Safe Drugs Save Lives

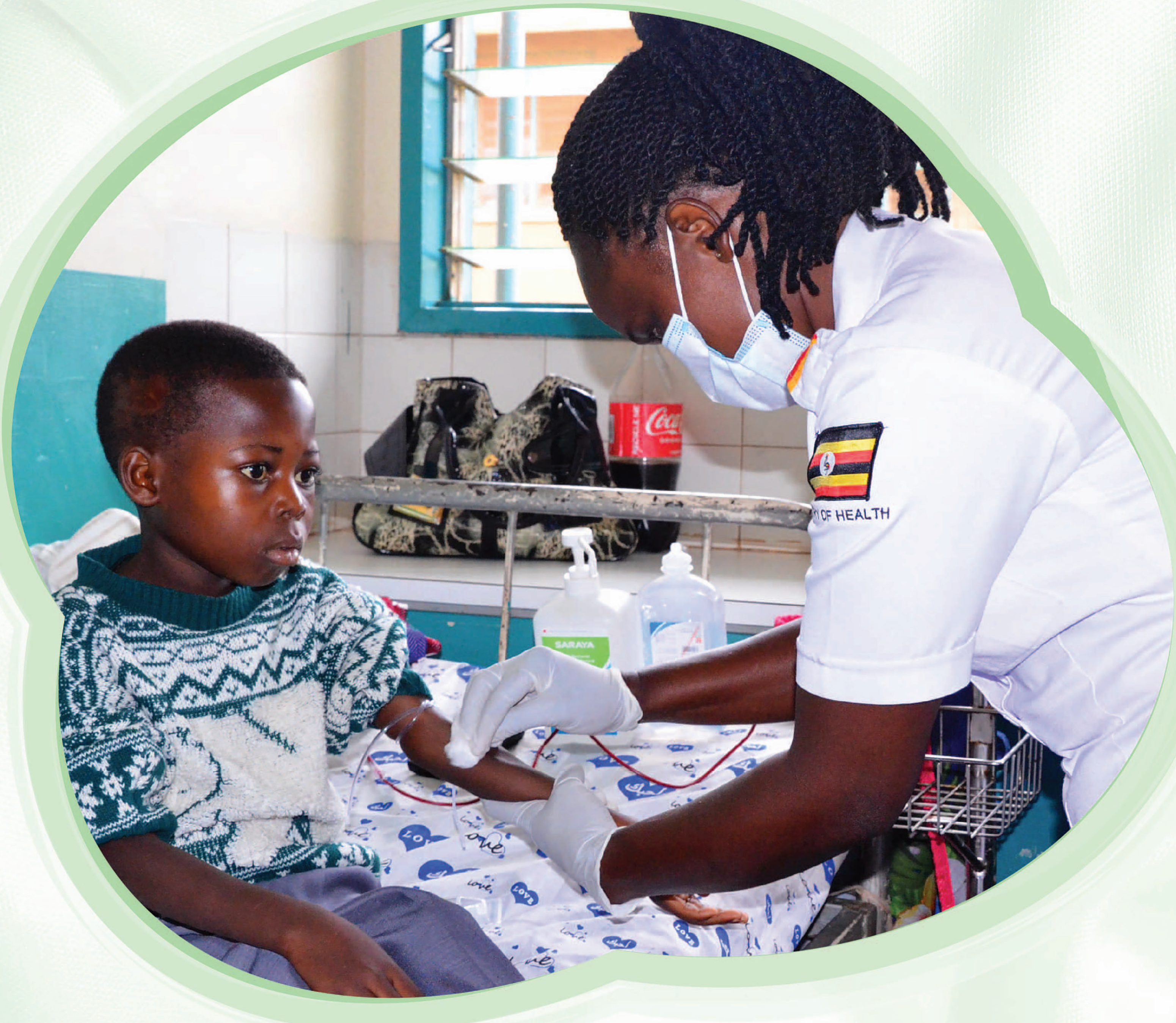
THE REPUBLIC OF UGANDA

A GUIDE TO DEVELOPING A PHARMACOVIGILANCE COURSE CURRICULUM FOR HEALTH PROFESSIONAL TRAINING INSTITUTIONS IN UGANDA

A COURSE GUIDE DEVELOPED FOR DIPLOMA AND CERTIFICATE PROGRAMMES

OCTOBER 2023

As a health professional, I always ask my patients to report back any side effects with the medicines I give them.



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Foreword

Pharmacovigilance is a critical component of patient safety that seeks to optimize benefits while minimizing risks associated with medicines. It guarantees that medicines are both safe and effective for their intended use. Because of the rising complexity and diversity of pharmaceutical products, as well as the increased demand for medicinal products, pharmacovigilance has become increasingly significant. As a result, robust pharmacovigilance systems are required to assure patient safety. A nationwide pharmacovigilance curriculum is essential to ensure that healthcare practitioners have the requisite knowledge and skills to develop comprehensive medicine monitoring systems at their respective institutions.

