the methods used for conducting surveillance

These factors can lead to variations in the system's ability to detect and monitor health-related events (224).

Timeliness

Timeliness can be defined as the speed of processes within the toxicovigilance system (202). Tracking the ratio of reports received within a target timeframe to the total number of reports, this measure provides valuable insights into the efficiency of the system's processes for promptly handling notifications. This metric allows health authorities to identify gaps or bottlenecks and make necessary improvements to ensure that the surveillance system can facilitate timely interventions and responses to emerging toxic exposure threats, ultimately enhancing public health protection (30).

To validate the system, a cross-sectional analysis is performed, comparing surveillance results against a gold standard, typically achieved through a review of medical records by trained professionals. This assessment requires careful analysis of clinical data, analytical or biological information, alternative diagnoses, the patient's exposure history, and toxicological plausibility (224).

Data Quality

High-quality data is essential for effective monitoring and decision-making, as it ensures that the findings reflect true conditions and trends. Factors affecting data quality include the methods of data collection, the consistency of definitions, and the training of personnel involved in data entry and management (30).

Simplicity

A simple system encourages efficient use, minimizes errors, and facilitates quick training for new users. This attribute is crucial for ensuring that stakeholders can effectively engage with the system without extensive technical knowledge (6).

Acceptability

Acceptability is the degree to which the toxicovigilance system is embraced by its users. A system that is perceived as useful and relevant is more likely to receive support and compliance from those involved in reporting and utilizing the data. Factors influencing acceptability include the system's ease of use, perceived value of information provided, and extent to which it meets users' needs (6).

7.4.8 SNTESS and its Role in Public Health Emergencies in KSA

Crises that could impact KSA primarily include natural disasters and mass gatherings (such as Hajj). MoH has developed an emergency framework alongside other governmental sectors responsible for disaster management (such as the Ministry of Defense) to delineate roles and responsibilities, facilitate prompt responses, and mitigate health risks. This framework includes a comprehensive risk assessment and grading system for classifying emergencies, the establishment of a National Emergency Committee for effective coordination, and the creation of a Strategic Health Operations Centre to enhance response capabilities. Ultimately, these initiatives aim to bolster the health system's preparedness and resilience against public health threats, ensuring the safety of both residents and visitors (186) .

However, significant gaps persist in health monitoring and surveillance of emergencies within KSA (225). It is crucial to protect the well-being of individuals exposed to hazardous conditions while responding to disasters, such as floods, earthquakes, or infectious disease outbreaks. The public health plan aims to ensure their ongoing health and safety by systematically tracking and evaluating their health status and addressing potential risks or health issues that may arise (226). This clearly illustrates the strong

connection between toxicovigilance and public health, as toxicovigilance is the active process of identifying and assessing toxic risks in a community and evaluating measures to mitigate them. Such an approach enables continuous risk management with up-to-date information, which can reduce the incidence of poisoning by effectively managing new, re-emerging, and known toxicological risks, including environmental factors, drug abuse, food poisoning, mass chemical exposure, and heavy metals (227).

On the other hand, emergency responders employ a time-critical intervention approach tailored to the individual patient's needs and medical context. This highlights the importance of early risk assessment, as responders rely heavily on the information available upon arrival (226). In situations where exposure is unavoidable, regional toxicology treatment networks are essential for supporting acute poisoning management by providing rapid access to toxicological information and expertise, enabling clinicians to assess risks promptly. Although this often allows for effective patient management without transferring them to larger hospitals, proper planning, delivery of antidotes, coordination with critical care transport teams, and continuity of care must be facilitated by the PHA (188).

Toxicovigilance systems are essential for managing CBRN incidents (Table 7-7) (229), which can result from various factors, whether unintentional like the Bhopal gas tragedy in India (230), and the Chernobyl nuclear accident in Ukraine (231), or intentional like the nuclear bombing of Hiroshima and Nagasaki in Japan during World War II (232), (233). In incidents such as these, toxicovigilance systems can act as an EWRS to detect unusual toxic exposures, track health effects in the population, provide data for rapid response, and facilitate collaboration among healthcare, public health, and emergency responders (234). This allows for effective risk communication, public education, and resource allocation to minimize the risk and impact on those in the surrounding areas.

Table 7-7: Examples of CBRN Materials

Chemicals	Include military-designed nerve agents like Sarin and Venomous agent VX, as well as industrial chemicals such as chlorine and cyanide
Biologicals	These are derived from living organisms (e.g., viruses and bacteria) that can be utilized to cause mass casualties. Notable historical instances include the use of contaminated food and water supplies
Radiological and Nuclear Agents	Radiological dispersal devices, often referred to as 'dirty bombs,' are primarily designed to cause disruption and fear, though they also pose radiation exposure risks to affected populations. Nuclear weapons are explosive devices that derive their destructive force from nuclear reactions and represent the most catastrophic category of CBRN threats due to their potential for mass casualties and long-term environmental contamination

Chapter 8: Recommendations

This chapter will discuss **four** recommendations that can be implemented to achieve the proposed SNTESS framework either individually as distinct steps or collectively as a single module. The implementation will begin with the most comprehensive step and move towards the least effective (Figure 8-1), offering flexibility to address the specific needs and contexts of the country.

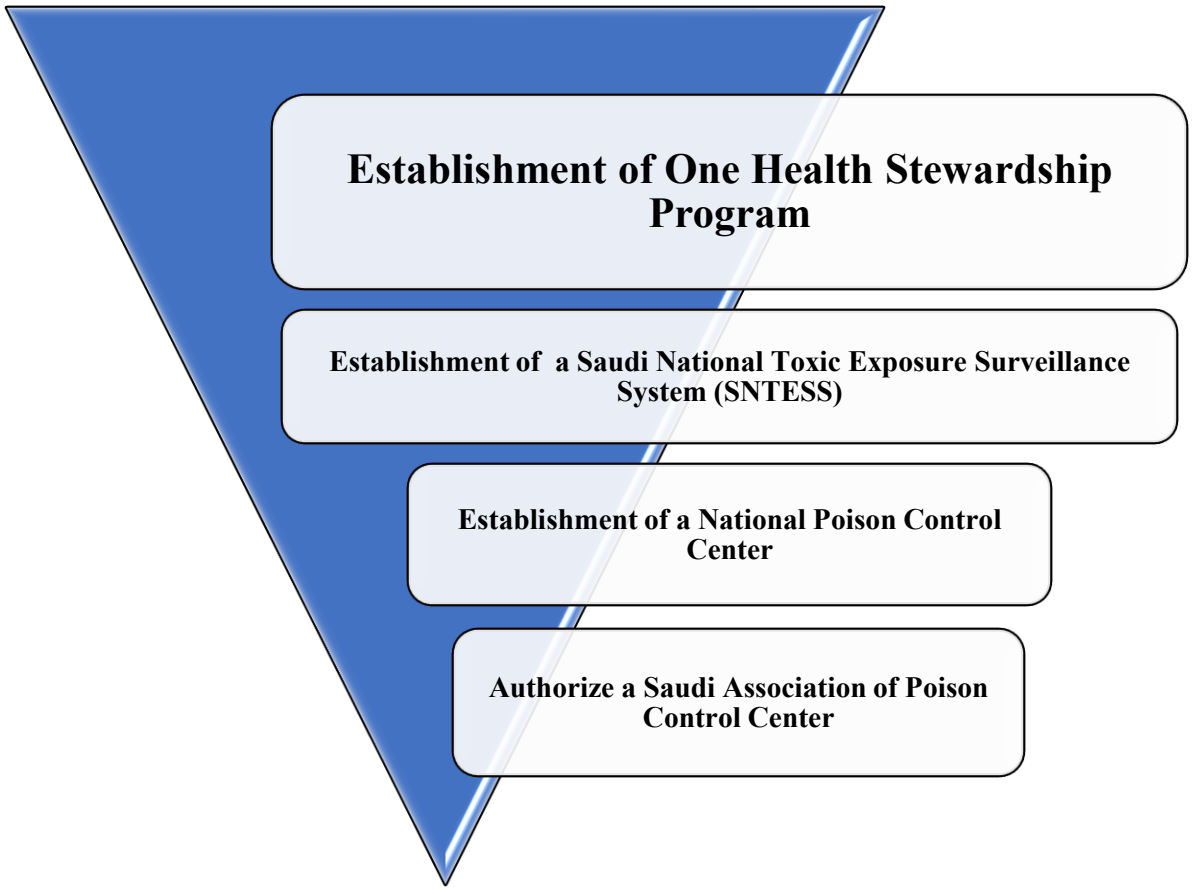

Figure 8-1: Recommendations summary

8.1 First Recommendation: Establishment of One Health Stewardship Program

8.1.1 Evidence Base and Rationale

This recommendation is grounded in the findings presented throughout this thesis, which collectively demonstrate the need for a multi-sectoral, integrated approach to establish and operate a toxicovigilance system. The One Health Stewardship Program offers the governance, coordination, and strategic framework necessary to implement evidence-based interventions across sectors, in line with the following specific recommendations:

8.1.1.1 Addresses Multi-Source Exposure Pathways

Chapter 3 identified multiple resources of poisoning in KSA, such as household chemicals, pharmaceuticals, environmental contaminants, and agricultural pesticides, highlighting the need for national data integration beyond health facilities. The One Health Stewardship Program will establish formal mechanisms for all relevant governmental agencies to contribute surveillance data on toxic exposures at their source—before human health impacts occur.

8.1.1.2 Fosters Cross-Sector Collaboration

In Chapter 4, fragmentation between MoH, SFDA, and Saudi Standards, Metrology & Quality Organization was highlighted as a significant gap limiting the ability to achieve effective toxicovigilance. The One Health Stewardship Program creates inter-ministerial governance structures—including steering committees, data-sharing protocols, and joint investigation teams—to unify previously fragmented efforts and enable cross-sector communication.

8.1.1.3 Operationalizes International Best Practices

Lessons from toxicovigilance systems in the US, Canada, and UK outlined in Chapter 5 highlight the importance of multi-stakeholder collaboration, cross-agency integration, and flexible emergency response capabilities. The One Health Stewardship Program provides the institutional architecture for embedding these international best practices through

formal partnerships, shared databases, and coordinated response mechanisms tailored for KSA.

8.1.1.4 Aligns with Conceptual Framework

As stated in Chapter 6, toxicovigilance represents a paradigm shift in public health surveillance with a specific focus on toxicological hazards. The One Health Stewardship Program will enable this shift to go beyond the health sectors and begin to address the environmental and animal health determinants of human toxic exposures more holistically, recognizing these threats as interdependent.

8.1.1.5 Enables SNTESS Implementation

The proposed SNTESS framework in Chapter 7 will operate through a model focused on surveillance integration, increased agility, and national intersectoral coordination. The governance mandate, political support, and operational protocols that SNTESS needs will come from the One Health Stewardship Program. Without this enabling governance environment, SNTESS would remain a technical system but would lack the cross-sectoral authority and coordination mechanisms needed for comprehensive toxicovigilance.

Unlike siloed health-sector-only approaches, the One Health Stewardship Program will ensure the organizational infrastructure, shared strategic vision, coordinated governance, and the collaborative culture to build the comprehensive and effective toxicovigilance system in KSA. It pivots SNTESS from a technical surveillance system into a whole-of-government, whole-of-society public health platform that can effectively cater to the multi-source, complex nature of toxic exposures described here.

8.1.2 Description of One Health Stewardship Program

The core principles of SNTESS — identifying exposure sources, intensity, locations, and affected populations — align seamlessly with the holistic, interdisciplinary approach of One Health (235). This allows for a more comprehensive understanding of toxic exposure risks and their multifaceted impacts on human, animal, and environmental health (116). By establishing shared health signal databases, regional monitoring and assessment

support groups, and strengthening regional health safety management through collaborative efforts between health agencies, toxicovigilance can be embedded within a One Health ecosystem. This facilitates the development of risk mitigation plans, targeted risk communication strategies, evidence-based policies, and legislation, public awareness campaigns, and systematic evaluation of intervention effectiveness. Furthermore, the insights gained through this integrated approach can drive academic research, training programs, and capacity building around human, environmental, and animal safety - with PCCs playing a crucial role (236).

Toxicological cases, such as those involving exposure to harmful chemicals or pollutants, highlight another critical area where One Health Stewardship Program can make a significant impact. For example, incidents of animal illness due to chemical exposure often act as early warnings for potential threats to human health. By promoting collaboration among health professionals across various sectors, One Health Stewardship Program enables the identification of common environmental sources of toxins and assists in implementing preventive measures. Furthermore, it emphasizes the importance of communication among these sectors, illustrating that effective collaboration and information sharing are vital for addressing health challenges. Overall, this approach advocates for a holistic view of health, supporting coordinated efforts to manage environmental factors, and enhance public health outcomes (Figure 8-2) (237).

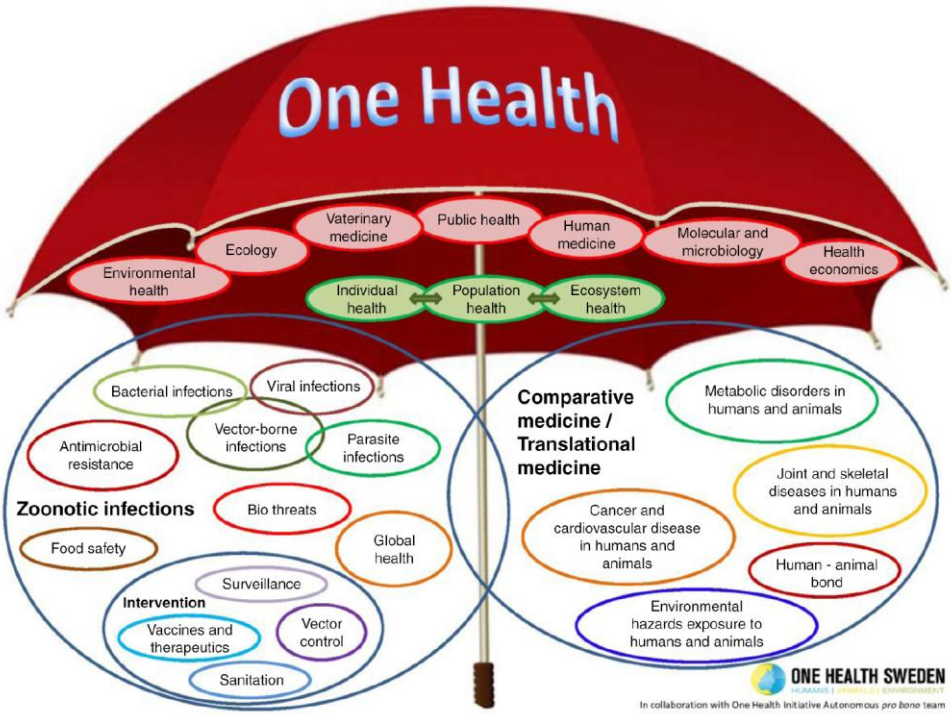

Figure 8-2: One Health Module

The integration of SNTESS within a One Health stewardship program represents a targeted response to the systemic gaps, particularly fragmentation of surveillance, delayed detection of emerging hazards, limited cross-sector data sharing, and weak early warning mechanisms for complex chemical and environmental exposures. In this context, stewardship moves beyond a conceptual principle and functions as an operational governance mechanism that coordinates multisectoral data, analysis, and response through SNTESS.

Within the proposed model, PCCs serve as the central human exposure intelligence hub, anchoring the toxicovigilance function of SNTESS. PCC-generated data—validated, case-based, and available in near real time—form the primary human health input against

which animal, environmental, and regulatory signals are assessed. This directly addresses the identified gaps of unvalidated data, duplication, and absence of a unified national dataset.

8.1.2.1 One Health Data Contributors to SNTESS

Under the One Health stewardship program, SNTESS integrates structured data streams from the following partners:

- **Human health sector:** PCCs, emergency departments, EMS, laboratories, and digital health systems provide validated human exposure cases, clinical severity, outcomes, and temporal trends.
- **Animal health sector:** Veterinary services and animal health surveillance systems contribute data on poisonings, toxic feed contamination, pesticide exposure, and unexplained morbidity or mortality events in animals.
- **Environmental sector:** Environmental monitoring authorities provide data on chemical releases, environmental contamination, industrial incidents, and hazardous waste events.
- **Regulatory sector:** SFDA and related authorities contribute regulatory alerts, product safety signals, recalls, and chemical risk notifications.

