

Revising Preservice Curriculum to Incorporate Rational Medicine Use Topics: A Guide



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Preservice curriculum, curriculum development, curriculum revision, curriculum reform, rational medicine use, antimicrobial resistance, AMR, pharmacovigilance

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ACRONYMS AND ABBREVIATIONS

AMR	antimicrobial resistance
ADE	adverse drug even
ADR	adverse drug reaction
CPM	Center for Pharmaceutical Management
DAV	Drug Administration of Vietnam
DI&ADR Center	Drug Information and Adverse Drug Reaction Center [Vietnam]
DIU	Drug Information Unit
DTC	Drug and Therapeutics Committee
EML	Essential Medicine List
EU	European Union
FDA	Federal Drug Administration
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
IMCI	Integrated Management of Childhood Illness
INN	International Nonproprietary Name
LMIS	Logistics Management Information System
MDR	multidrug resistance
MOH	Ministry of Health
MRSA	Methicillin-resistant <i>Staphylococcus aureus</i>
MSA	Medical Services Administration [Vietnam]
NGO	nongovernmental organization
PEPFAR	President's Emergency Plan for AIDS Relief
PHP	Public Health Program
PSM	postmarketing surveillance
PV	pharmacovigilance
RMU	rational medicines use
SCM	supply chain management
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
STG	standard treatment guidelines
STI	Sexually transmitted infection
TB	tuberculosis
USAID	U.S. Agency for International Development
UNZA	University of Zambia
WHO	World Health Organization

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INTRODUCTION

Rational medicines use requires that patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community (World Health Organization 1985). However, irrational medicine use is a widespread and persistent problem. The World Health Organization (WHO) estimates that as much as 50 percent of global medicine use is inappropriate (WHO 2010). Poor medicine use can harm individual patients through treatment failure, for example, or can harm society, through the promotion of antimicrobial resistance (AMR).

AMR is a steadily growing global health crisis that leaves established first-line treatments ineffective at managing several significant infectious diseases, such as malaria, tuberculosis, and gonorrhea. Irrational medicine use is a major contributor to this problem. AMR, and therefore, poor medicine use, requires an urgent and concerted response from health workers at every level and across many disciplines. Future health professionals must receive training on AMR to gain the knowledge and skills to contain its development and spread. Recognizing this need, WHO recommends undergraduate training of health care professionals on AMR-related issues as a first-priority intervention in the *Global Strategy for the Containment of Antimicrobial Resistance* (WHO 2001).

In this guidance document, the concept of rational medicine use (RMU) also encompasses medicine safety or pharmacovigilance. The three areas of pharmacovigilance include product quality, adverse drug reactions, and medication errors. It is easy to see how RMU, pharmacovigilance, and AMR fit together, and topics associated with all three should be a part of any comprehensive preservice training program. When you see “rational medicine use” or “RMU,” in this document, we intend to include all three concepts.

Purpose

The purpose of this document is to guide stakeholders, such as faculty and staff in the fields of medicine, pharmacy, nursing, and public health, through the process of integrating RMU-related content into their preservice training curricula for medical, nursing, pharmacy, or public health students. Many issues relating to RMU receive limited attention in health professionals' education curricula; for example, rational antimicrobial use, antimicrobial product quality, and infection control, are often inadequately covered during both preservice and in-service training programs. Preservice curriculum reform is a cost-effective and sustainable intervention that leads to broader health system strengthening. It provides students with a critical foundation of knowledge and skills and develops their competency to practice in the real world. Effective preservice training reduces the need for future large-scale and expensive in-service trainings.

RMU must be integrated into preservice health professional training to establish good attitudes and practices on medicine use (as well as to counter the future negative influences students will face on their RMU-related behaviors). However, preservice education alone cannot guarantee rational medicine use. Other determining factors such as work environment and work load will also influence prescribing behavior. Therefore, preservice education must be part of a wider group of containment activities that counter other determinants of prescribing behavior.

The objectives of these guidelines are to—

- Promote RMU, including AMR- and pharmacovigilance-related topics, as an urgent global health issue that needs to be included in preservice training curriculum across health care disciplines.
- Enable preservice health care training institutions to assess their current curriculum and identify gaps in RMU-related content.
- Equip stakeholders at training institutions with the knowledge and tools necessary to successfully incorporate RMU-related content changes to the preservice training curricula.

Who Should Use this Guide

These guidelines provide guidance for those who recognize the need to increase RMU training and seek to be change agents at their institutions—either individuals or groups, such as an official curriculum review board.

Schools in resource-limited settings need a tool to assess RMU content in existing curriculum and to guide changes where necessary. These guidelines attempt to outline a simple but systematic approach to assessment and implementation of AMR curriculum that can be used in the context of an institution's unique curriculum review process.

These guidelines are broken down into **five phases** which start with taking the user from their vision for bolstering academia's role in promoting RMU and end with approved RMU content in place in the curriculum. The phases are arranged linearly, although certain steps within a phase may be continuous throughout the process.

The five phases are as follows—

Phase 1: Understanding the context

Phase 2: Establishing a champion group

Phase 3: Assessing existing curriculum for RMU content

Phase 4: Designing RMU components for preservice training

Phase 5: Implementing the RMU curriculum

Despite the need for a well-trained corps of health workers, a systematic and organized effort does not exist to evaluate existing preservice training curricula for RMU coverage or to implement changes where gaps exist. These guidelines enable institutions that train health professionals at the preservice level to integrate and improve RMU topics in their curricula, including those related to AMR and pharmacovigilance. An independent RMU course is not necessarily required in preservice curriculum. Rational medicine use, antimicrobial resistance, and pharmacovigilance are cross-cutting issues that affect many content areas, which allow them to be covered in multiple existing courses. Therefore, barriers associated with establishing a new course should not inhibit the critical role preservice training can play in promoting RMU.

Phase 1: Understanding the context

Step 1. Analyze the local situation

Step 2. Identify stakeholders and notify them of the initiative



Phase 2: Establishing a champion group

Step 1. Recruit members

—Choose who should be in the champion group

—Choose a leader

Step 2. Develop an action plan

—Set objectives

—Identify key action steps

Step 3. Build support among relevant stakeholders



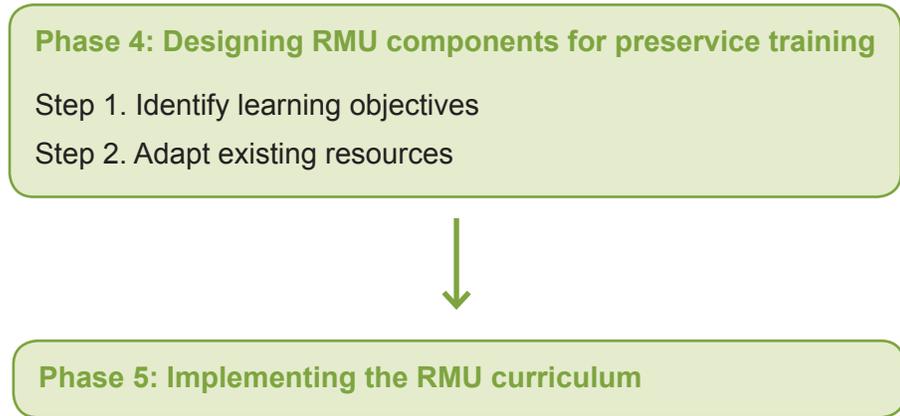
Phase 3: Assessing existing curriculum for RMU content

Step 1. Define the assessment methodology

Step 2. Identify gaps

Step 3. Identify appropriate content

Step 4. Determine an RMU incorporation strategy

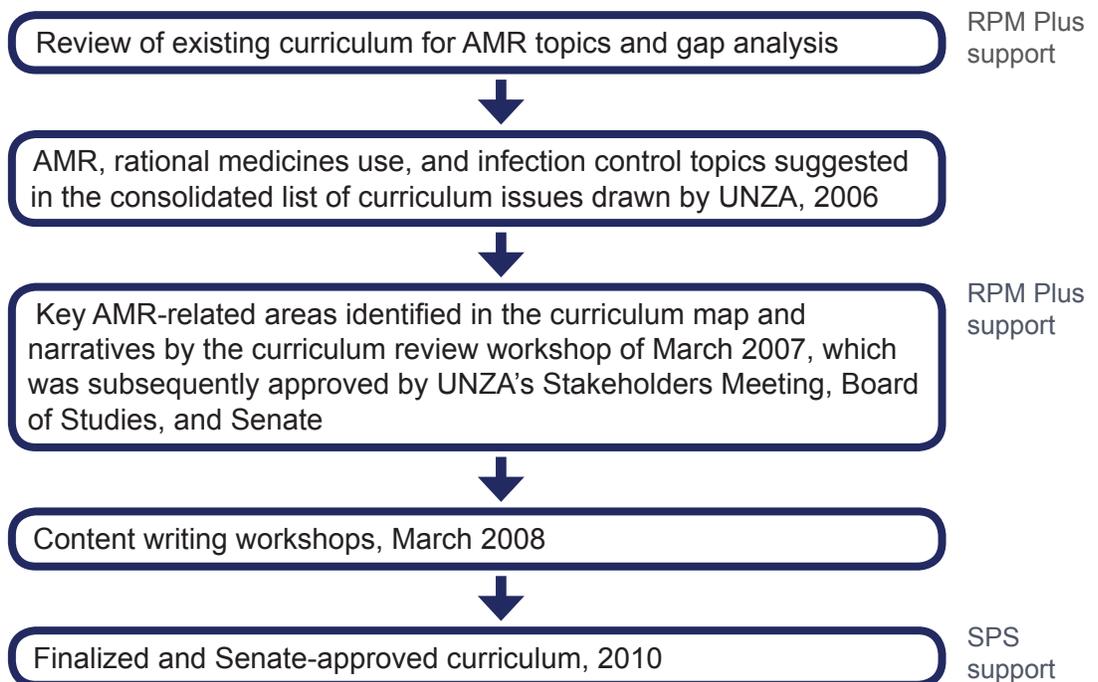


The Process to Add RMU Components to Preservice Training Curriculum

Influencing the necessary curriculum changes can seem like a daunting task. These guidelines break down the process into manageable pieces, which can be delegated and implemented by a committed group of individuals. The figure below, for example, shows the key components of the University of Zambia’s process to revise its AMR curriculum. As you can see, they tackled each component over a number of years.

We offer real-life examples of how stakeholder groups in different countries have approached preservice curriculum assessment and revision related to RMU, AMR, and pharmacovigilance. Although the examples may be specific to one of the three topics (for example, Zambia focused on AMR while Vietnam focused on pharmacovigilance), the process is the same for any of the components.

Figure 1.
Key steps in integrating AMR and RMU topics during revision of University of Zambia curriculum



(Joshi 2010)

PHASE 1: UNDERSTANDING THE CONTEXT

The context for local RMU context varies greatly around the world, and curriculum review procedures differ from one institution to another. Before planning any RMU curriculum assessment or development, you need to characterize the situation at the institution; for example, consider the institution's curriculum review rules, regulations, and cycle when starting the process of increasing RMU coverage. Most institutions have set times every few years when they review and make changes to the curriculum. You will need to know when this will happen at your institution and carefully structure your time and set your priorities accordingly.

The two steps in Phase 1 are to—

1. Analyze the local situation
2. Identify stakeholders and notify them of the initiative

Step 1. Analyze the Local Situation

Understanding the local impact of RMU is vital to gaining support for revising the preservice curriculum. Without convincing evidence that a problem exists that warrants the proposed response, chances are that people will not be willing to invest already limited resources in changing the curriculum.

