



Curriculum and Training Manual

RATIONAL USE AND ACCESS TO CONTROLLED MEDICINES IN NIGERIA

Federal Ministry of Health
Nigeria

2019

This publication has been printed with funding from the European Union (EU) under the framework of the "Response to Drugs and Related Organized Crimes in Nigeria" project, implemented by the United Nations Office on Drugs and Crime (UNODC). The contents of this publication are the sole responsibility of the Federal Ministry of Health and can in no way be taken to reflect the views of either the EU or UNODC.

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**RESPONSE TO DRUGS AND RELATED ORGANISED CRIME IN NIGERIA
(FED/2012/306-744) (NGAV16)**



Curriculum and Training Manual

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FOREWORD

In 2017, the Federal Ministry of Health in collaboration with the United Nations Office on Drugs and Crime (UNODC) and leveraging on the European Union (EU) funded Project: “Response to Drugs and Related Organized Crime in Nigeria, developed the National Policy for Controlled Medicines as part of the overall efforts to enhance accessibility to controlled medicines for medical purposes, while preventing diversion.

The Policy identified, among others, knowledge gap amongst healthcare professionals on access and evidenced-based use of controlled medicines as one of the major barriers limiting access to these essential medicines for medical purposes. This is because the academic curriculum of the relevant health institutions is deficient in these key areas. The result is a precarious balance in access and control, and phobia for prescribing and dispensing of controlled medicines to patients who need them. There is therefore, the need for a structured approach to close this gap in knowledge.

Pursuant to this, the Federal Ministry of Health constituted a Technical Working Group comprising experts from academia, professional bodies, regulatory bodies and health practitioners to support the development of course contents for training on access to and rational use of controlled medicines, for incorporation into the curricula of Medical, Pharmacy and Nursing Schools.

The curriculum has 5 core components, namely: Legislation and Policy Foundation, Pain Management including pharmacologic and non-pharmacological interventions, Rational Use and Pharmacology of Controlled Medicines, Supply Chain Management of Controlled Medicines, Safe Use of Controlled Medicines including pharmacovigilance and non-medical Use.

Following its finalization, this curriculum will serve as a working document for the National University Commission (NUC) in reviewing the curriculum of these health professionals to meet emerging needs.

While the Ministry is pursuing this, I wish to strongly recommend this course content for adoption and utilization by the regulatory and professional bodies for post qualification trainings and annual licensing requirements.



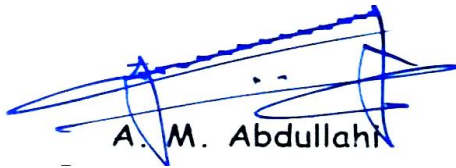
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ACKNOWLEDGEMENTS

The Federal Ministry of Health acknowledges with great appreciation the financial support by the European Union (EU) and the technical assistance provided by the United Nations Office on Drugs and Crime (UNODC) to effectively drive the laudable Project: “Response to Drugs and Related Organized Crime in Nigeria”

The Ministry also acknowledges with profound gratitude the technical input and contributions of the Technical Working Group to the development of curriculum for Medical, Pharmacy and Nursing Schools on rational use and access to controlled medicines.

The contribution of the stakeholders from the academia, professional bodies, regulatory agencies and practitioners in the successful development of this curriculum is deeply appreciated.



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The Ministry of Health would also like to thank the stakeholders who have contributed to this work for their gracious time, expertise and valuable inputs.

ACRONYMS

The following is a compilation of acronyms for use as it pertains to this document. It should be considered a guide and may not constitute an exhaustive list.

ADR	Adverse Drug Reaction
APCA	African Palliative Care Association
CSO	Civil Society Organization
DFDS	Department of Food and Drug Services
DRF	Drug Revolving Fund
EU	European Union
EML	Essential Medicines List
FMOH	Federal Ministry of Health
HF	Health Facility
HIV/AIDS	Human Immuno-Deficiency Virus/Acquired Immune Deficiency Syndrome
HPCAN	Hospice and Palliative Care Association of Nigeria
INCB	International Narcotics Control Board
LFN	Law of Federation of Nigeria
LMIS	Logistics Management Information System
LMCU	Logistics Management Coordination Unit
M&E	Monitoring and Evaluation
MDAs	Ministries, Departments and Agencies
NAFDAC	National Agency for Food and Drug Administration and Control
NCH	National Council on Health
NDLEA	National Drug Law Enforcement Agency
NHIS	National Health Insurance Scheme
NMA	Nigeria Medical Association
NMDC	Nigeria Medical and Dental Council
NMCN	Nursing and Midwifery Council of Nigeria
NPSCMP	National Product Supply Chain Management Programme
PCN	Pharmacists Council of Nigeria
PHC	Primary Health Care

PPP	Public Private Partnerships
PSN	Pharmaceutical Society of Nigeria
QA	Quality Assurance
STGs	Standard Treatment Guidelines
SDGs	Sustainable Development Goals
SMOH	State Ministry of Health
TWG	Technical Working Group
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

DEFINITIONS

The below is a compilation of terms and definitions for their use as it pertains to this document. It should be considered a guide and may not constitute an exhaustive list.

Acute pain: symptoms occurring for less than three months.

Abuse is defined by the WHO Expert Committee on Drug Dependence as “persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice”. The term “abuse” is sometimes used disapprovingly to refer to any drug use at all, particularly of illicit drugs.

Accessibility is the degree to which a medicine is obtainable for those who need it at the moment of need with the least possible regulatory, social or psychological barriers.

Addiction: a brain disorder characterized by compulsive engagement in rewarding stimuli despite adverse consequences.

Addictive behaviour: a behaviour that is both rewarding and reinforcing.

Adverse Drug Reaction is defined by WHO as response to a medicine which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases, or for modification of physiological function.

Addictive drug: a drug that is both rewarding and reinforcing.

Affordability is the degree to which a medicine is obtainable for those who need it at the moment of need at a cost that does not expose them to the risk of serious negative consequences such as not being able to satisfy other basic human needs.

Analgesic: an agent for producing insensibility to pain without loss of consciousness.

Anaesthetic: a substance that causes loss of sensation or consciousness.

Anticonvulsants: a medication used to control seizures or stop an ongoing series of seizures.

Availability is the degree to which a medicine is present at distribution points in a defined area for the population living in that area at the moment of need.

Breakthrough pain: a sudden temporary flare of severe pain that occurs on a background of otherwise controlled pain.

Chronic pain: symptoms occurring for greater than 3months

Consumption statistics have to be reported by governments (National Drug Regulatory Agencies) to the International Narcotics Control Board (INCB) annually and represent the amounts of narcotic drugs that were distributed in the country to the retail level, i.e. to hospitals, pharmacies and practitioners.

Counterfeit medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source. They may include products with the

correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging’.

Convention is a formal agreement between States. The generic term “convention” is thus synonymous with the generic term “treaty”. Conventions are normally open for participation by the international community as a whole, or by a large number of states.

Controlled medicines are medicines containing controlled substances.

Controlled substances are the substances listed in the International Drug Control Conventions¹.

Drug includes any substance or mixture of substances manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease disorder, abnormal physical state or the symptoms thereof, in man or in animals; restoring, correcting or modifying organic functions in man or in animals; disinfection or the control of vermin, insects or pests; or contraception².

Dependence is defined by the WHO Expert Committee on Drug Dependence as “A cluster of physiological, behavioural and cognitive phenomena of variable intensity, in which the use of a psychoactive drug takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behaviour.

Drug withdrawal symptoms: symptoms that occur upon cessation of repeated drug use.

Diversion refers to the movement of controlled drugs from licit to illicit distribution channels or to illicit use, non-medical use or use unrelated to scientific purposes.

Essential medicines are defined, as medicines or drugs that satisfy the health needs of the majority of the population. An Essential Medicine List is developed at the national level based on the needs of the majority of the population making them available in adequate amounts and in appropriate dosage forms at all levels of health care delivery system of the country.

Estimates are the requirements for controlled substances for legitimate purposes which have to be submitted to INCB by the national competent authority. For Narcotic medicines and certain precursor chemicals, estimates have to be submitted to INCB annually and for psychotropic substances, simplified estimates (known as assessments) have to be submitted at least every three years.

¹ Full list of these controlled substances can be obtained on the INCB websites

- https://www.incb.org/incb/en/narcotic-drugs/Yellowlist_Forms/yellow-list.htm;
- https://www.incb.org/incb/en/precursors/Red_Forms/red-list.htm;
- <https://www.incb.org/incb/en/psychotropic-substances/green-lists.html>

² National Drug Policy (2005)

Law refers to a set of rules on a specific topic enacted by the legislative body at the national, state or local level and having binding legal force.

Legislation refers to all rules having binding legal force at the national, state or local level.

Medicine: Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient.

Misuse (of a controlled substance) for the purposes of these guidelines, is defined as the non-medical and non-scientific use of substances controlled under the international drug control treaties or under national law.

Narcotic drug is a term that refers to all those substances defined in the 1961 Single Convention as such.

National authority, in these guidelines, refers to any government institution involved with the issues discussed in this document. The term applies not just to national government institutions but may equally apply to other relevant institutions in the national territory involved with these issues, such as federal, state or provincial institutions.

National competent authority, in these guidelines, refers to any government agency responsible under its national law for the control or regulation of a particular aspect of the country's legislation that pertains to controlled substances, in particular to issue certificates and authorizations for the import and export of narcotic drugs and psychotropic substances.

Non-medical use refers to use of any controlled substance outside the parameters of accepted, quality standards for medical practice.

Opioid means literally "opium-like substance". It can be used in different contexts with different but overlapping meanings.

Opioid Substitution Therapy (OST) refers to treatment of opioid dependence with relatively stable doses of the long acting agonists (usually **methadone** or **buprenorphine**) prescribed over prolonged periods of time (usually more than six months), which allows stabilization of brain functions and prevention of craving and withdrawal.

Pain: an unpleasant sensory or emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Palliative Care: The World Health Organization defines Palliative "as an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual."

Policy: A set of policies are principles, rules, and guidelines formulated or adopted by an organization to reach its long-term goals and typically published in a booklet or other form that is widely accessible.

Psychotropic substance is a legal term that refers to all those substances listed in the Convention on Psychotropic Substances.

Physical dependence: dependence that involves persistent physical–somatic withdrawal symptoms (e.g., fatigue and delirium tremens).

Psychological dependence: dependence that involves emotional–motivational withdrawal symptoms (e.g., dysphoria and anhedonia).

Rational drug use requires that patients receive medications 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. This implies rational prescribing, good dispensing practices and concordance.

Regulation refers to a set of rules on a specific topic with binding legal force at the national, state or local level and enacted by an administrative body to which the authority to issue such rules has been delegated by the national, state or local legislative body.

Side effect: a secondary effect of a drug or medical treatment.

Single Convention in this publication refers to *the Single Convention on Narcotic Drugs, 1961*, as amended by the 1972 Protocol.

Substance use disorder: a condition in which the use of substances leads to clinically and functionally significant impairment or distress.

Tolerance: the diminishing effect of a drug resulting from repeated administration at a given dose.

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1. INTRODUCTION

Controlled medicines are used in the management of a wide range of medical conditions, but these medicines may also be used in non-medical situations and cause significant harm. There are a number of controlled medicines recommended as a component of effective, and quality, medical care. Each controlled essential medicine has a unique purpose when used in medical settings. On the one hand psychedelic drugs, for example, LSD, and stimulants, such as amphetamine, are generally infrequently indicated in medical management³. Whereas Central Nervous System (CNS) depressants, such as benzodiazepines like alprazolam, and anaesthetic agents, like ketamine, may be used during surgeries/surgical procedures. Narcotic analgesics have wide applications in surgical and non-surgical patients and in traumatic or non-traumatic conditions across all populations.

The term, “controlled medicines”, applies to all the above-mentioned types of drugs. However, the socio-biological factors associated with narcotics/opioid analgesics have placed them in a position of focus. Narcotic analgesics play a pivotal role in the management of moderate to severe pain. Pain is the most common symptom that requires medicines, and therefore these medicines command great attention as a means of reducing sufferings⁴.

The World Health Organization (WHO) provides a universal essential medicines list that includes the medications considered to be most effective and safe to meet the most important needs in a health system. Countries around the world have used this list as a guide for the medications made available to patients at the national level. The Essential Medicines List includes controlled medicines as essential interventions in healthcare. However, controlled medicines must be accessed for their positive actions while making concerted efforts to prevent non-medical use which poses serious threat to individuals and the entire society.

Controlled medicines are made available for use in healthcare systems within a regulated environment. Regulations in the handling of controlled medicines are to ensure responsible access which ultimately promotes public health. Governments and societies are mandated through the International Drug Control Conventions⁵, to ensure adequacy of controlled medicines, such as narcotic analgesics, while establishing procedures aimed at preventing diversion and non-medical use. Government-imposed restrictions may

³ O'Brien CP. Drug addiction and drug abuse. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Edition. Ed. Brunton LL. Publisher: McGraw-Hill. 2006 pg: 607-627

⁴ Gutstein HB and Akil H. Opioid Analgesics. In: Goodman and Gilman's The Pharmacological Basis of Therapeutics 11th Edition. Ed. Brunton LL. Publisher: McGraw-Hill. 2006 pg: 547-590

⁵ UNODC. Technical Guidance: Increasing Access and availability of controlled medicines. Advanced Draft, March 2018.

precipitate scarcity and sub-optimal management of patients. Key factors that have been identified to account for the poor access to notably opioid or narcotic analgesics include inadequate human and material capacity within the health facility, poor funding, and lack of awareness by the public⁶.