These data streams are harmonized within SNTESS through standardized coding, shared minimum datasets, and de-duplication rules, enabling PCC-validated human exposure data to be analytically linked with upstream animal and environmental signals.

8.1.2.2 Mechanisms for Joint Risk Assessment and Early Warning

One Health stewardship enables joint risk assessment by operationalizing routine, structured signal triangulation across sectors. PCCs lead daily or scheduled signal reviews, where increases in specific exposure patterns are assessed alongside animal health events, environmental detections, or regulatory alerts. This mechanism directly addresses the previously identified weakness in early warning and cluster detection.

Early warning signals within SNTESS are generated through:

- Syndromic and agent-based thresholds derived from PCC and emergency data;
- Cross-sector corroboration using animal and environmental indicators; and
- Escalation protocols linking surveillance outputs to public health and emergency response authorities.

8.1.2.3 Coordinated Response and Governance

Effective stewardship within a One Health approach depends on structured collaboration across the human health, animal health, agricultural, and environmental sectors. This collaboration directly supports national health security by strengthening IHR-related capacities, which are assessed through established mechanisms such as the IHR Monitoring and Evaluation Framework (IHR-MEF), risk profiling, Joint External Evaluation (JEE), action plan reviews (AR), after-action reviews (AAR), and simulation exercises (SimEx). Collectively, these tools support continuous system improvement, enhance preparedness for public health threats, and strengthen cross-sector coordination within the One Health framework (Figure 8-3).

Figure 8-3: National action plan for health security through One Health concept

Informed by national risk management experience and best practices in One Health governance, this thesis proposes a phased One Health stewardship implementation for toxicovigilance that prioritizes surveillance integration, governance clarity, and operational readiness . Initial actions include establishment of a formal One Health governance structure for SNTESS, benchmarking of multisectoral surveillance capabilities, formal linkage with national IHR coordination mechanisms, and systematic mapping of human, animal, and environmental toxic hazards to inform joint risk assessment and response planning.

8.1.3 Strength and Limitation of This Recommendation

Strengths:

- Holistic risk visibility: Integrating human, animal, and environmental data addresses the fragmented and reactive approach to toxicological risks by enabling earlier detection of cross-sector exposure signals.
- Enhanced early warning capacity: Joint analysis of PCC data with animal health, environmental monitoring, and regulatory alerts strengthens sensitivity to emerging and regional toxicological threats.
- Improved governance and coordination: Alignment with national health security and IHR frameworks supports coordinated preparedness, risk assessment, and response across sectors.
- Awareness of interoperability needs: Recognition of cross-sector data harmonization requirements promotes long-term improvements in data sharing and communication.
- Strengthened public communication: Multisector stewardship enhances risk communication and public awareness for toxic exposures affecting human and environmental health.

Limitations:

- Complex coordination requirements: Effective One Health stewardship depends on sustained collaboration across multiple sectors, which can be challenging without strong governance and leadership buy-in.
- Data harmonization challenges: Differences in data standards, coding systems, and reporting practices across sectors limit seamless integration.
- Resource intensity: Establishing and sustaining multisectoral coordination requires significant time, funding, and technical capacity.
- Competing priorities: Other national initiatives may divert attention and resources away from toxicovigilance-focused One Health activities.

8.2 Second Recommendation: Establishment of a Saudi National Toxic Exposure Surveillance System (SNTESS)

8.2.1 Evidence Base and Rationale

As demonstrated in Chapter 7, the proposed SNTESS directly addresses the identified gaps by implementing standardized, case-based data collection anchored in PCCs and integrated with emergency, laboratory, and public health systems. The feasibility of this approach is supported by the pilot initiative described in Chapter 2, which demonstrated that structured access to KFMC-PCC data facilitated identification of exposure trends not captured by existing surveillance platforms. This pilot provides practical evidence that PCC-led toxicovigilance can generate actionable intelligence to inform prevention strategies and strengthen national health security.

8.2.2 Toxicovigilance Toolkit

This comprehensive Toxicovigilance Toolkit (Table 8-1), serves as a checklist for implementation. The toolkit is necessary to operationalize standardized datasets, coding structures, reporting workflows, governance arrangements, and alerting mechanisms across participating entities, ensuring consistency, interoperability, and sustainability. Without such a toolkit, the system risks reproducing the same fragmentation identified in the gap analysis. By enabling harmonized data collection, near–real-time analysis, and automated alerts through a cloud-based notification engine, the proposed system supports both routine surveillance and emergency preparedness, including CBRN-related threats. Collectively, the evidence generated across this thesis supports the conclusion that a national toxicovigilance system is not only operationally feasible but essential to address documented deficiencies and advance a proactive, intelligence-driven approach to toxicological risk management in KSA.

Table 8-1: Toxicovigilance Toolkit

Physical Location
It should be spacious enough to accommodate staff, trainees, and necessary storage and conference areas, while remaining secure and quiet. The center should operate 24/7, with a minimum of three front-line staff across three shifts. Each staff member should have a fixed 8-hour shift, with on-call rotation during weekends. Backup medical toxicologists should be available during each shift to provide additional support and training opportunities for medical residents.
Staff Qualifications
Should include competency in basic toxicology and poison control, with pharmacists and nurses having relevant backgrounds and additional training. To support the development of toxicologists and poison information specialists, the Ministry of Health should revise public health legislation to allocate funding for a regional Poison Prevention and Control System and establish the Toxicovigilance Enhancement and Awareness Act.
Workflow Organization
Should ensure that PCC staff report to a supervisor, maintaining continuous staffing during operating hours. The center should be secure, with protocols for evaluating calls and ensuring patient safety through follow-up. Sufficient additional staff should be available to handle incoming calls, with backup on-call support at all times. Engaging stakeholders is crucial for maintaining a proactive surveillance plan and effectively responding to public health threats. Their involvement is essential for safeguarding public health. Data management should focus on reporting statistical results to public health authorities, identifying at-risk populations during threats, and enabling timely protective measures.
Governance
The center should be either separate entity or part of the Ministry of Health
Stakeholders' engagement
Collaboration with stakeholders is necessary to develop a toxicology services system that aligns with international standards. This system should be supported by a poison

information database featuring standardized treatment protocols. Additionally, working with the Ministry of Commerce and Industry is crucial for implementing a coding system for registered items. This system will facilitate the categorization of substances by poisoning severity, first aid measures, and special instructions, including the creation of a local medication safety data sheet.	
System Requirements	
1.	Ensure access to health information infrastructure
2.	The electronic exchange of personal health information must comply with relevant patient privacy laws and standards
3.	Ensure that the surveillance system is compatible with the National Electronic Disease Surveillance System
4.	Ensure that all data resources have Electronic Case Reporting system
5.	Ensure that there will be an Integrated Data Repository well maintained and centralized
6.	Case Notification for Passive Monitoring and Early Intervention
7.	Establish a system or record locator that allows retrieval and review of all condition reports associated with an individual.
8.	Ensure access to necessary equipment for the electronic management and exchange of information, including laboratory test orders, samples, and results, with hospitals, doctors' offices, community health centers, and poison control centers.
9.	Understanding Product Coding and Reporting
10.	Implement the CLP Regulation to ensure it is realistic, acceptable to all stakeholders, and garners political support from the majority of Member States.
11.	Establish a Unique Product Identifier and utilize the Chemical Abstracts Registry number.
12.	Distinguish the characteristics of outbreaks caused by toxic agents.
13.	Define and identify toxidromes to aid in diagnosis and management.
14.	Identify and analyze factors that influence toxicity.
15.	Develop performance metrics to track the progression of technical steps, embedding key performance indicators into process phases for performance analytics and decision alerts based on benchmarks.
16.	Foster engagement and development within a Community of Practice for knowledge sharing and collaboration.

17.	Establish a mechanism for feedback to continuously improve the system.
18.	Create dashboards for monitoring and evaluating toxicovigilance efforts.
19.	Conduct robust evaluations of new and emerging innovative interventions in toxicovigilance.
20.	Assign and authorize a spokesperson for ongoing media communications related to poisoning. Designate one center as responsible for announcing outbreaks that are subject to obligatory notification.
Risk Assessment	
For the center: enterprise risk assessment	
For the scope: which hazardous should be monitored	
For the national resilience: analysis of out break through data monitoring	
Data Management	
Data In: Reports harmonization	
Data out: Reports facilitations	

Ultimately, the implementations can be bolstered by a wider network of PCCs to ensure coordinated efforts and information sharing. Incorporating an early warning system within this framework allows for the swift detection and response to emerging toxic exposure risks. The primary objective is to adopt a comprehensive toxicovigilance strategy that shifts from reactive to proactive, risk-based surveillance, engaging society. This module offers a robust and effective pathway to improve public health preparedness and responsiveness to poisoning threats.

8.2.3 Strength and Limitation of this Recommendation

Strengths:

- High specificity and granularity: PCC-led case documentation by trained poison information specialists enhances data quality and clinical relevance.
- Population-based surveillance: Use of the national and regional datasets enables detection of substance-specific and geographic exposure trends.

- Improved trend detection: The ability to identify statistically significant associations supports proactive monitoring and prevention strategies.
- Innovative data linkage: Mapping AAPCC-style exposure data to ICD-10 improves analytical resolution and interoperability with health systems.
- Pilot-supported feasibility: Evidence from the KFMC-PCC pilot demonstrates that structured toxicology data can reveal trends not captured by existing surveillance platforms.
- Foundation for national outputs: This foundation enables routine dashboards, alerts, and reports to support decision-making and health security.

Limitations:

- Coding limitations: ICD-10 lacks toxicological specificity, while AAPCC-style coding may use generic categories that limit detailed classification.
- Potential misclassification: Imperfect mapping between coding systems can result in classification errors.
- Incomplete case capture: PCC-based surveillance may underrepresent fatalities and exposures not reported by the public.
- Self-reporting bias: Reliance on caller-reported information affects exposure accuracy.
- Data quality gaps: Missing demographics and lack of confirmatory testing reduce analytical reliability.
- Interoperability barriers: Variability in electronic medical record systems and lack of common standards complicate data exchange.
- Funding and sustainability challenges: Standardization, cloud-based analytics, and automated alerting require sustained investment.

8.3 Third Recommendation: Establishment of a National Poison Control Center

8.3.1 Evidence Base and Rationale

It is imperative to create a fully operational PCC that functions 24/7 all year round, staffed by clinical toxicologists and equipped with a laboratory and a national antidote reservoir .This center should serve as a central hub for the collection and reporting of poisoning-related data (Figure 8-4). It is suggested that the SNTESS will emulate the functions of the NPDS, formerly known as TESS, in the USA. However, a key difference is the centralization of reporting; It is proposed that all reported cases should originate from a single entity, the National PCC. Designating the National PCC as the primary source for SNTESS is more efficient, as it is the only center staffed with clinically trained personnel available to handle toxicology cases 24/7, every day of the year.

In contrast, each PCC in the US automatically uploads case data to the NPDS. Staff members record cases in real-time using one of five electronic medical record systems, as referenced in NPDS (116). The NPDS functions as a data warehouse for PCCs (238). with all reported cases coming from the 55 PCCs in the USA after thorough validation of the information, which typically takes about eight minutes. Additionally, some cases in the NPDS are reported directly by public health offices or agencies (203). It is important to note that NPDS operates as a passive reporting system (132), (238).

Figure 8-4: Centralizing data sources in the National PCC: A hub-and-spoke model

Furthermore, it is recommended by the WHO to have at least one similar center per country (See Appendix 13). (239). The WHO has published a guideline for establishing a National PCC, which I had the privilege of contributing to as a subject matter expert back in 2017-2020. The guideline provides a framework

For countries to follow in developing effective poison control systems that can enhance public health and safety (Figure 8-5) the guideline available in this link: https://www.who.int/publications/i/item/9789240009523

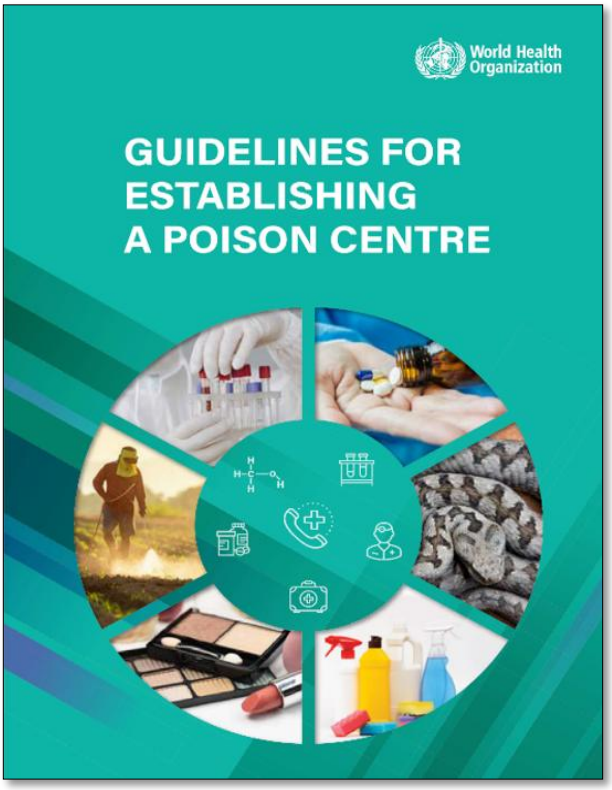

Figure 8-5: The WHO Guidelines for Establishing a Poison Center 2020

8.3.2 Description of National PCC

There are Two options to how can this be achieved from my view;

The First Option: Selecting one existing PCC to serve as the leading center in KSA for the national PCC's primary functions can be accomplished by first forming an advisory committee made up of representatives from each existing PCC. This committee will focus on developing and consolidating resources and communication systems. Following this, a formal agreement should be established, such as a Memorandum of Understanding (MOU) with a central or local clinical toxicology service. This will help oversee the operational plan and facilitate networking among PCCs. Implementation should take place one jurisdiction at a time to encourage collaborative commitment and optimize integration. This process may require a "Provider Service Level Agreement" with the most effective existing PCC, granting it authority as the national entity. Additionally, hiring

individual consultants can aid in establishing and planning operations for the National PCC within a national rotation framework.

This proposed option/module is the least favorable for me, but I believe it is the fastest approach, as it will enhance existing resources and consolidate various scattered efforts toward a unified goal. Achieving this requires informing a committee with high-level authority. However, the main obstacle when bringing multiple stakeholders together to agree on a predefined agenda is the execution time and the potential for repetitive tasks that individuals might claim to have already completed. Additionally, following up with these stakeholders can be challenging. If this module is selected, I believe it can be successfully implemented by creating a digital platform to integrate all efforts as a starting point.

The Second Option: This involves establishing a new center that functions as the hub, known as the National PCC. The National PCC should initially collaborate with existing services to develop, disseminate, and evaluate all necessary toxicology services for the nation until a full transition to a unified center is achieved. Learning from the approach employed in the USA described above, where PCCs report all cases annually to the national data surveillance system, this model has proven effective in raising awareness and saving lives through preventative measures and early interventions (132). The establishment of a new center is described in the WHO guidelines mentioned above. One of the most important steps in setting up a new center is establishing an organizational structure that serves as the backbone of the operation. See Figure 8-6 (240) for a good suggestion regarding the organizational structure of the National PCC center.