Gathering RMU data can be a tedious and time-consuming process, but it is crucial to the successful completion of the project. Government agencies, nongovernmental organizations (NGOs), hospitals, and other public health organizations often do not have RMU or AMR divisions, so data is diffuse, making locating it particularly difficult. In the context of preservice training of health professionals, the term “local” should be taken to mean the national situation because the professionals who graduate from an institution are national resources and will work in institutions across the country.

The method used will vary depending on available resources. A more formal and expensive approach would be to develop a survey tool and conduct a research study. You can search the literature to see if other researchers have published surveys on rational use issues in your country, such as prescribing or adherence to standard treatment guidelines (STGs) or on AMR. A more feasible approach in a resource-limited setting is to talk with the local specialists about their experiences with RMU and AMR and then come to a general consensus about the situation. An added benefit to the process of gathering data from these key informants is a chance to share your vision of RMU integration into preservice training programs. You may find that local experts are willing to invest time and resources in the process which will be vital to success later.

Regardless of the method used, the result should be a description of the local context that you can use to gain the support of important stakeholders.

Information to gather for a situational analysis

- Publication of previous studies on local RMU or AMR topics
- Local studies on specific medicine use problems (such as injection use)
- Information from household surveys on medicine use and seeking health care
- Incidence of AMR for specific pathogens
- Estimations of the cost of AMR
- AMR-related mortality and morbidity rates
- Medicine prescribing and dispensing practices
- Self-medication habits
- Pharmaceutical product quality
- Infection control practices
- Reports of adverse drug reactions and other medicine safety issues

Step 2. Identify Relevant Stakeholders and Notify Them of the Initiative

Two types of stakeholders are relevant to the RMU preservice training integration process—decision makers and technical experts in either RMU-related fields or preservice curriculum design.

Use the questions on the next page to help you start generating a list of relevant stakeholders and analyzing their position. The tool in appendix A can help you think about the status of each stakeholder and devise ways to engage supporters and defuse opponents.



Questions to ask when thinking about stakeholders

- What types of changes will be required in RMU-related content in the curriculum?
- Who is likely to lead the revision, implementation, and use of preservice RMU curriculum?
- What types of coordination do you need from which stakeholders to be successful?
- What kind of technical expertise will be required to make these changes?

Local opinion leaders can influence adoption of the curriculum changes. These leaders include physicians, nurses, pharmacists, public health specialists, and other respected faculty who teach preservice courses. Opinion leaders should be in the same peer group as those who will be affected by curriculum changes, such as other faculty and staff. If the preservice training is for nurses, then the opinion leaders should be nurses. There is little evidence suggesting that opinion leaders are successful outside of their peer group (Kitson 1998).

Seek feedback from current students who will need to take the course as well as former students—now practitioners—to find out their perspectives. Incorporating feedback from these stakeholders will encourage them to embrace the changes.

To influence the right people, make sure you have a good understanding of your institution's formal and informal communications channels. Determine an appropriate time and place to introduce the idea. Sell the vision through a powerful and persuasive argument that communicates the expected benefits of increasing the RMU content in the curriculum. When addressing high-level administrators, help them understand—

- How increasing RMU-related content in preservice training curriculum fits with the overall strategy and goals of the institution
- The implications of providing training with RMU content for the institution

In some cases, gaining approval from those in charge may take persistence. If the initial request is rejected, seek support from other important individuals who may have influence over those in charge. Perhaps seeing that your vision is shared by others in the organization will be enough to move the approval forward.

PHASE 2: ESTABLISHING A CHAMPION GROUP

Curriculum revision requires a diverse and committed group of individuals who are willing to volunteer their time to the vision. This group of people will “champion,” or take the lead on including RMU in the curriculum. Faculty can best assess the situation at individual institutions and correct any identified deficiencies. The major stakeholders identified in Phase 1 should be part of the champion group to ensure wide support of curriculum changes.

Establishing the champion group has three steps—

1. Recruiting members
2. Developing an action plan
3. Building support among relevant stakeholders

Step 1. Recruit Members

The champion group should consist of stakeholders who are opinion leaders in their areas and who can influence the opinions of other stakeholders. Many of these individuals will have been identified in phase 1’s stakeholder identification and analysis process. The medical education department, the academic section, or other relevant academic units of the university or the teaching institution can serve as the secretariat for this champion group’s work.

Choose Who Should Be in the Champion Group

To fully understand RMU’s cross-cutting nature, make an effort to recruit a multidisciplinary team of professionals to assist the review process, curriculum needs assessment, and content development. Including as many interested parties

as possible is important to canvass a wide range of inputs. Such a representative approach ensures that the whole faculty contributes their expertise, thereby maximizing wider ownership of the process and decisions.

Champion group members should represent different disciplines—

- Medical, nursing, pharmacy, or public health educators
 - Microbiology
 - Pharmacology
 - Therapeutics
 - Infectious disease
 - Relevant medical and surgical teams (e.g., internal medicine, general surgery, obstetrics/gynecology, pediatrics, orthopedics)
 - Members of the curriculum review committee
 - Current and former students
 - Stakeholders from outside the institution (e.g., professional organizations, licensing boards, government authorities, and laboratory personnel)
-

Choose a Leader

A good leader will be a prominent and respected figure who will inspire others. The leader should be skillful at directing, managing, and coordinating the champion group activities. The lead position will likely require the most time and thus should be highly motivated and committed to the project. The leader will, in many cases, be the same person who initiated the process and laid the ground work in phase 1, although this does not have to be the case.

Objectives should be S.M.A.R.T.

S = Specific

M = Measurable

A = Achievable

R = Relevant

T = Time-bound

Step 2. Develop an Action Plan

Action plans are working documents that will guide the process of curriculum review and development. An action plan distributes the workload and responsibilities, tracks progress, and determines accountability. The action plan will be heavily influenced by the existing institutional structure for curriculum review. The champion group needs to be aware of these regulations, so hard work is not wasted because of bureaucratic problems.

Set Objectives

Setting the objectives for the champion group is one of the most important steps in the planning process. An overall objective that is clearly understood and accepted by all group members is what you hope to accomplish through the action plan.

Specific objectives are linked to the steps of the action plan and used to measure progress. Setting objectives should be done at the first champion group meeting.



Examples of Overall Objectives for Reviewing and Integrating AMR in Curriculum

- Increase AMR coverage in the undergraduate medical curriculum by 2 hours in each major AMR-related subject area
- Establish a stand-alone course on antimicrobial resistance and the role of the practitioner

Note that the examples below closely parallel phases in the second half of these guidelines.



Examples of Supporting Objectives for Reviewing and Integrating AMR in Curriculum

- Assess the AMR content in current preservice curriculum
- Gain widespread support of AMR curriculum by relevant stakeholders
- Create a one-hour lecture on “AMR and rational prescribing” to integrate into a clinical program

Identify Key Action Steps

The action plan describes the steps needed to complete the project successfully. Each action step should be linked with at least one objective. This serves as a rationale for all activities and helps monitor progress. The main outline of your action plan will follow phases 3–5 of these guidelines, although practical implementation will vary according to the local context. Briefly, the main action steps to include in the action plan are to—

- **Conduct a preservice curriculum assessment:** An assessment or rapid appraisal of RMU content in the existing curriculum should identify gaps and focus the champion group on specific content areas found to be lacking. This step is a part of phase 3 and is discussed in detail in that section.
- **Design preservice RMU curriculum:** Based on the gaps identified in the assessment, make a decision on how best to fill those gaps. It will be crucial to gather feedback from a wide variety of stakeholders at this stage. This step is a part of phase 4.
- **Implementation:** Introduce the curriculum through the required formal curriculum review channels. This is part of phase 5.

Assign the responsibilities for each action step to a person or a group. Deadlines for each action step will hold responsible parties accountable and promote prompt completion. Deadlines should be realistic to motivate people to complete them.

Below is an example of an action plan, a template of which is included in appendix B. You will notice that every action step has a specific objective. However, multiple action steps may be needed to meet one supporting objective. Each supporting objective should be a critical component of obtaining your overall objective. The completed action plan should be distributed to all champion group members. However, the action plan is a living document and will be updated and revised as objectives are met and unforeseen issues arise.

Specific Objective	Action Required	Resources Needed	Who is Responsible	Deadline

Action plan adapted from National Institute for Health and Clinical Excellence 2005

Step 3. Build Support among Relevant Stakeholders

Early on, approval must be gained from specific stakeholders before much of the other work can be done. However, the process of building support occurs among a wide variety of stakeholders to inform them of the champion group activities, ensure their continued support, and get feedback and input.

Appendix C is a self-assessment that faculty can carry out to help them gauge their coverage on RMU-related topics. This kind of tool can open stakeholders' eyes to existing gaps in curriculum and motivate them to support integration of RMU into the curriculum. The self-assessment tool can also be used in the curriculum assessment discussed in phase 3.

Your communications strategy will keep stakeholders regularly informed of your progress. A communication strategy is a short statement that identifies how the champion group will communicate with each other and with key stakeholders. The strategy should be informed by your institution's existing formal and informal communication channels. The communications strategy should do the following—

- Ensure everyone involved in the initiative is able to be contacted and updated
- Set a schedule and method of regular progress updates
- Plan for promotional material if necessary

PHASE 3: ASSESSING EXISTING CURRICULUM FOR RMU CONTENT

Every institution will have addressed the issues of teaching RMU and antimicrobial resistance (AMR) differently. Each champion group should conduct a rapid assessment of RMU content in the curriculum to get a clear picture of the current situation.

Step 1. Define the Assessment Methodology

To accurately identify where and how RMU is taught, you need to carefully review the curriculum. The champion group may want to identify a core team of people (and team leader) from among themselves to conduct the assessment or rapid appraisal, or hire a consultant to do the job for them.

Curriculum mapping helps to identify—

- What is taught
 - How it is taught
 - When it is taught
 - Learning outcomes (student assessment)
-

An outline of suggested topics related to AMR is provided to help structure content development (appendix D). This list is not comprehensive, yet it is based on the recommendations of credible organizations, practitioners, and the experience of the

University of Zambia (UNZA) School of Medicine, which identified AMR as a key focus area for its 2006–2008 undergraduate curriculum review. Many of these topics also apply to RMU in general or can be revised or enhanced.

Appendix E has examples of the materials used to complete a detailed assessment of AMR content in the curriculum at the UNZA School of Medicine. Depending on financial resources, time constraints, and knowledge of the curriculum, you may choose to use, omit, or adapt different parts of the assessment. For example, it may be common knowledge that RMU is lacking in the curriculum, and if interest in an RMU course already exists, then a detailed assessment may not be the best use of time and resources.

The forms in appendix E can guide course-by-course evaluation through—

- Reviewing the current curriculum materials, such as text books, syllabi, and the official course catalogue
- Interviewing faculty to determine where AMR or RMU is taught
- Interviewing government or professional organization representatives regarding AMR and RMU issues
- Conducting focus group discussions with recent graduates to determine the extent to which the course materials reflect reality in the classroom

In addition, appendix C includes a self-assessment of faculty’s coverage of AMR-related material.

To greatly complement the curriculum review results, identify what the local stakeholders (faculty members, students who took the related course, and likely employers) regard as the expected competencies of graduates relating to RMU. Combining curriculum review and competency assessment provides a strong basis for identifying the appropriate theoretical and practical topics to include in the revised curriculum. Appendix F provides a survey tool that was used in Vietnam to conduct curriculum and competency assessments (Joshi 2012). Although this tool was used to assess pharmaceutical supply management topics, it can be easily adapted for RMU by changing the topic areas in the headings and subheadings column.