There has been severe shortage of narcotic analgesics in Nigeria for the better part of the last decade⁷. In tackling this shortage, there is need to take a holistic approach, that is, institute procedures and processes that will address the identified factors that perpetuate the status quo. The Nigerian Federal Ministry of Health has begun to take measures to increase access to and availability of affordable controlled essential medicines in medically supervised settings. In 2018, the Ministry launched the ***National Policy for Controlled Medicines and Its Implementation Strategies***⁸ as an overarching policy framework with explicit objectives to facilitate sustainable access and availability of controlled medicines. Efforts have also been made to align regulations with the National Policy, and Guidelines for the Management of Pain in Nigeria have been completed. The next logical component of a comprehensive approach is to address the inadequate human capacity through the provision of relevant informational materials through the development of curriculum, and by organizing relevant training workshops; to most immediately target the current healthcare professionals.

The Federal Ministry of Health ensured the engagement of relevant regulatory agencies such as Pharmacists' Council of Nigeria (PCN), Medical and Dental Council of Nigeria (MDCN), Nursing and Midwifery Council of Nigeria (NMCN) and professional associations such as the Nigerian Medical Association (NMA), National Association of Nigerian Nurses and Midwives (NANNM), and Pharmaceutical Society of Nigeria (PSN); encouraging them to take leadership roles in the development of each phase of the work related to increasing access to controlled medicines. The same Federal Ministry of Health has also realized the need to incorporate relevant instructional modules in the curricula of students of nursing, pharmacy, medicine and other health professions. This 'upstream' approach will help in inculcating the necessary knowledge and skills in the respective professionals and therefore, ensure sustainability of the process⁹.

The following document is meant to serve as a resource for all educators interested in health. This includes the academia at the university level, professional regulatory bodies

⁶ FMOH, Federal Ministry of Health, Nigeria. National Policy for Controlled Medicines and its Implementation Strategies. 2017

⁷ FMOH, Federal Ministry of Health, Nigeria. National Policy for Controlled Medicines and its Implementation Strategies. 2017

⁸ FMOH, Federal Ministry of Health, Nigeria. National Policy for Controlled Medicines and its Implementation Strategies. 2017

⁹ Wiese HJC, Piercey RR and Clark CD. Changing prescribing behavior in the United States: Moving upstream in the opioid prescription education. State of the Art. Vol. 103(6): doi:10.1002/opt.1015. www.cpt-journal.com Accessed 01 May 2018

and associations providing post qualification trainings. This manual was developed with the following objectives:

- ◆ To provide core information and knowledge to the future and current healthcare workforce related to the medical use of controlled medicines.
- ◆ To promote safe and effective healthcare practices related to controlled medicines as one of the core elements of a quality healthcare system.
- ◆ To serve as a foundation of knowledge that can be shared with the community including but not limited to policy makers, caregivers, patients and faith leaders.

The need to ensure access to controlled medicines and prevent non-medical use is the driver of this process. The project was facilitated by the Federal Ministry of Health, with the assistance of UNODC. The manual has been divided into five core components; legal and regulations, rational use of controlled medicines, pain management, pharmacokinetics and pharmacodynamics of controlled medicines, safe use of controlled medicines and pharmacovigilance, and supply chain. Each of these core components includes 1) an introduction that provides some background for the readers/learners, 2) a teaching template with topics and instructional goals, and 3) sample teaching strategies to promote skills-based learning and development.

It is important that all the five core components of the curriculum are taught but the details may have to vary depending on the target audience. Throughout this manual the importance of skill acquisition by the trainees or practitioners is emphasized while due cognizance is also paid to the level of care expected of the respective cadres of professionals/trainees. It is not intended that this manual replaces relevant textbooks, users should, therefore, avail other materials that are known to aid learning.

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2. IMPLEMENTING THE CURRICULUM

INTRODUCTION

This curriculum has been designed as a resource for educators of all types. It is organized in three steps:

1. An introduction including substantive information;
2. A teaching template with topic areas, instructional goals, and learning objectives; and
3. Sample teaching strategies.

Educators should be aware that the materials are not meant to stand alone. They can and should be integrated into any applicable area of teaching related to healthcare. Please note, the substantive materials included in this curriculum are not exhaustive. It is likely that educators will need to review other documents to support their knowledge prior to teaching this body of curriculum.

The process of teaching and learning is an exchange between the educator and the student. Both the educator and the student have a responsibility in the process of learning. Educators must bring accurate knowledge and teaching skills to the process. Students must bring a willingness to learn and grow to the process. However, it is critical to know that learning is a process and educators must be willing to be flexible to meet the learning needs of the students.

TARGET AUDIENCE

There are no limits to the type of students that can benefit from this curriculum. It has been specifically designed to be used with two target audiences,

- 1) students enrolled in higher education programs in the healthcare field, and
- 2) the healthcare workforce currently working in Nigeria.

Therefore, the setting for teaching this curriculum will be diverse – university classrooms, professional development classes, community settings, hospital conference rooms and any place of healthcare delivery.

Professionals in Health Institutions

Each and every healthcare worker, from the hospital administrator to the person who cooks the meals in the cafeteria, contributes to the health and well-being of patients. Not every healthcare worker needs to be trained in every aspect of this curriculum, but they should be exposed to the core elements as they help patients and families each day.

The lessons are designed to integrate the work of a number of healthcare professionals into each activity. Therefore, it is suggested that the lessons are taught to healthcare teams that include but are not limited to representatives from each sector:

1. Doctors
2. Pharmacists
3. Nurses
4. Radiologist
5. Dentists
6. Psychiatrist/Psychologist
7. Emergency responders
8. Physical Therapist
9. CHOS, CHEW, etc.

Regulatory Bodies and Staff

Whenever controlled medicines are being discussed it is critical to include representation from the regulatory bodies. Staff working with responsibilities to regulate controlled medicines should be exposed to all five core areas of the curriculum to support their overall understanding of the importance of the work they are engaged in to protect patients.

In Nigeria many persons currently working in regulatory positions have a healthcare background but not all. It is advised that this group participate in training sessions in all five areas of the curriculum in a heterogeneous group. This will allow them to discuss particular aspects related to regulatory issues.

Of note, it would be important to have one of the trainers at all levels of the continuum be a regulatory staff. This will provide a depth to the lessons that is invaluable.

Other Sectors

This topic is relevant to each and every person. First, each of us will age or face a medical situation that results in pain. When that happens, we will want the most knowledgeable persons helping us to access the medicines we need to manage that pain and hopefully get through the medical crisis. Therefore, underlisted list of audiences should be exposed to each of the five curricular area:

1. Trade unions;
2. Civil society, NGO'S, and Professional Developmental Organisations and Public servants;
3. Religious, community and other opinion leaders; and
4. Legislators, law and policy makers.

The intensity of the training does not need to be at the level of a healthcare professional but should be taught by those that have that experience and knowledge in order to enrich the learning experience. Therefore, it is also critical to know your audience.

The materials should be used in response to the level of knowledge and skills the students currently have. Educators can use electronic means to survey the students prior to the “class” to determine at what level they are and what prior knowledge they may have. Or an educator may choose to give a pre-test on the first day of the class. This can provide a base of knowledge upon which the educator can plan lessons and can also demonstrate a growth in knowledge if the students perform better on a post-test after the materials have been taught.

LEVELS

The lessons included in this curriculum can be used with students of any level. Each lesson has been developed with modifications and with ways to encourage skills-based learning in each area.

All undergraduate students pursuing a career in the healthcare system should be exposed to each of these five areas of the curriculum. And it should be noted that the lessons have been developed to be integrated into the minimum curriculum driving the higher education experience.

Educators should have the materials required to meet the needs of students at the level of knowledge which they have. Below is a chart of the possibilities for how the curriculum can be used, this is not intended to be a teaching template but rather to demonstrate how the different levels can still be challenged, learn and grow using the materials provided in this curriculum. The questions included in the chart are samples and reflect different aspects of the five CORE areas to be later introduced in the curriculum.

ADDRESSING THE DIFFERENT LEVEL OF LEARNING IN ALL 5 CORE CURRICULUM AREAS

<u>Topic Area</u>	<u>Beginners</u>	<u>Intermediate</u>	<u>Advanced</u>
Legal and Policy Foundation	<p>What laws exist in Nigeria related to controlled medicines?</p> <p>Who develops laws and policies related to controlled medicines?</p>	<p>Do the current laws and policies related to controlled medicines match with the practice of quality healthcare in Nigeria?</p> <p>Do healthcare settings all follow the same policies related to controlled medicines and are they in-line with national policy?</p> <p>How do policies impact patients?</p>	<p>Do the current laws and policies related to controlled medicines increase access to healthcare including pain medication?</p> <p>How do you balance the need to meet patients' human right to quality healthcare with a need to protect them from the potential harms of non-medical use of controlled medicines?</p>
Pain Management	<p>What "tools" are available to assess pain in patients?</p> <p>How do you monitor and "chart" pain in patients?</p> <p>How often do you assess patients for pain?</p>	<p>Are there different types of pain?</p> <p>What steps can be taken to manage all different types of pain?</p> <p>How do you use the World Health Organization "Pain Ladder"?</p> <p>What can be done to identify and screen a person at risk for using medications in a non-medical manner?</p>	<p>In what healthcare setting would you assess a person's pain level and how often?</p> <p>What happens to patients living with pain if the necessary medications are not available?</p> <p>How can non-pharmacological interventions help to control pain?</p> <p>How do you manage chronic pain in a patient?</p>

<p>Rational use and Pharmacology</p>	<p>What is the difference between rational and irrational use of medicines?</p> <p>What types of medication can be used to address pain and what are the risks involved in using those medications?</p>	<p>How do you develop a therapeutic relationship with a patient that influences the rational use of controlled medicines?</p> <p>What is the action of each medication and the risks to the patient inherent in prescribing that medication?</p> <p>What are good practices related to prescribing and dispensing controlled medications?</p>	<p>Is limiting the use of controlled medicines a rational approach to meeting the medical needs of patients?</p> <p>Should physicians prescribe medication, including controlled medications, based on the patient's needs or the medicines available in the pharmacy or based on fear of "addiction"?</p>
<p>Pharmacovigilance and non-medical use</p>	<p>What is pharmacovigilance?</p> <p>What are the types of non-medical use of controlled medicines that are a problem?</p> <p>How often are medications of any kind used properly and how often are they used in a non-medical manner?</p>	<p>What are the clear steps for practicing pharmacovigilance, monitoring and reporting data appropriately?</p> <p>For patients at risk of non-medical use of controlled medicines, how will you ensure healthcare that includes the relief of pain?</p>	<p>Is non-medical use of controlled medicines more likely to be from the use of medication diverted from the healthcare system or from medication illegally trafficked into the country?</p> <p>How can you best use the data collected as part of pharmacovigilance and how might you expand the data collected to best meet the patients' needs and the healthcare system needs?</p>

<p>Supply Chain Management</p>	<p>What is a supply chain? What are the components of a supply chain? What government Ministries are responsible to monitor and control the supply chain for controlled medications?</p>	<p>Map the supply chain for controlled medicines in Nigeria. How can you apply aspects of the supply chain to increase or decrease stocks of controlled medicines? What are the most important aspects of the supply chain for controlled medicines? Are there enough controlled medicines available for the patients in need of healthcare in Nigeria?</p>	<p>What steps can be taken to reduce the time required to safely procure controlled medicines in Nigeria? Where in the supply chain does diversion occur and how can it be reduced? How estimates for the amounts of controlled medication are determined and can that be better informed? Are essential medicines available in Nigeria, including essential controlled medicines?</p>
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As has been described, the curriculum has been developed to meet the needs of the students in the room. The chart below provides a guide as to how to approach the lessons at a basic, intermediate or advanced level.

LEVEL	AUDIENCE TO CONSIDER
<p>Basic level</p>	<ul style="list-style-type: none"> • CHOS, CHEW, etc • Religious, community and other opinion leaders • Civil society, NGO'S, and Developmental Organisations and Public servants.
<p>Intermediate level</p>	<ul style="list-style-type: none"> • Trade unions, etc • Legislators, law and policy makers

Advanced level	<ul style="list-style-type: none"> • Professionals in health • Doctors, Nurses, Pharmacists, Radiologists • Undergraduate students <ul style="list-style-type: none"> -Medical students -Nursing students -Pharmacy students • Regulatory bodies
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LEARNING STYLES

Educators now realize that each person learns differently and responds better to different learning styles and techniques. There is an extensive body of research focusing on how people learn and grouping them into common styles. However, it should be noted that each person is an individual and most people do not learn in only one way, but rather learn in a mix of different learning styles. Learning is a fluid process and can be different in different circumstances, in different settings and at different times of your life.