This is in line with the Uganda national pharmacovigilance strategy 2019-2024 which specifies the incorporation of pharmacovigilance into the national training curricula of health workers as a key intervention to enhance pharmacovigilance technical capacity of personnel at all levels of healthcare practice. The incorporation of pharmacovigilance into the national curriculum for training health professionals ensures an early exposure to the concept and relevance of pharmacovigilance for the various categories of personnel engaged in the care of patients. This exposure sensitizes the health professionals early in their career to issues regarding the safety of medicines and is an essential step in enhancing integration of medicine safety reporting within the health-care delivery system.

The pharmacovigilance curriculum has been developed in compliance with section 5 (i) and (j) of the National Drug Policy and Authority Act Cap.206 and Regulation 3 of the National Drug Policy and Authority (pharmacovigilance) Regulations No.37 and 40. It covers a wide variety of issues such as adverse drug reactions, medication errors, risk minimization, and safety communication. It is intended to give a flexible framework to accommodate the demands of all levels of healthcare and healthcare professionals such as doctors, pharmacists, nurses, and other allied healthcare practitioners. It underlines the need of reporting adverse drug reactions, which is the foundation of pharmacovigilance.

Pharmacovigilance is a rapidly evolving field and therefore healthcare providers should be encouraged to take advantage of opportunities for continuous learning and improvement regarding patient safety. We hope that this document will be a valuable resource in the establishment and maintenance of robust pharmacovigilance systems and ultimately improve patient safety across all levels of healthcare.

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Mr. David Nahamya.
Secretary to the Authority,

Acknowledgement

The development of the curriculum guide was a multi stakeholder engagement that brought together experts from academia, regulation, industry, health professional bodies and policy to ensure balanced, practical and timely curriculum. The National Drug Authority would like to recognize the invaluable contributions of Makerere school of pharmacy, the pharmaceutical society of Uganda (PSU), and the representatives from the various health professional bodies, universities and medical training institutions.

We would like in a special way to thank the World Health Organization (WHO) who funded the technical experts that were involved in the need's assessment, content development, as well as all the stakeholder consultations that led to the successful development of the curriculum.

Special thanks and recognition go to the technical experts whose names attached herewith in the appendix 2 for their time and dedication towards the development of this curriculum.

Lastly, we would like to acknowledge Management at National Drug Authority for the support towards the development of this curriculum and the implementation of pharmacovigilance strategy across different health care structures.

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Helen Byomire Ndagije PhD FISoP
(Director Product safety)

We would like to recognise the partners that supported this exercise

World Health Organization

THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

MAKERERE UNIVERSITY

Terms and Definitions

Adverse Drug Reaction: A response to a medicine which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.

Adverse Event Following Immunization (AEFI): Any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

Adverse Effect: A negative or harmful patient outcome that seems to be associated with treatment, including there being no effect at all.

Adverse Event: Any untoward medical occurrence that may present during drug treatment with a medicine, but which does not necessarily have a causal relationship with this treatment.

Appropriate Drug Use: Patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

Causality Assessment: The evaluation of the likelihood that a medicine was the causative agent of an observed adverse reaction.

Counterfeit: Medicine which is deliberately or fraudulently mislabeled with respect to source or identity. Counterfeit products may include products with the correct ingredients or those with the wrong ingredients, those without active ingredients, or those with fake packaging.

Drug Dependence: An adaptive state that develops from repeated drug administration, and which results in withdrawal upon cessation of drug use.

Drug Interaction: An event where one drug or any other chemical substance alters the pharmacological effect of another drug.

Drug Resistance: Reduction in effectiveness of a medication when used at the recommended therapeutic doses. It occurs mostly with anti-microbial agents whereby microbes tend to survive even in the presence of a drug that would normally kill them or inhibit their growth.

Drug/ Medicine: Is a pharmaceutical product used in or on the human body for the prevention, diagnosis or treatment of disease or for modification of physiological function.

Immunization Safety Surveillance: A system for ensuring immunization safety through detecting, reporting, investigating and responding to AEFIs.

Immunization Safety: The public health practices and policies dealing with the various aspects of the correct administration of vaccines, focusing on minimizing the risk of transmission of disease with the injection and maximizing the effectiveness of the vaccine. The term encompasses the spectrum of events from proper manufacture to correct administration. The term usually includes both injection safety (programmatic errors compromising injection safety) and vaccine safety (faults in the vaccine itself compromising vaccine safety).