Step 2. Identify Gaps

The champion group should analyze the curriculum and competency assessment to identify gaps and consider what changes may be needed to fill those gaps. First, look for any obvious holes in the curriculum. Second, compare the results of the assessment to the proposed overall objective of the curriculum outlined in the planning stage (phase 2, step 2).

Once gaps have been identified, the RMU curriculum champion group should develop a plan to modify existing content and teaching strategies to maximize the effectiveness of teaching about issues relating to AMR. The box on the next page describes the gaps found through a UNZA curriculum assessment, which the review committee used as they discussed AMR integration (Banda 2006).

AMR Curriculum Gaps Identified at the University of Zambia School of Medicine

- Inadequate or no exposure to key topics such as RMU, extent of the AMR problem and containment methods, standard treatment guidelines, counterfeit medicines, pharmaceutical promotion
 - Examples of resistance—such as multidrug resistance (MDR), methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococci—mentioned only in passing
 - AMR not taught in clinical courses as a specific topic
 - Vaccination as a strategy for infection prevention and reduction of AMR not covered in courses
 - Barrier precautions, isolation procedures, injection safety and appropriate use of injections, sterilization and disinfection of equipment, and aseptic technique for medical procedures not taught as topics in lectures and tutorials
 - Issues of patients' misconceptions about antimicrobial treatment, self-medication, and poor adherence not specifically addressed in either preclinical or clinical years
-

Step 3. Identify Appropriate Content

Rational prescribing is of paramount importance to RMU and AMR containment. Therefore, medical, pharmacy, and nursing programs should give special attention to rational prescribing and dispensing.

The WHO *Guide to Good Prescribing* is a generic outline of good prescribing practices that has been field tested in seven sites. The guide targets undergraduate medical students entering the clinical phase of their studies. It aims to help students acquire the skills and confidence needed to exercise independent judgment and make their own decisions about which drugs or non-drug treatments are best for each individual patient.

The British Society for Antimicrobial Chemotherapy has published [a comprehensive framework for preservice undergraduate medical curriculum in AMR](#) (Paterson 2005). The paper describes 12 learning domains for prudent antibiotic prescribing listed under three main headings. Within this framework are subheadings covering the entire range of topics. In practice, it may not be possible to include such a comprehensive list in a curriculum. The local context and the gaps identified in the assessment can help to target the most relevant RMU-related areas.

The following text relates the UNZA School of Medicine's experience and their discipline-specific AMR topical areas.

Practical Example from the University of Zambia School of Medicine

During an interactive curriculum review workshop focusing on the basic sciences and AMR, the participants identified discipline-specific AMR-related areas to be proposed to the higher bodies as part of the MBChB basic sciences curriculum map to form the basis for more detailed content development (Joshi 2007). These areas include—

Pharmacology

- Include and emphasize teaching about antimicrobial use and resistance
- Emphasize on major disease burden, i.e., antiretroviral therapy, tuberculosis, and malaria
- Methods of teaching to emphasize case-based teaching, practicals, treatment plans

Therapeutics

- Include emphasis on clinical and public health implications of AMR, prescribers' responsibility to preserve the effectiveness of antimicrobials through rational use, infection control, and patient counseling on adherence
- Expose students to STGs, national and hospital formulary, WHO guidelines for good prescribing
- Include pharmacovigilance/medication errors

Medical Microbiology

- Emphasize AMR (mechanisms, surveillance, efficacy, use of pathogen resistance reports to guide treatment)
- Emphasize national priorities of infectious diseases
- Emphasize infection prevention; nosocomial infections, epidemic preparedness
- Increase clinical relevance and context to local setting which maintaining comprehensiveness

General topics, such as patient education and adherence should be combined with locally relevant issues, such as local resistance patterns. Any new or modified curriculum should harmonize with national guidelines. Following are illustrative topics to consider. Actual topics should be chosen based on assessed needs and with the consensus of the curriculum committee—

- Overview and the extent of the problem of RMU and AMR
- Mechanisms of resistance
- Rational medicine use
- Diagnostic techniques

- AMR surveillance
- Control measures for nosocomial infections
- High-risk environments for AMR (intensive care, obstetrics, surgery)
- Patient education and adherence to treatment
- Complex decision-making and questions of ethics (economic incentives and promotional activities in relation to prescribing)
- Disease prevention/immunizations

Besides these core topics it may be necessary to include locally relevant issues including—

- Local resistance patterns
- Counterfeit and other product quality issues that affect the potency and bioavailability of antimicrobials
- Local drug sellers and their distribution of inappropriate medicines
- Patient demand for medicines and adherence to treatment
- Availability and use of standard treatment guidelines and other quality drug information sources
- Ministry of health policies and regulations that deal with medicine use and regulation of healthcare system including the licensing of practitioners and healthcare facilities

On the next two pages are examples of the AMR and RMU topics that UNZA included in their revised undergraduate medical curriculum, and the pharmacovigilance topics recommended for inclusion in the post-graduate pharmacy curriculum of the Hanoi University of Pharmacy. UNZA's full AMR-related curriculum text is included as appendix G. The full pharmacovigilance curriculum text recommended for Hanoi University of Pharmacy is included as appendix H.

Key AMR Topics and Recommended Readings Incorporated into UNZA Medical Curriculum

Key Topics	<ul style="list-style-type: none">• Factors contributing to AMR• Impact of AMR on individuals and public health• Examples/case stories of AMR• Multidrug resistance in tuberculosis, malaria, HIV/AIDS, nosocomial infections, and sexually transmitted infections• The role of effective immunization programs in reducing infectious disease burden and AMR• The role of prescribers in judicious antimicrobial prescribing, hospital infection control activities, and use of AMR surveillance information to guide prescribing• The role of prescribers as agents for advocacy on issues such as substandard/ counterfeit medicines and use of antimicrobials to promote growth in animals• Factors influencing prescribing• Patient counseling, including adherence• Critical analysis of promotional literature• Rapid diagnostic tests• Evidence-based medicine• Zambia Standard Treatment Guidelines, Essential Medicines List, Formulary• Pharmacovigilance, including adverse drug reactions, medication errors, and medicine quality problems• Role of prescribers in promoting medicine safety
Recommended Readings	<ul style="list-style-type: none">• World Health Organization's (WHO) <i>Guide to Good Prescribing</i>• WHO <i>Global Strategy for Containment of Antimicrobial Resistance</i>

Source: University of Zambia 2010, Joshi 2010

Step 4. Determine an RMU Incorporation Strategy

In addition to deciding on what content must be included, the champion group must decide how best to fill the gaps in the curriculum. There are two ways this could be done—

- Establish a short stand-alone RMU package
- Strategically integrate increased RMU content into existing courses

These two methods have their pros and cons, and several factors must be taken into account when deciding what method is best for a local context. Creating a new course is expensive and time consuming and can be constrained by lack of room in the curriculum and inadequate human resources. However, short courses of two weeks on rational prescribing, for example, have been shown to be both feasible and effective in resource-limited settings (Karaalp et al. 2003).

Key Pharmacovigilance Topics Recommended for Hanoi University of Pharmacy's Postgraduate Pharmacy Curriculum

Overview of Pharmacovigilance and Medication Safety	<ul style="list-style-type: none">• General overview of pharmacovigilance and medication safety• Pharmacovigilance program in Vietnam and in the world• Pharmacovigilance of herbal medicines in Vietnam and in the world
Risk Identification	<ul style="list-style-type: none">• Adverse drug reaction as a factor for adverse drug events• Medication error as a factor for adverse drug events• Other factors (such as product quality and therapeutic ineffectiveness) for adverse drug events• Adverse drug events: assessment of severity and causality
Risk Evaluation and Reporting	<ul style="list-style-type: none">• Passive and active methods of surveillance
Risk Communication, Risk Management, and Risk Minimization	<ul style="list-style-type: none">• Strategies to improve risk communications and principles of risk management and risk minimization
Pharmacovigilance in Public Health Programs	<ul style="list-style-type: none">• Importance of pharmacovigilance in public health programs, burden of adverse drug events in public health programs and strategies to improve reporting the adverse events

Source: Joshi 2011

For many institutions, particularly those in resource-constrained settings, integrating RMU content into existing courses will be a more viable option. In addition, starting the integration process may not require official institutional curriculum review. Even if the easier and more viable option of integrating RMU in the existing courses is chosen, stakeholders will still need to recruit the faculty to contribute to the teaching-learning process. With this option, however, existing faculty in the key subject areas would most likely be able to take on the small number of extra or reorganized teaching-learning tasks. The advocacy activities in phase 2 would be particularly important to sensitize and obtain the support of relevant faculty members.

The champion group must decide how best to fill the gaps in the curriculum

Key Technical Challenges to Revising Preservice Curriculum

- Faculty must be recruited to contribute
- Hesitation to include relatively unfamiliar topics even if highly relevant for current practice
- Competition for curriculum space

PHASE 4: DESIGNING RMU COMPONENTS FOR PRESERVICE TRAINING

After the champion group identifies RMU content gaps in and decides what the best method is to increase RMU content to fill those gaps, the curriculum must be designed. The multidisciplinary nature of the champion group will be helpful in this phase. Using curriculum developers or the people who designed the original material would also be useful. Incorporating opinion leaders' input in the design process will increase credibility among faculty and students.

The World Federation for Medical Education clearly states that any curriculum committee should accommodate the environment in which graduates will be expected to work (World Federation for Medical Education 2003). In practice, this means not taking a curriculum design from another source without adapting it. You need to take local and regional issues into account. For example, AMR training must include local examples of resistance and factors that affect AMR.

The two main ways to increase RMU content in the curriculum (establishing an independent RMU course or integrating into existing courses) will differ greatly in their design. If RMU content will be added to already existing content, then you will need to consult the faculty who teach these courses how best to place RMU in the existing content.

The National University of Rwanda curriculum committee developed objectives for what they wanted to achieve during their curriculum writing workshop.



- Develop the learning objectives for each topic
- Develop the contents of each topic
- Discuss and develop delivery methods for each topic
- Discuss and develop assessment methods for each topic
- Identify reference materials
- Discuss future plans and quality assurance methods for each topic

Source: Pastakia et al. 2011

Step 1. Identify Learning Objectives

A learning objective is a statement of what you expect the students to be able to do after the session or the course that they could not do before. Writing learning objectives at the beginning of the design phase will inform training content, suggest instructional strategies, and form the foundation of assessment in training programs.

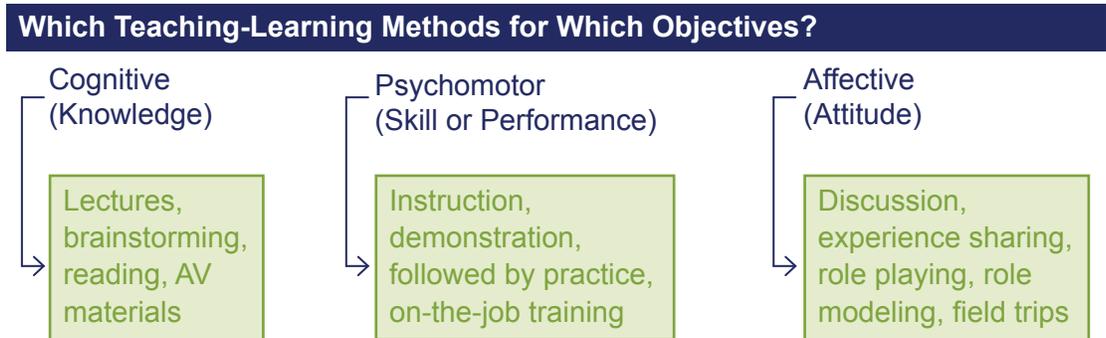
If the existing course already has objectives, you should consider them. Develop supporting objectives specific to RMU to complement existing training objectives. If RMU material is being created to integrate into an existing course, then perhaps only one or two new objectives will need to be created. For an independent RMU course, the number of objectives might be greater.