Sometimes different learning styles are referred to as multiple intelligences. Traditionally, education has been focused on using a logical teaching method with a focus on linguistic approach or “lectures”. The reliance on classroom and book-based teaching with a focus on repetition, homework and exams is shifting because the research suggests that not all students will respond positively to this learning style. And if a student does not respond positively to this learning style they will not be successful, and they are then often labelled as unable to learn or even worse unintelligent.

As an educator, it is critical to begin to teach with an understanding of the learning style of the students in the classroom. And it is important to note that young learners in a university setting may have very different learning styles than adults who already bring significant experience to the classroom. The following are common “groupings” to describe learning styles:

1. **Visual – spatial:** Learner responds well to using pictures, images and spatial understanding;
2. **Aural – auditory, musical:** Learner responds well to using sound and music in the lesson;
3. **Verbal – linguistic:** Learner responds positively to words, both spoken and written;

4. **Physical – kinaesthetic:** Learner responds well to opportunities to use their body, hands and sense of touch;
5. **Logical – mathematical:** Learner prefers to use logic, reasoning or systems thinking when learning;
6. **Social – interpersonal:** Learner responds well to working in groups or working in connection with other people; and
7. **Solitary – intrapersonal:** Learner prefers to work alone in a self-study or research type setting.

Research shows us that each learning style uses different parts of the brain. By involving more of the brain during learning, we remember more of what we learn. Researchers using brain-imaging technologies have been able to find out the key areas of the brain responsible for each learning style. For example, from the list above, visual learners tend to engage neurons in the occipital lobes of the brain related to the visual perceptions and both the occipital and parietal lobes of the brain related to spatial orientation. While it is unlikely that educators will be able to determine the exact section of the brain that a student is engaging with, it is important to provide a variety of learning opportunities that meet the needs of each learner and stretch the students in the room to learn in many ways without relying on one method.

TEACHING STYLES

Logically if the students in the classroom all have different learning styles, it means that educators must be comfortable using a variety of teaching styles to engage all the students equally in the material they must learn to be successful. This curriculum, the teaching template and the sample teaching strategies have been developed to support teaching styles that go beyond the knowledge and include a focus on skill development. When students engage with the material in a realistic and meaningful way the learning is more powerful.

Every teacher has her or his own style of teaching. And as traditional teaching styles evolve with the advent of differentiated instruction, more and more teachers are adjusting their approach depending on their students' learning needs. However, there are some basic styles that educators tend to rely on including but not limited to:

1. **Lecture:** authority-based approach that is teacher-centred and involves lengthy lectures and presentation; students role is to take notes, memorize the information either in the classroom during the lecture or outside as homework and study;
2. **Coach:** demonstrator approach expands the teaching beyond just lectures and includes such things as multimedia presentations, activities and problems to solve;

students are potentially more interested, but it is difficult to meet everyone's needs in a large class;

3. **Facilitator:** facilitators engage students in self-learning and support the students to develop critical thinking skills, with students retaining knowledge through self-actualization; when the learning is based on discovery rather than lecture and testing facts, it may be more challenging to measure success or assign grades;
4. **Delegator:** an approach that places students in groups to participate in activities; is often used in laboratory settings or other settings where peer feedback is important; when done well students participate in inquiry-based learning and are inspired to work together toward a common goal; note the teacher is more of a consultant rather than a traditional authority figure; and
5. **Hybrid:** this blended teaching style uses a variety of styles above to create an integrated approach that blends the teacher's personality with the student's needs and approved curriculum content; this approach is inclusive and recognizes students as individuals with different learning styles; note the teacher may find it difficult to draw boundaries and may potentially "spread themselves too thin".

Teaching styles are a reflection of the personality of the teacher and should be comfortable for the teacher or the students will recognize the contrast as not genuine teaching. While teaching styles should be respected, it is important that each teacher responsibly ensure that they remain guided by the agreed upon curriculum with the teaching objectives and learning competencies.

Although it is not the teacher's job to entertain students, it is vital to engage them in the learning process. Selecting a style that addresses the needs of diverse students at different learning levels begins with a personal inventory—a self-evaluation—of the educator's strengths and weaknesses. Teachers must develop their teaching styles and integrate them with effective classroom management skills. Please note that no one strategy is the most effective and the best educators are flexible and go between the styles explained above.

In closing there are a number of other elements to consider when developing a teaching style. These should be considered as part of the process when developing lessons plans, materials and other learning tools:

1. Today's emphasis is on student-centred classrooms, it requires planning ahead and flexibility in teaching;
2. Traditional teaching has made an assumption that students are "empty vessels" waiting for the "expert" teacher to fill them up. However, adult learners do not fit into this approach as they bring significant experience and existing knowledge. And, with the access to the internet and continuous information, we can no longer presume that traditional students are "empty vessels" either;

3. Learners can be active or passive and meeting the needs of both types of learners is often one of the biggest challenges a teacher can manage;
4. Many educators were themselves taught with the understanding that knowledge implies a complete understanding, full comprehension and the skills to inform behaviour. However, we have learned that knowledge of the facts will not always result in a full understanding or the ability to practice skills using the knowledge;
5. Classrooms have become more interactive and educators need to learn how to assess knowledge and skill development beyond the traditional exam. The use of rubrics, checklists and other assessment types can be critical to demonstrate learning; and
6. Group-focused or inquiry-based teaching lessons sometimes appear to favour extroverted students with highly developed social skills but when managed well the quieter students in the group learn by observing and listening.

3. CORE CURRICULUM COMPONENT: LEGAL AND POLICY FOUNDATION

INTRODUCTION

Access to controlled medicines is governed by 1) International Treaties¹⁰; 2) Nigerian Acts of parliament, Regulations¹¹; and 3) Policies¹², which cover the availability and use of controlled medicines. The varying levels of controls and regulations for this group of medicines are due to their medicinal values and perceived risk of non-medical use. The treaties and the national laws for controlled medicines need judicious and balanced interpretation and application to guarantee their seamless access for medical use and to prevent diversion. It is important that students have adequate and correct knowledge about these treaties and national laws.

Nigeria has a dual obligation, as a party to the treaties that regulate controlled medicines¹³. First, Nigeria has an obligation to maximize access to controlled medicines for medical and scientific purposes. Secondly, Nigeria must minimize the diversion of controlled medicines for non-medical use. These obligations are equally important and complementary for a healthy nation. Health has been framed as a fundamental human right for all¹⁴, and access to essential controlled medicines for medical use is paramount to sustaining a quality health system, which must be upheld to our utmost ability, as a nation.

Therefore, the treaties, laws, regulations and policy are a core component of the national curriculum for controlled medicines, which guide how controlled medicines are managed in Nigeria. The international treaties, to which Nigeria is a signatory, form the foundation for strong regulatory control at national levels.

¹⁰ Burke-Shyne, N., Csete, J., Wilson, D., Fox, E., Wolfe, D., & Rasanathan, J. (2017). How Drug Control Policy and Practice Undermine Access to Controlled Medicines. *Health and Human Rights Journal*, 19(1), 237-52.

¹¹ Pharmacists Council of Nigeria. (2014). A Compilation of Pharmacy, Drugs and Related Laws and Rules in Nigeria, 1935-2000.

¹² Federal Ministry of Health. (2017). National Policy for Controlled Medicines and its Implementation Strategies. Abuja, Nigeria: Federal Ministry of Health. Retrieved July 17, 2018, from <http://health.gov.ng/doc/Nat%20Policy%20for%20Controlled%20Med.pdf>

¹³ Burke-Shyne, N., Csete, J., Wilson, D., Fox, E., Wolfe, D., & Rasanathan, J. (2017). How Drug Control Policy and Practice Undermine Access to Controlled Medicines. *Health and Human Rights Journal*, 19(1), 237-52.

¹⁴ Hogerzeil, H., & Mirza, Z. (2011). Access to Essential Medicines as Part of the Right to Health. In World Health Organization: The World Medicines Situation (3 ed.). Geneva: WHO. Retrieved November 2, 2018, from <http://apps.who.int/medicinedocs/documents/s18772en/s18772en.pdf>

There are three main international drug control conventions, namely¹⁵:

1. The United Nations Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol;
2. The United Nations Convention on Psychotropic Substances (1971); and
3. The United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988).

Additional guidance to Nigeria is provided by the International Narcotics Control Board (INCB), an independent, quasi-judicial expert body established by the Single Convention on Narcotic drugs of 1961 for limiting the manufacture and regulating the distribution of Narcotic drugs¹⁶.

In Nigeria, the control, availability and access to narcotics, psychotropic substances and other controlled medicines are guided strictly by aforementioned Conventions and the following legislations and policies:

1. The National Agency for Food and Drug Administration and Control Act Cap N1, Laws of the Federation of Nigeria (LFN), 2004;
2. National Drug Policy 2005;
3. National Policy for Controlled Medicines and Its Implementation Strategies, 2017.
4. Dangerous Drug Act Cap D1, LFN, 2004; and
5. Poison and Pharmacy Act Cap 535 LFN, 1990.
6. National Drug Law Enforcement Agency Act, Chapter N30, LFN, 2004.
7. Pharmacists Council Of Nigeria Act, CAP P17, LFN, 2004

NATIONAL DRUG POLICY 2005

The National Drug Policy (NDP) is the document, where the government explicitly states its goal and aspirations for the pharmaceutical sector. NDP, 2005, provides a coordinating framework for all stakeholders in the sector. The document also stated the strategies to achieve the national goals, specifically the availability and affordability of essential medicines, as well as stimulation of local production of essential medicines.

¹⁵ United Nations Office on Drugs and Crime. (2013). The International Drug Control Conventions. New York: United Nations. Retrieved July 17, 2018, from https://www.unodc.org/documents/commissions/CND/Int_Drug_Control_Conventions/Ebook/The_International_Drug_Control_Conventions_E.pdf

¹⁶ Federal Ministry of Health. (2017). National Policy for Controlled Medicines and its Implementation Strategies. Abuja, Nigeria: Federal Ministry of Health. Retrieved July 17, 2018, from <http://health.gov.ng/doc/Nat%20Policy%20for%20Controlled%20Med.pdf>

NATIONAL POLICY FOR CONTROLLED MEDICINES AND ITS IMPLEMENTATION STRATEGIES, 2017

The Federal government, through the Federal Ministry of Health (FMOH), developed and adopted in 2018 a National Policy for Controlled Medicines (NPCM) based on the current national laws and regulations. The primary goal of the policy is to ensure seamless access to affordable controlled medicines for medical and scientific purposes, while it prevents diversion. It highlights, in detail, the duties and responsibilities of different cadres of the health force to ensure availability of control medicines in Nigeria. Students, at all levels and sectors of training in health institutions, as well as health professionals, must be familiar with the NPCM. As they understand the NPCM, they will likely promote its goal in practice, dispelling all misconceptions about the legal controls on controlled medicines in Nigeria and helping to remove barriers to controlled medicines for medical and scientific purposes at pre-service and continuing education trainings. This will create opportunities for sustainable quality healthcare through safe regulatory measures.

THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT CAP N1, LAWS OF THE FEDERATION OF NIGERIA (LFN), 2004

This Act established The National Agency for Food and Drug Administration and Control (NAFDAC) as the Nigerian National Medicines Regulatory Authority. Among other functions and power granted the agency is the power to grant authorization to import, and to export, controlled medicines. In collaboration with National Drug Law Enforcement Agency (NDLEA), NAFDAC sets out to prevent and eradicate non-medical use of controlled substances in Nigeria.

NAFDAC enforces the provisions of the conventions and legislations that promote access to controlled medicines for medical and scientific purposes only. This includes regulation of importation, manufacture, distribution, warehousing, sales and use of controlled medicines. The Agency also ensures that Nigeria fulfils its obligation under the relevant United Nations Conventions¹⁴. Furthermore, the agency interfaces with the INCB to make sure that up-to-date consumption data and other reports, as required by international conventions are met. This includes an adequate supply of controlled medicines for medical purposes.

DANGEROUS DRUG ACT CAP D1, LFN, 2004

This Act regulates the importation, exportation, manufacture, sale and use of controlled medicines, referred to as 'opium and other dangerous drugs' in the Act. In the context of licit medicine distribution channels, the controlled medicines referred to are in the national schedule, as listed in the National Policy for Controlled Medicines (2017). Though this national law seems to have derived its language and context from international treaties that predates the Single convention, it supports the concept that

licensed use of control medicines for medical and scientific purposes in no way hampers access to these essential medicines.

POISON AND PHARMACY ACT CAP 535 LFN, 1990

This Act regulates pharmacy practice in Nigeria. It regulates the sale, distribution and dispensing of medicines, including controlled medicines. It compels the registration and licensure of pharmaceutical chemists.

It is important that relevant health professionals and students know that though these laws are dated, they should not be interpreted to impede access to controlled medicines for medical use.

The international treaties, national laws and regulations for controlled medicines are in-tune with the enforcement and regulatory agencies to help achieve our dual obligations. Therefore, students and the current healthcare workforce must have deep understanding and appreciation of the laws, functions and limits of the different agencies (INCB, NAFDAC, PCN, NDLEA) involved with regulation of the controlled medicines.