Medication Error: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

Pharmacovigilance: Is the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions or any other medicine/ vaccine related problems.

Poisoning: Occurs when any substance interferes with normal body functions after it is swallowed, inhaled, injected, or absorbed.

Quality Defects: These are attributes of a medicinal product which may affect the quality, safety and/or efficacy of the product, and/or which is not in line with the approved Product Authorization.

Therapeutic Failure: Failure to accomplish goals of treatment resulting from inadequate or inappropriate drug therapy and not related to natural progression of the disease.

Serious Adverse Drug Reaction: Any untoward medical occurrence that at any dose results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistence of significant disability or incapacity, or is a congenital anomaly/ birth defect.

Side effect: Any unintended effect of a pharmaceutical product occurring at doses normally used in man, which is related to the pharmacological properties of the drug.

Substandard Medicine: A genuine, authorized medical product that fails to meet the quality specifications acceptable as per national standards. Therefore, their composition or ingredients may not meet specifications; and consequently, they may be dangerous to the patient.

Unexpected Adverse Drug Reaction: ADR whose nature or severity isn't consistent with the applicable product information.

Vaccine: A biological preparation that improves immunity to a particular disease.

Signal: Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.

Spontaneous Reporting: System whereby case reports of adverse drug events are voluntarily submitted from health care workers and pharmaceutical manufacturers to the national regulatory authority.

Justification of the Curriculum

The incorporation of pharmacovigilance into the national curriculum for training health professionals ensures an early exposure to the concept and relevance of pharmacovigilance for the various categories of personnel engaged in the care of patients. This exposure sensitizes the health professionals early in their career to issues regarding the safety of medicines and is an essential step in enhancing integration of medicine safety reporting within the health-care delivery system.

4.1 The Objectives of the Curriculum

The curriculum aims to offer a practical guidance to medical training institutions intending to incorporate or include pharmacovigilance in the training package of various medical courses on the;

i. Scope of training for the course at different education levels
ii. Content to be covered to ensure students acquire the necessary skills and knowledge for effective drug safety monitoring during their professional careers.
iii. Proposed training methods that can be used to deliver the course
iv. Reference materials, books, papers and other materials that can be used by trainers as well as trainees for further understanding and grounding of pharmacovigilance principles

4.2 How to use this document

This document is intended to be a guide and not prescriptive or binding. Stakeholders can adopt it wholly or with modifications tailored to meet training objectives and available resources. Notwithstanding, it is advised that institutions strive to cover all the content detailed in the curriculum to ensure students acquire all necessary skills and knowledge for effective drug safety monitoring during their professional careers.

This Guide is available electronically on the National Drug Authority website:

Key Players and their Responsibilities in the approval, implementation and review of this curriculum

a. **National Council for Higher Education (NCHE):** To adopt, approve and accredit the training curricula of various medical training programs submitted after incorporation of the pharmacovigilance course. The NCHE is encouraged to leverage on provisions of its mandate to support the incorporation and implementation of pharmacovigilance into all medical training curricula submitted to it for consideration and approval.

b. **Medical professional bodies, associations and or councils;** To mandate and support efforts for the incorporation of pharmacovigilance in the training programs of their respective professionals. Councils may also support and collaborate with training institutions, NCHE, NDA and other stakeholders to ensure their professionals acquire the requisite knowledge and skills for effective drug safety monitoring during pre-service training.

c. **Medical training institutions** To incorporate pharmacovigilance training in all their medical training packages and use this curriculum as one of the main reference documents to this end. Seek (e.g. through partners, grants, government, etc.) and provide for the necessary resources needed to implement the course within their institutions. This may include; trainers, time schedule, skill labs and student project resources.

d. **National Drug Authority** To approve and revise in collaboration with other stakeholders, the curriculum guide to keep up with existing and emerging needs as well as developments in the pharmacovigilance profession. NDA, where resources allow, may extend to medical training institutions that have incorporated pharmacovigilance into their institutional curricula, technical support to enable them initiate and implement pharmacovigilance training following incorporation.

Overall, all stakeholders are encouraged to offer feedback and input into the curriculum at any time to ensure it meets existing and emerging needs and expectations.

Policy

Section 5 of the National Drug Policy and Authority Act Cap. 206.

Functions of the drug authority.