The box on the right lists the learning objectives for a rational medicine use training module in Rwanda.

Figure 2 below shows the process of identifying the best learning methods depending on the course objectives (Joshi 2008).

The boxes on the following pages outline a new course that the National University of Rwanda organized on RMU and the process.

Figure 2.
Process of identifying the best learning methods depending on the course objectives



National University of Rwanda Examples of Recommended Learning Objectives for Rational Medicine Use Module

Knowledge and understanding objectives:

Having successfully completed the course, students should be able to explain:

- The concept of RMU
- RMU Determinants

Cognitive/intellectual skills/application of knowledge:

Having successfully completed the course, students should be able to:

- Provide appropriate dosing for different categories of patients
- Define the areas and factors that influence RMU
- Identify food and medicine interactions
- Develop the skills to apply evidence based medicine to patient care
- Interpret laboratory diagnostic support to enhance RMU

Analytic techniques:

Having successfully completed the course, students should be able to:

- Apply strategies to improve medicine use process
- Analyze routine data to measure RMU
- Identify harmful consequences of irrational medicine use

General transferable skills:

Having successfully completed the course, students should be able to:

- Critically evaluate and adjust care to prevent irrational medicine use

Source: Pastakia et al. 2011

National University of Rwanda Curriculum Committee's Proposed Session of a RMU Module

Session 1 – Overview/Introduction of RMU module

Session 2 – Determinants of RMU (case-based assessment of each determinant) and monitoring and evaluating RMU (lecture-based)

Session 3 – Agents with high risk for irrational medicine use

Session 4 – Strategies to promote RMU

Session 5 – Polypharmacy

Session 6 – Interactions

Session 7 – Diagnostic support

Module Contents

(Example from Session 4 Strategies to Promote Rational Medicines Use)

1. Education: (lecture based)

- a. Public
- b. Healthcare workers
 - i. Drug information center
 - ii. Continuing education

2. Regulations or laws (lecture-based, case-based)

3. Funding for essential medications (lecture-based)

4. Guidelines: clinical vs. institutional vs. managerial (lecture-based with examples)

5. DTCs: formulary, activities of the committee (lecture based plus group work)

6. Policies: Ministry of Health, National Pharmacovigilance and Medicines Information Center, etc. (lecture based with examples)

- a. International vs. national (World Health Organization vs. the above)
- b. Essential drug list

7. Drug advertising and promotion (lecture based, case based)

8. Independent information on medicine: unbiased source of info (case based)

9. Supervision and auditing (lecture based)

Evidence-based medicine (lecture based and examples)

1. Introduction of evidence based medicine

- a. Scientific methodology (basic statistics, clinical trials, application of information to make clinical decisions)
- b. Tutorial on how to find evidence (Pubmed, Ovid, etc.)

Delivery Method

Lectures

Have students complete many of the online tutorials on evidence-based medicine (<http://medlib.bu.edu/tutorials/ebm/intro/>)



Cases/Examples:

Guidelines:

WHO TB/HIV/Malaria vs. Rwanda TB/HIV/Malaria guidelines (international vs. national vs. local formularies)

Drug advertising:

- Give examples of advertising in other places (US vs. Europe vs. sub-Saharan Africa)
- Give examples of industry promoting to physicians here

Formulary:

- Group work on choosing a medicine for a formulary
- Give examples of differences between international vs. national vs. local use of medications

Evidence-based medicine:

- Why did the country change to using Coartem™ vs. chloroquine?
- Choosing the right antibiotic based on the antibiogram

Regulations or laws:

- Give the link between the laws and the rational medicine use

Source: Pastakia et al. 2011

Drafting the Pharmacovigilance Curriculum for Postgraduate Pharmacy Students at Hanoi University of Pharmacy (preservice training)

- Clinical Pharmacy Department and Postgraduate Department of Hanoi University of Pharmacy (HUP) reviewed existing postgraduate level curriculum in collaboration with the Strengthening Pharmaceutical Systems Program
- Identified gaps, deficiencies, and need for modifications regarding pharmacovigilance contents through a process of curriculum mapping
- Made the draft of the new in-service pharmacovigilance curriculum the basis for identifying the competencies that the students would require after they graduate and join the workforce
- Drafted the revised pharmacovigilance curriculum with key behavioral objectives and contact hours (Appendix H)
- Reviewed and revised the seminar contents, teaching-learning methods, and student assessment methods
- Kept the pre- and in-service curricula as closely aligned as possible

- Conducted a stakeholder curriculum review workshop attended by internal HUP stakeholders as well as external stakeholders followed by finalization of the curriculum
- Developed a detailed instructor’s guide matching the reformed curriculum to help the teaching faculty members facilitate the pharmacovigilance sessions. (See Appendix I for an illustrative excerpt from the guide).

Source: Joshi 2011, Garb and Joshi 2012

Step 2. Adapt Existing Resources

Rather than starting from scratch, curriculum development should build on existing resources. Resources may already exist in the institution, they may come from the content outlines mentioned earlier, or for specific content detail, they may be sourced from existing programs at other medical schools or from external organizations.

Selected external resources are—

- Teaching Safe and Effective Prescribing in UK Medical Schools: a Core Curriculum for Tomorrow’s Doctors <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1884249/pdf/bcp0055-0496.pdf>
- An Outcome-Based Approach for Teaching Prudent Antimicrobial Prescribing to Undergraduate Medical Students: Report of a Working Party of the British Society for Antimicrobial Chemotherapy. <http://jac.oxfordjournals.org/content/56/1/196.full.pdf>
- WHO. Outline of a Core Curriculum for a Standard Course in Pharmacovigilance. <http://www.who-pvtraining.org/content/13.html>
- General Medical Council. 2008. Good Practice in Prescribing Medicines. London: General Medical Council. http://www.gmc-uk.org/static/documents/content/Good_Practice_in_Prescribing_Medicines_0911.pdf
- Hogerzeil, H. V., (ed.) 2001. *Teacher’s Guide to Good Prescribing*. Geneva: World Health Organization. <http://whqlibdoc.who.int/hq/2001/WHO_EDM_PAR_2001.2.pdf>.
- WHO’s Essential Medicines Teaching Resources: <http://www.who.int/medicines/training/en/>

Rather than starting from scratch, curriculum development should build on existing resources

PHASE 5: IMPLEMENTING THE RMU CURRICULUM

To implement changes, you will need support primarily from the academic staff involved, but also perhaps from the dean of the school, outside professional organizations, or the university administration itself. The university may have a formal process to make curriculum changes. Competing priorities within the curriculum review process need to be built into the planning process.

For example, in some universities, individual schools may make minor curriculum changes. Other universities may have formal procedures that include—

- Proposal submissions and due dates
- The role of coordinators in the curriculum process
- The responsibilities of departments, school, college, dean, and university curriculum committee in the curriculum review, development, or modification process
- Responsibilities for consultation

Resource implications to consider include personnel, time allocations, different or more facilities, and funding to cover additional costs. For example, if the new curriculum requires moving to a small group discussion instead of a lecture-based format, extra rooms and facilitators may be needed; computer-assisted learning may require extra library resources or technology; and field visits to hospitals would take additional resources. Any increase in time allocation may need to be negotiated with other disciplines within the school, and interdepartmental funding issues may have to be resolved.

You can achieve a lot within the existing structure and even with limited resources. Getting faculty to address additional RMU-related issues while covering the existing topics in different disciplines can make a substantial difference. These small reorientations do not require significant resources and may not even require a formal change of curriculum.

Important questions to consider include—

- Is change needed in the experiential component of training to cover the new focus on RMU (for example, more time practicing communication skills under supervision to increase patient adherence to antibiotic treatment)?
- Will any suggested changes require administrative support?
- Will the reporting requirements for academic records be different?
- Will room or class schedules change?
- Will there be new communication issues (for example, more interdepartmental meetings, and assessment requirements)?

As with the planning stage, staff participation and ownership must be fostered during the implementation phase and are even more important if new teaching methods are to be implemented successfully.

If curricula change will occur over stages, careful planning will ensure a smooth transition. As one curriculum is phased in the previous course work will be phased out. Full implementation may take several years to accommodate ongoing modifications in content, teaching methods, and assessment procedures. Consistent communication with all relevant stakeholders is important to successful implementation and adoption of the curriculum changes.

Curriculum Reform: Some Lessons Learned in Zambia

- Advocate for preservice curriculum reform as a sustainable, low-cost intervention that results in an early and lasting influence on students' competencies for practice. Enlist the support of local opinion leaders during the initial advocacy-building process.
- Engage and work with all the key stakeholders in a step-wise manner to secure their continued commitment and help them make informed and collaborative decisions throughout the process of curriculum reform.
- Gather and disseminate examples of tools and templates that local stakeholders can customize and use during key steps such as curriculum mapping, competency analysis, and curriculum development.
- Use the opportunity provided by cross-cutting and practical topics such as AMR, rational medicine use, and pharmacovigilance to promote application of basic science for public health and clinical disciplines.
- Remember that curriculum reform is often a multiyear commitment, which affects action and funding plans; however, focus on key areas and avoid overambitious recommendations

- Do not view the work as finished when the curriculum has been reformed. Continue engaging and working with the related stakeholders, at least during an initial round of implementing the new curriculum.

Source: Joshi 2010

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APPENDIX A: Team Member and Stakeholder Analysis Worksheet¹

Person ¹	Role ²	Interest in AMR ³	Influence and Support ⁴	Management Strategies ⁵

1. Write person's name here.
2. Write the person's title/role here.
3. Write a brief note of why the person may be interested or have a stake in AMR.
4. Record the person's formal and informal amount of influence and support in important organizations, associations, etc.
5. List strategies to elicit the support of the person or neutralize them as a barrier.

¹ Adapted from Titler, M.G. 2002. Toolkit for Promoting Evidence-Based Practice. Iowa City, IA: Department of Nursing Services and Patient Care, University of Iowa Hospitals and Clinics.

APPENDIX B: Action Plan Template²

Date: _____

Draft: _____

Purpose: _____

Objectives	Action Steps	Accountable Person(s)	Projected Completion Date	Actual Completion Date

² Adapted from Titler, M.G. 2002. *Toolkit for Promoting Evidence-based Practice*. The University of Iowa Hospitals and Clinics, Department of Nursing Services and Patient Care. Iowa City, IA.

APPENDIX C:

Sample Self Assessment to Evaluate Current Curricula for Antimicrobial Resistance in Undergraduate Education and Training in Medical Schools

Medical School AMR Self Assessment Questions	Yes	No
Is the teaching of antimicrobial resistance (AMR) containment consistent with the goals of the faculty/school?		
Is the teaching of AMR containment a school priority?		
Are there specific written aims and objectives for teaching antimicrobial resistance containment?		
Is AMR containment taught as part of a specific subject area on rational prescribing?		
Is AMR containment taught as a single subject?		
Is AMR containment taught within a range of topic areas that are independent of each other, e.g. microbiology, therapeutics, public health?		
If AMR is taught in a range of topic areas, is there a coordinated articulated plan for its teaching?		
Is the content structured vertically to allow for continuity?		
Is the content structured horizontally to allow for integration?		
Do the experiential elements of clinical training incorporate AMR containment?		
Can knowledge and skills relating to AMR containment be identified in the assessment processes of the school?		
Does the university have a formal process for curriculum development?		
Do existing curriculum development committees include input professional organizations and licensing boards?		
If electronic resource materials are available in AMR does the school have adequate facilities for all students to access them?		