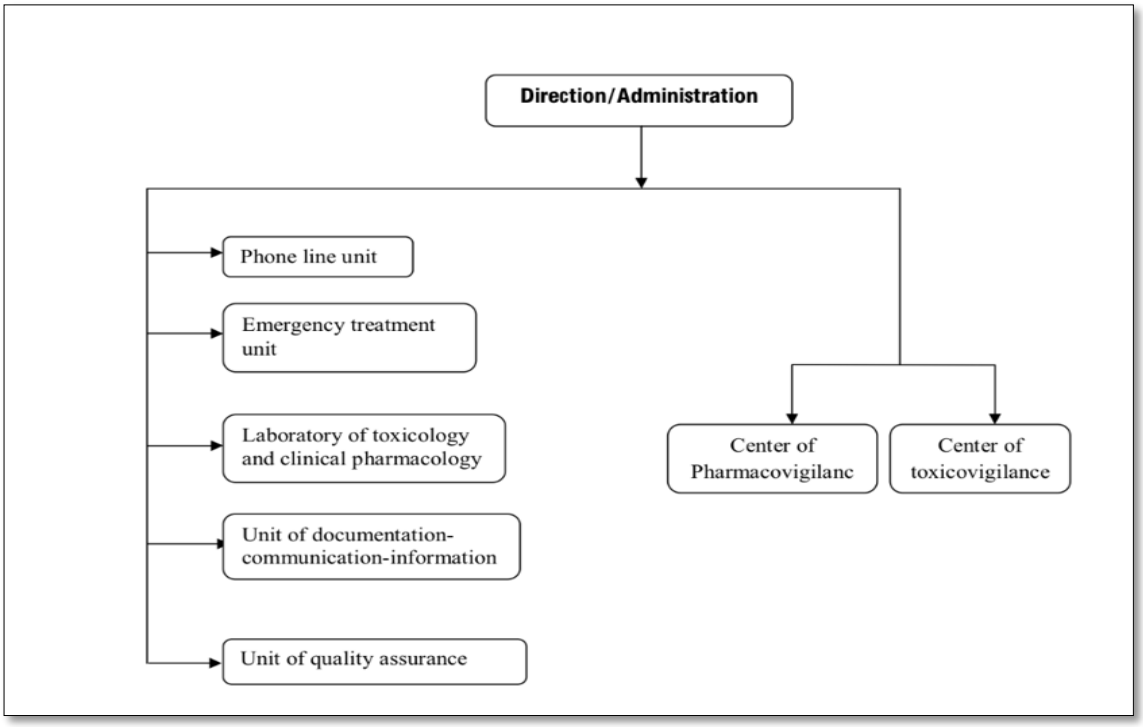

Figure 8-6: Sample organogram for the National PCC

Additionally, the National PCCs personnel are typically trained to respond to biological threats and disaster preparedness through a national emergency hotline, making their role critical in both immediate and long-term patient care. The provision of direct patient care services to the public and healthcare professionals is invaluable for governmental public health entities at local, regional, and national levels, especially in response to natural and manmade disasters, including chemical, biological, and radiological threats. This highlights the critical need for establishing a National PCC in KSA and other Gulf Cooperation Council (GCC) countries (Figure 8-7). Such centers would not only offer immediate, free consultations but also play a vital role in data collection and implementing preventive measures Once operational, these centers could generate comprehensive national data on the prevalence and severity of poisoning cases.

Moreover, collaboration among PCCs across the GCC will enhance the sharing of expertise and resources, allowing for a unified approach to toxicology. This regional

cooperation can lead to standardized data collection and reporting practices, enabling a better understanding of poisoning trends and risk factors unique to the Gulf region. The insights gained would not only support the proposed health-related SDGs but also inform the formulation of regulations aimed at improving toxicology data and enhancing public health responses to poisoning incidents.

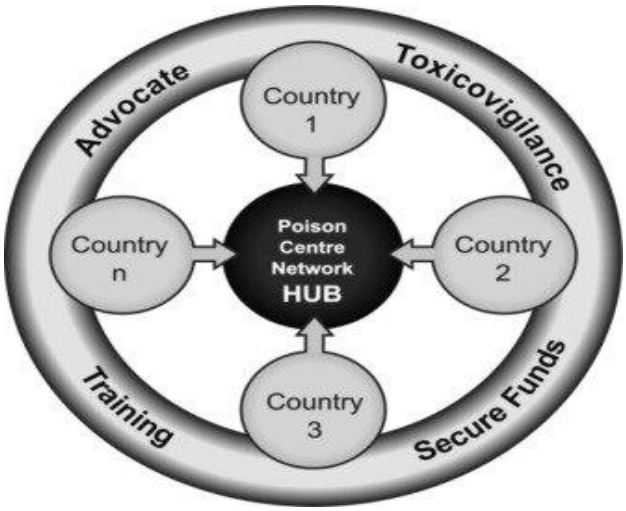

Figure 8- 7: Illustration of the PCC network hub concept at the country level

Finally, creating a National PCC in either way requires developing laboratory infrastructure to support sample handling, result reporting, and clinical operations, including staff health and safety. The National PCC should work closely with the laboratory to fulfill several key functions: providing data on the epidemiology of poisoning to prioritize laboratory services; informing relevant authorities and professionals about the appropriate use of existing laboratory services for diagnosing and managing poisonings; offering guidance on suitable assays and methodologies for specific clinical situations; and monitoring internal quality control while participating in external quality assessment schemes. Furthermore, analyzing inquiries received by the poisons center can identify specific subpopulations and emerging circumstances related to poisoning. Involvement in training and professional development for clinicians and

laboratory personnel is crucial, focusing on the effective use of analytical facilities and result interpretation. This comprehensive approach will significantly enhance the overall effectiveness of toxicological services (see Appendix 14 Minimum operation standards for a PCC).

8.3.3 Strength and Limitation of this Recommendation

Strengths:

- Centralized national function: A National PCC provides a unified hub for toxicological expertise, surveillance, and response.
- 24/7 clinical validation potential: Continuous availability enables real-time validation, follow-up, and escalation of poisoning cases.
- Enhanced triage and care coordination: Integration with EMS and emergency departments improves patient routing and reduces unnecessary transfers.
- Teleconsultation capability: Use of tele-video and remote consultation improves access to toxicology expertise across regions.
- Risk stratification and prevention: Analysis of PCC inquiries identify high-risk populations, substances, and circumstances.
- Alignment with international best practice: Mirrors successful models contributing to national systems such as NPDS.

Limitations:

- Operational hour constraints: Current PCC-like services in KSA are largely limited to office hours, while peak poisoning incidents occur overnight.
- Workforce capacity gaps: Limited availability of trained toxicologists and poison information specialists restricts scalability.
- Compliance challenges: Low adherence to PCC advice for ED attendance, particularly among vulnerable populations, affects outcome tracking.
- Underrepresentation of mortality: Fatal cases may bypass PCC reporting, necessitating integration with mortality and forensic systems.

- Leadership and organizational buy-in: Lack of awareness of PCC value can hinder establishment and sustainability.
- Resource constraints: Funding, staffing, and infrastructure limitations pose challenges to 24/7 national coverage

8.4 Fourth Recommendation: Authorize a Saudi Association of Poison Control Center

8.4.1 Evidence Base and Rationale

The establishment of a Saudi Association of Poison Control Centers will aim to enhance public health safety by providing specialized support in the management of poisoning incidents. This association will serve as a central body to coordinate poison control efforts across the country, facilitating the sharing of expertise, resources, and data among various centers. By authorizing this association, KSA will improve the response to poisoning cases, promote education on poison prevention, and foster research initiatives that address the specific toxicological challenges faced in the region. This collaborative approach will ultimately contribute to better health outcomes, reduce the burden of poison-related incidents, and align with international best practices in toxicovigilance.

8.4.2 Description of the Association Functions

The suggested main roles for this association are as follow:

- **Unified Definition of PCCs:** This will come with an amendment prohibiting the use of the words “Poisoning Control Center” unless authorized. The proposed National PCC will conduct authorization as a certification body. This appropriate action will give strength and legal protection to the National PCC and avoid data discrepancies or loss. Data at national PCC is susceptible and should be kept under high-security level protection.

- **Enhance Resources Allocation**: By coordinating efforts among various stakeholders, the association can identify gaps in resources and streamline their distribution to areas of highest need. This includes advocating for funding, training, and infrastructure improvements, ensuring that PCCs have the necessary tools and personnel to respond swiftly and effectively to poisoning incidents. For example, the association will play a vital role in allocating antidotes and establishing testing facilities, which are essential for timely and accurate treatment. Ultimately, a well-resourced association not only

improves response capabilities but also fosters greater public health outcomes through proactive poison prevention initiatives.

- **Enhance Public Awareness and Education**: To enhance public awareness and education about poisoning risks, particularly for caregivers of young children, it is essential to launch comprehensive educational programs by the association. Promoting safety measures within households is also crucial; families should adopt practices such as using child-proof containers for medications, securing hazardous substances out of children's reach, and developing household action plans for poisoning emergencies.
- **Leverage Technology for Data Integration:** To leverage technology for data integration, it is essential to utilize modern technologies to create interconnected data systems across healthcare facilities. For instance, collaborating with higher organizations to promote the implementation of an EHR system can integrate data from hospitals, clinics, and PCCs. This integration assists in identifying high-risk individuals by monitoring medication prescriptions and emergency visits related to poisoning. Furthermore, it enables healthcare providers to track substance abuse patterns over time, facilitating timely interventions and personalized care. Encouraging hospitals through the association to share data and collaborate with various healthcare entities can significantly enhance overall patient safety and improve response strategies in cases of poisoning (see Appendix 15 an example of a platform).
- **Conduct Focused Research:** In future research studies, it is essential to conduct separate analyses for specific toxins or categories of poison. This method will yield detailed insights into the prevalence, impact, and demographics affected by each type of poisoning. By analyzing the data at a granular level, policymakers will gain access to more comprehensive information to support their decision-making.
- **Training for healthcare in the field of toxicology:** The association will play a vital role in facilitating training for healthcare professionals in toxicology. While it will not directly offer specialized training programs, the association will coordinate access to various training resources and locations, ensuring that healthcare providers can gain practical experience. Additionally, it will organize training sessions on essential

topics, such as the management of poisoning cases and the use of antidotes, while promoting best practices and keeping providers updated on the latest guidelines.

This module can be achieved through the Saudi Council for Health Specialties (SCHS) in KSA. The SCHS is a governmental authority responsible for healthcare commissioning. Although, when I proposed the association initiative to the council back in 2018, there was overlap with two other associations—Emergency Medicine and Clinical Pharmacy. Therefore, I recommend seeking collaboration with the private sector to advance this initiative. Engaging the private sector appears to be more attainable, particularly from a governance perspective, as it can foster collaboration and support among various stakeholders more effectively. This collaboration is crucial for ensuring a cohesive approach to healthcare and enhancing the overall effectiveness of the proposed module.

8.4.3 Strength and Limitation of This Recommendation

Strengths:

- National coordination and standardization: A Saudi Association of Poison Control Centers would provide a formal platform to harmonize PCC practices, data standards, training requirements, and quality assurance across regions, directly addressing fragmentation identified in the gap analysis.
- Professional leadership and advocacy: The association would increase awareness among policymakers and health system leaders of the value of toxicovigilance and PCC services, supporting sustained leadership buy-in and organizational support.
- Workforce development and credentialing: By coordinating education, training, and certification pathways for poison information specialists and toxicologists, the association would strengthen national workforce capacity and consistency.
- Knowledge sharing and best practices: The association would facilitate exchange of operational experiences, emerging toxicological threats, and lessons learned among PCCs, enhancing surveillance sensitivity and response effectiveness.

- Support for interoperability and data quality: A unified professional body can promote adoption of common data standards, interoperability frameworks, and reporting requirements aligned with SNTESS.
- International alignment: Establishing a national association enables structured collaboration with international poison center networks and professional bodies, supporting benchmarking and continuous improvement.

Limitations:

- Dependence on regulatory authorization: The effectiveness of a national association depends on formal recognition and mandate from health authorities, without which its influence may remain advisory rather than operational.
- Resource and sustainability challenges: Establishing and maintaining an association requires dedicated funding, administrative capacity, and long-term commitment from member organizations.
- Variation in PCC maturity: Differences in staffing, operating hours, and technical capacity among existing PCCs may limit uniform participation and implementation of association-led standards.
- Risk of limited impact without integration: If not formally linked to SNTESS governance and national health security structures, the association may have limited influence on surveillance and response activities.
- Competing organizational priorities: PCCs and host organizations may face competing operational demands, reducing engagement in association activities.
- Initial resistance to standardization: Adoption of common protocols and reporting requirements may face resistance from centers accustomed to local practices.

8.5 Afterword by The Author

The implementation of a toxicovigilance system in KSA aims to complement existing public health initiatives, ensuring that research findings effectively inform the management of poisoning incidents. The success of this initiative depends on collaboration among various stakeholders. This thesis represents the sole work of the author, Najla Khoja, encompassing the established objectives, methodologies employed, analyses conducted, findings presented, conclusions reached, and recommendations proposed, all showcasing the author's dedication and expertise.

The goals of this thesis include improving reporting mechanisms to address preventable poisoning incidents. The initiative promotes the slogan "See Something, Say Something, Do Something," highlighting the importance of voluntary reporting from intermediary agencies. Engaging the community and raising awareness are essential to encourage reporting, especially since many existing systems are not easily accessible or convenient. I aim to foster a community of practice to facilitate this process and enhance the overall effectiveness of the toxicovigilance system.

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Appendices

Appendix 1: Service Flyer (KFMC-PCC)

King Fahad Medical City
Emergency Medicine Administration
Poison Control Department

STOP POISON & TAKE ACTION
ASK POISON CONTROL DEPARTMENT FOR HELP

Who we are:
We are a newly opened department under Emergency Medicine Administration. We have been approved in 2012. Since then we started as a consultation service. By the beginning of 2015 we started our service in a well established center. The center is established and designed upon international standards.

Who can work in PCD:
Clinical pharmacists, certified poison information specialists, clinical and medical toxicologists, emergency medicine and pediatrics physicians, pharmacologists and also nurses.

What we do:
KFMC Poison Control Department is a provider of immediate, free, and expert treatment advice and assistance over the telephone for cases of exposure to poisonous, hazardous, or toxic substances.

Working hours:
KFMC Poison Control Department is accessible toll-free 24 hours a day, 7 days a week, 365 days a year. Pharmacists, nurses, and poison information providers will answer the phones, in many cases to prevent a trip to the emergency room.

When to call:
1. If someone has been poisoned.
2. If someone has taken too many drugs or unknown medications intentionally or accidentally.
3. If you need information about preventing accidental poisonings.
4. If you need information about potential poisoning from medications, household products, venomous insects and plants

Why Toxicology is a career for pharmacist:
The specialty of poison control is not newly established. However, its importance what become recognized lately. Positions are become available at many hospitals, universities and research centers

Why KFMC poison control department :
Our department is considered one of the very first poison control service in the country. Its special location in a tertiary care hospital with its strong supporting leaders make it a very promising department to work in.

We encourage to call us for further information:

00-966-11-288-9999
Ext: 29590 / Pager: 4955

nkhojah@kfmc.med.sa

Appendix 2: The Published Article From this Thesis

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RESEARCH ARTICLE

OPEN ACCESS Check for updates

Prevalence and characteristics of poisoning calls/cases in Saudi Arabia: a single-center experience from a tertiary care hospital

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ABSTRACT

Objectives: Poison centers (PCs) are few in Saudi Arabia. This study aimed to describe the poisoning pattern among exposures reported at the specialized PC of a tertiary care hospital in Riyadh, Saudi Arabia.

Methods: A retrospective study was conducted to review all cases of acute poisoning reported at the PC specialized call center from January 2013 to June 2021.

Results: A total of 2168 exposures were documented, the majority of which occurred at home ($n=2090$, 96.4%) and were accidental in nature ($n=1739$, 80.2%) Ingestion was the most common route of exposure ($n=2026$, 93.4%). Children less than five years old registered the highest number of cases ($n=1508$, 69.6%) and pharmaceuticals ($n=1485$, 68.5%) were the most common substance reported in poisoning cases.

Conclusion: In this retrospective study spanning 8.5 years, a snapshot of poisoning cases has been documented. While the study cannot be generalized throughout Saudi Arabia, it is apparent that public health awareness on the prevention of poisoning cases is warranted as the data suggests significant underestimation. A specialized call center should be made available to the public and a more comprehensive documentation of cases to include outcomes of management may provide compelling evidence to establish a national PC.