The drug authority shall be charged with the implementation of the national drug policy and, in particular, but without derogation of the foregoing, shall—

(h) Promote rational use of drugs through appropriate professional training;
(i) Establish and revise professional guidelines and disseminate information to health professionals and the public;

Have you had a **bad reaction** after taking any **medicine?**

NOTIFY THE NATIONAL DRUG AUTHORITY

Med Safety App

Toll Free Line - 0800 101 999

Whatsapp - 0740 020070

Email - druginfo@nda.or.ug

Online - Https://primaryreporting.who-umc.org

UGANDA

NATIONAL DRUG AUTHORITY

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Introduction

The increasing access to medicines in low and middle income countries is not matched with the capacities to monitor the safety of the medicines. Adverse Drug Reactions (ADRs) contribute to the morbidity and mortality rates in Sub Saharan Africa (SSA) and yet majority of these ADRs are preventable. Pharmacovigilance (PV) as defined by World Health Organization (WHO) is the science and activities relating to the detection, assessment, understanding and prevention of ADRs or any other medicine/ vaccine related problems. This important science, PV, is used globally to prevent medicine related ADRs and improve public health and safety through assessment of benefits, effectiveness and risk of harm from medicine use. PV requires continuous monitoring of the safety of drugs on market in order to detect, prevent and control ADRs that could not be identified during the clinical phases. However, under-reporting of ADRs continues to be a major global and national challenge. In Uganda the reporting rate is still below the WHO effective reporting criteria of 200 reports per a million inhabitants annually. The low rate of reporting of ADRs underestimates the magnitude and risk related to safety and efficacy of medicines impacting decision making and can lead to serious harm to the patient and increased health care costs.

The main contributing factors from studies to the under-reporting of ADRs among health care professionals include; lack of knowledge and awareness of the ADR reporting systems, inadequate teaching and training of ADR reporting, delayed feedback from the National Pharmacovigilance Centers (NPCs), fear of legal litigation, unavailability of reporting forms and indifference of professionals. Therefore, addressing knowledge gaps on PV remains a major intervention to prevent medicine related ADRs and improve public health and safety. Enhancement of knowledge among health science students creates awareness on their obligations as future healthcare professionals in the PV system and benefits of spontaneous reporting of ADRs, and increase their vigilance in preventing ADRs.

Rationale of the training course

Adequate education of health science students on PV is one of the core sustainable interventions to improve the current PV systems. The training needs assessment conducted on PV showed inadequacies in the education curricula of health science programs in Uganda. The curricula for Nursing, Allied health, Medicine and Surgery and Bachelor of dentistry all lack PV modules and course units (content) in their curriculum. The pharmacy training program also lack adequate PV content and PV as a course unit in their curricula. In addition, the Uganda National PV strategy 2019-2024 provides for the incorporation of PV in to the national training curricula of health workers as a key intervention to enhance knowledge and skills of personnel at all levels of the health care system on PV. Further, the advancement in technology for development of new therapies and public health emergencies such as COVID-19 which require emergency use of new therapies sometimes with inadequate information on safety profile necessitate the need for continuous safety monitoring and reporting.

This national curriculum will enhance PV education in Uganda which will ultimately improve the detection, recognition and timely reporting of medicine safety by the future health care professionals. The incorporation of PV curriculum in the pre-service training curricula will also enable NPC to achieve its strategic area 1 of Uganda national PV strategy 2019-2024 and comply with WHO Core Structural (CST8) indicator for PV.

Module Unit Details

Module Unit Name	TH	CLH	PH	CH	CU
Pharmacovigilance	25	20	20	45	3

Note:
TH = Teaching Hours; PH = Practical Hours;

CLH = Clinical Hours; CH = Contact Hours;

CU = Credit Units

1 CH = 1 TH = 2 PH = 2 CLH

1 CU = 15 CH

Course Description

This module unit is designed to equip learner(s) with requisite knowledge and skills in the detection, assessment, understanding, monitoring, managing and reporting of adverse drug reactions and other medication use problems to promote the safe and effective use of medicines. It explains the scope, purpose, the regulatory framework and history of pharmacovigilance. The course will further teach the students the pharmacovigilance systems and causality assessment.

Expected Learning Outcomes

By the end of this module unit, the leaner(s) will be able to;

1. Describe pharmacovigilance, its scope, purpose and importance
2. Identify prominent events in the history of drug safety and draw lessons from the history to promote safe medicine use practices
3. Describe national drug safety regulations, terminology and guidance documents
4. Define, identify, classify and manage ADRs and other medication use problems
5. Spontaneously and actively report ADRs, medication errors and product quality related problems
6. Perform causality assessment

Suggestions on organization of learning

The acquisition of competencies (skills, knowledge, and attitudes) described in this module may take place at an accredited health professional training institution or its equivalent provided all equipment and materials required for training are in place. Delivery modes may include theory instruction (lectures/seminars), hands-on practice (Clinical clerkships/Case presentations) and tutorials (discussions).