APPENDIX D:

AMR-related Topics Identified in Medical Curriculum Study at Zambia University Medical School³

Specific Topics/Content Covered in Literature Under Each Broad Area
<p>Antimicrobial Use</p> <ul style="list-style-type: none"> • Antibiotics (treatment and mechanism of action) • Antifungals (treatment and mechanism of action) • Antiparasitics (treatment and mechanism of action) • Antivirals (treatment and mechanism of action) • Patients' (mis)perceptions • Self medication issues • Poor adherence issues
<p>Infectious Diseases of Major Public Health Importance (diseases with high rates of associated AMR)</p> <ul style="list-style-type: none"> • HIV/AIDS • TB • Malaria • STIs • Diarrhoeal diseases (salmonella, cholera, shigella) • Acute Respiratory Infections

³ Banda, S. 2006. Curriculum review and interview of experts to identify topics on antimicrobial use and antimicrobial resistance included in the undergraduate medicine training program in Zambia. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Science For Health.

Infection Prevention/ Immunization

- Vaccinations
- Integrated Management of Childhood Illnesses (IMCI)
- Barrier precautions (handwashing, gloves, gowning)
- Isolation procedures
- Injection safety and appropriate use
- Sterilization and disinfection of supplies and equipment
- Aseptic techniques for medical and nursing procedures.
- Recognition and investigation of outbreaks or clusters of infections

Rational Drug Use

- Accurate diagnosis (laboratory diagnostic support)
- Selection of correct drugs
- Selection of correct dosages
- Optimum treatment durations
- Patient education on appropriate use
- Standard Treatment Guides (STGs)
- Need for community to have appropriate access to antimicrobials (Essential Drug Lists)
- Counterfeit drugs
- Role Pharmaceutical Promotions
- Prescribing audits

Antimicrobial Resistance

- Mechanism of Development of Resistance
- Extent of AMR problem
- AMR Surveillance
- Research
- Prevention and Control
- Multi-Drug Resistance (MDR)
- Methicillin Resistant Staphylococcus Aureus (MRSA)
- Vancomycin Resistant Enterococci

Science of Microbes

- Bacteria (structure and pathogenesis)
- Viruses (structure and pathogenesis)
- Fungi (structure and pathogenesis)
- Parasites (structure and pathogenesis)
- Mechanism of action of antimicrobials
- Development of Resistance

APPENDIX E: Needs Assessment

(Adapted from the Medical Curriculum Study at Zambia University Medical School)⁴

To accurately identify where AMR is taught in the medical school and the extent of that teaching, the following methodology helps make the determination. Use this information along with the AMR self-assessment to make rational decisions on where AMR topics can be improved or added to the current medical school curriculum.

The survey methodology is recommended as follows:

Step 1

- Using the curriculum review forms found in this appendix, review all courses. These include Curriculum Review Form (Part A): A Course-by-Course Review. This review identifies the title of the course, learning objectives, content, and the amount of time spent on AMR related issues for each course. Information can be obtained from course catalogue and/or interviewing professors and instructors
- Categorize each course as related or not related to AMR using the general themes from the *WHO Global Strategies for Containment of Antimicrobial Resistance*

Step 2

- Curriculum Review Form Part B: Course Summary. Complete this form to summarize the information from Course Review Form from Step 1.

⁴ Banda, S. 2006. Curriculum review and interview of experts to identify topics on antimicrobial use and antimicrobial resistance included in the undergraduate medicine training program in Zambia. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Science For Health.

Step 3

- From the Course Summary form calculate the following—

Total number of courses and hours spent on all courses

Total number of courses and hours spent on antimicrobials

Total number of courses and hours spent on infection prevention/
immunizations and infection control

Total number of courses and hours spent on AMR

Total number of courses and hours spent on rational drug use topics

Step 4

- Interview key public health officials, staff, and students using interview form in this appendix. Tally the number of responses to each question and classify by respondent type (e.g., Malaria program manager) This information will be important for giving appropriate weight to antimicrobial resistance curriculum changes.

After reviewing each medical school course and interviewing teaching staff, students, and public health officials, assess the AMR course gaps. The medical curriculum review committee may use this information to institute reforms in the medical school curriculum that provides adequate time to important AMR-related topics and courses.

Curriculum Review Form

Part A: Course-by-Course Review

Directions: Make one copy of Part A for each course. Review each course. Show what content the course covers, a note on the focus of the content covered. Use the letter codes for teaching methods used for each course. Write the approximate number of hours spent for each content area.

Title of Course: _____

Learning goals/Objectives of Course:

What Type of Content is Taught in This Course?

Antimicrobial Use: Yes / No

If yes, please list topics.

Infectious Diseases: Yes/No

If yes, please list topics.

Infection Prevention/Immunization: Yes / No

If yes, please list topics.

Rational drug use: Yes / No

If yes, please list topics.

Antimicrobial Resistance: Yes / No

If yes, please list topics.

Science of Microbes: Yes/No

If yes, please list topics.

Other: Yes/ No.

If yes please describe briefly.

How strong is the link between the course content and overall WHO Global Strategy for Containment of Antimicrobial Resistance?

Very strong Strong Moderate Not very strong Not strong

Codes for teaching methods:

- | | |
|-------------------------------------|--------------------------------------------|
| A. Lecture | D. Assignment |
| B. Small Group Teaching (Tutorials) | E. Laboratory Practical |
| C. Seminar | F. Individual activities (worksheets, etc) |

Curriculum Review Form

Part B: Course Summary

Directions: Use the table below to summarize the information from the Course Review Form for Part A.

Name of Curriculum: _____

Source of Curriculum: _____

Total Number of Courses in Curriculum: _____

Approximate Length of Each Course: _____(Hours).

Overall Length of Curriculum: _____(Hours)

Total Number of Courses in Which this Type of Content Appears: _____

Total Length of Courses in Which this Type of Content Appears: _____

Total Number of Rational Drug Use Courses: _____

Total Length of Rational Drug Use Courses: _____

Total Number of Infection Prevention and Control Courses: _____

Total Length of Infection Prevention and Control Courses: _____

Total Number of Antimicrobial Resistance Related courses: _____

Total Length of Antimicrobial Resistance Courses: _____

Content Covered	Total Number of Courses that Cover this Topic	Total Number of Hours Devoted to this Topic	Teaching-Learning Method
<p>Antimicrobial Use</p> <p>Antibiotics (treatment and mechanism of action)</p> <p>Antifungals (treatment and mechanism of action)</p> <p>Antiparasitics (treatment and mechanism of action)</p> <p>Antivirals (treatment and mechanism of action)</p> <p>Patients' (mis)perceptions</p> <p>Self medication issues</p> <p>Poor adherence issues</p>			
<p>Infectious Diseases</p> <p>HIV/AIDS</p> <p>TB</p> <p>Malaria</p> <p>STIs</p> <p>Diarrhoeal diseases (salmonella, cholera, shigella)</p> <p>Acute Respiratory Infections</p> <p>Measles</p>			
<p>Infection Prevention/ Immunization</p> <p>Vaccinations</p> <p>Integrated Management of Childhood Illnesses (IMCI)</p> <p>Barrier precautions (handwashing, gloves, gowning)</p> <p>Isolation procedures</p> <p>Injection safety and appropriate use</p> <p>Sterilization and disinfection of supplies and equipment</p> <p>Aseptic techniques for medical and nursing procedures.</p> <p>Recognition and investigation of outbreaks or clusters of infections</p>			

Content Covered	Total Number of Courses that Cover this Topic	Total Number of Hours Devoted to this Topic	Teaching-Learning Method
<p>Rational Drug Use</p> <p>Accurate diagnosis (laboratory diagnostic support)</p> <p>Selection of correct drugs</p> <p>Selection of correct dosages</p> <p>Optimum treatment durations</p> <p>Patient education on appropriate use</p> <p>Standard Treatment Guides (STGs)</p> <p>Need for community to appropriate access to antimicrobials (Essential Drug Lists)</p> <p>Counterfeit drugs</p> <p>Role Pharmaceutical Promotions</p> <p>Prescribing audits</p>			
<p>Antimicrobial Resistance</p> <p>Mechanism of Development of Resistance</p> <p>Extent of AMR problem</p> <p>AMR Surveillance</p> <p>Research</p> <p>Prevention and Control</p> <p>Multidrug Resistance (MDR)</p> <p>Methicillin-Resistant Staphylococcus Aureus (MRSA)</p> <p>Vancomycin-Resistant Enterococci</p>			
<p>Science of Microbes</p> <p>Bacteria (structure and pathogenesis)</p> <p>Viruses (structure and pathogenesis)</p> <p>Fungi (structure and pathogenesis)</p> <p>Parasites (structure and pathogenesis)</p> <p>Mechanism of action of antimicrobials</p> <p>Development of Resistance</p>			

Were there any courses in which you rated the link between the content/activities and the overall WHO Global Strategy for Containment of Antimicrobial Resistance? (e.g., does each course move closer to reaching the stated WHO strategies) as “Very strong,” “Strong,” or “Moderate”?

Yes. If so, please list:

Other comments:

Interview Schedules

Interview questions for Medical Council and Ministry of Health officials concerning antimicrobial use and antimicrobial resistance issues.

Accurate Diagnosis and Management of Common Infections

Introduction: Your organization is obviously concerned with several health issues.

Does your institution have a policy (or strategies/interventions) about accurate diagnosis and management of common infections, e.g., laboratory supported diagnosis and treatment of infections?

Disease Prevention including Immunization

Introduction: Your institution deals with issues related to disease prevention.

What aspects of infection prevention are covered in the policy (or strategies/interventions) that you deal with?

Patient Education

Introduction: The community has an important role to play in issues of antimicrobial use.

Does your institution have a policy (or strategies/interventions) concerning patient education with regard antimicrobial use?

What aspects about patient education are covered?

Antimicrobial Use and Containment of Antimicrobial Resistance

Does your institution have a policy (or strategies/interventions) about antimicrobials (antibiotics, antifungals, antivirals, and antiparasitics)?

If yes:

What aspects of appropriate antimicrobial use are covered?

Is antimicrobial resistance recognized as a problem per se?

If so, what and how much addresses AMR as a problem?

Is rational medicine use a component of appropriate antimicrobial use, if so what is being done about it?

What aspects of containment of antimicrobial resistance are covered in the policy (or strategies/interventions)?

What is your opinion about the amount and scope of coverage about antimicrobial resistance? Do you think enough is being done?

Other

Is the issue of AMR problem amongst nosocomial infections covered in any of your institutions policies (strategies/interventions)?

With the increase in access to antimicrobials through Global Fund, PEPFAR funds, and others, is the escalation of AMR being covered?

Is irrational use and AMR covered for infectious diseases of major public health importance (HIV/AIDS, TB, malaria, sexually transmitted infections (STI), diarrheal diseases, and acute respiratory infection)?

