

# Technical Assistance for the Development of Pre-service and In-service Pharmacovigilance Curriculum at the Hanoi University of Pharmacy in Vietnam

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## **About SPS**

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

## **ABSTRACT**

*Practical issues relating to pharmacovigilance (PV) often receive limited coverage in health professional training curricula at both pre- and in-service levels. Substantive and sustainable progress in the pharmacovigilance front to improve patient outcomes can only be achieved when current as well as future health care providers are adequately trained to use medicines not only “effectively” but also “safely.” In this context, the Hanoi University of Pharmacy (HUP) authorities in Vietnam expressed to the USAID-supported Strengthening Pharmaceutical Systems (SPS) Program of MSH that the University had a strong interest to ensure adequate coverage of PV topics at both pre- and in-service levels, and requested SPS to help support this process. Based on this request, SPS worked with the National Drug Information and Adverse Drug Reaction Monitoring Center (DI & ADR Center) to develop a detailed curriculum for in-service training, and with HUP’s Clinical Pharmacy Department to develop a similarly detailed curriculum for pre-service training at post-graduate pharmacy level. Both these draft curricula were reviewed by a wide group of stakeholders during a curriculum review meeting held at HUP in August 2011. This technical report briefly describes the process and includes the products of this curriculum-related SPS technical assistance.*

## **Recommended Citation**

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## ACRONYMS

ADE	Adverse drug event
ADR	Adverse drug reaction
AEFI	Adverse event following immunization
ART	Antiretroviral therapy
DAV	Drug Administration of Vietnam
DI & ADR Center	National Drug Information and Adverse Drug Reaction Monitoring Center
DIU	Drug Information Unit
DTC	Drug and Therapeutics Committee
EU	European Union
FDA	Food and Drug Administration
HCPs	Health care professionals
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
HSS	Health systems strengthening
HUP	Hanoi University of Pharmacy
IEC/BCC	Information, Education, Communication/ Behavior Change Communication
MOH	Ministry of Health
MSA	Medical Services Administration
NMCP	National Malaria Control Program
NTP	National TB Control Program
OSPE	Objective Structured Practical Examination
PBL	Problem-based learning
PHP	Public health program
PMS	Post-marketing surveillance
PV	Pharmacovigilance
QA	Question-answer
RPM Plus	Rational Pharmaceutical Management Plus Program [MSH]
SAQs	Short-answer questions
SE	Side effect
SPS	Strengthening Pharmaceutical Systems Program [MSH]
TB	Tuberculosis
TOT	Training of trainers
VAAC	Vietnam Administration of AIDS Control
WHO	World Health Organization

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## BACKGROUND

Pharmacovigilance (PV) is defined as the science and activities related to the detection, assessment, understanding and prevention of medicines related problems. According to the World Health Organization (WHO), adverse drug reactions (ADR) are a common, yet often preventable, cause of illness, disability and death. In some countries, ADR ranks among the top 10 leading causes of mortality. In recent years, the scope of pharmacovigilance has slowly broadened from its traditional approach of focusing mainly on adverse drug reactions to one that includes additional critical issues such as medication errors, product quality, and treatment failure.

Pharmacovigilance is an over-arching issue that is related with medicines regulation systems, clinical practice and public health programs. Public health programs and other stakeholders of resource-constrained countries as well as donors and development partners are thus increasingly laying strong emphasis on the need to conduct pharmacovigilance activities in a systematic, coordinated and organized manner to enhance safe use of medicines. The issue has now become especially urgent due to a big increase in the availability and use of new essential medicines such as artemisinin combination therapies (ACTs), antiretroviral (ARV) medicines, and reserve drugs for the treatment of tuberculosis (TB) in many countries as a result of multiple global health initiatives.