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KEYWORDS
Exposure; acute poisoning; toxicovigilance; retrospective; poison center; Saudi Arabia

Introduction

According to the World Health Organization (WHO), toxicovigilance is the

> active process of identifying and evaluating the toxic risks existing in a community and evaluating the measures taken to reduce or eliminate them. It involves the analysis of poison center enquiries to identify whether there are specific circumstances or agents giving rise to poisoning, or certain populations suffering a higher incidence of poisoning. [1]

The existence of poison centers (PC) is therefore essential in implementing effective toxicovigilance within a general community [2]. Globally, while the foundation and purpose of PCs vary in every country, there is a universal agreement that at a minimum, a PC is first and foremost an information service, which may include a clinical treatment unit and/or a laboratory that can provide toxicological analyses [2]. As of 2023, only 47% of member states of the WHO had a PC, with significant gaps between the developing and developed countries, specifically in the African and Eastern Mediterranean regions [3].

Saudi Arabia, which is part of the Eastern Mediterranean region with the least established PCs, has 5 listed in the 2019 WHO directory [4]. Despite this low number of PCs relative to the population in Saudi Arabia, few studies have been conducted. Some of the published articles showed variable findings that strengthen the case for better toxicovigilance through improved reporting of cases to PCs. For instance, a single center study conducted in the Al Majmaah region involving 591 cases of acute poisoning gathered from 2009 to 2012 confirmed that snake and

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scorpion envenomation were the leading causes of poisoning among adults in that area [5]. In another study conducted in multiple health centers in Al-Qassim region, the highest percentage of poisoning was from pesticides based on 404 cases of acute chemical poisoning [6]. In contrast, a study carried out at a government hospital in Riyadh retrospectively reviewed a total of 9584 poisoning cases over a 10-year period (1986–1996) and found that poisoning was mostly caused by medications [7], with similar findings reported in the same hospital in 2010 [8]. Most hospitals rely on pharmacists to provide some toxicology treatment advice, in addition to their role in disaster management [9]. However, it has been found that pharmacists managing acute poison consult services in hospital settings are not common, and the few that have been described in published reports appear to have been limited to the monitoring of specific therapeutic pharmaceuticals, medication history-taking, and the provision of drug information by experienced pharmacists involved in emergency medical services [10].

Owing to the paucity of available literature on exposure and poisoning cases in Saudi Arabia over-all, there is a need to fill this gap by conducting epidemiological studies addressing this public health issue. Currently, Saudi Arabia has a 24/7 hotline (#937) courtesy of the Ministry of Health (MoH), dedicated to the public for general medical inquiries which also provides telephone consultations, advice for at-home treatment and referrals when necessary. As of 2020, this hotline has received more than 20 million calls [11], but only 20,500 calls were attributed to poisoning, 41% of which are from Riyadh with household chemicals representing the highest risk of exposure [12]. In the same study, 93% of the calls were from public places and only 7% from hospitals, with no further breakdown as to whether the calls were from primary, secondary, or tertiary type of hospitals [12]. This hotline however has several limitations: it caters for all general health inquiries, it is not affiliated with any hospital [4], does not provide training, cases are entered in MS Excel and the 5 PCs listed in WHO do not operate 24/7. In addition, while the affiliation of the mentioned study is with the General Directorate of Poison Control Centers, this directorate actually operates under blood banks, forensic toxicology and toxicology laboratories. It is clear that improvements can be made and a specialized PC dedicated to clinical poison information service is warranted [13]. Furthermore, the most recent studies have been conducted based on presentations of poisoning cases to emergency departments and not on referrals to PCs, giving limited indication of community awareness on the existence of available facilities [14,15]. This study aimed to evaluate and describe the poisoning pattern among exposures reported at the first specialized PC of a tertiary care hospital with two secondary hospitals in Riyadh, Saudi Arabia to show case the importance of toxicovigilance

Methods

Study design and setting

This is a retrospective study conducted at the PC of a tertiary care hospital in Riyadh, Saudi Arabia. This PC was established as a quality project in 2012 and is one of the very first poison control services in the country [16]. The PC covers the second health cluster (central region), including one tertiary care hospital, two secondary care hospitals, and 48 primary care clinics. In brief, health clusters under the MoH in Saudi Arabia are integrated networks of health care providers (primary care, general hospitals and specialized services) under one administrative structure serving approximately one million people per cluster. As of 2022, the MoH has launched two clusters (Riyadh health cluster one and central region health cluster two) [17].

This PC operates through a specialized call center available 24/7 to the different clinics and hospitals in the central region (second health cluster) and offers immediate clinical telephone consultation, specialized clinical care, and evaluation of patients exposed to poisonous or hazardous substances. It is not open to the public because of the existence of the hotline 937. It also serves as a major training site. The PC is staffed by specialists in poison information (SPIs), clinical toxicologists, lab toxicologists, and back-up medical toxicologists (on-call, bedside). Every year, PC responds to hundreds of calls from different clinics concerning substance ingestions and is captured through a web-based electronic documentation system (poison-call) which has three main components: demographic data, product data, and clinical data (Figure 1). The system was tailored according to the American Association of Poison Control Centers (AAPCC), and the following information are available on any case login system answering sheet to generate meaningful historical/clinical data: date/time of call, SPI information, caller zip code, region, age, sex, call type (exposure, information), reason for call, acuity (time of exposure), exposure quantity, exposure duration, exposure route, number of substances, exposure site, caller site, management site, clinical effects, decontamination, management, treatment, medical outcome, and level of healthcare provided. SPIs and graduate pharmacists are trained in this PC through a constructed training

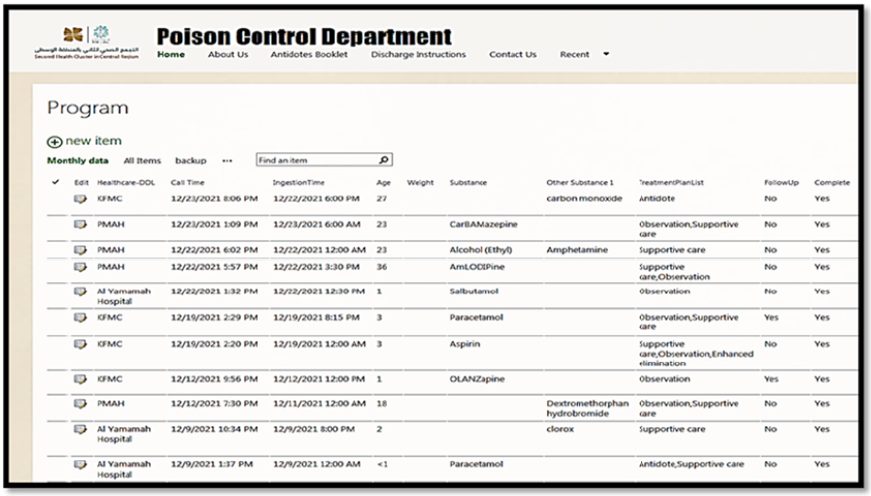


Figure 1. Poison-call system.

program (Supplementary Table 1 example of guiding material of how to answer a poison call). Treatment plans are based on standard treatment protocol, guidelines, and algorithms (Supplementary Table 2).

Data collection

Data review was based on records obtained from the poison-call system, a computerized data system designed at the PC. This data system is used to register all poison related inquiries received through the call center in a standardized form. For the purpose of this study, data extracted included age, sex, year of exposure, type of exposure (classified as pharmaceuticals and non-pharmaceuticals), exposure location, route, and number of substances. All cases of acute poisoning reported to the specialized PCs from January 2013 to June 2021 were included in this study. Cases covered from 2013 to 2018 included one tertiary hospital, while cases from 2018 to 2021 covered three hospitals (inclusion of two secondary hospitals) belonging to the same cluster. Ethical approval was obtained from the Institutional Review Board before starting this study (IRB Log Number: 20-690E).

Data analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) 22.0 (SPSS Inc., Chicago, IL, USA). Descriptive analysis was performed to determine the frequencies (%) of the categorical variables and plotted in MS Excel, where applicable.

Table 1. Characteristics of patients.

Parameters	All	Males	Females
n	2168	1244	924
Age (%)			
0–5	1508 (69.6)	916 (73.6)	592 (64.1)
6–18	227 (10.5)	110 (8.8)	117 (12.7)
19–29	215 (9.9)	83 (6.7)	132 (14.3)
30–59	187 (8.6)	117 (9.4)	70 (7.6)
≥60	31 (1.4)	18 (1.4)	13 (1.4)
Exposure location (%)			
Home	2090 (96.4)	1205 (96.9)	902 (97.6)
Hospital	16 (0.7)	12 (1.0)	4 (0.4)
Outdoor	35 (1.6)	23 (1.8)	12 (1.3)
Other	27 (1.2)	4 (0.3)	6 (0.6)
Exposure intent (%)			
Intentional	388 (17.9)	158 (12.7)	230 (24.9)
Unintentional	1739 (80.2)	1056 (84.5)	683 (73.9)
Withdrawal	14 (0.6)	12 (0.9)	2 (0.2)
Unknown	26 (1.2)	17 (1.3)	9 (0.9)
Other	1 (0)	1 (0.0)	0
Route (%)			
Ingestion	2026 (93.4)	1152 (92.6)	873 (94.5)
Inhalation	50 (2.3)	30 (2.4)	20 (2.2)
Bite/sting	22 (1)	15 (1.2)	7 (0.8)
Dermal	19 (0.9)	6 (0.5)	13 (1.4)
Parenteral	15 (0.7)	14 (1.1)	3 (0.3)
Unknown	36 (1.7)	27 (2.2)	8 (0.9)
Exposed substances (%)			
1	1980 (91.3)	1148 (92.3)	832 (90)
2	113 (5.2)	55 (4.4)	58 (6.3)
3	38 (1.8)	19 (1.5)	19 (2.1)
>3	18 (0.8)	7 (0.7)	10 (1.1)
Unknown	19 (0.9)	14 (1.1)	5 (0.5)

Note: Data are presented as n (%).

Results

Table 1 shows the characteristics of all patients and separated according to gender. Overall, more than two thirds of poisoning cases were children five years and below ($n = 1508$, 69.6%) while elders 60 and above constitute the least number of reported cases ($n = 31$,

1.4%). A majority ($n = 2090$, 96.4%) of those exposures occurred at home. Many of those exposures were also unintentional in nature, representing $n = 1739$ (80.2%) of all cases. Ingestion was overwhelmingly the most common route of exposure ($n = 2026$, 93.4%) and involved a single substance ($n = 1980$, 91.3%). Males represented 57.4% of all cases, with the highest proportion in boys aged five years and younger ($n = 916$, 73.6%). On the other hand, there is a higher proportion of female cases in the 6–18 ($n = 117$, 12.7%) and 19–29 ($n = 132$, 14.3%) age groups than males ($n = 110$, 8.8% and $n = 83$, 6.7%, respectively). Furthermore, females also had a higher prevalence of intentional exposure than males (24.9% vs 12.7%). No significant differences were noted in terms of exposure location, route, and number of ingested substances in males and females. The rest of the characteristics are shown in 1.

Comparisons of demographic characteristics between children (17 years and below) and adults (18 and above) are shown in Table 2. In terms of sex, a higher proportion of males were children (59.5% vs 49.4%). While home was the most common exposure location in both children and adults, adults had more outdoor exposures than children (6.0% vs 0.5%). Unintentional exposure was the most common intent in children ($n = 1621$, 93.4%) while intentional exposure was most prevalent in adults ($n = 283$, 65.4%). Ingestion was the most common route of exposure in both children and adults, and inhalational exposure was higher in adults than children (7.5% vs 0.9%). Lastly, adults were more likely to be exposed to multiple (2 or more) substances than children, although single substance exposure remains to be more prevalent. The rest of the differences are shown in Table 2.

Figure 2 shows the number of cases documented per year, highlighting a substantial increase in cases from 2019 representing a quarter of all cases recorded ($n = 539$, 24.9%). While the frequency of poison cases decreased in the years 2020 and 2021, the number of cases recorded was still higher than any of the previous years starting 2013 to 2018, owing to the inclusion of other hospitals in the documentation of cases.

Lastly, the majority of poisoning cases were due to pharmaceuticals ($n = 1485$, 68.5%). The top 3 most frequent substance classes were analgesics ($n = 397$, 18.3%), household cleaning substances ($n = 216$, 10%) and hormones and hormone antagonists ($n = 151$, 7%). The rest of the pharmaceuticals are shown in Figure 3(A,B).

Table 2. Exposure differences in children and adults.

Parameters	Children (≤17 years)	Adults (≥18 years)
N	1735	433
Sex (%)		
Males	1033 (59.5)	214 (49.4)
Females	702 (40.5)	219 (50.6)
Exposure location (%)		
Home	1716 (98.9)	392 (90.5)
Hospital	7 (0.4)	9 (2.0)
Outdoor	9 (0.5)	26 (6.0)
Other	3 (0.2)	6 (1.5)
Exposure intent (%)		
Intentional	105 (6.1)	283 (65.4)
Unintentional	1621 (93.4)	118 (27.3)
Withdrawal	0	14 (3.2)
Unknown	8 (0.5)	18 (4.2)
Other	1 (0.1)	0
Route (%)		
Ingestion	1670 (96.2)	359 (82.9)
Inhalation	16 (0.9)	32 (7.5)
Bite/sting	14 (0.8)	9 (2.0)
Dermal	17 (1.0)	1 (0.2)
Parenteral	5 (0.3)	10 (2.4)
Unknown	15 (0.8)	21 (4.9)
Exposed substances (%)		
1	1626 (93.7)	357 (82.5)
2	64 (3.7)	47 (10.9)
3	24 (1.4)	13 (3.1)
>3	11 (0.6)	6 (1.4)
Unknown	9 (0.5)	10 (2.2)

Note: Data are presented as n (%).

Discussion

The new data highlights pharmaceutical ingestion by children, suggesting a need for initiatives such as better public awareness and packaging legislation. The

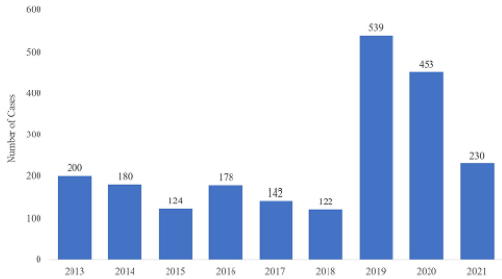
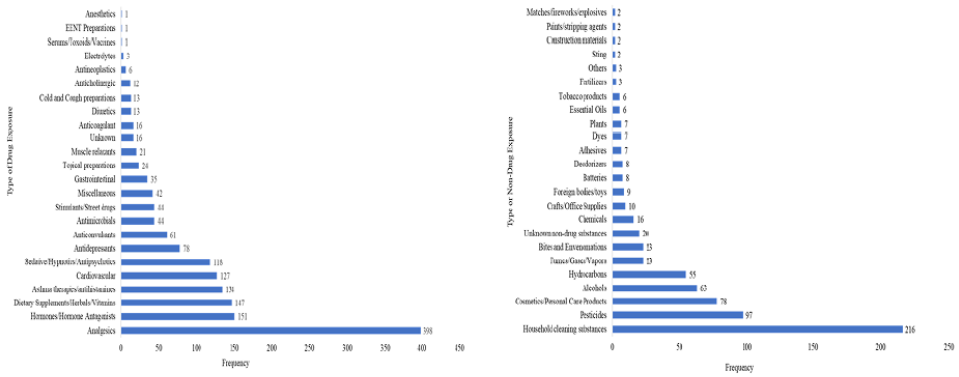


Figure 2. Registered cases (n) per year (note that year 2021 is only six months of data).