NATIONAL DRUG LAW ENFORCEMENT AGENCY ACT, CAP N30, LFN, 2004

The Agency shall have responsibility for the enforcement and the due administration of the provisions of this Act; and the coordination of all drug laws and enforcement functions conferred on any person or authority, including Ministers in the Government of the Federation by any such laws.

The Agency is to also adopt measures to eradicate illicit cultivation of narcotic plants and to eliminate illicit demand for narcotic drugs and psychotropic substances with a view to reducing human suffering and eliminating financial incentives for illicit traffic in narcotic drugs and psychotropic substances.

It is the responsibility of NDLEA to also take such measures which might require the taking of reasonable precautions to prevent the use of ordinary means of transport for illicit traffic in narcotic drugs including making special arrangements with transport owners; and taking measures for the early destruction or disposal of the narcotic drugs and psychotropic substances which have been seized, confiscated or forfeited.

NDLEA shall also be involved in the exchange of information concerning offences and improving international cooperation in the suppression of illicit traffic in narcotic drugs and psychotropic substance by road, sea and air etc.

The Agency shall function by reinforcing and supplementing the measures provided in the Convention on Narcotic Drugs 1961, as amended by the 1972 Protocol, the 1971 Convention on Psychotropic Substances and the United Nations Convention Against illicit traffic in Narcotic Drugs and Psychotropic Substances 1989 as adopted by the

Nigerian domestic law, in order to counter the magnitude and extent of illicit traffic in narcotic drugs and psychotropic substances and its grave consequences. It is to take such measures that may ensure the elimination and prevention of the root causes of the problems associated with narcotic drugs and psychotropic substances.

The Act empowers the Agency to strengthen and enhance effective legal means for international cooperation in criminal matters for suppressing the international activities of illicit traffic in narcotic drugs and psychotropic substances; and also collaborating with government bodies both within and outside Nigeria carrying on functions wholly or in part analogous to those of the Agency concerning the movement of narcotic drugs and psychotropic substances specified in the Second Schedule to this Act, and instrumentalities used or intended for use in the commission of such offences; amongst others.

PHARMACISTS COUNCIL OF NIGERIA ACT, CAP P17, LFN, 2004

The Pharmacists Council of Nigeria shall be charged with determining the standard of knowledge and skill to be attained by persons seeking to become registered members of the pharmacy profession (in this Act referred to as "the profession") and reviewing those standards, from time to time, as circumstances may require. It shall also secure, in accordance with the provisions of this Act, the establishment and maintenance of registers of persons entitled to practice as members of the profession and the publication, from time to time, of lists of those persons; and reviewing and preparing from time to time, a statement as to the Code of Conduct which the Council considers desirable for the practice of the pharmacy profession.

The Act also empowers the Council to regulate and control the practice of the profession in all its aspects and ramifications; and as well as performing such other functions as may be required of the Council under this Act.

A CALL TO ACTION

To achieve all the aforementioned, we must:

1. Teach the treaties, policies and national laws in a way that demonstrates their support for access to controlled medicines for medical use;
2. Inspire every health care worker to protect patients' fundamental and legal rights to health, which include access to controlled medicines;
3. Provide hands-on training for students and health care workforce about legal and policy foundation for controlled medicines. This reinforces their confidence to use controlled medicines safely in practice; and

4. Show that the National Policy for Controlled Medicines spelt out the responsibility and duties of each cadre of health workers. We must carry out these duties competently at all levels of care.

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TEACHING TEMPLATE

MODULE	TOPICS	COMPETENCY STATEMENT	INSTRUCTIONAL GOALS	LEARNING OBJECTIVES
1.2.1 International Conventions	Definition of terms	Understand the three conventions and their implications to Nigeria as a signatory, as well as the application of the three international conventions in practice	To explain the history and development of the three international conventions as well as how the international conventions affect the procurement, storage, distribution and use (prescribing,	To define and review the three international conventions.
	History and development of 3 International Drug Conventions			To develop an appreciation of the magnitude of pain globally and nationally.

	Impact of Drug Conventions on all aspects of the supply chain		dispensing and administration) of controlled medicines.	To analyse how the conventions affect the procurement, storage, distribution and use (prescribing, dispensing and administration) of controlled medicines.
1.2.2 National Laws and Legislation - Nigeria	Introduction to major laws and regulations relevant to this issue	Understand and recognize the effective application of the laws and regulations guiding controlled medicines use in Nigeria	To have a comprehensive understanding of the national laws and regulations guiding controlled medicines use in Nigeria. To emphasize how the language of the law has the potential to act as barriers to medical use and to highlight the actions that can be taken to interpret the language from a proactive health perspective.	To review and analyse the existing laws in Nigeria: *Poisons and Pharmacy Act Cap 535 LFN 1990 *NAFDAC Act Cap N1 LFN 2004 **NDLEA Act 253 LFN 1990 *Dangerous Drugs Act Cap D1 LFN 1990 Pharmacists Council Of Nigeria Act, CAP P17, LFN, 2004
	How are laws and regulations applied in healthcare system			To develop skills and knowledge to analyse the application of the above-mentioned laws and regulations in practice

	Practice within a legal framework			To review and debate barriers and challenges to effective practice
1.2.3 National Policy for Controlled Medicines (NPCM)	Content areas of NPCM	Familiarise participants with the NPCM	Introduce the National Drug Policy, the rationale, goals and objectives	Define the NPCM and highlight its importance in improving access to medical use of Controlled medicines.
				To explain the goals, objectives, targets and strategies of NPCM
				To teach the NPCM deliverables to the various health care workers
				To teach how to evaluate health facility-controlled medicines policy (written and unwritten) vis-à-vis the NPCM

SAMPLE TEACHING STRATEGIES

The following are sample teaching strategies that may be utilized to engage students with the materials and lessons as described in the Teaching Template above. Please note these are samples and may be revised or changed to meet the unique classroom setting, the specific needs of the students or the teaching style of the instructor.

Group Presentations

Materials needed: 3 copies of each document to be reviewed

Overview of activity:

Instructor divides the large group into smaller groups and provides each small group with a document to be reviewed. The small group is given adequate time to review the document and prepare a presentation to be made to the larger group.

Modifications:

- Provide guiding questions to help the group organize their thoughts and presentation.
- Provide a template for each group to use for their presentation.
- For documents with multiple parts or of a significant length, it may be advisable to divide the document into sections, one section covered by each small group. However, please note each group should see the full document and only present on the part they are assigned.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style in areas such as content knowledge; members of the group that participated, demonstrated understanding of the main concepts, and conveyed a meaningful message. The rubric is also shared with the small groups in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the presentation. The audience rates on what they experienced and the group self-rates their own performance.

Create a quiz activity

Materials needed: Materials or documents to be discussed

Overview of activity:

Instructor provides each student with a copy of the material to be discussed. Each student must review the material and develop an assessment to be given to other students. This can be done in class or as an assignment. When the assessments are complete, put the students in groups of 2 and allow them to assess their partner. Grading will also be done by the student that created the quiz.

Modifications:

- Give the students only 3 options for how to create an assessment.
- Provide a template for each group to use for their assessment.
- For longer or denser materials/documents it may be advised to have the students create the assessments for homework and then disseminate in class for a test.

Evaluation method:

It is not suggested to use the “grades” from the assessment as the grade for the activity. Rather, it is suggested that students complete a short essay about what they have learned and self-evaluate their grade during this process. The instructor will then provide a grade for the short essay.

Web-based Research

Web-based research on the Nigerian policies related to controlled medicines

Materials needed: Access to the internet

Overview of activity:

Instructor divides the large group into smaller groups and provides each small group with a different topic area related to controlled medicines. The small group is given adequate time to research and prepare a presentation to be made to the larger group.

Modifications:

- Assign as a homework or library assignment to be completed within the course of a week so each group has adequate time to access the internet.
- Provide guiding questions to help the group organize their thoughts and presentation.
- Keep the topic areas appropriate for the age and comprehension of the students.

Evaluation method:

Use a checklist to determine if the students were able to find the key information on each topic area.

The instructor may also use a checklist that is shared with the class, so all students rate the presentation. The audience rates on what they experienced and the group self-rates their own performance.

Write an essay

Write an essay comparing Nigerian law with current hospital policy in practice in Nigeria as it relates to controlled medicines

Materials needed: Copy of Nigerian Law and access to hospital policy

Overview of activity:

Students are instructed to compare Nigerian law with current hospital policy and practice in Nigeria, related to access to controlled medicines. Depending on the level of the students, direction is given, related to structure of the essay and arguments to be made.

Modifications:

- Assign as homework or to be done during class time.
- Provide guiding questions to help the group organize their thoughts and essay.
- Pre-discuss topic areas appropriate for the age and comprehension of the students.

Evaluation method:

Develop a rubric that assigns value to areas such as content; demonstrated knowledge and understanding, persuasiveness, and development of comprehensive approach.

The instructor may also use a checklist that can be shared with students in advance as a way to help students organize their essay.

Survey Healthcare Sites

Survey 5 different healthcare “sites” – public, private, clinics, hospital, or other healthcare setting – to determine what the policies are related to controlled medicines

Materials needed: Ability for advanced level students to access information from different healthcare sites such as hospitals, private clinics or pharmacies.

Overview of activity:

The class reviews the materials learned thus far on access to controlled medicines. The class then develops a template that can be used to survey different healthcare sites. The template should be used universally for all sites and should be inclusive of the important areas as determined by the class based on current understanding of the material. The surveys should be implemented in five different healthcare sites and a report of the findings generated.

Modifications:

- It may be helpful to assign this activity to small groups instead of each individual student.
- This can be done as a class activity where more than 5 sites are selected, and the results compiled into one report after each student surveys a separate healthcare site.
- This is an advanced activity, but it can be modified to be a more basic activity by creating sample scenarios for the class to consider, instead of collecting the information in a survey outside the classroom.

Evaluation method:

The final report developed by the students is in part an evaluation of their work. In addition, each student should be required to complete an essay demonstrating their knowledge and understanding of the topic.

Create hospital policy

Materials needed: Sample hospital policy or template of a hospital policy to guide the development

Overview of activity:

Instructor provides a sample hospital policy and the students discuss the key components and the areas in which access to controlled medicines is potentially a challenge. Students are then instructed to create a hospital policy that will allow patients who are in pain to access the medicines that they need.

Modifications:

- Provide guiding questions to help the group organize their thoughts and presentation.
- Provide a template for each student to follow in writing the policy document.
- Identify the key areas that the instructor wants students to focus on, for example assessing pain and putting information in patient charts or identifying when physicians are authorized to prescribe morphine.

Evaluation method:

Each student's policy should be "tested" using an assessment developed by the students. Any barriers to accessing medicines should be identified and discussed. Evaluation should be based on a final reckoning of the hospital policy and the student's defence of the policy.

4. CORE CURRICULUM COMPONENT: PAIN MANAGEMENT INCLUDING THERAPEUTIC AND NON-PHARMACOLOGY INTERVENTIONS

INTRODUCTION

The management of pain is a process that involves several interconnected healthcare practitioners but ultimately is driven by the needs of the patient to have their medical needs, including relief of pain, met. The Guidelines for the Management of Pain in Nigeria define pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage¹⁷. Healthcare practitioners must consider a full complement of factors, such as patient condition, disease conditions, co-morbidities, severity of pain and any side effects associated with the selected intervention to manage the pain.

What is pain?

Pain can be either a disease or a symptom, or both. It could rapidly change and develop depending on persons. This is the reason for careful routine assessment of pain in comparison with previous or subsequent experience(s), these episodes could be monitored, managed and kept at a minimum.

The measurement of pain therefore becomes a vital/key element in the assessment, which should be comprehensive clinical approach, hence the need for professionals to develop proficient skills for effective management and necessary prevention before it ever occurs.

Goals and Strategies

The entire goals of a robust treatment, which will be the basis for this pillar, are:

1. To understand the experience of the patient and the underlying holistic factors and pathophysiology contributing to the pain;
2. To understand and know how pain is treated through assessment, measurement and management; and
3. To prevent the onset of detrimental effects either/both psychological and physical resulting from untreated pain.

The strategies for education and training should be multifaceted being that the subject of pain itself is multidisciplinary. The workshop, seminar, group discussion, didactic teaching, activity, practical skill education, extra or ongoing support, role play/vignette models, also, the interviews, questionnaires, system log, pre and post testing, focused groups and nominal group techniques could be utilized for training or educating students

¹⁷ Guidelines for the Management of Pain in Nigeria, 2018 pp. 20

and health professionals using either the practical based or self-directed learning education skills in the management of pain.

Screening and Assessment

This section provides information on screening and assessment of pain in patients, as well as pharmacology and non-pharmacological interventions. Proper and continuous screening and assessment of pain is critical in determining the appropriate strategy to manage pain in patients. Trained, knowledgeable and skilled healthcare workers are essential to determine the safest and most effective interventions to manage the unique experiences and situations for each patient, tailored to the needs of the patient and with an expectation of continued monitoring and feedback. Information is separated into the following key areas:

1. Introduction to pain management;
2. Patient Care: management of pain in different populations;
3. Managing pain in special patient populations such as children, elderly, patients with mental health issues; and
4. Experiential training in pain management.