Underpinning Knowledge

For occupational theory suggested for instruction/demonstration, the teacher is not limited to the outline given. In any case, underpinning knowledge/ theory may be obtained from various recognized reference materials as appropriate. The listed underpinning theory is presented and will be instructed as topics

- Importance of medication safety
- Detection and assessment of medication use problems
- Reporting of medication use problems

Occupational health, safety and environmental concerns to be observed
Observe laws and regulations, observe safety precautions, put on protective gear, manage and dispose, maintain conducive work environment, maintain personal hygiene, use recommended tools/equipment, administer first aid, Clean/sanitize tools and equipment, emphasize Continuous Quality Improvement, Total Quality Management, (CQI, TQM,) and 5S (Sort, Set, Shine, Standardize and Sustain).

Work behaviour/attitudes to be instilled and observed during training
Responsible, willingness to learn, committed, having team spirit, hardworking, accurate, social, industrious, time conscious, cooperative, ethical, smart, accountable, trust worthy, result oriented, honest, courteous, humility.

Learning Working Assignments (LWAs) and Practical Exercises (PEX)

1.0 Topic: Introduction to pharmacovigilance (4 CH)
Subtopic 1.1: Definition of pharmacovigilance

Subtopic 1.2: Scope of pharmacovigilance

Subtopic 1.3: History of pharmacovigilance

Subtopic1.4: Importance of pharmacovigilance (Aims. Goals and Purpose of Pharmacovigilance)

Subtopic 1.5: Regulatory framework for Pharmacovigilance in Uganda

PEX 1.6: Summary of key events in the history of pharmacovigilance

2.0 Adverse Drug Reactions (ADRs) (8 CH)
Subtopic 2.1: Definition of terms

Subtopic 2.2: Classification and mechanisms of ADRs

Subtopic 2.3: Risk factors for ADRs

Subtopic 2.4: Detection of ADRs

Subtopic 2.5: Management of ADRs

Subtopic 2.6: Prevention of ADRs

Subtopic 2.7: Adverse Events Following Immunization (AEFI)

Subtopic 2.8: ADRs due herbal medicines

PEX 2.9: Case write ups of a patient with an ADR

3.0 Topic: Medications Errors (4 CH)
Subtopic 3.1: Definition and types of medication errors

Subtopic 3.2: Risk factors for medication errors

Subtopic 3.3: Prevention of medication errors

Subtopic 3.4: High alert medications and associated risk reduction strategies

PEX 3.5: Identifying medication errors from patient records

PEX 3.6: Case write up of a patient with a medication error

4.0 Topic: Substandard and falsified medicines (SFM) (4 CH)
Subtopic 4.1: Definition of substandard and falsified medicines

Subtopic 4.2: Consequences of SFM

PEX 4.3: Assessment of medicines to identify possible SFM

Subtopic 4.4: Prevention of SFM

5.0 Topic: Drug interactions (3 CH)

Subtopic 5.1: Definition and types of drug interactions

PEX 5.2: Predicting drug interactions from prescriptions

Subtopic 5.3: Prevention of drug interactions

6.0 Substance abuse/misuse, Poisoning and Resistance (4 CH)

Subtopic 6.1: Substance abuse/misuse (definition, common drugs/substances of abuse, identification and prevention)

Subtopic 6.2: Poisoning (definition, common substances causing poisoning, general management and prevention of poisoning)

Subtopic 6.3: Drug resistance (definition, causes, strategies to slow down emergence and spread of resistance

PEX 6.4: Review culture and sensitivity report

7.0 Pharmacovigilance systems (4 CH)

Subtopic 7.1: Structure of pharmacovigilance system in Uganda

Subtopic 7.2: Functions of a national pharmacovigilance center

Subtopic 7.3: Roles and responsibilities of key stakeholders in the pharmacovigilance system

PEX 7.4: Exercises on role of stakeholders in pharmacovigilance

8.0 Reporting of ADRs and other medication use problems (8 CH)

Subtopic 8.1: Reporting of ADRs and other medication use problems (What, who, when, where and how to report)

Subtopic 8.2: Completing and submitting an ADR/ medication error/ product quality problem report form

PEX 8.3: Completing an ADR and medication use report

PEX 8.4: Submitting an ADR and medication use report to the national pharmacovigilance center

9.0 Causality assessment (6 CH)

Subtopic 9.1: Definition and importance of causality assessment

Subtopic 9.2: WHO/NDA causality assessment system

Subtopic 9.3: Categories and process of causality assessment

PEX 9.4: Exercises on completing WHO and Naranjo causality assessment tools

Methods of Assessment

- Progressive assessment (30%): Case presentation and reports, Practical assessments, Written test, Tutorial assessments
- Summative assessment (70%): Written examinations, Viva/voce

Minimum required teaching/learning resources

Flip charts, masking tape, markers, reference books, computers and its accessories, projector, printing papers, pens, exercise books, patient files, dispensing logs, OPD register, Laboratory register, ADR and medicine use report forms, causality assessment forms and National Drug Policy and Authority regulations.