A. Pharmaceuticals B. Non-Pharmaceuticals

Figure 3. Type of exposure substance (A) pharmaceuticals and (B) non-pharmaceuticals.

findings also provide a reason to support better PC systems/network nationally which will allow better data collection on outcomes, hospital length of stay and resource optimization. Most referrals to the PCs in our series were for unintentional pediatric exposures, most commonly to pharmaceuticals, similar to other studies conducted elsewhere [14,15]. This can be explained by children's curiosity to explore surroundings and their hand-to-mouth behavior, and/or when pharmaceutical products are being used (ie a toddler grabs the bottle while in use, or inadvertent poisonings occur when two parents give a medicine twice in error, etc.…) which lead to accidental exposure to toxic substances [18]. Furthermore, some pharmaceuticals and household products resemble candies. The findings suggest that most of those products do not come in child-resistant packaging and are haphazardly stored in places that can be easily accessed by children. A combination of public and parental educational awareness for prevention, along with regulatory processes to maximize medication storage and formulation safety, could be effective in reducing the burden of poisoning [19,20]. Our finding corresponds to previous observations showing that children are at higher risk of exposure to poisonous substances [14,15]. It is worth noting that 2168 cases over a period of 8.5 years is relatively small compared to similar developing nations such as Malaysia ($N = 39{,}088$ poison exposure calls from 2006 to 2015) [21], Egypt ($N = 9713$ cases from 2017 to 2021) [22], and Iran ($N = 5777$ cases from 2015 to 2019) [23], all of which are also single-center studies. The relatively smaller number of cases can be attributed to several factors: it excludes calls from the public, covers a smaller population compared to other studies and reflects a lack of public awareness about the existence of such facilities, as the specialized call center is not accessible to the general public. Nevertheless, the hotline available to the public, based on over >20,000 calls related to poisonings [12], provides advice when sought. This opens an opportunity to increase publicity of the PC so it can better serve individuals and populations at higher risk of poisoning, given that such a facility reduces and prevents inappropriate ER and hospital visits [24,25].

In this study, although there is a close proportion of males and females in total over the adult range, there was a notable difference in the age groups 6–18 and 19–29 ranges, with females being more represented. Females also had a higher proportion of intentional exposure than males. These findings largely echo the gender-specific trends in acute exposure among adolescents and young adults in recent studies, with a general observation that females are more often involved in intentional exposure than males [26–28].

In this study, we found that pharmaceuticals were the most common poisoning substances (68.5%), followed by household cleaning substances (10%), cosmetics/personal care products (3.6%), and alcohols (2.9%). Analgesics in particular is the single biggest subclass of pharmaceuticals attributed to poisoning and this is in line with a recent review stating that pharmaceuticals acting on the nervous system (eg antipsychotics, anti-depressants and analgesics) is the overwhelming type of pharmaceutical toxicity worldwide [20]. The findings are also similar to other studies whereby poisoning caused by analgesics is very

common in adult cases and is likely due to the easy accessibility, over prescription, dependence and the high prevalence of self-medication practices in Saudi Arabia [29,30]. Drug labeling with special warnings such as "keep out of reach of children" in native language is just one way to prevent unintentional ingestion in children and while this requires good pharmacist practice, it does not remove the requirement for good parental supervision, proper storage and disposal of medications [31].

PCs were historically regarded as sources of information about the management of pediatric poisonings and for less severe exposure. Currently, the expansion of PC services encompasses a wide range of additional functions. PC staff plays an important role in poison prevention, especially with preschool and elementary children [32]. Accidental poisoning, especially in children, can be prevented by enhancing awareness among families about the proper storage and handling of pharmaceuticals, household products and any other substances that can cause harm to the human body. Better legislation is needed to enforce improved safety measures for dangerous pharmaceuticals and chemicals (eg child-resistant containers), and introduce restrictions on sales of pesticides. Appropriate counseling centers should be established for addiction and drug abuse.

Finally, evidence suggests that the availability of a PC services can provide timely epidemiologic information and guidance on managing poisoned patients [33]. This support for both public and healthcare professionals can help save lives and reduce healthcare costs. The American Center for Disease Control is one benchmark, where based on PC data obtained from 2022, it showed that unintentional poisoning is the number one cause of death in USA for ages 1–44 years, followed closely by motor vehicle accidents [34]. In Saudi Arabia, however, the critical role of PCs under the MoH has not yet been fully realized [35], resulting in a limited amount of published data that accurately reflect the true scope of poisoning as a public health issue. There is also a gap when it comes to the availability of credentialled toxicologists or specialists in poison information under any specialty except consultant emergency medicine. Good collaboration between stakeholders is needed to progress poisoning services in Saudi Arabia. This study aimed to add to the current body of published literature to enhance collective understanding of the etiology of poisoning in the population served by the second health cluster in Riyadh region.

Implementation of a robust computerized system that connects all PCs, facilitating nationwide coordination and data sharing, would be a considerable improvement for toxicovigilance in Saudi Arabia. This system would ensure seamless communication and data exchange between PCs at a national level. To effectively handle and analyze data, it is recommended to register poisoned patients using diagnostic codes. Additionally, establishing a standardized mechanism for notifying poisoning incidents is crucial and should be circulated among all relevant entities. Furthermore, collaboration with manufacturing companies and laboratories is crucial in proactively gathering comprehensive information about their products. This approach enables better anticipation and evaluation of both short- and long-term consequences and effects of chemicals. By involving these stakeholders, the ability to effectively assess and mitigate the risks associated with exposures can be enhanced.

The authors acknowledge some limitations. The findings are limited by the inherent disadvantages of a retrospective design. As such, other variables such length of hospital stay, treatment interventions, follow-up and patient outcomes are not fully included in the data captured. Further studies at the multicenter level (primary, secondary, and tertiary care centers) to establish a national PC database that will shed light in these factors are necessary to provide the bigger picture of the incidence and management of acute poisoning cases and exposure management in Saudi Arabia. Nevertheless, the study is scientifically valid and adds useful data to the limited existing literature on the overall toxicovigilance information in the country and supports the need to establish a nationwide toxicovigilance PC system.

Standardization in handling toxicology data is recommended to address various gaps. This will elevate healthcare services to a new level of optimal care, ensuring the efficient management and treatment of exposures. Meanwhile, PCs and toxicology expertise are needed nationally in recognition of their role in the prevention and management of poisonings. In this study, the PC is described a system for toxicology services that have been developed based on international standards. As poisoning is a real health issue of global importance, the availability of a toxicology surveillance system specific for each country is necessary to determine the existing risks of poisoning in the community and to take the appropriate elimination measures.

Conclusions

This retrospective study showed a series of poisoning cases documented in a specialized PC in Saudi Arabia and revealed that most cases are accidental pharmaceutical ingestion by children. Due to the

lack of comprehensive national data, the true incidence of domestic poisoning may be significantly underestimated. A specialized hotline operated by a designated national PC is recommended where toxicovigilance data are processed. This approach necessitates operating within a hub-and-spoke model integrating all PCs for MoH and other organizations to enhance collaboration and data sharing.

Disclosure statement

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Data availability statement

Data are available within the article.

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Appendix 3: Ministry of Health Poisoning Case Reporting Form

Kingdom of Saudi Arabia
Ministry of Health

Reporting Form

for Drug over dosage or Chemical Poisoning
(Send by Fax with Lab. Results within a week from date of receiving the case)

1

Region ..... Name of Hospital / Center.....
Incident No. (.....) Date of Reporting (/ /200 G.)
No. of Patients*(.....)

Patient Information: Name (.....) Telephone No.(.....)
Name of Health Center Patient belongs to: (.....) File No. (.....)
Nationality: ☐ Saudi ☐ Non – Saudi
Age: ☐ (0 – 4 years) ☐ (5-14 years) ☐ (15- 24 years) ☐ 25 years and above

Sex: ☐ Male ☐ Female
Place of incident ☐ Home ☐ Outside Home, specify (.....)
Date & Time of exposure: Date (/ /200) Time (.....) ☐ AM ☐ PM
Date & Time of arrival to Hospital: Date (/ / 200) Time (.....)
☐ AM ☐ PM

2

Condition of Patients at time of arrival to Hospital: ☐ Stable ☐ Deteriorated ☐ ** DEATH

Type of Poisining:

☐ Over Dosage: Name of drug (.....)
Name of Group: ☐ Analgesic & Antipyretics ☐ Antibiotics ☐ Antihistaminic ☐ Anthypertensive ☐ Antidiabetics
☐ Anti asthmatic ☐ Antiemetic ☐ Antiepileptic ☐ Contraceptive ☐ Antipsychotic ☐ Unknnown ☐ Others (.....)

☐ Chemical poisining: Name of Sbstance (.....)
Main Use: ☐ Insecticide ☐ Rodenticide ☐ Fungicide ☐ Hrbicide ☐ Veterinary therapy ☐ Antiseptic & Disinfectant
☐ Cleansing substance ☐ Fuel ☐ Unknown ☐ Others (.....)

Physical Form: ☐ Gas ☐ Liquid ☐ Solid ☐ Powder ☐ Unknown ☐ Other (.....)

Circumstances of exposure: ☐ Intentional ☐ Accidental ☐ Unknown

Route of Exposre: ☐ Oral ☐ Dermal ☐ Inhalation ☐ Ocular ☐ Unknown ☐ Other (.....)

Date & time of appearance of Signs & Symptoms: Date (/ /200) Time(.....) ☐ AM ☐ PM

Signs and Symptoms: 1..... 2..... 3.....4.....
5.....6.....

Lab Results:
☐ ☐ Blood result (.....)
Urine result (.....)
☐ Gastric lavage result (.....)
☐ Sample of poisoning substance result (.....)
☐ Others result (.....)
☐ Sample not taken.

Treatment: (.....)
Was antidote given ☐ No ☐ Yes if yes mention it (.....)

Management: ☐ No Admission in Hospital ☐ Admission in Hospital ☐ DAMA
Outcome: ☐ Recovery ☐ Death

If incident involves more than one patient, mention the number of patients and fill separate from for each patient and send immediately to the directorate to take preventive measures and to complete the investigations.
** Death Cases should be immediately reported by fax to the regional directorate of health affairs and from directorate to Chemical Safety Program in MOH with medical & forensic reports.

1. This part is to be filled by health inspector.
2. This part is to be filled by the doctor

Name of Health Inspector..... Sign .....
Name of Doctor..... Sign. & Stamp .....

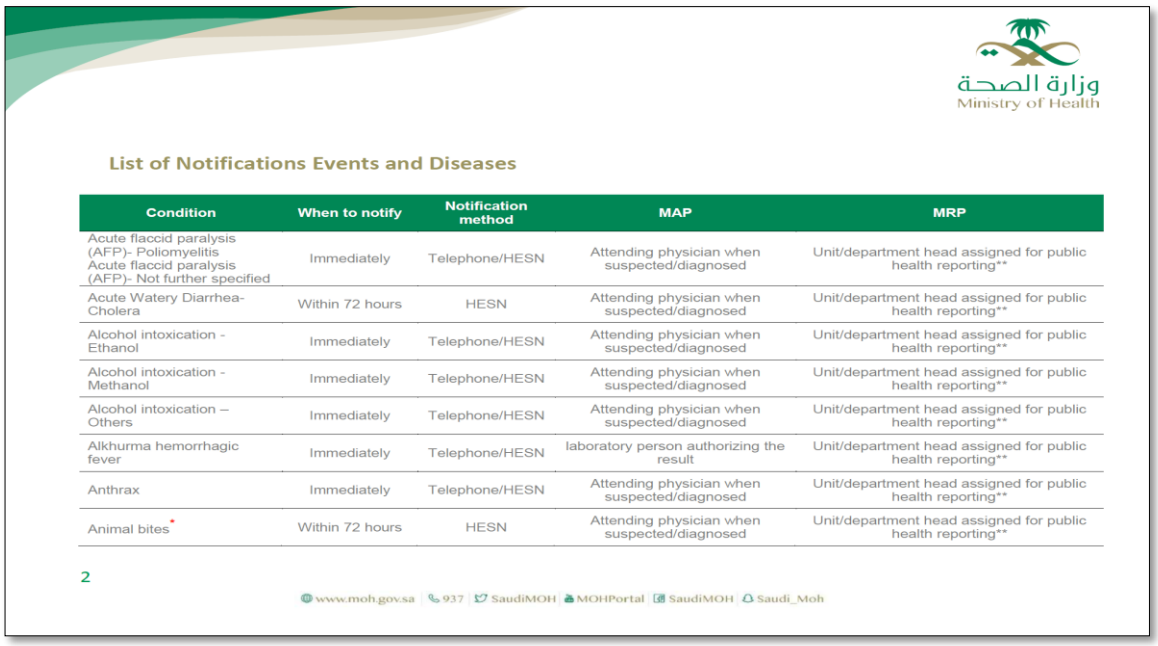
Appendix 4: MoH's Notifiable Diseases/Conditions List

وزارة الصحة
Ministry of Health

Notifiable diseases/conditions	الأمراض والأحداث الصحية واجبة التبليغ
Article 11 of the health profession regulation in The Kingdom of Saudi Arabia requires the health practitioner, once he/she examined a patient who is suspected to have an infectious disease, to report the event to the health authorities. Accordingly, the ministry of health requests from health practitioner and the laboratory services providers notify certain types of diseases of public health importance to the Public Health Agency. This document list of Notification events and diseases.	توجب المادة الحادية عشرة من نظام مزاولة المهن الصحية في المملكة العربية السعودية على الممارس الصحي فور معاينته لمريض مشتبه في إصابته بمرضٍ معدٍ أن يبلغ الجهات الصحية المختصة. وبناءً عليه تطلب وزارة الصحة أن يتم إخطار وكالة الصحة العامة من قبل الممارسين الصحيين المسؤولين عن الخدمات المخبرية والممارسين الطبيين بالإبلاغ عن الأمراض ذات الأثر على الصحة العامة. توضح هذه الوثيقة قائمة الأمراض التي يجب الإبلاغ عنها.

1

www.moh.gov.sa | 937 | SaudiMOH | MOHPortal | SaudiMOH | Saudi_Moh



وزارة الصحة
Ministry of Health

List of Notifications Events and Diseases

Condition	When to notify	Notification method	MAP	MRP
Acute flaccid paralysis (AFP)- Poliomyelitis Acute flaccid paralysis (AFP)- Not further specified	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Acute Watery Diarrhea-Cholera	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Alcohol intoxication - Ethanol	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Alcohol intoxication - Methanol	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Alcohol intoxication – Others	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Alkhurma hemorrhagic fever	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Anthrax	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Animal bites*	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**

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Condition	When to notify	Notification method	MAP	MRP
Chancroid	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Chlamydia trachomatis infection	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Cholera (V. Cholera O1 and O139)	Immediately	Telephone/HESN	Laboratory person authorizing the result	Unit/department head assigned for public health reporting**
COVID-19 (SARS-CoV-2) - laboratory confirmed- Death	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting
COVID-19 (SARS-CoV-2) - laboratory confirmed- Hospitalized	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting
Crimean-Congo hemorrhagic fever	Immediately	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Cryptosporidiosis	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Dengue virus infection	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Diphtheria	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Ebola viral hemorrhagic fever	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**

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Condition	When to notify	Notification method	MAP	MRP
Any case or cluster of cases that is suspected to be due to bioterrorism	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Any suspected infectious disease of non-specified etiology or unlisted above	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Arbovirus infections - West Nile virus or not further specified	Within 72 hours	HESN	Laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Avian influenza	Immediately	Telephone/HESN	Laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Bilharzia -Schistosomiasis	Within 72 hours	HESN	Laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Botulism foodborne or not further specified	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Brucellosis	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Campylobacter infection	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Carbon monoxide poisoning	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Chikungunya virus	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**

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Condition	When to notify	Notification method	MAP	MRP
Extra pulmonary tuberculosis	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Food or water borne illness outbreak (2 or more related cases)	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Food or water borne illness - Bacillus cereus	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Food or water borne illness –Staphylococcus aureus	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Food or water borne illness – salmonella spp	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Food or water borne illness - Escherichia coli- Enterotoxigenic (ETEC), E. coli, Enteropathogenic EPEC), E.coli Enteroinvasive (EIEC), E.coli Eterohemorrhagic (EHEC), E.coli O157: H7	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Food or water borne illness - Norovirus	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**

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وزارة الصحة
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Condition	When to notify	Notification method	MAP	MRP
Fever and Rash Illness((Measles/Rubella)	Immediately	HESN/Telephone	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Giardiasis	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Genital ulcer	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Genital Herpes (Herpes Simplex Virus)	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Gonorrhea	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Granuloma Inguinale (Donovanosis) (Klebsiella granulomatis)	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Haemophilus influenzae type b infection (Hib), invasive	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Hepatitis A, acute	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Hepatitis B – newly diagnosed	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Hepatitis C – newly diagnosed	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**