Call to Action

We must remove the barriers to effective pain management, and the barriers include;

1. Differentiate between assessment and measurement of pain;
2. Inadequacy of age-appropriate and validated pain-measurement tools;
3. Inadequate training on the use and implementation of pain measurement tools;
4. Inadequate knowledge on the interpretation of pain score when obtained;
5. Inadequate knowledge on differentiating between pain, anxiety, and emotional issues such as fear, depression and discomfort;
6. Inadequate skill in applying information obtained during assessment to the process of measurement and management;
7. Inadequate skill to having an open attitude where patient is listened to and their experience validated.

Bibliography

Guidelines for the Management of Pain in Nigeria, 2018 pp. 20

TEACHING TEMPLATE

MODULE	TOPICS	COMPETENCY STATEMENT	INSTRUCTIONAL GOALS	LEARNING OBJECTIVES
2.2.1 Introduction to pain management	Definition of terms	Know the meaning of terms used in pain management, appreciate the burden of pain, understand the different types of pain and why they should be managed	To stimulate the interest of participants in the burden of pain and its management in Nigeria.	To define terms used in pain management.
	Epidemiology of pain globally and in Nigeria			To appreciate the magnitude of pain globally and nationally
	Classification of pain			To be able to recognise the different types of pain
	Rationale for pain management			To understand why pain should be managed
2.2.2 Patient Care: management of pain in different populations	Introduction to patient care	Be able to use assessment tools in pain management and make beneficial interventions that improve patient outcomes	To expose participants to the skills required to assess and manage pain	To understand the general principles of patient care
	Introduction to the use of different assessment tools for pain recognition and management			To introduce different assessment tools for pain recognition
	Patient assessment			To understand patient assessment such as history taking, physical examination etc.
	Patient intervention: Pharmacological & non-pharmacological			To know the different choices available for pain management

2.2.3 Managing pain in special patient populations such as children, elderly, patients with mental health issues including addiction	Tools for assessing pain in special populations	Be able to use assessment tools in pain management and make beneficial interventions that improve patient outcomes in special populations	To give participants the skills required to assess and manage pain in special patient populations	To introduce specific (non-generic) assessment tools for pain recognition in special patient populations
	General use of controlled medicines in special populations			To know the different indications for controlled medicines in special populations
2.2.4 Experiential training in pain management	Case studies	To acquire practical skills to manage all categories of patients with pain	To expose participants to practical skills required to assess and manage pain	To acquire the ability to assess case notes and make decisions
	Clinical ward rounds			To practically expose participants to patients with various types of pain and how to communicate and make specific clinical interventions
	Presentation of case studies, assessment and evaluation using generic and specific tools			To give participants the skills necessary to present cases and communicate results of patient assessment using different tools

SAMPLE TEACHING STRATEGIES

The following are sample teaching strategies that may be utilized to engage students with the materials and lessons as described in the Teaching Template above. Please note these are samples and may be revised or changed to meet the unique classroom setting, the specific needs of the students or the teaching style of the instructor.

Case presentations and class discussions

Materials needed: Case materials (sample patients)

Overview of activity:

Instructor divides the large group into smaller groups and provides each small group with a sample patient to be reviewed. The small group is given adequate time to review the documents and prepare a presentation to be made to the larger group.

Modifications:

- Provide guiding questions to help the group organize their thoughts and presentation.
- Provide a template for each group to use for their presentation.
- For complex patient cases, it may be advisable to divide the document into patient aspects, one aspect covered by each small group. However, please note each group should see the full patient case and only present on the part they are assigned.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style in areas such as content knowledge; members of the group that participated, demonstrated understanding of the main concepts, and conveyed a meaningful message. The rubric is also shared with the small groups in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the case study presentation. The audience rates on what they experienced and the group self-rates their own performance.

Role play using pain screening and assessment tools

Materials needed: Multiple copies of the screening and assessment tools

Overview of activity:

Instructor divides the large group into smaller groups and provides each small group with the screening and assessment tools. The small group is given adequate time to practice and role play the experience using each of the tools. The instructor then pairs the students and provides each pair with a scenario. One student is the patient and one student role-plays the healthcare provider. The “patient” is screened and assessed, and an intervention is selected.

Modifications:

- Provide guiding questions to help the student whose role is to play the healthcare practitioner.
- For advanced students, following role play in class, they should then be assigned homework to screen and assess five additional persons outside of the classroom.
- To increase engagement with the screening and assessment tools an additional perspective may be that the role play is done in front of the class and following the role play students discuss and justify the tools selected and the methods practiced.

Evaluation method:

The instructor may use a checklist that is shared with the class, so all students rate the case study presentation. The audience rates on what they experienced and the group self-rates their own performance.

Create a visual representation of pain

Materials needed: Art materials as available

Overview of activity:

Students are asked to develop a visual representation of pain. This is meant to be a timed session and students should be expected to present and explain their representation to the class. Discussion will include the importance of taking a holistic approach to each patient with a critical component of addressing pain to aid in healing.

Modifications:

- This can be done as homework and presented in class if students have access to materials.
- This can be done by individual students, in small groups or even as a class. Any of the scenarios would require discussion and consensus regarding creative ways to demonstrate the various types of pain and the ways in which patients express or feel pain. For example, there may be a difference in how acute pain is depicted as compared to chronic pain.
- If the students express being uncomfortable with sharing their representations of pain in front of the class, instructors may ask students to keep a journal for a number of days and describe pain differently each day. The journal will then be collected and graded by the instructor only.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge, demonstrated understanding of the main concepts, and conveyance of a meaningful message. The rubric is also shared with the students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the presentation. The audience rates on what they experienced and the group self-rates their own performance.

Self-assessment of pain and journaling

Self-assessment of pain with written journal entries describing a time when the student experienced pain

Materials needed: Writing materials and/or journals

Overview of activity:

Instructor asks students to keep a journal of pain. Students will self-assess their level of pain and then keep a daily journal entry describing their own pain. The students should also expand their journal entries to include observations of persons around them experiencing pain, describing the circumstances and the situation. For example, a student may write about a sibling that fell and bumped their head – how they felt and what was done to alleviate the pain.

Modifications:

- Provide guiding questions or a template to help the students know what to write in their journal.
- Allow daily time in class for the journal writing and keep the journals in the classroom where the teacher can review and grade when needed.

Evaluation method:

The instructor may decide to only assign a grade based on participation. For example, students who complete the journal entries receive full credit and those that only do half the entries will only receive half the credit.

Grades can also be assigned based on insightful understanding of pain and ability to convey that understanding in writing. It is suggested to develop and share a rubric to guide the students of the expectations of the instructor prior to assigning the task.

Grand rounds and Sample Charting

Materials needed: Sample scenarios and patient charts

Overview of activity:

Instructor provides students with a patient scenario. The class is then transformed into a “Grand rounds” experience where the students are encouraged to discuss, assess and suggest interventions to manage the patient’s pain level as appropriate. Following the role play, each student is then provided a patient chart and they must complete the chart. Discussion should then ensue related to the most effective ways to include pain assessment in a patient chart and the importance of charting pain regularly to note any fluctuations in what the patient is experiencing.

Modifications:

- This is an advanced activity and should be done with students that have knowledge of patient care.
- Allow time for class discussion about the barriers that may prevent a patient from having access to interventions for pain management and what options might be available.

Evaluation method:

The instructor can create a checklist to ensure that all aspects of the process are reviewed, and students demonstrate knowledge of both assessment and charting pain.

Assessing pain and determining pharmacological interventions

Materials needed: Sample patient scenarios and copies of essential medicines list

Overview of activity:

Instructor provides students with a patient scenario. The student is then required to assess the level of pain, determine a strategy to manage the pain and defend the strategy. It is critical that the student be able to combine and justify both non-pharmacological and pharmacological interventions, including any concerns related to contraindications.

Modifications:

- This is an advanced activity and should be done with students that have knowledge of patient care.
- Allow time for class discussion about the barriers that may prevent a patient from having access to interventions for pain management and what options might be available.

Evaluation method:

The instructor can create a checklist to ensure that all aspects of the process are reviewed, and students demonstrate knowledge of assessment and comprehensive patient care.

5. CORE CURRICULUM COMPONENT: PHARMACOLOGY AND RATIONAL USE OF CONTROLLED MEDICINE

INTRODUCTION

The concept of rational use of medicines is central to effective and safe use of controlled medicines, as well as to ensure good quality healthcare. Rational use of medicines involves appropriate prescription, appropriate medicines, appropriate patient, appropriate dosage, appropriate dispensing and administration for the requisite duration and the provision of appropriate information¹⁸. These themes are very relevant in this curriculum that focuses on the handling of controlled medicines; given the potentials for non-medical use as well as the concern that misinformation may fuel some stereotypes. Access to, and rational use of controlled medicines will secure the fundamental rights to health of all Nigerians.

Irrational use of controlled medicines, or non-medical use, may result from health workers' perception of controlled medicines as "drugs of abuse", their reluctance to handle controlled medicines due to fear of legal consequences, and their inadequate knowledge and skills in the safe handling of these useful medicines in practice¹⁹. According to WHO, a systematic review of research papers concludes that only 0.43% (43 in 10,000) of patients with no previous history of substance abuse treated with opioid analgesics to relieve pain abused their medication and only 0.05% (5 in 10,000) developed dependence syndrome.

There appear to be some gaps in the current curricula of health professionals with respect to rational use of controlled medicines. Hence, this curriculum attempts to address the rational use of controlled medicines, with a view to improving the knowledge base and ultimately practice regarding controlled medicines among the various health professionals. One key benefit of the practice of rational use of controlled medicines is the likelihood of preventing diversion and reducing non-medical use in the society.

It must be emphasized that while the knowledge and practice of rational use of controlled medicines holds promise of improved medical access for the vulnerable people and supports the fair-minded practitioners, the challenge of non-medical use of these

¹⁸ Management Sciences for Health (2012). MDS-3: Managing for rational medicine use. In *MDS-3: Managing Access to Medicines and other Health Technologies*. Arlington, VA: Management Sciences for Health.

¹⁹ INCB/WHO. (2012). Guide on Estimating Requirements for Substances Under International Control. New York: United Nations. Retrieved from https://www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating_requirements/NAR_Guide_on_Estimating_EN_Ebook.pdf

medications may not be fully deterred. Such challenge should, however, not determine how vulnerable patients are treated; rather appropriate safeguards should be instituted.

Essential Medicines List (EML) consists of medicines considered important to cater for the health needs of majority of the populace. Therefore, inclusion of any medicine or group of medicines implies the importance of such medicines in tackling health challenges of humans. In Nigeria, some narcotic analgesics and other controlled medicines have always been duly listed in the EML.²⁰ These essential medicines were selected based on sound scientific evidence and are the focus of this curriculum for rational use training and awareness.

Both the training of health workers and raising the awareness of patients should be adequately addressed for proper use of controlled medicines²¹. If there are deficiencies in health workers training, there will be lethargy to prescribe and dispense controlled medicines, even when it is clearly evident that patients require the medicines.

All health professionals should be adequately educated about all aspects of rational use of controlled medicines so as to ensure synergy. For example, a doctor's training responsibilities does not end with appropriate prescription; the pharmacist's advice on formulation or duration that may be used must also be known. Therefore, this section of the curriculum is expected to be used in tandem with the other sections of this document and with other relevant documents, such as standard treatment guidelines and the national guidelines for pain management.

For controlled medicines to be used rationally, the target audience for learning must be grounded in key pharmacology and in particular know the pharmacology of these medicines as appropriate for their levels. Therefore, this section has been divided to more clearly address both, concepts related to pharmacology and, to rational use of controlled medicines. It emphasizes the need for relevant information about biologic processes that are influenced by controlled medicines. It also focuses on patient education, adherence, and policy requirement when prescribing and dispensing controlled medicines and covers common errors that may occur in the use of controlled medicines.

The curriculum identifies the general principles related to the rational use of medicines. However, in the delivery of the learning materials attention should be given to different target audiences. There is the need to discuss specifics of rational prescribing, dispensing, and administering for controlled medicines, depending upon the needs of the audience. The policies that guide the prescribing, dispensing, and administering of controlled medicines differ slightly from that of other essential medicines because of additional controls associated with essential controlled medicines. The essence of additional

²⁰ The Federal Ministry of Health (2016). Nigeria Essential Medicines List. <http://apps.who.int/medicinedocs/documents/s23528en/s23528en.pdf> Accessed 5/12/2018.

²¹ Ibid.

controls is important to prevent diversion to illicit use while improving access and ensuring rational use of controlled medicines for medical purposes.

Learners are expected to be sufficiently knowledgeable in the clinical pharmacology of controlled medicines in order to guide their rational use. The various classes of the controlled medicines in addition to their clinical indications, as well as management of drug-related conditions should be well-discussed. Sufficient knowledge of clinical pharmacology of controlled medicines will appropriately position health professionals for proper management of patients' conditions and ultimately improve their health. Clinical pharmacology of controlled medicines will provide the needed platform for health professionals to understand the basics of drug action, therapeutic as well as adverse effects of these groups of drugs. It should be expected that possession of adequate knowledge and imbibing the right skills relating to controlled medicines will enhance their rational use in medical settings.