APPENDIX F: Questionnaire Tool for Curriculum Review and Competency Assessment on Pharmaceutical Supply Management⁵



USAID
FROM THE AMERICAN PEOPLE

SIAPS
Systems for Improved Access
to Pharmaceuticals and Services



HANOI UNIVERSITY OF PHARMACY

Stakeholder Interviewed or Document Reviewed:

Tally the number of opinions for each column classified by respondent type (e.g. 10Y Students; 2N Faculty)

UG = undergraduate

TL = teaching learning

PG = post-graduate

EC = essential competency

Y = yes

DC = desirable competency

N = no

NEC = non-essential competency

SCM= supply chain management

⁵ Reproduced from: Joshi M. 2012. *Preservice Curriculum Reform on Pharmaceutical Supply Management at the Hanoi University of Pharmacy: Technical Assistance for Curriculum Review and Competency Assessment*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

	PG Curriculum	UG Curriculum
1 Introduction		
1.1 Purpose of SCM system for pharmaceuticals and other commodities	PG Theory (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) PG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (PG)	UG Theory (Y/N) if Y, approx. time (min) T-L Method Competency (EC, DC, NEC) UG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (UG)
1.2 The SCM context: Definition, SCM alignment into the health system, the SCM environment, financing and human resources for SCM, performance measures and its key components.		More relevant for PG
1.3 Importance of uninterrupted product availability as a prerequisite for rational use of medicines		
1.4 Overview of the various elements of the SCM system (e.g., selection, forecasting, procuring/ordering, warehousing/storing, managing inventory, recording/reporting) and how they are interlinked		
1.5 Governance in SCM (policy and legal framework, regulations and acts, fraud, etc.)		

	PG Curriculum	UG Curriculum
	PG Theory (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) PG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (PG)	UG Theory (Y/N) if Y, approx. time (min) T-L Method Competency (EC, DC, NEC) UG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (UG)
2 Product Selection		
2.1 Importance of selection of the right products as a key initial step for subsequent actions of quantification, procurement, distribution and use		
2.2 Concept of developing Essential Medicines List (EML) at national/ facility level		
2.3 Concept of standard treatment guidelines (STG) at national/ facility level		
2.4 Importance of using international nonproprietary name (INN) or generic names in the EML and STG		
2.5 Choosing medicines for different levels of facility, e.g., primary care, secondary care, tertiary care		

	PG Curriculum	UG Curriculum
3 Forecasting / Quantification and Supply Planning		
3.1 Importance of carefully quantifying medicine requirements	PG Theory (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) PG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (PG)	UG Theory (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) UG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (UG)
3.2 Use of various quantification methods such as consumption and morbidity methods		
3.3 The concept of supply planning, resources mobilization, including financing		Relevant for PG only
3.4 Factors to consider during quantification		
4 Procurement and Quality Assurance		
4.1 Relevance of good pharmaceutical procurement practices		
4.2 Selecting procurement methods		
4.3 Managing tenders		

	PG Curriculum	UG Curriculum
	PG Theory (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) PG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (PG)	UG Theory (Y/N) if Y, approx. time (min) T-L Method Competency (EC, DC, NEC) UG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (UG)
4.4	The processes for selecting suppliers (prequalification)	
4.5	Managing contracts (contract negotiation, management, importance of understanding procurement/contract implementation)	Relevant for PG
4.6	Managing procurement/supplies relationship (good procurement practice context)	Relevant for PG
4.7	Various purchasing methods (e.g., annual purchasing, scheduled purchasing, perpetual purchasing)	
4.8	Consequences of poor medicine quality	
4.9	Selecting good quality products and suppliers	
4.10	Ensuring quality adherence to contract terms	
4.11	Problems with medicine donations and need for national donations policy	

	PG Curriculum	UG Curriculum
5 Storage and Distribution		
5.1 Understanding of the objectives and scope of warehousing/ storage, distribution and the link between the two	PG Theory (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) PG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (PG)	UG Theory (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) UG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (UG)
5.2 Organizing warehouse or storage facility (e.g., stacking supplies properly, organizing commodities, preventing expiration, temperature control, ventilation, dryness, workspace, lighting, cleanliness, orderliness, pests control, security and safety, authorized access)		
5.3 Guidelines, planning, managing and the role of technology, tools and software in warehousing and distribution		Relevant for PG
5.4 Commodity controlling, handling, and safety/protection		
5.5 Managing transport: planning distribution routes, fleet management, delivery schedules and transport options		

	PG Curriculum	UG Curriculum
	PG Theory (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) PG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (PG)	UG Theory (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) UG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (UG)
6 Inventory Management		
6.1	Assessing stock status, determining safety stock levels, avoiding stock-outs, and determining quantities to order for resupply	
6.2	Lead time, maximum and minimum stock levels	
6.3	Data needed to assess stock status (e.g., stock on hand, and rate of consumption)	
6.4	Types of inventory management systems, e.g., push or pull	
6.5	Maintaining accurate stock records, e.g., up-to-date and accurate stock card and bin card; conducting physical inventories	
6.6	Value of ABC and vital, essential and nonessential analysis in inventory management	
6.7	Issuing and receiving procedures in a medical store	
6.8	Accounting for and minimizing losses through expiry, spoilage, fraud	

	PG Curriculum	UG Curriculum
7 Logistics Management Information System (LMIS)		
7.1 Purpose of LMIS	PG Theory (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) PG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (PG)	UG Theory (Y/N) if Y, approx. time (min) T-L Method Competency (EC, DC, NEC) UG Practical (Y/N) if Y, approx. time (min) TL Method Competency (EC, DC, NEC) Other comments (UG)
7.2 Key records and data needed for LMIS		
7.3 Various types of logistics records (storekeeping records, transaction records, consumption records)		
7.4 Logistics reporting (summary reporting and feedback reporting)		
7.5 Using LMIS for decision-making		

APPENDIX G:

AMR-Related Curriculum Incorporated in the 2010 Undergraduate Medical Curriculum of the University of Zambia⁶

Chemotherapy

Clinically relevant general issues relating to chemotherapy

- General principles of rational antimicrobial therapy, including the importance of accurate diagnosis and selection of the appropriate agent
- The importance of rapid diagnostic tests for quick and proper management of infections, and locally available tests
- Principles of rational use of antimicrobials for prophylaxis
- The problem of widespread overprescribing and inappropriate prescribing of antimicrobials and list factors responsible for such practices
- Antimicrobial resistance (AMR) and multidrug resistance (MDR) and the mechanism of AMR
- Diseases of major public health importance for which AMR is an issue (TB, malaria, pneumonia, bacillary dysentery, STI, HIV/AIDS)
- The role of effective immunization programs in reducing infectious disease burden and AMR

General Topics and Therapeutics

Evidence-Based Medicine

- Evidence-Based Medicine and its importance in attaining rational therapeutics.

6 Source: University of Zambia (UNZA), School of Medicine. MB ChB Curriculum, 2010.

Principles of rational prescribing and monitoring drug therapy (as recommended in the WHO *Guide to Good Prescribing*).

- Selecting and prescribing medicines appropriately as recommended in the WHO's *Guide to Good Prescribing*
- Effectively communicating with and counseling patients/caregivers regarding appropriate medicines use, adherence to treatment, responsible self medication, and infection prevention

Prescribing for children, pregnant women, lactating mothers, and the elderly

- Principles of prescribing for special groups of patients such as children, pregnant women, lactating mothers, and the elderly

Pharmacovigilance (adverse drug reactions and their monitoring, adverse drug interactions, medication errors, drug quality)

- Pharmacovigilance-related issues such as adverse drug reaction (ADR), medication errors, and poor drug quality;
- The role of prescribers in addressing such issues and promoting drug safety
- Mechanisms of drug interactions and their clinical implications

Management of drug overdose and poisoning

- General principles of management of drug overdose and poisoning
- The management of overdose and poisoning with selected drugs and poisons

Zambian STGs, Essential Medicines List, and Formulary, and their roles in RMU

- Standard treatment guidelines/drug formularies/essential drugs lists, and locally produced documents and their role in promoting RMU

Antimicrobial resistance (factors contributing to AMR; impact of AMR; global and local examples of AMR; strategies to contain AMR)

- Key factors contributing to emergence and spread of AMR
- Individual and public health consequences of AMR
- Selected local and global examples/case stories of AMR, including MDR (e.g., in TB, malaria, HIV/AIDS, hospital-acquired infections, STIs)
- The role of prescribers in containing AMR such as judicious antimicrobial prescribing, patient education, hospital infection control activities, and use of AMR surveillance information to guide prescribing
- The role of prescribers as agents for awareness and advocacy on issues such as substandard/counterfeit drugs, use of antimicrobials for growth promotion in animals, and overall AMR containment

Factors influencing prescribing and critical analysis of promotional literature

- Factors influencing prescribing
- Promotional drug information provided by pharmaceutical industry

APPENDIX H:

Renewal of the Pharmacovigilance Curriculum for Training of Post-graduate Pharmacy Students at Hanoi University of Pharmacy–Curriculum Mapping and Recommended Revision⁷

⁷ Source: Joshi M. 2011. *Technical Assistance for the Development of Preservice and In-service Pharmacovigilance Curriculum at the Hanoi University of Pharmacy in Vietnam*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health. http://www.msh.org/projects/sps/SPS-Documents/upload/SPS_Vietnam_Joshi_Technical-Report_PV_Aug2011.pdf

Existing curriculum		Recommended revised curriculum	
Topic covered	Modifications needed	Suggested topic areas	Key behavioral objectives
<p>1. Overview of PV and Medication Safety</p> <p>100 Minutes</p> <ul style="list-style-type: none"> • Definition of PV • History of PV • Goals of PV (rational medicine use, communication of risk and benefit of medicines, health worker and patient education) • Widening scopes of PV—adverse drug reaction (ADR), medication error, product quality, therapeutic ineffectiveness • PV of herbal medicines 	<ul style="list-style-type: none"> • Need and importance of PV (burden of ADRs; morbidity and mortality, cost burden of ADRs, benefits of PV. • Clinical trials of medicines and post-marketing surveillance, and how PV fits in all these steps (life-cycle approach) • PV information influencing medicines policy and regulation: recall, labeling changes, reschedule withdrawal, policy change. 	<p>100 Minutes</p> <p>1.1. General Overview of PV and Medication safety</p> <ul style="list-style-type: none"> • Definition of PV • Brief history of PV • Goals of PV (rational medicine use, communication of risk and benefit of medicines, health worker and patient education) • Widening scopes of PV—adverse drug reaction (ADR), medication error, product quality, therapeutic ineffectiveness • Brief overview of the need and importance of PV (burden of ADRs; morbidity and mortality, cost burden of ADRs, benefits of PV. • Brief revisit on the various phases of clinical trials of medicines and post-marketing surveillance, and how PV fits in all these steps (life-cycle approach) • Brief introduction on how PV information can influence medicines policy and regulation: recall, labeling changes, reschedule withdrawal, policy change. 	<p>At the end this session, the student will be able to:</p> <ul style="list-style-type: none"> • define PV and emphasize that its scope includes not only ADRs but also medication errors, product quality issues, and therapeutic ineffectiveness • explain the burden and impact of adverse drug events (ADE) and use this context to articulate the need to support PV activities • link PV as a key ingredient to achieving the broader goals of rational medicine use and pharmaceutical care • emphasize that monitoring the safety of a medicine is an ongoing process, and needs to happen both during pre-marketing and post-marketing periods • tell how PV information provides evidence for and influences regulatory decision, giving one example of such a decision taken by drug regulatory authority