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List of Notifications Events and Diseases

وزارة الصحة
Ministry of Health

Condition	When to notify	Notification method	MAP	MRP
Leishmaniasis - visceral	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Leprosy	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Listeriosis	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Lymphogranuloma Venereum	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Marburg viral hemorrhagic fever	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Malaria	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Meningococcal infection – invasive	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Meningococcal meningitis	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Ophthalmia neonatorum	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Others-Meningitis	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**

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List of Notifications Events and Diseases

وزارة الصحة
Ministry of Health

Condition	When to notify	Notification method	MAP	MRP
Hepatitis D	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Hepatitis E	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Hepatitis viral (not further specified)	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Human immunodeficiency virus (HIV) infection	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Influenza –laboratory confirmed- hospitalized	Immediately	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Influenza –laboratory confirmed- Death	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Lassa fever	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Lead (blood lead >5 µg/dL)[HAMA7]	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Legionellosis	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Leishmaniasis - cutaneous/mucocutaneous	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**

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List of Notifications Events and Diseases

وزارة الصحة
Ministry of Health

Condition	When to notify	Notification method	MAP	MRP
Middle East Respiratory Syndrome (MERS)	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/deprtement head assigned for public health reporting**
Monkeypox	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Mumps	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Multidrug resistant organism outbreak: Vancomycin-Intermediate/Vancomycin-Resistant Staphylococcus aureus (VISA/VRSA), Carbapenemase Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE)	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Nipah virus diseases	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Novel influenza	Immediately	Telephone/HESN	Laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Paratyphoid	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Pertussis	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**

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List of Notifications Events and Diseases

وزارة الصحة
Ministry of Health

Condition	When to notify	Notification method	MAP	MRP
Plague	Immediately	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Pneumococcal infection – invasive	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Poliomyelitis	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Psittacosis	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Pulmonary Tuberculosis	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Q fever	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Rabies	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Respiratory syncytial virus-Hospitalized	Immediately	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Respiratory syncytial virus--laboratory confirmed-Death	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Rift valley fever	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**

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List of Notifications Events and Diseases

وزارة الصحة
Ministry of Health

Condition	When to notify	Notification method	MAP	MRP
Congenital Rubella	Immediately	HESN/Telephone	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Salmonellosis	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Scabies	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Shigatoxin and verotoxin producing *Escherichia coli* (STEC/VTEC)	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Shigellosis	Within 72 hours	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Smallpox	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Syphilis – (>2 years, or unknown duration)	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Syphilis – congenital	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Syphilis – infectious (<2 years)	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Toxic shock syndrome, streptococcal or others	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**

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List of Notifications Events and Diseases

وزارة الصحة
Ministry of Health

Condition	When to notify	Notification method	MAP	MRP
Tetanus	Immediately	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Trichomonas Vaginalis	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Typhoid fever	Within 72 hours	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Varicella – chickenpox	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Varicella – herpes zoster (shingles)	Within 72 hours	HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Viral hemorrhagic fevers	Immediately	Telephone/HESN	Attending physician when suspected/diagnosed	Unit/department head assigned for public health reporting**
Yellow fever	Immediately	Telephone/HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**
Zika virus infection	Immediately	HESN	laboratory person authorizing the result	Unit/department head assigned for public health reporting**

*include wild and domestic animals, snakes, scorpions and Venomous spiders

Note: Notification will be through the Health Electronic Surveillance Network (HESN Plus) and phone or email to the higher authority of the region/ Province

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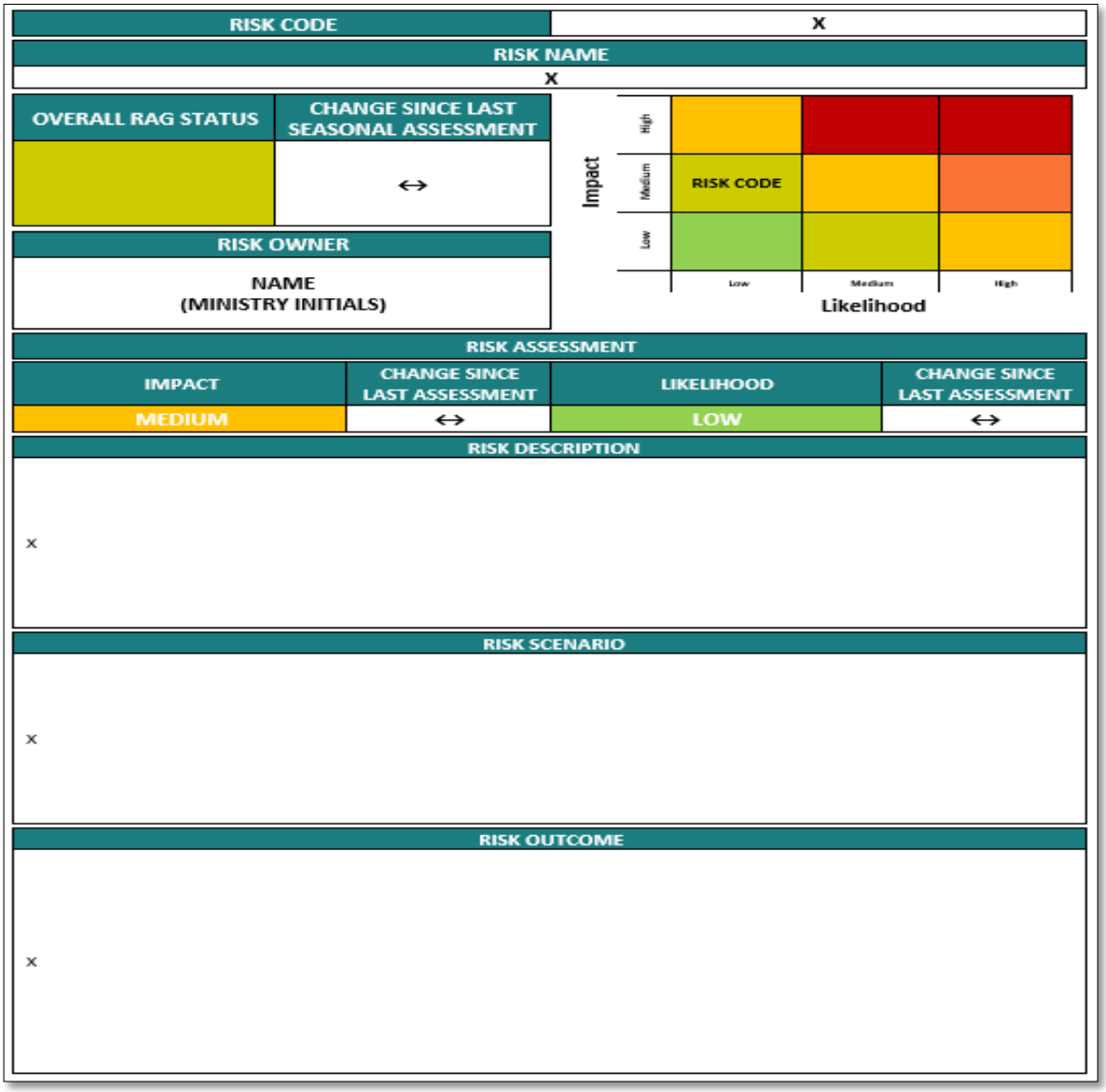
Appendix 5: Example of Risk Card



RISK CODE	X

RISK NAME
X

OVERALL RAG STATUS	CHANGE SINCE LAST SEASONAL ASSESSMENT
	↔

RISK OWNER
NAME (MINISTRY INITIALS)

RISK ASSESSMENT			
IMPACT	CHANGE SINCE LAST ASSESSMENT	LIKELIHOOD	CHANGE SINCE LAST ASSESSMENT
MEDIUM	↔	LOW	↔

RISK DESCRIPTION
x

RISK SCENARIO
x

RISK OUTCOME
x

Appendix 6: The Toxicovigilance Brochure

Appendix 7: Standards Operation Criteria for a National PCC

Physical Location
It should be spacious enough to accommodate staff, trainees, and necessary storage and conference areas, while remaining secure and quiet. The center should operate 24/7, with a minimum of three front-line staff (SPIs & PIPs) across three shifts. Each staff member should have a fixed 8-hour shift, with on-call rotation during weekends. Backup medical toxicologists should be available during each shift to provide additional support and training opportunities for medical residents.
Staff Qualifications
Should include competency in basic toxicology and poison control, with pharmacists and nurses having relevant backgrounds and additional training. To support the development of toxicologists and poison information specialists, the Ministry of Health should revise public health legislation to allocate funding for a regional Poison Prevention and Control System and establish the Toxicovigilance Enhancement and Awareness Act.
Workflow Organization
Should ensure that PCC staff report to a supervisor, maintaining continuous staffing during operating hours. The center should be secure, with protocols for evaluating calls and ensuring patient safety through follow-up. Sufficient additional staff should be available to handle incoming calls, with backup on-call support at all times. Engaging stakeholders is crucial for maintaining a proactive surveillance plan and effectively responding to public health threats. Their involvement is essential for safeguarding public health. Data management should focus on reporting statistical results to public health authorities, identifying at-risk populations during threats, and enabling timely protective measures.
Governance
The center should be either separate entity or part of the Ministry of Health
Stakeholders' engagement
Collaboration with stakeholders is necessary to develop a toxicology services system that aligns with international standards. This system should be supported by a poison

information database featuring standardized treatment protocols. Additionally, working with the Ministry of Commerce and Industry is crucial for implementing a coding system for registered items. This system will facilitate the categorization of substances by poisoning severity, first aid measures, and special instructions, including the creation of a local medication safety data sheet.
System Requirements
Ensure access to health information infrastructure
The electronic exchange of personal health information must comply with relevant patient privacy laws and standards
Ensure that the surveillance system is compatible with the National Electronic Disease Surveillance System
Ensure that all data resources have Electronic Case Reporting system
Ensure that there will be an Integrated Data Repository well maintained and centralized
Case Notification for Passive Monitoring and Early Intervention
Establish a system or record locator that allows retrieval and review of all condition reports associated with an individual.
Ensure access to necessary equipment for the electronic management and exchange of information, including laboratory test orders, samples, and results, with hospitals, doctors' offices, community health centers, and poison control centers.
Understanding Product Coding and Reporting
Implement the CLP Regulation to ensure it is realistic, acceptable to all stakeholders, and garners political support from the majority of Member States.
Establish a Unique Product Identifier and utilize the Chemical Abstracts Registry number.
Distinguish the characteristics of outbreaks caused by toxic agents.
Define and identify toxidromes to aid in diagnosis and management.
Identify and analyze factors that influence toxicity.
Develop performance metrics to track the progression of technical steps, embedding key performance indicators into process phases for performance analytics and decision alerts based on benchmarks.
Foster engagement and development within a Community of Practice for knowledge sharing and collaboration.
Establish a mechanism for feedback to continuously improve the system.
Create dashboards for monitoring and evaluating toxicovigilance efforts.

Conduct robust evaluations of new and emerging innovative interventions in toxicovigilance.
Assign and authorize a spokesperson for ongoing media communications related to poisoning. Designate one center as responsible for announcing outbreaks that are subject to obligatory notification.
Risk Assessment
For the center: enterprise risk assessment
For the scope: which hazardous should be monitored
For the national resilience: analysis of out break through data monitoring
Data Management
Data In: Reports harmonization
Data out: Reports facilitations

Appendix 8: Example of SPI Training Curriculum: The Saudi Experience (Four Months)

Who are SPIs?

Specialists in Poison Information (SPIs) offer prompt assessment and triage guidance via phone at Poison Control Centers (PCCs). These specialists may include trained nurses, pharmacists, or physicians with toxicology expertise. PCCs generally employ SPIs, Poison Information Providers (PIPs), medical toxicologists, and epidemiologists. While PIPs may lack formal training in nursing, pharmacy, or medicine, they carry out comparable duties within PCCs under the oversight of an SPI or a medical/managerial director.

What are the main roles of SPIs?

Triage and case documentation are key responsibilities of SPIs, essential for ensuring prompt responses to exposure incidents. SPIs must quickly evaluate the severity of the exposure and the urgency of the information requested, gathering details about the substance, context, and symptoms. The caller's background—whether a layperson or healthcare provider—affects the level of detail and terminology used. Accurate documentation is vital for tracking cases, enhancing toxicology education, identifying exposure trends, and improving public health initiatives and patient care quality.

MODULES	ITEMS
Introduction to Clinical Toxicology	• Introduction and history of clinical toxicology • Toxidromes • Management of the poisoned or overdosed patient • Laboratory principles • Pharmacokinetics and Toxicokinetic overview • Administration, liberation, and absorption of toxicants • Prevention of absorption from the gastrointestinal tract • Distribution and Metabolism of Toxicants in the body • Elimination of toxicants • Enhancement of elimination of toxicants
General Poison Information Module	• General orientation in the poison information centre • Telephone communication skills for a poison information specialist • Using information resources to search for an answer

	• Systematic approach for answering a question • Documentation system
Basic clinical toxicology module	• General management principles (gut decontamination and antidotes) • Principles of clinical pharmacology and drug information • Critical evaluation of literature references and information in different databases • Updates and the recent changes in practice of poison management • Case-based diagnostic reasoning focusing on: o Taking case history o Calculations of Toxic Doses o General Management Principles o Emergency Management and Supportive Care o Decontamination o Antidotes o Biologicals (Bites, Stings, Envenomation, Food Poison, Mushroom and Plants) o Chemicals o Drugs o Household Products o Pesticides o Toxidromes o Interpretation of laboratory investigations
Advanced clinical toxicology module	1. Case-based diagnostic reasoning, developing competence in case history, evaluation, and interpretation of laboratory investigations. 2. Recognition of various diagnosis and treatment of the following ingestions: • Anti-depressants, including SSRI's, Serotonin syndrome and TCA's • Anticoagulants • Anticonvulsants • Antihistamines • Antipsychotics • Lithium • Barbiturates • Phenothiazines • Phenytoin and other anti-epileptics • Opioids • Clonidine

	• Toxic alcohols • Cocaine • Amphetamines • Hallucinogens • Salicylates • Acetaminophen • Iron • Hydrocarbons • Heavy Metals • Herbicides • Isoniazid • Caustic Ingestions • Organophosphates • Mushroom/ Plants • Cyanide and Carbon Monoxide • Neuroleptics • Sedative/ Hypnotics • Cardiovascular drugs: Beta-blockers, Digoxin, Calcium Channel Blockers • Envenomation: snakes, spiders and scorpions

Appendix 9: An Example of Awareness Brochure

Appendix 10: An Example of a Training Project (Out-Of-Hospital Management card)

OUT OF HOSPITAL MANAGEMENT OF HOUSEHOLD PRODUCT POISONING CARD

How this card works: Match the colour of the substance swallowed to the same colour in the treatment

Acetone
Acid
Alcohol
Ammonia
Aspirin
Battery acid
Battery (button)
Benzine
Bleach
Calamine lotion
Camphorate oil
Carbon tetrachloride
Caustic soda
Cement
Chlorine (for pools)
Condo's crystals
Cosmetics
Deodorants
Detergents
Dish washing liquids
Dish washing power (automatic)
Disinfectants
Drain cleaners

Dyes (fabric or hair)
Fabric softener
Fertilizers
Firelighters
Fluoride tablets (give milk)
Glue (contact and other)
Hair colorants
Hair perms, straighteners
Hydrochloric acid
Hydrogen peroxide
Iron tablets
Insect repellent
Insecticides
Liniments (e.g. Wintergreen)
Medicines
Mercurochrome
Metal cleaner & polishes
Methylated spirits
Mothballs (naphthalene)
Mushrooms (poisonous)
Nail polish remover
Oven cleaner
Paint (oil)
Paint remover (caustic)

Paint remover (solvent)
Paracetamol
Paraffin
Perfumes
Pesticides
Petrol
Pills
Plants
Rat bait (e.g. Rattex)
Shampoos
Snail bait
Surgical spirit
Tablets
Thinners
Toilet cleaners
Turpentine (mineral)
Varnish
Vitamins
Vitamins & Iron
Washing powder
Washing soda
Weed killers (herbicides)
Window (glass) cleaners

Do not make the person vomit. Do not give them anything to drink or eat. Contact the poison information centre and/or get the patient to the clinic/hospital as soon as possible.