Objectives

The objectives of this section are to ensure that appropriate teaching related to rational use and safe handling and management of controlled medicines is a component of all healthcare education programs. It is also essential that healthcare providers are equipped with relevant knowledge, skills and the right attitude to identify and report any incidents of diversion of controlled medicines.

Key Messages

1. The key messages in the pharmacology section of the document are:
 - a. Understanding of, and classification of controlled medicines,
 - b. Pharmacology of controlled medicines used in various clinical settings and practice,
 - c. Management of overdose toxicity, in particular as it relates to controlled medicines.
2. The key messages in the rational use section of the document are:
 - a. Drug use process, patient education and adherence,
 - b. Policy requirements for prescribing and dispensing of controlled medicines,
 - c. Potential medication errors in the use of controlled medicines.

Non-medical use of medicines is a concern in Nigeria and should not be taken lightly. A clear teaching on the clinical pharmacology and rational use of controlled medicines will support Nigeria to address the concerns related to this problem.

A Call to Action

We must:

1. Build into every clinical pharmacology class for controlled medicines, a clear message for the rational prescribing, dispensing, administering, of this important class of medicines.
2. Emphasize at every training point that additional regulations of controlled medicines, which are encountered in practice, are necessary safeguards for their rational use.
3. Equip the health work force to identify any irrational use of controlled medicines, in whatever guise, and to mitigate it.

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TEACHING TEMPLATES

Pharmacology

MODULE	TOPICS	COMPETENCY STATEMENT	INSTRUCTIONAL GOALS	LEARNING OBJECTIVES
3.2 a1 Introduction to controlled medicines	Definition of controlled medicines and review of related terminologies in pharmacology	Understand the pharmacology of controlled medicines and other related terminologies and appreciate the roles of international agencies in scheduling and its classification as well as managing toxicity of overdose resulting from controlled medicines.	To acquaint the participants with the pre-requisite knowledge needed to understand the pharmacology of controlled medicines and other related terminologies and also appreciate the roles of international agencies in scheduling and its classification as well as managing toxicity of overdose resulting from controlled medicines.	To be able to define controlled medicines and other related terms
	A brief mention of the roles of WHO, INCB and UNODC in scheduling of controlled medicines.			To explain the roles of international agencies in scheduling of controlled medicines
3.2 a2 Classification of controlled medicines	The different classes of controlled medicines and some specific examples.			To enumerate the different classes of controlled medicines and give specific examples
3.2 a3 Pharmacology of selected examples of controlled medicines in clinical practice	Mechanism of action			To explain the mechanism of action of selected controlled medicines
	Pharmacokinetics			Explain the absorption, distribution, metabolism, excretion and drug monitoring of selected controlled medicines
	Clinical use			To discuss the clinical uses of selected controlled medicines based on their mechanism of action and pharmacokinetics

	Side effects/ adverse reactions and contraindications			To mention the side effects/ adverse reactions and precautions/contraindications
3.2 a4 Toxicity of controlled medicines	Identification and management of toxic levels of controlled medicines			To be able to recognize signs and symptoms of toxicity and its management

Rational Use

MODULE	TOPICS	COMPETENCY STATEMENT	INSTRUCTIONAL GOALS	LEARNING OBJECTIVES
3.2 b1 Concept of rational use of controlled medicines	Definition of rational drug use; its benefit and consequences of irrational use.	Understand the complete drug use process from concepts to medication errors and their preventive measures in the current legal and policy framework	To arm participants with the knowledge needed to function in a setting that practices the rational use of controlled drugs	To define rational drug use; list its benefits and consequences of irrational use
3.2 b2 Drug use process, patient education and adherence	Good prescribing practice			To be able to explain good prescribing practice of controlled medicines
	Good dispensing practice			To be able to explain good dispensing practice of controlled drugs
	Good drug administration practices			To be able to explain good drug administration practices as it relates to controlled drugs
	Good documentation practice	To be able to explain good documentation practice		

3.2 b3 Legal/policy requirements of prescribing and dispensing of controlled medicines	Legal/policy requirements of prescribing and dispensing of controlled medicines			To be abreast of the laws and policies guiding drug use
3.2 b4 Common medication errors in the use of controlled medicines	Identification and different types of medication errors			To identify the different types of medication errors associated with controlled medicines
	Prevention and resolution of medication errors			To highlight the different preventive measures and resolution of medication errors associated with controlled medicines

SAMPLE TEACHING STRATEGIES:

The following are sample teaching strategies that may be utilized to engage students with the materials and lessons as described in the Teaching Template above. Please note these are samples and may be revised or changed to meet the unique classroom setting, the specific needs of the students or the teaching style of the instructor.

Develop a weekly blog on controlled medicines

Materials needed: Eventual access to internet and blogging site

Overview of activity:

Instructor assigns each person in the class a topic area to be researched. Each student drafts one blog entry that will be posted each week. Students will submit their work to be presented to the class with the group making final edits and prioritizing the order in which topics will be posted. Sample topics include but are not limited to the following 1) essential medicines list; 2) adverse drug reactions, 3) medication and contraindications, or 4) rational use.

Modifications:

- The process of prioritizing and the entire class coming to a consensus on the order of presentation will ensure students know and understand enough to discuss.
- Provide a template to guide the development of each blog post.
- Allow for video presentations instead of written blogs. This would be done similar to a webinar.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge, demonstrated understanding of the main concepts, and conveyance of a meaningful message. The rubric is also shared with students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the blog post.

Case presentations and class discussions

Materials needed: Case materials (sample patients)

Overview of activity:

Instructor divides the large group into smaller groups and provides each small group with a sample patient to be reviewed. The small group is given adequate time to review the documents and prepare a presentation to be made to the larger group.

Modifications:

- Provide guiding questions to help the group organize their thoughts and presentation.
- Provide a template for each group to use for their presentation.
- For complex patient cases, it may be advisable to divide the document into patient aspects, one aspect covered by each small group. However, please note each group should see the full patient case and only present on the part they are assigned.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge; members of the group that participated, demonstrated understanding of the main concepts, and conveyed a meaningful message. The rubric is also shared with the small groups in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the case study presentation. The audience rates on what they experienced and the group self-rates their own performance.

Chart controlled medicines

Create a chart of controlled medicines; include the name of the medicine, the action and the contraindications associated with that medication

Materials needed: Presentation paper

Overview of activity:

Instructor assigns students the task of charting controlled medicines. Each student will create a chart including the name of the medication, the action of that medication and the contraindications associated with that medication. The class will then work together to combine information from each student's chart into one large chart to be displayed in the classroom.

Modifications:

- Provide guiding questions to help the students organize their thoughts and chart presentation.
- Provide a sample for students to see how it should look.
- Manage group dynamics so all students have a responsibility in developing the class chart. No student should be excluded, and all students should contribute in some way.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge; members of the group that participated, demonstrated understanding of the main concepts, and conveyed a meaningful message. The rubric is also shared with the students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students can check the information is complete and accurate.

Write an essay

Describe rational use of controlled medicines and make a case for who has the highest responsibility to the patients in relation to protecting patients from harm, including the prevention of non-medical use

Materials needed: Copy of all Nigerian documents that reference use of controlled medicines

Overview of activity:

Students are instructed to describe rational use of controlled medicines. They are also then instructed to identify the person who has the highest responsibility to the patients in relation to preventing non-medical use. Depending on the level of the students, more or less direction is given, related to structure of the essay and arguments to be made.

Modifications:

- Assign as homework or to be done during class time.
- Provide guiding questions to help the group organize their thoughts and essay.
- Pre-discuss topic areas appropriate for the age and comprehension of the students.

Evaluation method:

Develop a rubric that assigns value to areas such as content, demonstration of knowledge and understanding, persuasiveness, and development of comprehensive approach.

The instructor may also use a checklist that can be shared with students in advance as a way to help students organize their essay.

Create an experiential learning experience set in a fictional pharmacy

Materials needed: Copy of all Nigerian documents that reference use of controlled medicines

Overview of activity:

Students are instructed to create a fictional pharmacy. This would include how the environment is organized, policies that govern practice and all other means to run a successful pharmacy. The instructor then provides the students with sample data including daily, weekly, monthly and yearly data points to analyse. Students then review and analyse the data to determine any trends related to controlled medicines, any potential areas of diversion and any stocking or supply chain concerns.

Modifications:

- Assign elements of the larger project as homework or set aside time for the tasks to be done during class time.
- Provide guiding questions to help the group organize their thoughts and essay.

- Pre-discuss topic areas appropriate for the age and comprehension of the students.

Evaluation method:

Develop a rubric that assigns value to areas such as content; demonstration of knowledge and understanding, persuasiveness, and development of comprehensive approach.

The instructor may also use a checklist that can be shared with students in advance as a way to help students organize their essay.

Create a matching exercise

Match healthcare professional with the role they play related to controlled medicines.

Materials needed: Any creative materials needed to create the experience.

Overview of activity: Students are instructed to create an exercise that will challenge others to match healthcare professionals with the role they play related to controlled medicines. The instructor may help by suggesting that the students' list healthcare providers and the role they play. This list is then divided into the two sections and "mixed" to challenge those who are taking the test.

Modifications:

- Split group into smaller groups to go through the steps
- Provide guiding questions to help the group organize their thoughts and essay.
- Pre-discuss topic areas appropriate for the age and comprehension of the students.

Evaluation method:

Develop a rubric that assigns value to areas such as content; demonstration of knowledge and understanding, persuasiveness, and development of comprehensive approach.

The instructor may also use a checklist that can be shared with students in advance as a way to help students organize their task.

6. CORE CURRICULUM COMPONENT: PHARMACOVIGILANCE AND NON-MEDICAL USE OF CONTROLLED MEDICINES

INTRODUCTION

Controlled medicines have brought significant benefit to lives, especially by removing or reducing sufferings associated with pains. However, like most medicines, they are capable of producing adverse or unwanted effects.

There is also the risk of their non-medical use, with attendant consequences. Healthcare providers must practice the highest standards of care and consider those that are vulnerable, including factors that may contribute to non-medical use that may need additional screening and monitoring. The possibility of unwanted or adverse effects combined with the risk of non-medical use, present safety challenges and may negatively impact access to appropriate use of controlled medicines in Nigeria.

Pharmacovigilance

Pharmacovigilance refers to the system of continuous and diligent watch or vigilance over the use of all medicines. It is defined as the science and activities relating to the knowledge, detection, assessment and prevention of adverse effects of medicines or any other drug-related problem²².

The major aims of pharmacovigilance include the early detection of occurrence and increases in frequency of previously unknown and known adverse reactions and interactions and other noxious drug induced problems; identification of predisposing risk factors and possible mechanisms underlying adverse drug reactions; the estimation of quantitative aspects of risk benefit analysis and the dissemination of information needed to improve drug prescribing, use and regulations. The ultimate goals are the assessment and communication of risks and benefits of drugs on the market, the promotion of their rational and safe use and the education of patients, who are the end users of these medicines.

Patients who need controlled medicines, often, suffer from challenging health conditions that can be worsened or their treatment made more complicated by the occurrence of adverse drug reactions. Adverse drug reactions can also be a challenge to adherence, proper use and could even limit access to controlled medicines. A good understanding,

²² World Health Organization. (2019). Essential medicines and health products Pharmacovigilance. Retrieved from WHO on January 27, 2019: https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/

knowledge and institutionalization of the practice of pharmacovigilance is essential for health workers and other caregivers involved in the management of patients in pain.

Non-Medical Use

The non-medical use of controlled medicines remains a major challenge in Nigeria. Non-medical use can be defined as the taking of prescription drugs, whether obtained by prescription or otherwise, other than in the manner or for the reasons or time period prescribed, or by a person for whom the drug was not prescribed²³. Unfortunately, the perceptions of the risks related to non-medical use of controlled medicines are known to negatively affect the level of prescription and use of these medicines. Additionally, there are other aspects that contribute to the fears of increasing access to these essential controlled medicines such as existing loopholes in the regulatory systems, and poorly enforceable regulatory frameworks that include challenges with supply chain management.

The fear of non-medical use, with the perception of all the negative consequences, remains a major influence on policy decisions, clinical management guidelines and prescription practices. However, scientific evidences have shown that, compared to those that need these medicines, the percentage of those that participate in non-medical use is very low.

It is also known that those that engage in non-medical use may likely show a pattern of vulnerability and predisposition. Consideration of these, in clinical management decisions involving the use of controlled medicines, along with other measures (regulatory, managerial and administrative) aimed at promoting their availability, rational use and preventing diversions as well as parallel imports can significantly address the challenges of abuse and non-medical use.

Controlled drugs have an added layer of regulation which serves to protect patients from harm and healthcare providers from mishandling. This layer of regulation should not result in the failure to use controlled medicines for patients who require them but should be adequately supported by a good knowledge and practice of Pharmacovigilance and identification of factors that predispose them to abuse and non-medical use and incorporation of these factors and their management towards ensuring safe use of controlled medicines.