Existing curriculum		Recommended revised curriculum	
Topic covered	Modifications needed	Suggested topic areas	Key behavioral objectives
	<ul style="list-style-type: none"> Brief overview of the problems of drug overuse and misuse in Vietnam; safety issues with traditional and herbal medicines in Vietnam; weaknesses of the health care system regarding medicine safety activities Overview of the legal basis for PV system and framework of the PV system in Vietnam PV roles and activities the Ministry of Health (MOH), especially the National DI&ADR Center, Drug Administration of Vietnam (DAV), and Medical Services Administration (MSA) of Vietnam 	<p>50 Minutes</p> <p>1.2. PV Program in Vietnam and in the world</p> <ul style="list-style-type: none"> Brief overview of the problems of drug overuse and misuse in Vietnam; safety issues with traditional and herbal medicines in Vietnam; weaknesses of the health care system regarding medicine safety activities Overview of the legal basis for PV system and framework of the PV system in Vietnam PV roles and activities the Ministry of Health (MOH), especially the National DI&ADR Center, Drug Administration of Vietnam (DAV), and Medical Services Administration (MSA) of Vietnam Brief overview of PV management model of WHO, Federal Drug Administration (FDA), and EU (European Union) 	<p>At the end this session, the student will be able to:</p> <ul style="list-style-type: none"> Describe the legal basis of PV activities in Vietnam List the key national stakeholders with regard to PV in Vietnam Briefly describe PV management model of WHO, FDA and EU
		<p>50 Minutes</p> <p>1.3. PV of herbal medicines in Vietnam and in the world</p> <ul style="list-style-type: none"> Brief overview of the issues with PV of herbal medicines in Vietnam Brief overview of the issues with PV of herbal medicines in other countries of the world 	<ul style="list-style-type: none"> Describe the key problems and clinically significant toxicities associated with the use of herbal and traditional medicines in Vietnam

Existing curriculum	Recommended revised curriculum	Key behavioral objectives
Topic covered	Suggested topic areas	
<p>2. Risk Identification</p> <p>100 Minutes</p> <ul style="list-style-type: none"> Definition: Adverse drug reactions (ADR), adverse drug event (ADE), Side effect, post-marketing surveillance (PMS), and other PV-related terminologies Classification of ADRs (e.g., Type A and B and others; immediate, delayed) Pre-disposing factors of adverse drug reactions: age, gender, pregnancy, previous history of allergy or reaction, multiple drug therapy, ethnic and genetic factors and concomitant disease processes Brief overview of strategies that minimize the occurrence or early detection of ADRs Method of assessing causality of ADRs 	<p>100 Minutes</p> <p>2.1. Adverse Drug Reaction as a Factor for Adverse Drug Event:</p> <ul style="list-style-type: none"> Definition: Adverse drug reactions (ADR), adverse drug event (ADE), Side effect, post marketing surveillance (PMS), and other PV-related terminologies Classification and mechanism of ADRs (e.g., Type A and B and others; immediate, delayed etc), Predisposing factors of adverse drug reactions: age, gender, pregnancy, previous history of allergy or reaction, multiple drug therapy, ethnic and genetic factors and concomitant disease processes Brief overview of strategies that minimize the occurrence or early detection of ADRs 	<p>At the end this session, the student will be able to:</p> <ul style="list-style-type: none"> Define the various terms related to PV Differentiate the various types of ADRs List predisposing factor for ADRs, giving at least one example for each factor (age, gender, previous history of allergy, multiple drug therapy, ethnic/genetic factors, and co-morbidities) List at least 5 drugs known to cause major teratogenic effects; list pregnancy risk categories of drugs, giving at least one drug example for each category Discuss strategies that help minimize or prevent the risk of ADRs Narrate self-perception of his/her role in minimizing or preventing ADRs upon joining the pharmacy workforce after graduation

Existing curriculum		Recommended revised curriculum	
Topic covered	Modifications needed	Suggested topic areas	Key behavioral objectives
	<ul style="list-style-type: none"> • Burden of medication error; causes of medication error; • Common problem-prone areas with regard to medication errors • Approaches to prevent medication errors 	<p>35 Minutes</p> <p>2.2. Medication Error as a Factor for Adverse Drug Events</p> <ul style="list-style-type: none"> • Burden of medication error; causes of medication error; • Overview of common problem-prone areas with regard to medication errors • Approaches to prevent medication errors 	<p>At the end this session, the student will be able to:</p> <ul style="list-style-type: none"> • Highlight the burden of medication error in hospitals • Analyze how system weakness contributes to medication errors in hospitals • Highlight key strategies that can be used to prevent or minimize medication errors • Narrate self-perception of his/her role in minimizing or preventing medication errors upon joining the pharmacy workforce after graduation
	<ul style="list-style-type: none"> • Burden of substandard and counterfeit products, and the impact of low quality medicines • Therapeutic ineffectiveness and the factors contributing to it, including drug resistance 	<p>15 Minutes</p> <p>2.3. Other Factors for Adverse Drug Events</p> <ul style="list-style-type: none"> • Brief overview of the burden of substandard and counterfeit products, and the impact of low quality medicines • Brief overview of therapeutic ineffectiveness and the factors contributing to it, including drug resistance 	<p>At the end this session, the student will be able to:</p> <ul style="list-style-type: none"> • Briefly describe the burden of substandard and counterfeit products • Articulate that treatment failure is an important issue in public health programs such as HIV/AIDS, malaria, and TB, and that it needs to be tracked for informing future treatment decisions

Existing curriculum		Recommended revised curriculum	
Topic covered	Modifications needed	Suggested topic areas	Key behavioral objectives
	<ul style="list-style-type: none"> Assessing severity of ADRs (mild, moderate, severe, fatal) 	<p>50 Minutes</p> <p>2.4. Adverse Drug Events: Assessment of Severity and Causality</p> <ul style="list-style-type: none"> Assessing severity of ADRs (mild, moderate, severe, fatal) Method of assessing causality of ADRs: WHO-UMC scale and Naranjo Algorithm 	<p>At the end this session, the student will be able to:</p> <ul style="list-style-type: none"> Distinguish ADRs of various severity (mild, moderate, severe and fatal) Briefly explain the WHO-UMC scale and Naranjo Algorithm for assessing causality of ADRs

Existing curriculum		Recommended revised curriculum	
Topic covered		Suggested topic areas	
Modifications needed		Key behavioral objectives	
3. Risk Evaluation and Reporting	<p>300 Minutes</p> <ul style="list-style-type: none"> Sources of ADE data: premarket safety data, spontaneous reports, Phase IV studies, scientific literature, product inquires and complaints, unpublished manuscripts, internet Passive surveillance methods — roles of spontaneous reporting; strengths and limitations of spontaneous reporting; key data fields in Vietnam spontaneous reporting form: patient details, description of the adverse event or product quality problem, suspected drug(s) or vaccine(s), reporter details Active surveillance methods: case control study, cohort study, prescription events monitoring, registries, sentinel surveillance Strategies to improve ADE reporting and analysis 	<p>200 Minutes</p> <p>3.1. Passive and Active Methods of Surveillance</p> <ul style="list-style-type: none"> Sources of ADE data: premarket safety data, spontaneous reports, Phase IV studies, scientific literature, product inquires and complaints, unpublished manuscripts, internet Passive surveillance methods — roles of spontaneous reporting; strengths and limitations of spontaneous reporting; key data fields in Vietnam spontaneous reporting form: patient details, description of the adverse event or product quality problem, suspected drug(s) or vaccine(s), reporter details Brief introduction to active surveillance methods: case control study, cohort study, prescription events monitoring, registries, sentinel surveillance Strategies to improve ADE reporting and analysis (e.g., ADR form widely available, reporting as routine and normal part of administering healthcare, distribution network, feedback to reporters) 	<p>At the end this session, the student will be able to:</p> <ul style="list-style-type: none"> Explain strengths and limitations of spontaneous reporting Demonstrate competence and confidence in filling the various fields of the spontaneous reporting form currently used in Vietnam Through a personal narrative, demonstrate enthusiasm and conscientiousness (in his/her role as a health care worker) toward filling and sending spontaneous reporting form upon joining the pharmacy workforce after graduation Demonstrate correct understanding by telling that spontaneous reporting and active surveillance approaches are complementary methods Describe strategies to improve ADE reporting

Existing curriculum		Recommended revised curriculum	
Topic covered	Modifications needed	Suggested topic areas	Key behavioral objectives
4. Risk Communication, Risk Management, and Risk Minimization			
<p>150 Minutes</p> <ul style="list-style-type: none"> • PV communications to healthcare professionals and in public healthcare mission • Principles and methods of risk-benefit assessment 	<ul style="list-style-type: none"> • The Erice Declaration on effective communication • Role of the National DI&ADR Center, DAV, hospital DTCs (Drug & Therapeutics Committees) and Drug Information Units (DIUs) and other stakeholders in communicating medicine safety information; relevant circulars from MOH relating to such roles for key MOH bodies • Examples from other countries and organization on communicating messages about medicine safety • Examples from other countries and organizations regarding strategies and tools for risk management and minimization 	<p>150 Minutes</p> <p>4.1. Strategies to improve risk communications, and principles of risk management and risk minimization</p> <ul style="list-style-type: none"> • Principles and methods of risk-benefit assessment • The Erice Declaration on effective communication in PV • Role of the National DI&ADR Center, DAV, hospital DTCs and DIUs and other stakeholders in communicating medicine safety information; relevant circulars from MOH relating to such roles for key MOH bodies • Examples from other countries and organization on communicating messages about medicine safety (e.g., “Dear Doctor” letters, medicine alerts, media statements, patient information leaflets, newsletters, and personal feedback to reporters) • Selected examples from other countries and organizations regarding strategies and tools for risk management and minimization 	<p>At the end this session, the student will be able to:</p> <ul style="list-style-type: none"> • Through a personal narrative, demonstrate commitment to communicating drug safety information ethically and effectively • Cite actual examples of strategies, approaches or tools used in Vietnam or other countries or organizations to promote and support risk communication, management and minimization • Through a personal narrative, demonstrate commitment to promoting safety and preventing risks, taking a “proactive” rather than a “reactive” approach for the safe use of medicines, planning and implementing “risk management” and “risk minimization” strategies upon joining the pharmacy taskforce after graduation

Existing curriculum		Recommended revised curriculum	
Topic covered	Modifications needed	Suggested topic areas	Key behavioral objectives
<p>5. Pharmacovigilance in public health programs</p> <p>30 Minutes Implementing PV in public health care</p>	<p><i>(In the existing curriculum the topic of implementing PV in public health care is stated very generally, but no specific details are provided)</i></p> <ul style="list-style-type: none"> • Importance of PV in public health programs (PHPs); strengths, challenges and mutual benefits • Epidemiology of adverse events and drug-related morbidity and mortality in PHPs (HIV/AIDS, TB, Malaria, Immunization); problem of treatment failure in PHPs • Improving adverse event reporting within PHPs (HIV/AIDS, TB, Malaria, Immunization) 	<p>50 Minutes</p> <p>5.1. Importance of PV in PHPs, burden of ADEs in PHPs, strategies to improve adverse events reports in PHPs</p> <ul style="list-style-type: none"> • Importance of PV in PHPs (HIV/AIDS, TB, malaria, immunization): strengths, challenges and mutual benefits • Epidemiology of adverse events and drug-related morbidity and mortality in PHPs (HIV/AIDS, TB, malaria, immunization); problem of treatment failure in PHPs • Improving adverse event reporting within PHPs (HIV/AIDS, TB, malaria, immunization) 	<p>At the end this session, the student will be able to:</p> <ul style="list-style-type: none"> • Explain why the conduct of PV is critical for a “safe” and rational use of medicines in the major PHPs such as HIV/AIDS, malaria, TB, and Immunization • Show awareness of the significant problem of ADEs in PHPs by describing the burdens of ADRs and treatment failures • Describe locally feasible measures that can help improve adverse event reporting within PHPs

APPENDIX I:

Excerpt from Hanoi University of Pharmacy Instructor's Guide⁸

Session 2.2: Medication Error as a Factor for Adverse Drug Events

Topics to cover in this session:

- Burden of medication error; causes of medication error
- Overview of common problem-prone areas with regard to medication errors
- Approaches to prevent medication errors

Objectives: By the end of the session, students will be able to:

- Highlight the burden of medication error in hospitals
- Analyze how system weakness contributes to medication errors in hospitals
- Highlight key strategies that can be used to prevent or minimize medication errors
- Narrate self-perception of his/her role in minimizing or preventing medication errors upon joining the pharmacy workforce after graduation

⁸ Source: Garb, M. and Joshi, M. 2012. *Technical Assistance for the Development of Instructor's Guides for Implementing Preservice and In-service Curricula on Pharmacovigilance in Vietnam*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health. Downloadable from http://www.msh.org/projects/sps/SPS-Documents/upload/TechnicalReport_PV-Curriculum_Vietnam_April2012.pdf

Content Summary and Process Overview / Instructional Methodology (Total Duration: 35 Minutes)

A. Burden of medication error; causes of medication error. (Sources: Ref. 062, Ref. 059 page 18, Ref. 064)

Medication error includes any error occurring in the medication use process. One US study found that each preventable ADE that took place in a hospital added about \$8,750 (in 2006 dollars) to the cost of the hospital stay. Assuming 400,000 of these events each year, the total annual cost would be \$3.5 billion in this one group. Another study looked at preventable ADEs in US's Medicare system enrollees aged 65 and older and found an annual cost of \$887 million for treating medication errors in this group. These figures do not take into account lost earnings or compensation for pain and suffering.