The Ministry of Health (MOH) and other key stakeholders in Vietnam are strengthening the PV system in their country. A major step was taken when the National Drug Information and Adverse Drug Reaction (DI & ADR) Center was established at the Hanoi University of Pharmacy (HUP) in 2009. Management Sciences for Health's Strengthening Pharmaceutical Systems (SPS) Program and its predecessor, Rational Pharmaceutical Management Plus (RPM Plus) Program, collaborated with the national stakeholders in Vietnam to support this process, particularly focusing on activities that strengthen broader pharmacovigilance systems. RPM Plus provided technical assistance in 2009 to hold a consensus meeting which developed a pharmacovigilance framework for Vietnam that included active surveillance as a key element. It also supported training-of-trainers on pharmacovigilance for staff members from public health programs and other key local stakeholders.

The SPS Program built on these efforts and provided further technical support in 2010 and 2011 to the MOH's DI & ADR Center, and Vietnam Administration of AIDS Control (VAAC) in carrying out the following activities —

- Including a pharmacovigilance component in the Global Fund Round 10 application. WHO and SPS provided technical assistance to the national counterparts in conceptualizing and developing this component.
- Training DI & ADR Center staff on drug information and pharmacovigilance, including development of standard operating procedures, question-answer forms for drug information service, and revision of the spontaneous reporting form.

- Conducting ‘Training and Workshop on Strengthening the Network for Safety of Medicines and Pharmacovigilance’ in Vietnam. SPS collaborated with WHO and the University of Bordeaux (Bordeaux, France) to provide technical support to MOH/HUP/DI & ADR Center to conduct this event.
- Developing a framework and protocol for sentinel site-based pilot active surveillance pharmacovigilance within the antiretroviral therapy (ART) program, developing ADR database for ART sentinel sites and the DI&ADR Center, and conducting a hands-on training of trainers (TOT) for 39 national stakeholders involved in the active surveillance program.

## SPS TECHNICAL ASSISTANCE FOR CURRICULUM REFORM ON PHARMACOVIGILANCE

Adequate, up-to-date, and locally relevant pre-service as well as in-service trainings are critical to develop and maintain appropriate professional competencies. Training curricula are dynamic documents that require periodic review and reform in order to accommodate changing needs and professional competencies. Practical issues relating to pharmacovigilance often receive limited coverage in health professional training curricula at both pre- and in-service levels. Substantive and sustainable progress in the pharmacovigilance front to improve patient outcomes can only be achieved when future as well as current health care providers are adequately trained to use medicines not only “effectively” but also “safely.”

In this context, the Hanoi University of Pharmacy (HUP) authorities expressed to SPS that the University had a strong interest to ensure adequate coverage of PV topics at both pre- and in-service levels, and requested SPS to help support this process. Based on this request, SPS worked with the HUP’s Clinical Pharmacy Department and the National DI & ADR Center to reform PV curricula for both pre- and in-service trainings.

SPS started collaboration for this task by working with HUP to identify the key contact persons to catalyze the process of review and reform. SPS then worked with these contact persons at HUP Clinical Pharmacy Department and the DI & ADR Center to review the existing university curriculum in order to identify what was included relating to PV and to determine the actual content being covered, the hours of exposure, and the teaching-learning methods used.