²³ United Nations Office on Drugs and Crime. (2011). The non-medical use of prescription drugs Policy direction issues. Vienna: United Nations. Retrieved January 27, 2019, from <https://www.unodc.org/documents/drug-prevention-and-treatment/nonmedical-use-prescription-drugs.pdf>

Call to Action

This curriculum calls for the following; we must

1. Teach and train all health care workers in proactive pharmacovigilance such that adverse drug events including non-medical use of controlled medicines are quickly identify and resolved in practice
2. Emphasize the signs and symptoms as well as screening and monitoring of patients for non-medical use of controlled medicines, during training.
3. Provide clear channels to collect, document and report adverse drug events of controlled medicines during training.

Bibliography

United Nations Office on Drugs and Crime. (2011). The non-medical use of prescription drugs Policy direction issues. Vienna: United Nations. Retrieved Jan 27, 2019, from <https://www.unodc.org/documents/drug-prevention-and-treatment/nonmedical-use-prescription-drugs.pdf>

World Health Organization. (2019). Essential medicines and health products Pharmacovigilance. Retrieved from WHO on January 27, 2019: https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/

TEACHING TEMPLATE

MODULE	TOPICS	COMPETENCY STATEMENT	INSTRUCTIONAL GOALS	LEARNING OBJECTIVES
4.2.1 Pharmacovigilance	Introduction Definition/ Explanation of terms and concepts; Proactive Pharmacovigilance	Students should be able to identify, complete Adverse Drug Reaction Form, report and transmit accordingly Students should be able to identify and manage cases of ADRs arising from commonly used	To stimulate participatory learning through lectures, discussions and demonstrations so that; learners can: 1. Explain the concept of pharmacovigilance, have background knowledge and epidemiology of	Define Pharmacovigilance Explain proactive pharmacovigilance

	Adverse drug reactions, Causality assessment,	controlled medicines in Nigeria Identify predispositions to ADRs, especially severe forms and how to use this knowledge to influence management decisions	adverse drug reaction, international best practices of pharmacovigilance	Recognize adverse drug reactions.
	Treatment and follow up and		2. Understand the concept of proactive pharmacovigilance	Complete adverse drug reaction form Report and transmit adverse drug reaction information
4.2.2 Non-Medical Use of Controlled Medicines	Introduction Definition/ Explanation of terms and concepts of controlled medicines and its non-medical use Predispositions and Vulnerabilities	Students should have the ability to improve access and curb inappropriate use of controlled medicines Students should be able to identify common predispositions to abuse and non-medical use of Controlled Medicines and use this to influence clinical management decisions	To stimulate participatory learning through lectures, discussions and demonstrations so that Learners can: 1. explain non-medical use of controlled medicines 2. identify predisposing factors and vulnerabilities 3. describe strategies for controlling non-medical use of controlled medicines 4. support modalities for improving access to controlled medicines	Define controlled medicines and its non-medical use
	Strategies for controlling non-medical use of controlled medicines			To identify predisposing factors and vulnerable groups
	Improved access to controlled medicines			To promote strategies to control non-medical use of controlled medicines and improve access

	<p>Management of abuse of Controlled Medicines (within the context of Medical Use).</p> <p>Evaluation and Management of Health challenges arising from non-medical use of controlled medicines</p>			<p>To promote strategies to manage abuse of controlled medicines</p> <p>To promote strategies to evaluate and manage health challenges arising from non-medical use of controlled medicines</p>
	<p>Management of toxicity or adverse drug reactions from medical or non-medical use of controlled medicines</p>			<p>To promote strategies to identify and manage adverse drug reaction and toxicities</p>

SAMPLE TEACHING STRATEGIES

The following are sample teaching strategies that may be utilized to engage students with the materials and lessons as described in the Teaching Template above. Please note these are samples and may be revised or changed to meet the unique classroom setting, the specific needs of the students or the teaching style of the instructor.

Group Presentations

Materials needed: Foundation information on pharmacovigilance

Overview of activity:

Instructor divides the large group into smaller groups and provides each small group with a document to be reviewed. The small group is given adequate time to review the information and prepare a presentation to be made to the larger group.

Modifications:

- Provide guiding questions to help the group organize their thoughts and presentation.
- Provide a template for each group to use for their presentation.
- For documents with multiple parts or of a significant length, it may be advisable to divide the document into sections, one section covered by each small group. However, please note each group should see the full document and only present on the part they are assigned.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge; members of the group that participated, demonstrated understanding of the main concepts, and conveyed a meaningful message. The rubric is also shared with the small groups in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the presentation. The audience rates on what they experienced and the group self-rates their own performance.

Develop a weekly blog on pharmacovigilance

Materials needed: Eventual access to internet and blogging site

Overview of activity:

Instructor assigns each person in the class a topic area to be researched. Each student drafts a blog entry that will be posted, one each week. Students will submit their work to be presented to the class with the group making final edits and prioritizing the order in which topics will be posted. Sample topics include but are not limited to the following 1) essential medicines list, 2) adverse drug reactions, 3) medication and contraindications, or 4) rational use.

Modifications:

- The process of prioritizing and the entire class coming to a consensus on the order of presentation will ensure students know and understand enough to discuss.
- Provide a template to guide the development of each blog post.
- Allow for video presentations instead of written blogs. This would be done similar to a webinar.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge, demonstrated understanding of the main concepts, and conveyance of a meaningful message. The rubric is also shared with students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the blog post.

Debate medical use vs. fear of non-medical use

Debate the need for medical use of controlled medicines vs. the fear of non-medical use of controlled medicines

Materials needed: Research opportunities

Overview of activity:

Instructor assigns each person to participate in one side of the debate or the other, ensuring the class is split evenly. Each student has two days to collect evidence for the debate. On the third day the students work in groups to strategize and prioritize the arguments. The fourth day is to practice and on the final day a debate is staged.

Modifications:

- Students could be allowed to select the side of the debate they would like to advocate for and the assignment would be about persuasive argument.
- Provide a template to guide the development of persuasive arguments on each side of the debate.
- Provide in advance the materials by which the students will create their arguments for basic learners and advanced learners would be held accountable to do the research themselves.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge, demonstrated understanding of the main concepts, and conveyance of a meaningful message. The rubric is also shared with students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the persuasiveness of the argument.

Role play

Healthcare worker discussing cancer treatment options with a patient and family members, including access to controlled medicines for pain management.

Materials needed: Creative material for role play

Overview of activity:

Instructor breaks the class into small groups of no more than five. Each group prepares a role play to demonstrate how a healthcare worker would discuss the need for pain management and the options available to the patient. After a short time for practice the groups present the role play to the larger class.

Modifications:

- Students could be allowed to select the scenario as long as it is based in a healthcare setting and demonstrates a conversation about access to controlled medicines.
- Provide a checklist to remind the students of each element that must be present in the role play interactions related to controlled medicines.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge, demonstrated understanding of the main concepts, and conveyance of a meaningful message. The rubric is also shared with students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the persuasiveness of the argument.

Create a visual “map” of the supply chain for controlled medicines

Materials needed: Creative material for creation of visual “map”

Overview of activity:

Instructor breaks the class into small groups of not more than five. Each group prepares a visual to demonstrate the supply chain for controlled medicines. The group is then instructed to highlight in yellow the areas that controlled medicines could be diverted and list steps that can be taken to prevent diversion. The “map” is then shared with the whole class.

Modifications:

- Students could be asked to work individually and present to the class or the entire class could work on one large map with each student contributing specifically to one area.
- Provide a checklist to remind the students of each element that must be included in the “map”.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge, demonstrated understanding of the main concepts, and conveyance of a meaningful message. The rubric is also shared with students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the persuasiveness of the argument.

7. CORE CURRICULUM COMPONENT: SUPPLY CHAIN MANAGEMENT

INTRODUCTION

It is not uncommon to find frustrated patients who genuinely need a narcotic pain killer but are unable to obtain it to use when they need it even if they can pay for it. Several factors may be responsible. Either the medicine is not available or the medication that is available has expired or the right quantities are not getting to the facilities where they are needed to serve customers with pain. There is a need to train all health workers on the importance of a supply chain that delivers a reliable uninterrupted supply of the right quality and quantity of controlled medicines to the right location at the right price.

Defining a Supply Chain

Logistics is the operational component or tasks of supply chain management which includes planning, implementation and control of the efficient flow and storage of health commodities and related information from the point of manufacture to the service delivery points (SDP) where clients' requirements are met. Supply chain management involves the coordination and optimization of all logistics activities such as selection, quantification, procurement, inventory management, transportation, data collection and reporting²⁴. A well-functioning logistics and supply chain system increases program impact, improves the quality of care given to clients and improves cost efficiency and effectiveness by reducing losses due to overstocking, waste, expiry, pilferage, diversion and damage. It can therefore maximize the potential for cost recovery.

Six Rights

Health products and health commodity security is only said to exist if a person can obtain and use quality health products whenever s/he needs them. This can only happen if the following six rights exist:

1. The right medication, including controlled medication is selected for the needs of the patient;
2. In the right quantity;
3. In the right condition;
4. Is delivered to the right place;
5. At the right time; and
6. At the right cost.

²⁴ USAID/DELIVER PROJECT, Task Order 1. 2011. The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities. Arlington, Va.: USAID/DELIVER PROJECT, Task Order 1.

Customers' expectations are what define the purpose of a logistics system; *and that purpose is to make sure that the patient receives the highest quality healthcare intervention.*

Logisticians must forecast product requirements accurately, obtain adequate financial resources, procure the needed health commodity timely and ensure a reliable delivery of these products to customers. These are the four logistics pillars that can make controlled medicine security possible. Therefore, controlled medicines' security exists when every person that needs drug treatment is able to obtain and use the required quality of the controlled medicinal product. This is serving the patient as a customer.

Controlled medicines are part of a regulated market and are thus closely monitored at all stages in the supply chain. Management of the special challenges that can be associated with scheduled drugs requires a thorough understanding of the policy environment, meticulous planning and the skills necessary to successfully adapt the supply chain to meet changing needs of the citizenry. It is the main thrust of this segment of the curriculum that those trained will have the skill set that is required to fully function in all or a specific point of the supply chain, whether it be as LMIS data collectors in line with INCB requirement or workers (prescribers, dispensers etc.), collaborators, policy makers, evaluators and supervisors within the logistics system to ensure controlled medicine security. This regulatory system protects both patients and healthcare workers from fraudulent, expired or otherwise damaged medication, with a strong and consistent pharmacovigilance component.

Identification and Estimation

Controlled medicinal products that are needed to serve customers must first be identified. It is practically impossible for the healthcare system to stock all products that are indicated for pain management. Therefore, selection of products defines what medicines are procured and used in serving customers that have pain. It limits the range of health commodities that are stocked to a manageable level within the supply chain and allows for the redistribution of products within the logistics system. Healthcare products which meet the needs of the customers to be served are selected on the basis that they meet the legal framework that exist in Nigeria. For example, a selected controlled medicine should have been registered by NAFDAC. Other considerations in product selection include its existence in the essential medicines' list and standard treatment guidelines. It is of note that a product may be selected if donated but it is important that such a product is first registered for use within Nigeria.

Quantification is the process of forecasting and supply planning. It is an ongoing exercise that requires monitoring and routine updates. Forecasting is the estimation of the quantities of healthcare products or commodities and cost required to serve customers for a specific health program, in a specific time period in the future. Supply planning is the determination of when supplies should be delivered to ensure an uninterrupted

availability and access thus preventing stock-outs. Not having controlled medicines in stock when patients have pain should be eliminated as much as possible from our healthcare system because it denies access to those who need treatment. Once quantification has been done, program managers will be able to identify short falls in funding and thus be able to negotiate for additional funding or timing of funding commitments such that the use of scarce resources is maximized in a transparent procurement system. In addition to this they will be able to coordinate supply needs to ensure product security.

Inventory Control

An inventory control system helps us to determine when and how much stock should be ordered or issued. It also enables us to avoid under and overstocking. To be able to manage an inventory effectively one must understand how to assess stock status of controlled medicines which is the determination of how long stocks will last in the management of patients with pain. This is expressed as months of stock (MOS) on hand (how long stock will last) and is obtained by dividing stock on hand (SOH) by average monthly consumption (AMC). To determine stocks on hand we need to conduct a physical inventory which is the process of counting the total quantity of health commodity in your pharmacy or dispensary at a given time in order to know the useable amount you currently have. This should be done regularly for fast moving products. Average monthly consumption is the average quantities of the commodity that is dispensed to users or patients in the most recent three months which represents the amount we actually use in a month.

There are three Max-Min Inventory Control Systems. They are designed to ensure that the amount of stock we have is always within an established range. Under normal conditions the max stock level is the level of stock above which inventory levels should not rise. It is set as a number of months of stock and is fixed even when average monthly consumption changes regularly from month to month. The min stock level is the level at which stock replenishment should occur under normal conditions. However, sometimes unexpected events such as natural disasters like flood or earthquakes do occur and supplies of healthcare commodities may fail to arrive at a specific facility. Risk management as a result of these occurrences takes care of this by ensuring that “Safety Stock” is built into what will eventually be operated as the max stock level. Both the minimum and safety stock are also expressed in months of stock. It is essential that those working in logistics and supply chain of controlled medicines acquire these essential skills not only to prevent wastages in the system but to ensure continued supply of medicines in times of natural disasters and even wars.