Do not make the person vomit. Small amounts of water may be given by mouth. Do not neutralize the poison. Contact the poison information centre and/or get the patient to the clinic/hospital as soon as possible.

Do not make the person vomit. Small amounts (half a cup) of water or milk may be given by mouth. Contact the poison information centre and/or get the patient tothe clinic/hospital as soon as possible.

The induction of vomiting is recommended if within 1 hour of taking the poison and the patient is awake and alert. This can be achieved by giving a glass of lukewarm water followed by stimulation of the throat by gently inserting a finger or blunt handle of a spoon. Contact the poison information centre and/or get the patient to the clinic/hospital as soon as possible.

Prepared by: Pharm.D Candidate Joud Al-fraih Supervised by: Najla Khoja. R.Ph., MSc

Appendix 11: Summary of Case Information Coding Arranged Alphabetically

Field	Coding Description	
AGE	NULL if actual age not available	
	1-120 Years Actual age value	Age unit: unit of measurement for the patient's age. Code Age in days if child is <1 month old. Code Age in months if child is between the age of 1 month and 23 months. Code Age in years if patient is 2 years and older.
ANIMAL TYPE	NULL if no animal available	
	Codes for Animal -1-9	Cat. Dog. Bird. Aquatic. Cow. Horse. Rodent/Lagomorph. Sheep/Goat. Other.
CALL SITE CODE	NULL if no location is available	
	Codes for location	Health care. Others.
CALL SUBCATEGORY	NULL if no sub location is available	
	Codes for Further specifies the type of information call	Drug Information. Drug Identification. Environmental Information. Medical Information. Occupational Information. Prevention/Safety/Education Information. Teratogenicity Information.

		Substance Abuse Information. Other.
CALL TYPE	NULL if no type of call is available	
	Codes if Nature of the call is available	Exposure Call. Drug Information Call. Drug Identification. Environmental Information. Medical Information. Occupational Information. Poison Information. Prevention/ Safety/ Education Information. Teratogenicity Information. Substance Abuse. Administrative. Caller Referred. Other.
CASE NUMBER	Unique identifier for the case	Center Code-Case Number-Year.
CASE STATUS	Code for the Status of the case	Open. Closed. Rejected by NPDS. Deleted at Regional Poison Center.
CALLER SITE	NULL if no site is available	
	Location from where the call originated	Own residence. Other residence. Workplace. Health Care Facility. School. Restaurant/Food Service. Public Area. Others.
CHRONICITY	Duration or frequency of the exposure	Acute. Acute-on-Chronic. Chronic. Unknown.
CLINICAL EFFECT	NULL If clinical effects occur that are not listed below, document them in the medical record and select 'Other' for that category	
	Health effects observed from exposure will be	Cardiovascular. Dermal.

	categorized (included in this description) and subcategorized into up to 169 effects (not included)	Gastrointestinal. Heme/Hepatic. Miscellaneous. Neurological. Ocular. Renal/GU. Respiratory.
CLINICAL EFFECT RELATEDNESS	NULL if no relation is available	
	Relationship of the clinical effect to the exposure	Related to the exposure. Not related to the exposure. Unknown if related to the exposure.
CLINICAL EFFECT DURATION	Length of time the clinical effect lasts	≤ 2 hours. > 2 hours to ≤ 8 hours. > 8 hours to ≤ 24 hours. > 24 hours to ≤ 3 days. > 3 days to ≤ 1 week. > 1 week to ≤ 1 month. > 1 month. Anticipated permanently. Unknown.
EXPOSURE DURATION	Duration of exposure to the substance	> 8 hours to ≤ 24 hours. > 24 hours to ≤ 1 week. > 1 week to < 1 month. > 1 month to ≤ 3 months. > 3 months. Unknown.
EXPOSURE SITE	Location where the exposure occurred	Own residence. Other residence. Workplace. Health Care Facility (HCF). School. Restaurant/Food Service. Public Area. Other. Unknown.
GENDER	Gender of the patient	Male. Female. Unknown Gender. Pregnant.
GENERIC CODE	NULL if no generic code is available	
	General classification of the substance	Product Codes must also be entered whenever a more specific code than the Generic Code is

		available. Generic Code when a Poisindex® Product Code is selected.
INITIAL SPI CODE	NULL if no SPI code is available	
	Code for the initial specialist in poison information	Unique code 1 to 4 digits.
MEDICAL OUTCOME	Medical outcome of the patient following exposure based upon all available information	No effect. Minor effect. Moderate effect. Major effect. Death. Not followed. Confirmed non-exposure. Death, indirect report.
REASON	The underlying reason, purpose, or intent for which the exposure occurred	Unintentional -General. Unintentional Environmental. Unintentional – Occupational. Unintentional – Therapeutic error. Unintentional – Misuse. Unintentional - Bite / sting. Unintentional – Food poisoning. Unintentional – Unknown. Intentional - Suspected suicide. Intentional – Misuse. Intentional – Abuse. Intentional - Unknown Other - Contamination / tampering. Other – Malicious. Other – Withdrawal. Adverse reaction – Drug. Adverse reaction – Food. Adverse reaction – Other. Unknown reason.
THERAPY OPTION	The reason the case has no Therapies recorded.	No Therapy Provided. Observation Only. Patient Refused Any Help.

		Unknown if Therapy Provided.
THERAPIES	Therapies that were recommended and/or performed in relation to the exposure reported.	1) Ipecac 2) Charcoal, multiple dose 3) Charcoal, multiple dose 4) Lavage 5) Cathartic 6) Whole bowel irrigation 7) Other emetic 8) Dilute/rinse/wash 9) Fresh air 10) Food 11) Alkalinization 12) Amyl nitrite 13) Antiarrhythmic 14) Anticonvulsants 15) Antihistamines 16) Antihypertensives 17) Antivenin/antitoxin 18) Atropine 19) BAL 20) Bronchodilators 21) Calcium 22) Cardioversion 23) CPR 24) Deferoxamine 25) ECMO 26) EDTA 27) Ethanol 28) Extracorp procedure 29) Fab fragments 30) Fluids, IV 31) Flumazenil 32) Folate 33) Glucagon 34) Glucose, > 5% 35) Hemodialysis 36) Hemoperfusion 37) Hydroxocobalamin 38) Hyperbaric oxygen 39) Intubation 40) Methylene blue 41) NAC, IV 42) NAC, PO 43) Naloxone 44) Neuromuscular blocker

		45) Oxygen 46) 2-PAM 47) Penicillamine 48) Physostigmine 49) Phytonadione 50) Pyridoxine 51) Sodium nitrite 52) Sodium thiosulfate 53) Succimer 54) Transplantation 55) Vasopressors 56) Ventilator 57) Other 58) Antibiotics 59) Antiemetics 60) Antivenin (fab fragment) 61) Benzodiazepines 62) Fomepizole 63) Insulin 64) Nalmefene 65) Octreotide 66) Pacemaker 67) Sedation (other) 68) Steroids 69) Other Decontamination 70) Acidification 71) Exchange transfusion 72) Forced diuresis 73) Peritoneal dialysis

Appendix 12: The Poisoning Severity Score (PSS)

ORGAN	NONE	MINOR	MODERATE	SEVERE	FATAL
	0	1	2	3	4
	No symptoms or signs	Mild, transient and spontaneously resolving symptoms or signs	Pronounced or prolonged symptoms or signs	Severe or life-threatening symptoms or signs	Death
GI-tract		• Vomiting, diarrhoea, pain • Irritation, 1st degree burns, minimal ulcerations in the mouth • Endoscopy: erythema, oedema	• Pronounced or prolonged vomiting, diarrhoea, pain, ileus • 1st degree burns of critical localization or 2nd and 3rd degree burns in restricted areas • Dysphagia • Endoscopy: ulcerative transmucosal lesions	• Massive haemorrhage, perforation • More widespread 2nd and 3rd degree burns • Severe dysphagia • Endoscopy: ulcerative transmural lesions, circumferential lesions, perforation	
Respiratory system		• Irritation, coughing, breathlessness, mild dyspnoea, mild bronchospasm • Chest X-ray: abnormal with minor or no symptoms	• Prolonged coughing, bronchospasm, dyspnoea, stridor, hypoxemia requiring extra oxygen • Chest X-ray: abnormal with moderate symptoms	• Manifest respiratory insufficiency (due to e.g. severe bronchospasm, airway obstruction, glottal oedema, pulmonary oedema, ARDS, pneumonitis, pneumonia, pneumothorax) • Chest X-ray: abnormal with severe symptoms	
Nervous system		• Drowsiness, vertigo, tinnitus, ataxia • Restlessness • Mild extrapyramidal symptoms • Mild cholinergic/anticholinergic symptoms • Paraesthesia • Mild visual or auditory disturbances	• Unconsciousness with appropriate response to pain • Brief apnoea, bradypnoea • Confusion, agitation, hallucinations, delirium • Infrequent, generalized or local seizures • Pronounced extrapyramidal symptoms • Pronounced cholinergic/anticholinergic symptoms • Localized paralysis not affecting vital functions • Visual and auditory disturbances	• Deep coma with inappropriate response to pain or unresponsive to pain • Respiratory depression with insufficiency • Extreme agitation • Frequent, generalized seizures, status epilepticus, opisthotonus • Generalized paralysis or paralysis affecting vital functions • Blindness, deafness	

ORGAN	NONE	MINOR	MODERATE	SEVERE	FATAL
	0	1	2	3	4
	No symptoms or signs	Mild, transient and spontaneously resolving symptoms or signs	Pronounced or prolonged symptoms or signs	Severe or life-threatening symptoms or signs	Death
Cardio-vascular system		• Isolated extrasystoles • Mild and transient hypo/hypertension	• Sinus bradycardia (HR ~40-50 in adults, 60-80 in infants and children, 80-90 in neonates) • Sinus tachycardia (HR ~140-180 in adults, 160-190 in infants and children, 160-200 in neonates) • Frequent extrasystoles, atrial fibrillation/flutter, AV-block I-II, prolonged QRS and QTc-time, repolarization abnormalities • Myocardial ischaemia • More pronounced hypo/hypertension	• Severe sinus bradycardia (HR ~<40 in adults, <60 in infants and children, <80 in neonates) • Severe sinus tachycardia (HR ~>180 in adults, >190 in infants and children, >200 in neonates) • Life-threatening ventricular dysrythmias, AV block III, asystole • Myocardial infarction • Shock, hypertensive crisis	
Metabolic balance		• Mild acid-base disturbances (HCO_3 ~15-20 or 30-40 mmol/l; pH~7.25-7.32 or 7.50-7.59) • Mild electrolyte and fluid disturbances (K^+ 3.0-3.4 or 5.2-5.9 mmol/l) • Mild hypoglycaemia (~50-70 mg/dl or 2.8-3.9 mmol/l in adults) • Hyperthermia of short duration	• More pronounced acid-base disturbances (HCO_3 ~10-14 or >40 mmol/l; pH ~7.15-7.24 or 7.60-7.69) • More pronounced electrolyte and fluid disturbances (K^+ 2.5-2.9 or 6.0-6.9 mmol/l) • More pronounced hypoglycaemia (~30-50 mg/dl or 1.7-2.8 mmol/l in adults) • Hyperthermia of longer duration	• Severe acid-base disturbances (HCO_3 ~<10 mmol/l; pH ~<7.15 or >7.7) • Severe electrolyte and fluid disturbances (K^+ <2.5 or >7.0 mmol/l) • Severe hypoglycaemia (~<30 mg/dl or 1.7 mmol/l in adults) • Dangerous hypo- or hyperthermia	
Liver		• Minimal rise in serum enzymes (ASAT, ALAT ~2-5 x normal)	• Rise in serum enzymes (ASAT, ALAT ~5-50 x normal) but no diagnostic biochemical (e.g. ammonia, clotting factors) or clinical evidence of liver dysfunction	• Rise in serum enzymes (~>50 x normal) or biochemical (e.g. ammonia, clotting factors) or clinical evidence of liver failure	
Kidney		• Minimal proteinuria/haematuria	• Massive proteinuria/haematuria • Renal dysfunction (e.g. oliguria, polyuria, serum creatinine of ~200-500 µmol/l)	• Renal failure (e.g. anuria, serum creatinine of >500 µmol/l)	

ORGAN	NONE	MINOR	MODERATE	SEVERE	FATAL
	0	1	2	3	4
	No symptoms or signs	Mild, transient and spontaneously resolving symptoms or signs	Pronounced or prolonged symptoms or signs	Severe or life-threatening symptoms or signs	Death
Blood		• Mild haemolysis • Mild methaemoglobinemia (metHb ~10-30%)	• Haemolysis • More pronounced methaemoglobinemia (metHb ~30-50%) • Coagulation disturbances without bleeding • Anaemia, leukopenia, thrombocytopenia	• Massive haemolysis • Severe methaemoglobinemia (metHb >50%) • Coagulation disturbances with bleeding • Severe anaemia, leukopenia, thrombocytopenia	
Muscular system		• Mild pain, tenderness • CPK ~250-1,500 iu/l	• Pain, rigidity, cramping and fasciculation • Rhabdomyolysis, CPK ~1,500-10,000 iu/l	• Intense pain, extreme rigidity, extensive cramping and fasciculation • Rhabdomyolysis with complications, CPK ~>10,000 iu/l • Compartment syndrome	
Local effects on skin		• Irritation, 1st degree burns (reddening) or 2nd degree burns in <10% of body surface area	• 2nd degree burns in 10-50% of body surface (children: 10-30%) or 3rd degree burns in <2% of body surface area	• 2nd degree burns in >50% of body surface (children: >30%) or 3rd degree burns in >2% of body surface area	
Local effects on eye		• Irritation, redness, lacrimation, mild palpebral oedema	• Intense irritation, corneal abrasion • Minor (punctate) corneal ulcers	• Corneal ulcers (other than punctate), perforation • Permanent damage	
Local effects from bites and stings		• Local swelling, itching • Mild pain	• Swelling involving the whole extremity, local necrosis • Moderate pain	• Swelling involving the whole extremity and significant parts of adjacent area, more extensive necrosis • Critical localization of swelling threatening the airways • Extreme pain	

Appendix 13: WHO One Center for Each Country Flyer

World Health Organization
European Region

At least one poison centre in each country

Summary for policy makers

A poison centre is a specialized unit advising on and assisting in the prevention, diagnosis and management of acute and chronic poisoning. Poison centres contribute to reducing the burden of diseases related to exposure to hazardous chemical agents in emergencies and in everyday life.

Why a poison centre should be established in each country

1. Poisonings are a matter of public health concern.
2. Human exposure to chemical agents is increasing, and additional preventive action is required.
3. Poison centres play a pivotal role in management of poisonings, detection and public health management of chemical emergencies, implementation of the International Health Regulations *(2005)* (IHR), sound management of chemicals and other specialized functions.[1]
4. To achieve progress in implementation of global and regional chemical safety-related strategies, poison centres are crucial.
5. Poison centres add meaningful value to health-care systems – they actively save lives and reduce the costs of health care related to poisonings.

1 Poisonings are a matter of public health concern

The negative health impacts of poisonings are vast and varied, as illustrated by global health statistics.

In 2019, **0.5 million fatalities** were attributed to illicit drug use, and **18 million years of healthy life** were lost owing to drug use disorders *(1)*.

In 2016, **106 683 deaths** and the loss of **6.3 million years of healthy life** were attributed to acute chemical poisoning *(2)*.

Every year, **651 279 deaths** are caused by hazardous substances at workplaces *(3)*.

Annually, **4.5–5.4 million people** are bitten by snakes; of these, **1.8–2.7 million** develop a clinical illness, and **81 410–137 800** die from snake bites *(2)*.

Every year, **385 million** cases of unintentional, acute poisonings occur; 44% of farmers world-wide are affected by pesticides *(4)*.