Most causes of medication errors can be attributed to the following three factors:

- Human factors: Heavy staff workload and fatigue, Inexperience, lack of training, poor handwriting, and oral orders
- Workplace factors: Poor lighting, noise, interruptions, excessive workload
- Pharmaceutical factors: Excessive prescribing; confusing medicine nomenclature; packaging, or labeling; increased number or quantity of medicines per patient; frequency and complexity of calculations needed to prescribe, dispense, or administer a medicine; lack of effective policies and procedures

Activity	Time (Min)
Describe the enormity of the financial burden of medication errors in hospitals using example from US study quoted in Ref. 062 that each preventable ADE that took place in a hospital added about \$8,750 (in 2006 dollars) to the cost of the hospital stay, resulting in an estimated total annual cost of \$3.5 billion.	5
<p>Ask students to think of possible factors that contribute to medicine errors. Then, show them the following so they can see how many of the factors they identified:</p> <p>Most causes of medication errors can be attributed to the following three factors:</p> <ul style="list-style-type: none"> • Human factors: Heavy staff workload and fatigue, Inexperience, lack of training, poor handwriting, and oral orders • Workplace factors: Poor lighting, noise, interruptions, excessive workload • Pharmaceutical factors: Excessive prescribing, confusing medicine nomenclature, packaging, or labeling, increased number or quantity of medicines per patient, frequency and complexity of calculations needed to prescribe, dispense, or administer a medicine, lack of effective policies and procedures 	5

- B. Overview of common problem-prone areas with regard to medication errors
Sources: Ref. 060, Ref. 063 slide 9, Ref. 056 slides 14 and 16, Ref. 066,
Ref. 065)

One study of where medication errors take place showed the breakdown as follows:

Prescribing and transcribing – 60%

- Illegible and/or imprecise prescription
- Incomplete, inadequate or incorrect instructions
- Wrong indication, dose, duration, dilution, formulation
- Identity of the patient unclear
- Failure to consider a contra-indication (medical history, pre-existing condition, or interaction with a co-prescribed drug)

Administration – 30%

- Wrong patient
- Wrong dose, time, route of administration, site
- Inadequate preparation before administration
- Errors of manipulation : contaminants (air, others) when injected
- Incompatible drugs mixed in the same injectable solution

Dispensing – 10%

Dispensing errors usually occur due to wrong drugs being dispensed because of the problem of sound-alike or look-alike medications.

High-risk drugs cause harm in 6% or more of reported medication errors (USP)

Top 10 drugs most frequently reported in Canada as causing harm because of medication error—

Insulin	Morphine
Hydromorphone	Heparin (unfractionated)
Fentanyl	Warfarin
Furosemide	Dalteparin
Metoprolol	Ramipril

These 10 drugs accounted for 199 of 465 harmful medication incidents that were voluntarily reported to ISMP (Institute for Safe Medication Practices) Canada over a 5-year period (2001 to 2005). Ref. 060

Activity	Time (Min)
<p>Show students the percentages of medication errors that one study associated with:</p> <ul style="list-style-type: none"> • Prescribing and transcribing – 60% • Administration – 30% • Dispensing – 10% <p>Ask them to provide examples of each. Then, compare the examples they provided with the list shown in the content summary above.</p>	5
<p>Case Study</p> <p>If time permits, discuss one or both of these case studies about medication error from page 4 of Ref. 070</p> <p>The first example involves an insulin order written for “4 U NPH insulin.” However, because of poor handwriting, the “U” for “units” was mistaken for a zero, and the patient received 40 units of neutral protamine Hagedorn insulin.</p> <p>The second example shows a breakdown in communication that occurred when a physician gave a verbal order for insulin. Although the physician ordered 16 units of regular insulin, the nurse heard it as an order for 60 units; therefore, a 60-unit dose was administered.</p>	

C. Approaches to prevent medication errors (Source: Ref. 059 pages 18 and 19, Ref. 070)

Broad interventions to reduce medication errors are—

Improving physician prescribing

- Institute educational programs that focus on the most common prescribing errors.
- Require legible handwriting by ordering physicians.
- Require complete spelling of a medicine’s name.
- Use a standardized designation for doses (i.e., milligrams = mg, micrograms = mcg, and grams = g; use the word “units” rather than “U”; and use a leading zero for values less than 1 but not a trailing zero after a decimal, e.g., write 0.2 mg or 2 mg instead of .2 mg or 2.0 mg).
- Write the route of administration on all orders.
- Write out directions completely. Write “daily” instead of “QD” and “every other day” instead of “QOD.”
- Limit the use of oral or telephone orders to emergency situations, and require that the order be read back to the prescriber.

Improving dispensing

- Separate the storage of drugs that have similar packages and names.
- Change the appearance of look-alike drug names on order entry screens and alter the sequence of the products so that look-alike names are not right next to each other on the screen.
- Apply uppercase lettering to different portions of drug names of drugs with similar names.

Improving drug administration

- Check the patient's identity.
- Ensure that dosage calculations are checked independently by another health care professional before the drug is administered.
- Ensure that the prescription, drug, and patient are in the same place in order that they may be checked against one another.
- Ensure the medication is given at the correct time.
- Minimize interruptions during drug rounds.

Correcting systems flaws that predispose to error

- Introduce a system to identify and record information about medication errors.
- Where feasible, institute pharmacy-based admixture of IV fluids. If ward personnel must perform IV admixture, there should be clear written procedures and skills certification of the personnel.
- Develop special procedures for high-risk drugs. These procedures should include written guidelines, checklists, and educational materials.
- When preparing to administer a medication, confirm the identity of the patient by reading the patient's wristband and talking to the patient or family member.
- To minimize the likelihood that a dose will be missed, standardize administration times and develop a policy to provide doses when a patient is off the floor.
- Analyze medicine names as new products are added to the formulary. For look-alike and sound-alike names, establish a policy requiring that prescribers write both brand and generic name.
- Use pharmacy staff effectively to monitor and manage medicine use and distribution.

Activity	Time (Min)
Ask students to review the causes to determine three of the causes that are the easiest to deal with and will have the greatest impact on reducing medication error at the least cost. Ask a few students to share their choices and the reasons for their choices. Confirm or refute their responses.	10
Show Ref. 061 “What you can do to avoid medication errors” as a reminder that patients can play an important role in reducing medication error, too.	2
<p>Ask the students to vote by show of hands</p> <p>Which is better?</p> <ul style="list-style-type: none"> • 150 microgram of clonidine — OR— 15 mg • 0.25 mg of digoxin —OR— 250 microgram • 1 mg atropine —OR— 1.0 mg • .5 mg atropine —OR— 0.5 mg atropine <p>If time permits, ask students to identify what error might occur if the better choice is not used.</p> <p>(Source: Ref. 057, slide 45)</p>	5
<p>Ask students to interpret the following dates:</p> <ul style="list-style-type: none"> • Expiry date 12 09 04 • Expiry date 09 12 04 • Expiry date 25 09 04 <p>Stress the importance of using unambiguous dates. In the example above, it is easy to confuse December 9, 2004 with September 12, 2004.</p>	3
<p>Case Study</p> <p>If time permits, discuss case study from Ref. 069 highlighting a potentially fatal error associated with a morphine pump.</p>	
<p>Case Study</p> <p>If time permits, discuss case study from Ref. 067 describing using technology to reduce medication error.</p> <p>The Physician order entry (POE) at Brigham and Women’s Hospital. This computerized medication order entry system has the potential to prevent an estimated 84 % of dose, frequency, and route errors. Such a system eliminates illegible orders that lead to medication errors. Also, because the system requires the name of the medication, dosage, route, and frequency of administration to be entered, errors that arise from omission of critical information are eliminated. Programmed within the system are algorithms that check dosage frequency, medication interactions, and patient allergies. Once an order is entered, this computerized system also provides physicians with information about the consequences of therapy, benefits, risks, and contraindications.</p>	

Sources used in this session:

- Ref. 056 Moore, N. Medication Errors. Training Course in Pharmacovigilance. Hanoi. [PowerPoint slides]. Dec. 2010.
- Ref. 057 Hartigan-Go, K. Patient Safety & Medication Errors *International Society of Pharmacovigilance (ISoP)*. [PowerPoint slides]. 2009.
- Ref. 059 Rational Pharmaceutical Management Plus, Center for Pharmaceutical Management, & Management Sciences for Health. *Drug and Therapeutics Committee Training Course, Session 4, Assessing and Managing Medicine Safety: Participants' Guide*. 2007.
- Ref. 060 Institute for Safe Medication Practices Canada. Top 10 Drugs Reported as Causing Harm through Medication Error. *ISMP Canada Safety Bulletin*, 6.1 (Feb. 2006).
- Ref. 061 Institute of Medicine of the National Academies. What You Can Do To Avoid Medication Errors. *Fact Sheet*. Jul. 2006.
- Ref. 062 Institute of Medicine of the National Academies. Preventing Medication Errors. *Report Brief*. Jul. 2006.
- Ref. 063 Federal Ministry of Health, Nigeria. *Safety of Medicines in Nigeria; National Pharmacovigilance Training Curriculum: Medication Errors and Patient Safety* [PowerPoint slides]. Jan. 2011.
- Ref. 064 Institution for Safe Medication Practices. *Frequently Asked Questions (FAQ)*. Web.
- Ref. 065 Williams, D.J.P. Medication Errors. *J R Coll Physicians Edinb*, 37 (Jul 2007):343–346.
- Ref. 066 Olsson, S. *Current trends in pharmacovigilance – a global perspective*. WHO Collaborating Centre for International Drug Monitoring. [PowerPoint slides]. Web. 2005.
- Ref. 067 Agency for Healthcare Research and Quality. Reducing and Preventing Adverse Drug Events To Decrease Hospital Costs. Web. Mar 2001.
- Ref. 069 U.S. Food and Drug Administration. Strategies to Reduce Medication Errors: Working to Improve Medication Safety. Web. Last Updated: 12 Aug. 2011.
- Ref. 070 Grissinger, M. *Avoiding Medication Errors with Insulin Therapy*. May 2010.

Additional Reading and Resources:

- Ref. 058 Hartigan-Go, K. *Principles and Mechanisms of ADR* International Society of Pharmacovigilance (ISoP). [PowerPoint slides]. Dec. 2009.
- Ref. 068 U.S. Food and Drug Administration. Preventable Adverse Drug Reactions: A Focus on Drug Interactions. Web. Last Updated: 30 Apr 2009.

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