Storage and Transport

Products are stored to ensure stock security and the maintenance of the quality of drugs throughout their shelf life. Hence safe and proper storage makes products available for distribution. Key storage activities include: receiving and inspecting incoming

commodities, put away, picking and packing and shipping. All pharmaceutical products have a shelf-life which is the length of time that a product can be stored without affecting its usability, safety, purity or potency. Proper procedures for storage of health commodities maximize a product's shelf life and make it readily available for distribution when needed. It is important that adequate security of a controlled medicine (locking rooms, cabinets, shelves etc.) and cold chain when required should be provided. Disposal of expired products (some products may require certificate for proper disposal) should also receive adequate attention. Important storage guidelines should be an integral part of the skillset of a well-trained store keeper.

A pipeline refers to the entire chain of physical storage facilities and transportation links through which supplies move from the manufacturer to the user and includes the port facilities, central warehouse, regional warehouses, district warehouses, all service delivery points, and transport vehicles, including community-based distribution networks. A pipeline can be adjusted by eliminating a level (or more) of distribution and or by reducing the max at one or more levels to prevent wastage. At all levels of the logistics system evaluation, supervision and monitoring should be done regularly to ensure continued efficiency. Those with the responsibility of supervising, evaluating and monitoring the logistics system should acquire this skill.

Records Management

Logistics management information system (LMIS) is the system of records, to remain in the facility where they are collected, and reports, to move from one level to another, that is used to collect, organize and present logistics data generated at all levels of the system. Supplies are either stored or moved between facilities or dispensed to end users. These activities are captured in LMIS. It differs from a Health Management Information System (HMIS) because the latter collects data on patients' health condition. The essential data that is collected include: stock on hand, rate of consumption, average monthly consumption, and losses/adjustment (damages/transfers). The key reason for the existence of an LMIS is to inform decision making. Hence if the right data, of the right quantity and quality, is not collected and made available, at the right time and place, at the right cost, there could be systemic failure. The type of data collected is influenced by the type of decisions that logistics managers will need to make for the efficient running of the system. The three types of logistics records are: stock keeping records (e.g. bin card, inventory control card) which holds information about products in storage, transaction records (requisition and issues vouchers) which holds information about products being moved; and consumption records (daily, treatment/dispensing register, logs/tick/tally sheets) which holds information about products being used. This section of the curriculum addresses the acquisition of this skill.

Call to Action

We must:

1. Emphasize that patients with pain (customers) can only be adequately cared for (served) when they have the right narcotic medicine at the right price to use for treatment in the correct quantities whenever they need it.
2. Train all health care providers to adequately understand the importance of their role in supply chain management of controlled medicines as detailed in the National Policy for Controlled Medicines.
3. Emphasize the importance of the stringent rules associated with supply chain management of controlled medicines but these rules should in no way prevent patients who need care from having uninterrupted access to controlled medicines.
4. Highlight the functions and expectations of INCB in controlled medicines supply chain management.

Bibliography

USAID/DELIVER PROJECT, Task Order 1. 2011. The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities. Arlington, Va.: USAID/DELIVER PROJECT, Task Order 1.

TEACHING TEMPLATE

MODULE	TOPICS	COMPETENCY STATEMENT	INSTRUCTIONAL GOALS	LEARNING OBJECTIVES
5.2.1 Overview of Logistics Cycle and Supply Chain Management for Controlled Medicines	Overview of the Logistics Cycle and its relationship with policy and adaptability	Familiarise participants with the Logistics Cycle, policy and Supply Chain activities as it relates to Controlled Medicines	To teach and demonstrate the importance of a logistics system in serving clients/patients that require Controlled Medicines	Understand the different components of the Logistics Cycle with explanation of key terms
	Serving Customers and Product Selection		To expose students to practice sites and Logistics system activities	Explain the relationship between the Logistics Cycle, the six rights and controlled medicines security in the context of product selection and serving clients with pain.
	Quantification			Explain the basis of forecasting, procurement and supply planning
	Introduction to Inventory Management and LMIS with emphasis on Controlled Medicines			Understand pipeline, distribution channels, levels (warehouse, central stores and service delivery points), storage and identify LMIS forms
5.2.2 Product Selection	Selection of controlled medicines for inclusion in the Essential Medicines List or a formulary	Participants to understand the rationale for selection of available controlled medicines	Identify controlled medicines in the essential medicines list, treatment guidelines and NAFDAC list.	To briefly review the criteria for EML selection, NAFDAC registration and treatment guideline

			Identify criteria required for a medicine to be selected.	
	Compare and contrast EML and NAFDAC			Discuss and explain differences in EML and NAFDAC lists
5.2.3 Forecasting and Supply planning of Controlled Medicines (Quantification)	Forecasting based on the INCB Regulations	Participants to understand the INCB requirements for forecasting and supply planning.	To be able to perform forecasting for different types of facilities using appropriate data sources and systematically plan supplies to arrive in a timely and efficient manner to guarantee availability of controlled medicines.	To explain quantification based on the INCB Regulations
	Roles and functions of NAFDAC in the National Quantification of Controlled Medicines			Demonstrate ability to use demographic, consumption, program objective and morbidity data in quantification and supply planning exercises for controlled medicines
5.2.4 Procurement	Rationale for procurement of Schedule 1 Narcotics by FMOH NAFDAC approval system for the procurement of other controlled medicines	Participant to understand the role and functions of FMOH, NAFDAC and health facilities in controlled medicines procurement	To discuss the FMOH procurement functions for Schedule 1 Narcotics and the NAFDAC approval processes for other controlled medicines.	To explain the rationale for procurement of Schedule 1 Narcotics by FMOH To explain NAFDAC approval system for the procurement of other controlled medicines

5.2.5 Inventory Management	Warehousing and distribution of schedule 1 controlled medicines as detailed by FMOH	Participant to highlight the requirements for warehousing and distribution of controlled medicines	To discuss the national warehousing and distribution of controlled medicines plan. Storage guidelines, physical count and inspection.	To explain the warehousing and distribution of schedule 1 narcotic medicines as detailed by FMOH. Space requirement calculations for product storage. Storage activities, guidelines, physical count (stock taking) and inspection.
	National distribution guidelines as it pertains to other controlled medicines Designing a max-min inventory control system	To understand the technique of designing a Max-Min Inventory Control System (ICS)	To learn the storekeeper decision rules of the different types of ICS and be able to design a functional logistics system from scratch.	To discuss the National distribution guidelines as it pertains to other controlled medicines Be able to demonstrate and explain each step in determining safety stock, max and min stock levels including Emergency Order Point (EOP) and when to apply the triggers for each ICS.

<p>5.2.6</p> <p>Logistics Management Information System (LMIS)</p>	<p>Pipeline monitoring and adjustment, supervision and evaluation</p> <p>LMIS Forms (Bin cards, ICC, RIRV, tally sheets etc.): reporting and feedback</p>	<p>To be able to recognize when and how to adjust a pipeline and be able to supervise and monitor a logistics system.</p> <p>To identify and understand the use of LMIS forms</p>	<p>To discuss and demonstrate components of a pipeline and how it can be adjusted. To explain the use of Logistics Indicator Assessment Tools (LIAT) and Logistics System Assessment Tools (LSAT).</p> <p>To discuss and interpret different LMIS data and their related forms</p>	<p>Know how to adjust a pipeline, create indicators for monitoring and evaluation including using existing instruments like LIAT and LSAT. Understand the principles of supervision of a logistics system.</p> <p>Be able to fill LMIS forms correctly and demonstrate their use as reports and feedback</p>
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SAMPLE TEACHING STRATEGIES

The following are sample teaching strategies that may be utilized to engage students with the materials and lessons as described in the Teaching Template above. Please note these are samples and may be revised or changed to meet the unique classroom setting, the specific needs of the students or the teaching style of the instructor.

Group Presentations

Materials needed: Foundation information on supply chain

Overview of activity:

Instructor divides the large group into smaller groups and provides each small group with a document to be reviewed. The small group is given adequate time to review the information and prepare a presentation to be made to the larger group.

Modifications:

- Provide guiding questions to help the group organize their thoughts and presentation.

- Provide a template for each group to use for their presentation.
- For documents with multiple parts or of a significant length, it may be advisable to divide the document into sections, one section covered by each small group. However, please note each group should see the full document and only present on the part they are assigned.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge; members of the group that participated, demonstrated understanding of the main concepts, and conveyed a meaningful message. The rubric is also shared with the small groups in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the presentation. The audience rates on what they experienced and the group self-rates their own performance.

Write an essay

Describe the impact of a parallel market that is unregulated on the current supply chain.

Materials needed: Foundation information

Overview of activity:

Students are instructed to describe the impact of the unregulated parallel market on the current supply chain, relating to access to controlled medicines. Depending on the level of the students, more or less direction is given, related to structure of the essay and arguments to be made.

Modifications:

- Assign as a homework or to be done during class time.
- Provide guiding questions to help the group organize their thoughts and essay.
- Pre-discuss topic areas appropriate for the age and comprehension of the students.

Evaluation method:

Develop a rubric that assigns value to areas such as content, demonstrated knowledge and understanding, persuasiveness, and development of comprehensive approach.

The instructor may also use a checklist that can be shared with students in advance as a way to help students organize their essay.

Develop a weekly blog on the supply chain for controlled medicines

Materials needed: Eventual access to internet and blogging site

Overview of activity:

Instructor assigns each person in the class a topic area to be researched related to the supply chain. Each student drafts a blog entry that will be posted, one each week. Students will submit their work to be presented to the class with the group making final edits and prioritizing the order in which topics will be posted. Sample topics include but are not limited to the following 1) elements of the supply chain, 2) preventing diversion, 3) rational use of controlled medicines, or 4) addressing barriers to access to controlled medicines. Include a posting related to the use of morphine in Nigeria and the steps from import to use in a clinic.

Modifications:

- The process of prioritizing and the entire class coming to a consensus on the order of presentation will ensure students know and understand enough to discuss.
- Provide a template to guide the development of each blog post.
- Allow for video presentations instead of written blogs. This would be done similar to a webinar.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge, demonstrated understanding of the main concepts, and conveyance of a meaningful message. The rubric is also shared with students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the blog post.

Create a visual “map” of the supply chain for controlled medicines

Materials needed: Creative material for creation of visual “map”

Overview of activity:

Instructor breaks the class into small groups of not more than five. Each group prepares a visual to demonstrate the supply chain for controlled medicines. The group is then instructed to highlight in yellow the areas that represent a barrier to patients accessing the medication that they need to be healthy. Each highlighted area should include a list of ways to address this barrier and increase access to medicines. The “map” is then shared with the whole class.

Modifications:

- Students could be asked to work individually and present to the class or the entire class could work on one large map with each student contributing specifically to one area.
- Provide a checklist to remind the students of each element that must be included in the “map”.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge, demonstrated understanding of the main concepts, and conveyance of a meaningful message. The rubric is also shared with students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the persuasiveness of the argument.

Create a student workbook or activity book

Materials needed: Creative material for activities and means to create a book for each student

Overview of activity:

Instructor breaks the class into small groups of not more than five. Each group prepares an activity to be included in a class workbook, to demonstrate the supply chain for controlled medicines. Each activity is then incorporated into a workbook with samples that are adjusted to meet different ages of learners.

Modifications:

- Students could be asked to work individually and present to the class or the entire class could work on one large workbook with each student contributing specifically to one area.
- Provide a checklist to remind the students of each element that must be included in the “map”.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge, demonstrated understanding of the main concepts, and conveyance of a meaningful message. The rubric is also shared with students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the persuasiveness of the argument.

Experiential learning opportunity

Materials needed: Access to a warehouse or area where controlled medicines are stocked

Overview of activity:

Take students on a tour of a warehouse or area where controlled medicines are stocked. Have them take on the role of inspectors using the existing monitoring forms in Nigeria.

Modifications:

- If you are not able to take students on a tour in person, simulate the experience in the classroom. Have student's complete actual forms such as LMIS forms and practicing a quantification or estimating stock exercise.
- Provide a checklist to remind the students of each element that must be included in each step of the process.

Evaluation method:

Prepare a rubric in advance to rate or grade the presentation style including areas such as content knowledge, demonstrated understanding of the main concepts, and conveyance of a meaningful message. The rubric is also shared with students in advance, so they will know how they are being graded.

The instructor may also use a checklist that is shared with the class, so all students rate the persuasiveness of the argument.

A publication of,

Federal Ministry of Health, Nigeria



EUROPEAN UNION



UNODC

United Nations Office on Drugs and Crime

**RESPONSE TO DRUGS AND RELATED ORGANISED CRIME IN NIGERIA
(FED/2012/306-744) (NGAV16)**

This publication is funded by the European Union
under the 10th EDF “Response to Drugs and Related Organized Crimes in Nigeria” Project