1 In some countries, poison centres mandate can include management of emergency situations with involvement of radioactive substances and materials and biological emergencies as well as diseases of unknown etiology.

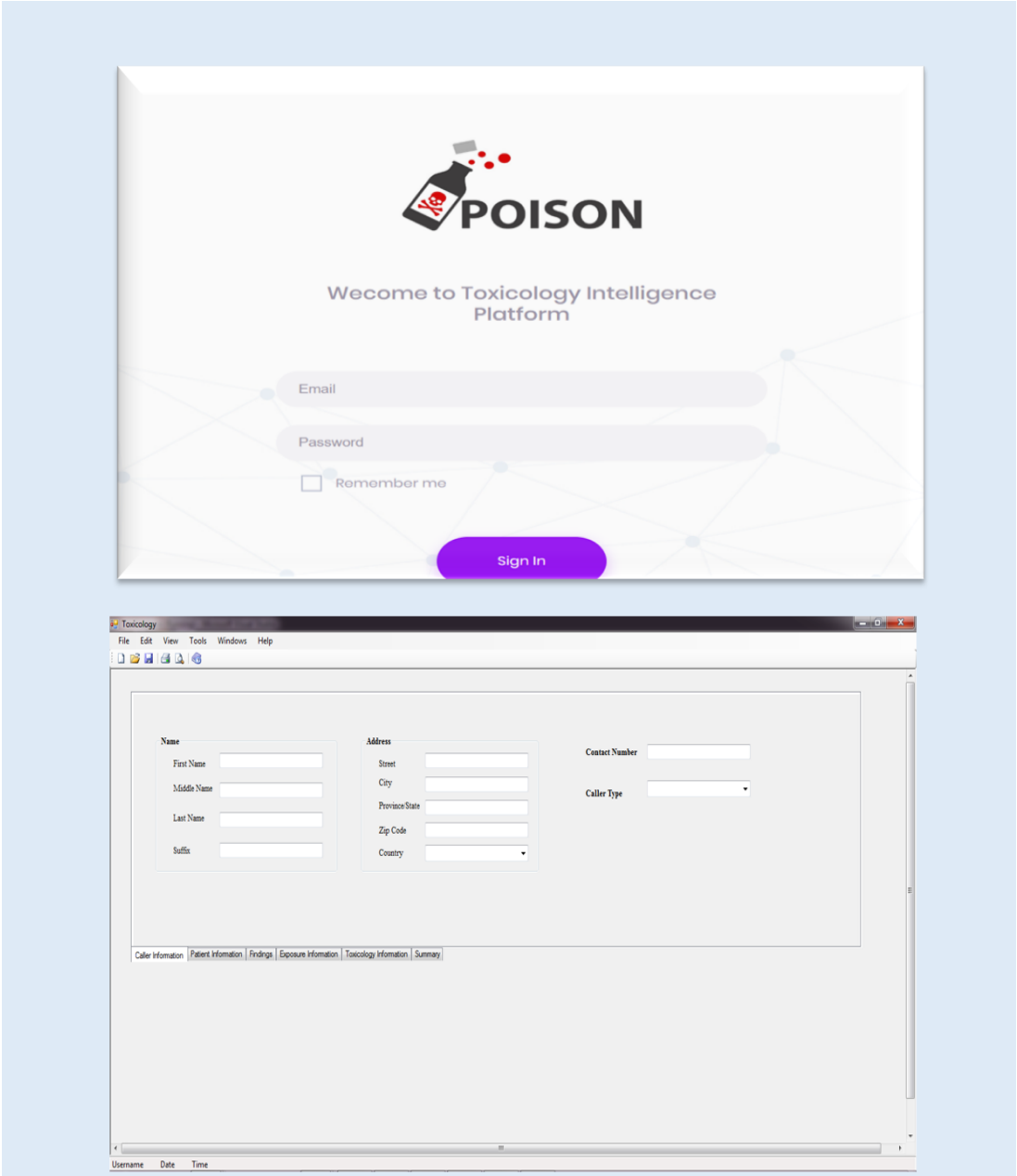
Appendix 14: Minimum Operation Standards for a National PCC (toolkit)

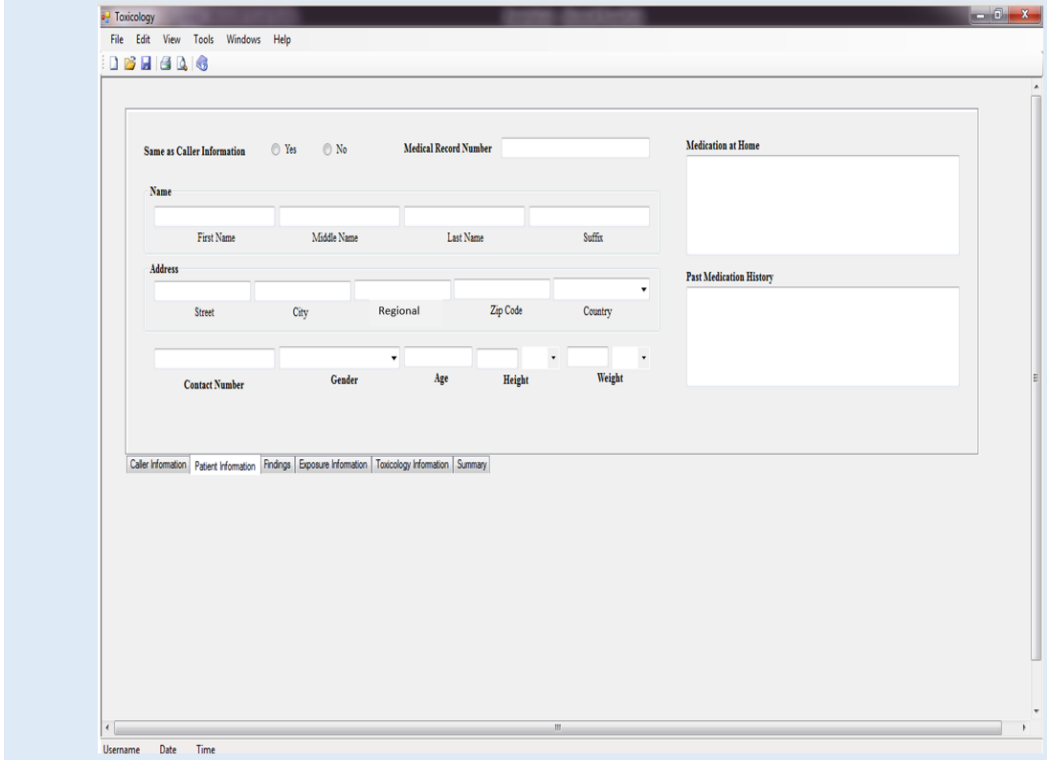
Category	Checkpoints
General Requirements	
A. Services Provided	□ Link to other emergency hotlines.
	□ Serve the designated service area population 24 hours per day every day of the year.
	□ Provide expert consultation on poisoning diagnosis and treatment over the phone and at bedside.
	□ Offer information and referral services to the public (open access).
	□ Accessible on a toll-free (freephone) number.
	□ The service can be provided on a 24-hour basis in all the languages officially recognized within the user population.
	□ Identify tertiary referral treatment centers for poison patients.
	□ Policies and Protocols: Must be developed for consistent evaluations and treatment of toxic exposures.
	□ Coordinate poison prevention and medical management program
	□ Report and investigate new toxic risks and injuries.
	□ The poison information service keeps computerized records of enquiries.
	□ Collect data and engage in research for poison prevention and control.
	□ The poison information service has an established role in the management of CBRN incidents.
	□ The poison information service has its own dedicated and adequate budget.
	□ The poison information service has a contingency plan to

	ensure continuation of the service in the event of a natural or technological disaster such as a power failure, fire etc.
Staffing Requirements	
B. Medical Director	□ Relevant medical training and certification in toxicology.
	□ Responsible for training specialists and overseeing medical decisions.
	□ Dedicate at least 20 hours per week to the center.
	□ The Director of the poison information service is professionally qualified in a relevant field i.e. medicine or pharmacy.
C. Specialists in Poison Information (SPIs)	□ Interpret and communicate poison information effectively.
	□ All staff who provide the poison information service are educated to university degree level in a relevant subject e.g. biochemistry, medicine, nursing, pharmacology, pharmacy, toxicology etc., or are experienced, qualified nurses.
	□ All staff who provide the poison information service have received specific and adequate training to enable them to carry out this task to a good standard.
	□ There are written guidelines on how new staff should be trained and on the subjects to be included in the training program.
	□ The poison information service has adequate, up-to-date information sources including: □ Product data, including pharmaceutical data.

	□ Treatment protocols. □ Textbooks.
Operational Requirements	
D. Location	□ The poison center is located within, or proximal to, a healthcare facility.
	□ If the poison information service is provided from more than one location during the 24-hour period, then there are measures and procedures should be in place to ensure that the quality of the service is consistent at all locations and that confidentiality is not compromised.
	□ Backup location should always be considered.
E. Documentation	□ The poison information service keeps computerized records of enquiries.
	□ The poison information service has defined a minimum set of data that must be documented for each enquiry.
	□ The poison information service can produce a regular report of its activities and statistics e.g. an Annual Report.
	□ Regional data collection system. Each regional program shall utilize a data collection system that includes recording of all inquiries and cases handled or admitted by the center.
F. Quality Control	□ The poison information service conducts periodic audits of its own activities to ensure that internal procedures and standards are being observed.

Appendix 15: An Example of Toxicovigilance Platform

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Medication at Home
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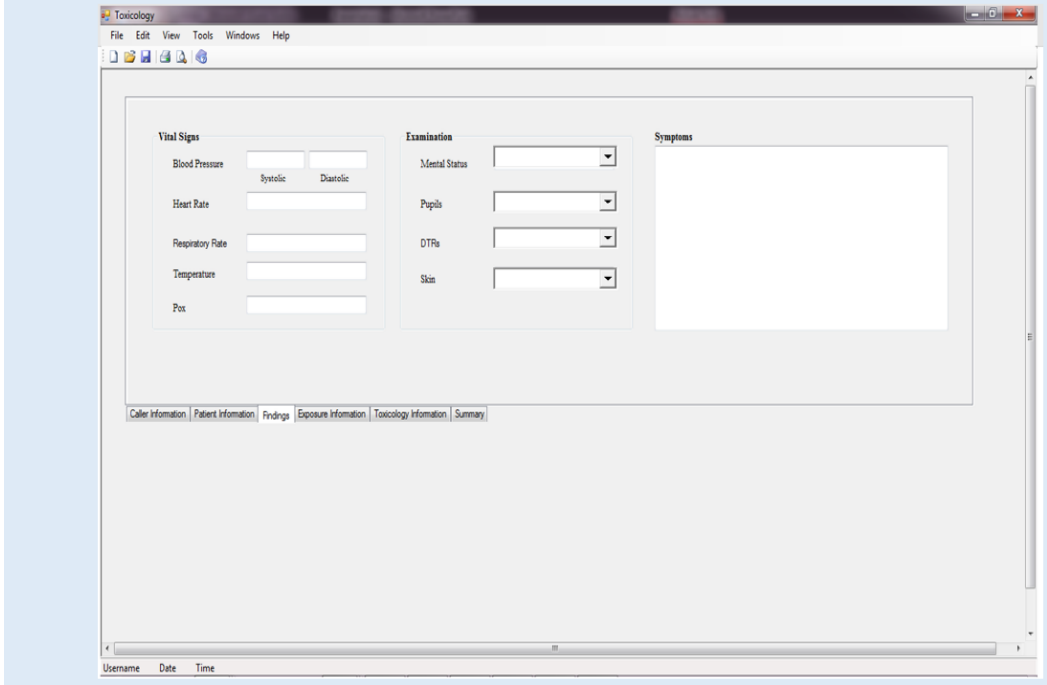
Patient Information
Findings
Exposure Information
Toxicology Information
Summary
Username
Date
Time


Toxicology
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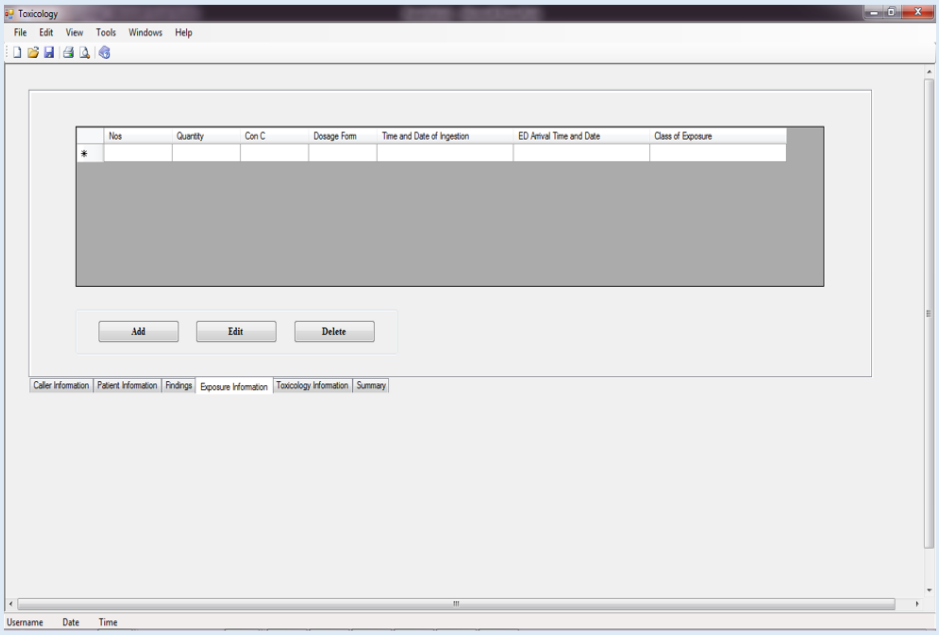
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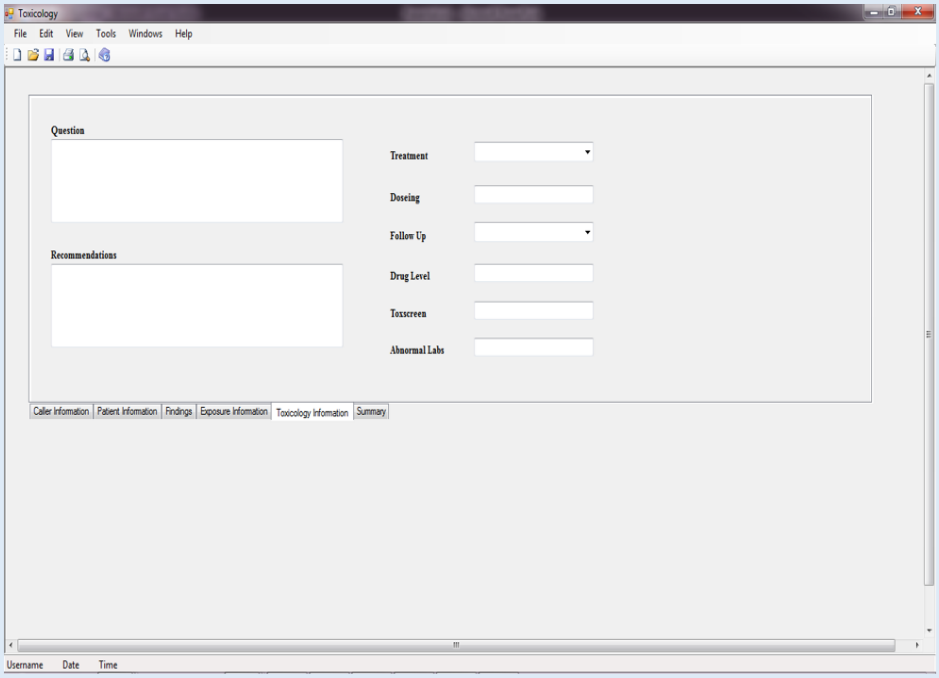
Toxicology
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Treatment
Dosing
Follow Up
Drug Level
Toxscreen
Abnormal Labs
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Patient Information
Findings
Exposure Information
Toxicology Information
Summary
Username
Date
Time

Thank you