References

The tutor is advised to make reference to relevant and applicable reading materials that could be in form of textbooks, publications, video clips/demonstrations, authenticated internet sites and any other.

Text books

1. Brian L. Strom, Stephen E. Kimmel, Sean Hennessy (2013): Textbook of Pharmacoepidemiology, 2nd Edition.
2. Elizabeth B. Andrews, Nicholas Moore (2014). Mann's Pharmacovigilance, 3rd Edition.
3. K. P. R. CHOWDARYA (2021).Textbook of Clinical Research and Pharmacovigilance.
4. Prabal Kumar, Manna Guru, Prasad Mohanta (2020). Textbook of Pharmacovigilance: Concept and Practice, second edition.
5. SK Gupta (2011). Textbook of Pharmacovigilance.
6. Thao Doan, Cheryl Renz, Fabio Lievano, Mondira Bhattacharya, and Linda Scarazzini (2019). Pharmacovigilance: A practical approach.

Publications

7. Aronson, J. K. (2009). Medication errors: what they are, how they happen, and how to avoid them. QJM: An International Journal of Medicine, 102(8), 513-521.WHO. The SAFETY of MEDICINES IN PUBLIC HEALTH PROGRAMMES: Pharmacovigilance an essential tool.
8. Cohen, M. R. (Ed.). (2007). Medication errors. American Pharmacist Association
9. Definitions and Applications of Terms for Vaccine Pharmacovigilance: ***https://cioms.ch/publications/product/definitions-and-applications-of-terms-for-vaccine-pharmacovigilance/***
10. Fornasier, G., Francescon, S., Leone, R., & Baldo, P. (2018). An historical overview of Pharmacovigilance. International journal of clinical pharmacy, 40(4), 744-747.
11. Uganda National Policy and Authority (Pharmacovigilance) Regulations No. 37 of 2014.
12. Uganda National Policy and Authority Act; Cap 206
13. WHO (2017). Report on the WHO global surveillance and monitoring system for substandard and falsified medical products. Guide for healthcare professionals.
14. World Health Organization (2002). The importance of pharmacovigilance
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17. World Health Organization (2014). Reporting and learning systems for medication errors: the role of pharmacovigilance centres.
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20. World Health Organization (2018). Substandard and falsified medical products.. Available at: ***https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products***

Appendices

Appendix 1: DESCRIPTION OF THE TOPICS

1.0 Topic: Introduction to Pharmacovigilance

Topic Description

This topics introduces and defines the concept of pharmacovigilance and associated key terms such as Adverse Drug Reactions, Adverse Drug events and Medication Errors. The topic will explore the origins and historical evolution of pharmacovigilance (methods and institutional developments) up to the current forms in which it is practiced today.

It will go on to outline the wide ranging scope of pharmacovigilance and discuss the core activities at the heart of modern pharmacovigilance systems. This will also include a description of the rationale and benefits of implementing pharmacovigilance in various practice areas and the goals and aims sought there. Finally, the topic will layout the international and local regulatory and legal frameworks that guide the establishment and practice of pharmacovigilance activities in all applicable fields.

Learning Outcomes

By the end of this topic, the student will be able to;

1. Define pharmacovigilance and related key terms
2. Describe the history of pharmacovigilance highlighting major disasters and their influence on shaping pharmacovigilance methods and institutions over time.
3. Outline the scope of modern pharmacovigilance and discuss its goals, aims
4. Understand and apply local and international guidance and regulatory framework in implementing pharmacovigilance.

2.0 Topic: Adverse Drug Reactions

Topic Description

This topics provides a comprehensive instruction on aspects of adverse drug reactions through the medicine use cycle. This topic will provide the scientific basis for the detection, assessment, understanding and prevention of adverse effects of medicines by discussing terminology and definitions of ADRs and related terms, the pharmacological classification of adverse drug reactions, reporting suspected adverse drug reactions, frequencies of adverse drug reactions, risk perception and adverse drug reactions, class effects of drugs, preventing adverse drug reactions, and publishing accounts of adverse drug reactions.

Learning Outcomes

By the end of this topic, the student will be able to;

1. Define Adverse Drug Reactions, side effects and hypersensitivity reactions
2. Describe the predisposing factors to ADRS and preventive measures
3. Classify ADRs and describe the mechanisms of occurrence
4. Predict and correctly identify ADRS
5. Clinically manage ADRs

3.0 Topic: Medications Errors

Topic Description

Medication errors can cause or lead to inappropriate medication use and patient harm yet they are preventable. They can occur when the drug is in the hands of the healthcare provider or the patient. This topic will describe the types of medication errors, their risk factors and risk reduction strategies for high alert medicines and how medication errors can be prevented.