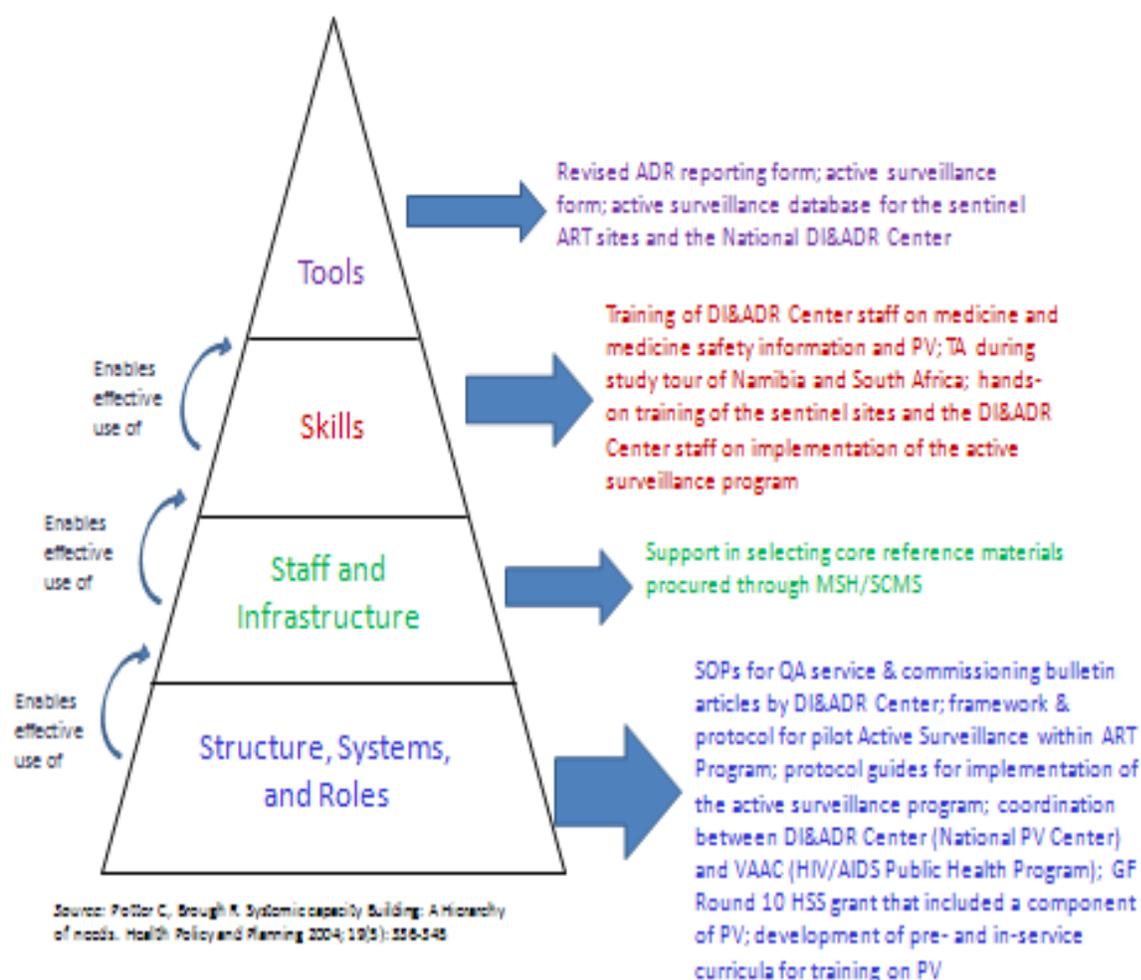
Following this initial work, SPS technical staff Mohan Joshi visited Hanoi from August 10 to 20, 2011 to help achieve additional progress on the activity. The specific tasks completed during Dr. Joshi’s visit were:

- Further review of the draft mapping of the existing PV curriculum prepared by HUP Clinical Pharmacy Department (for pre-service training at post-graduate pharmacy level) and the DI&ADR Center (for in-service training of health care professionals)
- Identification of currently relevant competencies through discussions with the HUP and DI&ADR Center staff and review of PV training curricula available from elsewhere
- Identification of the gaps or deficiencies in the existing curriculum that would need to be filled
- Development of the draft pre-service and in-service curricula in collaboration with HUP’s Clinical Pharmacy Department and the DI & ADR Center staff. See *Annex 1* for the pre-service curriculum, and *Annex 2* for the in-service one.
- A wider review of the draft of both pre- and in-service PV curricula at a half-day meeting with other key local stakeholders. *Annex 3* gives the list of participants. The meeting was organized by HUP with technical support from SPS. Vietnamese translations of the curricula

were provided to the participants of this review meeting. *Annex 4* includes the presentation made by Dr. Joshi during the meeting.

## SYSTEMIC CAPACITY-BUILDING ACHIEVED THROUGH SPS SUPPORT

USAID places strong focus on local capacity-building and health systems strengthening (HSS) to help host countries achieve sustainable improvements. To support this USAID goal, SPS takes deliberate care to help build lasting local capacity while collaborating with in-country organizations and stakeholders. Although some use the term “capacity-building” as interchangeable with “training,” at MSH/SPS, we see training as only one facet of helping to achieve greater health impact. SPS supported *systemic capacity-building* in pharmacovigilance in Vietnam by doing not only trainings but also various other system-strengthening activities, as depicted in *Figure 1* below.



**Figure 1: Systemic Capacity for PV in Vietnam: Activities Facilitated by MSH/SPS**

## **NEXT STEPS**

The national stakeholders have requested SPS to assist with the development of an instructor's guide to help implement this newly reformed curriculum. SPS is currently preparing such a guide, and will make a technical assistance visit to Hanoi to go over the guide with the HUP stakeholders in the first quarter of 2012. SPS will then finalize the guide by making necessary changes based on the feedback and deliver it to HUP to help facilitate implementation of the PV curricula.

## ANNEX 1. RENEWAL OF THE PHARMACOVIGILANCE CURRICULUM FOR TRAINING OF POST-GRADUATE PHARMACY STUDENTS AT HANOI UNIVERSITY OF PHARMACY – CURRICULUM MAPPING AND REVISION

Existing curriculum		Gaps/ deficiencies/ redundancies / need for modifications	Recommended revised curriculum		
Topic covered	Contact time		Suggested topic areas	Suggested contact time	Key behavioral objectives
<b>1. Overview of PV and Medication Safety</b>					
<ul style="list-style-type: none"> <li>• Definition of PV</li> <li>• History of PV</li> <li>• Goals of PV (rational medicine use, communication of risk and benefit of medicines, health worker and patient education)</li> <li>• Widening scopes of PV—adverse drug reaction (ADR), medication error, product quality, therapeutic ineffectiveness</li> <li>• PV of herbal medicines</li> </ul>	100 min	<ul style="list-style-type: none"> <li>• Need and importance of PV (burden of ADRs; morbidity and mortality, cost burden of ADRs, benefits of PV.</li> <li>• clinical trials of medicines and post-marketing surveillance, and how PV fits in all these steps (life-cycle approach)</li> <li>• PV information influencing medicines policy and regulation: recall, labeling changes, reschedule withdrawal, policy change.</li> </ul>	<b>1.1. General Overview of PV and Medication safety</b> <ul style="list-style-type: none"> <li>• Definition of PV</li> <li>• Brief history of PV</li> <li>• Goals of PV (rational medicine use, communication of risk and benefit of medicines, health worker and patient education)</li> <li>• Widening scopes of PV—adverse drug reaction (ADR), medication error, product quality, therapeutic ineffectiveness</li> <li>• Brief overview of the need and importance of PV (burden of ADRs; morbidity and mortality, cost burden of ADRs, benefits of PV.</li> <li>• 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)</li> <li>• Brief introduction on how PV information can influence medicines policy and regulation: recall, labeling changes, reschedule withdrawal, policy change.</li> </ul>	100 min	At the end this session, the student will be able to: <ul style="list-style-type: none"> <li>-define PV and emphasize that its scope includes not only ADRs but also medication errors, product quality issues, and therapeutic ineffectiveness</li> <li>- explain the burden and impact of adverse drug events (ADE) and use this context to articulate the need to support PV activities</li> <li>- link PV as a key ingredient to achieving the broader goals of rational medicine use and pharmaceutical care</li> <li>- emphasize that monitoring the safety of a medicine is an ongoing process, and needs to happen both during pre-marketing and post-marketing periods</li> <li>- tell how PV information provides evidence for and influences regulatory decision, giving one example of such a decision taken by drug regulatory authority</li> </ul>
		<ul style="list-style-type: none"> <li>• Brief overview of the problems of drug overuse and misuse in Vietnam; safety issues with traditional and</li> </ul>	<b>1.2. PV Program in Vietnam and in the world</b> <ul style="list-style-type: none"> <li>• Brief overview of the problems of drug overuse and misuse in Vietnam; safety issues with traditional and herbal</li> </ul>	50 min	At the end this session, the student will be able to: <ul style="list-style-type: none"> <li>- Describe the legal basis of PV activities in Vietnam</li> <li>-List the key national stakeholders</li> </ul>