Learning outcomes

By the end of this topic, learners should be able to;

1. Define medication errors and describe the types of medication errors
2. Identify the risk factors for medication errors and the risk reduction strategies for high alert medicines
3. Identify medication errors from patient records
4. Prevent medication errors

4.0 Topic: Substandard and falsified medicines (SFM)

Topic Description

Substandard and falsified medicines include medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source and those products that do not meet the quality specifications set for them by national standards for such products. These are an important aspect of PV as they can cause deaths, treatment failure, promote antimicrobial resistance and increase health care costs. This topic will cover the definition and identification of SFM, the consequences and prevention of SFM.

Learning Outcomes

By the end of this topic, learners should be able to;

1. Define and identify SFM
2. Outline the consequences of SFM
3. Identify and report product quality problems

5.0 Topic: Drug interactions

Topic Description

Drug interactions are reactions between two or more drugs or a drug and a food, beverage, herb, or supplement. They can affect how the drug works and cause unwanted side effects. This topic will cover the definition of drug interactions, description of the types of drug interactions and prevention strategies.

Learning Outcomes

By the end of this topic, learners should be able to describe drug interactions and preventive strategies

6.0 Topic: Substance abuse/misuse, Poisoning and Resistance

Topic Description

This topic will look briefly at the other important medication use problems that are part of the scope of pharmacovigilance including substance abuse/misuse, poisoning and drug resistance. Emphasis will be placed on their definition, identification and prevention.

Learning outcomes

By the end of this topic, learners should be able to

1. Define substance abuse/misuse, identify the common drugs of abuse and outline prevention strategies for substance abuse.
2. Define poisoning, outline common substances causing poisoning, describe the general management poisoning and prevention strategies.
3. Describe drug resistance, its causes, and strategies to slow down emergence and spread of drug resistance.

7.0 Topic: Pharmacovigilance Systems

Topic Description

This topic introduces the organizational structure of the pharmacovigilance system in Uganda highlighting the roles and responsibilities of the key stakeholders in the pharmacovigilance system. In this topic, the functions of the national pharmacovigilance center will also be discussed.

Learning outcomes

By the end of this topic, learners should be able to

1. Describe the organizational structure of the National Pharmacovigilance System in Uganda.
2. Explain the functions of the National Pharmacovigilance System in Uganda.
3. Identify the key stakeholders in the Pharmacovigilance System and their roles and responsibilities.

8.0 Topic: Reporting of ADRs and other Medication Use Problems

Topic Description

Pharmacovigilance requires continuous monitoring of the safety of drugs on the market in order to detect, prevent and control ADRs and other medication use problems. However, under-reporting of ADRs continues to be a major national challenge. This topic will explain the importance and professional responsibility of all health care workers of reporting ADRs and other medication use problems. The topic will discuss what, who, when, where and how to report. The completing and submission of medication safety reporting forms will be covered in this topic.

Learning outcomes

By the end of this topic, learners should be able to

1. Describe reporting of ADRs and other medication use problems (What, who, when, where and how to report)
2. Complete and submit an ADR/ medication error/ product quality problem report form
3. Spontaneously and actively report ADRs and other medication use problems

9.0 Causality assessment

Topic Description

It is important to conduct systematic review of data about a suspected ADR to determine the likelihood of a causal association between the event and the medicine received. This topic covers definition of causality assessment and its importance, WHO causality assessment criteria and the process of causality assessment.

Learning outcomes

By the end of this topic, learners should be able to

1. Define causality assessment
2. Explain the importance of causality assessment
3. Describe the categories and process of WHO/NDA causality assessment system
4. Conduct causality assessment using WHO causality assessment tool.

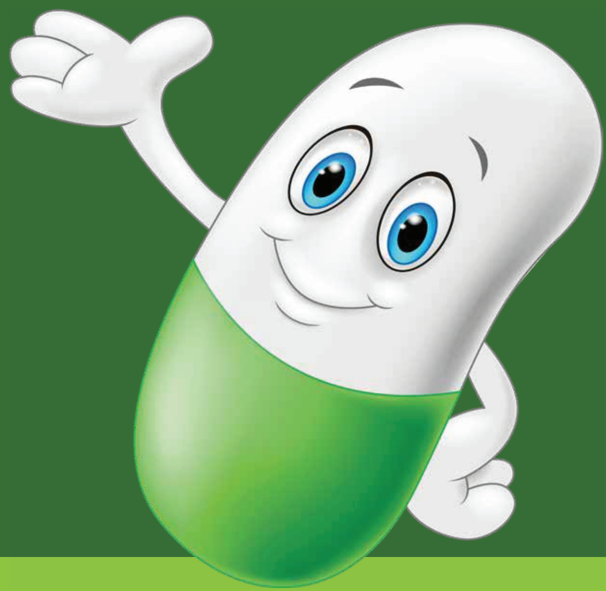
Appendix 2: List of technical experts

No.	NAME	INSTITUTIONS
1	Babalanda Jean	Gulu College of Health Sciences
2	Danson Sembatya	Uganda Institute of Allied Health and Management Sciences
3	David Walusimbi	National Drug Authority
4	Davidson Ndyabalika	Makerere University
5	Dr. Helen Byomire Ndagije	National Drug Authority
6	Edson Ireeta	Pharmaceutical Society of Uganda
7	Emmaculate Kwikiriza	National Drug Authority
8	Eva Laker	Infectious Disease Institute
9	Falisy Lule	Kiruddu NRH
10	Frances Philomena Namatovu	CIPLA QCIL
11	Hassan A Matovu	Makerere University
12	Jackie Nanteza	Makerere University
13	Jackson Mukonzo	Makerere University
14	Jonans Tusiimire	Mbarara University of Science and Technology
15	Jonathan Owiny	National Drug Authority
16	Joseph Agondua	Uganda Allied Health Examination Board
17	Joseph Mwoga	World health organisation
18	Julius Mayengo	National Drug Authority
19	Kafumbe Moses	Gulu School of Clinical Officers
20	Kakiya Robinah	Makerere University
21	Kalidi Rajab	Makerere University
22	Katumba Ssentongo Gubala	Uganda Medical and Dental Practitioners Council
23	Kiryowa Uthman	Laborex (U) Ltd
24	Kisembo Eseza Harriet	FINS Medical University
25	Kyeyune Henry	Makerere University
26	Kyomuhendo Wycliff	FINS Medical University
27	Masengere Betty	Uganda Nurses and Midwives Examinations Board
28	Mbina Solomon	Kampala International University
29	Morris Seru	MOH, Pharmacy Department
30	Mugide Nuru	Kamapala International University
31	Muwanika Emmanuel	Makerere University
32	Mwawule Wedulo Fredrick	Makerere University
33	Ninyeto Daniel	Gulu University
34	Nyombi Vicky R Babirye	Mulago National referral Hospital

No.	NAME	INSTITUTIONS
35	Odokonyero Kennedy	KIMS MEDS
36	Odokonyero Kennedy	Makerere University
37	Ojaki MIkloth	Uganda Allied Health Examination Board
38	Ojara William Francis	Gulu University
39	Okidi Patrick Oboke	Gulu School of Nursing and Midwifery
40	Okiror Adukun	Rene Industry
41	Okiror Anthony	Makerere University
42	Okumu Peter	Gulu School of Nursing and Midwifery
43	Olum William	Jinja Hospital
44	Otiti Emmanuel	Gulu School of Clinical Officers
45	Pakoyo F Kamba	Makerere University
46	Patrick Ogwang	Mbarara University of Science and Technology
47	Robert B D Otto	Makerere University
48	Sharon Ighirobi	Kampala International University
49	Sulah Balikuna	Makerere University
50	Tenywa Mercy	Kampala International University
51	Tumwesigye Ambrose	Uganda Institute of Allied Health and Management Sciences
52	Twikirize Gad	Butabika NRH
53	Walakira Joshua Felix	Makerere University
54	Winnie Nambatya	Makerere University

DRUGS

All medicine can cause side effects, particularly if you dont use them as advised.



HERE IS HOW TO STOP AND OR MINIMISE THESE SIDE EFFECTS.

STEP 1

Carefully read the Patient Information Leaflet(PIL) supplied with your medicine.

STEP 2

Ask your healthcare provider about the expected side effects and how to reduce the risks of their occurence.

STEP 3

Report to National Drug Authority

REACH US VIA : **MED SAFETY APP**
TOLL- FREE LINE : **0800 101 999**
WHATSAPP : **0740002070**
EMAIL: **druginfo@nda.or.ug**
https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=UG

UGANDA
NATIONAL DRUG AUTHORITY
Safe Drugs Save Lives

National Drug Authority

"Maximising Quality Human and Animal Health"

UGANDA
NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

In case you experience any side effects, please report to NDA via

Toll free: 0800 101 999

Dial *284*99# for Covid-19 Vaccine AEFI reports

Med safety mobile app

NDA reporting Cards

Whatsapp: 0740002070

druginfo@nda.or.ug

*This will help us to keep monitoring the safety of medicines in Uganda