Existing curriculum		Gaps/ deficiencies/ redundancies / need for modifications	Recommended revised curriculum		
Topic covered	Contact time		Suggested topic areas	Suggested contact time	Key behavioral objectives
		herbal medicines in Vietnam; weaknesses of the health care system regarding medicine safety activities <ul style="list-style-type: none"> <li>• Overview of the legal basis for PV system and framework of the PV system in Vietnam</li> <li>• PV roles and activities the Ministry of Health (MOH), especially the National DI&amp;ADR Center, Drug Administration of Vietnam (DAV), and Medical Services Administration (MSA) of Vietnam</li> </ul>	medicines in Vietnam; weaknesses of the health care system regarding medicine safety activities <ul style="list-style-type: none"> <li>• Overview of the legal basis for PV system and framework of the PV system in Vietnam</li> <li>• PV roles and activities the Ministry of Health (MOH), especially the National DI&amp;ADR Center, Drug Administration of Vietnam (DAV), and Medical Services Administration (MSA) of Vietnam</li> <li>• Brief overview of PV management model of WHO, FDA, and EU</li> </ul>		with regard to PV in Vietnam <ul style="list-style-type: none"> <li>- Briefly describe PV management model of WHO, FDA and EU</li> </ul>
			<b>1.3. PV of herbal medicines in Vietnam and in the world</b> <ul style="list-style-type: none"> <li>• Brief overview of the issues with PV of herbal medicines in Vietnam</li> <li>• Brief overview of the issues with PV of herbal medicines in other countries of the world</li> </ul>	50 min	<ul style="list-style-type: none"> <li>- Describe the key problems and clinically significant toxicities associated with the use of herbal and traditional medicines in Vietnam</li> </ul>
<b>2. Risk Identification</b>					
• Definition: Adverse drug reactions (ADR), adverse drug event (ADE), Side effect (SE), post marketing surveillance (PMS), and other PV-related	100 min		<b>2.1. Adverse Drug Reaction as a Factor for Adverse Drug Event:</b> <ul style="list-style-type: none"> <li>• Definition: Adverse drug reactions (ADR), adverse drug event (ADE), Side effect (SE), post marketing surveillance (PMS), and other PV-related terminologies</li> <li>• Classification and mechanism of ADRs (e.g., Type A and B and others;</li> </ul>	100 min	At the end this session, the student will be able to: <ul style="list-style-type: none"> <li>-Define the various terms related to PV</li> <li>- Differentiate the various types of ADRs</li> <li>- List predisposing factor for ADRs, giving at least one example for each factor (age,</li> </ul>

*Annex 1. Renewal of the Pharmacovigilance (PV) Curriculum for Training of Post-graduate Pharmacy Students at Hanoi University of Pharmacy – Curriculum Mapping and Revision*

Existing curriculum		Gaps/ deficiencies/ redundancies / need for modifications	Recommended revised curriculum		
Topic covered	Contact time		Suggested topic areas	Suggested contact time	Key behavioral objectives
terminologies • Classification 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 • Method of assessing causality of ADRs			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		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
		• Burden of medication error; causes of medication error; • Common problem-prone areas with regard to medication errors • Approaches to prevent medication errors	<b>2.2. Medication Error as a Factor for Adverse Drug Events</b> • Burden of medication error; causes of medication error; • Overview of common problem-prone areas with regard to medication errors • Approaches to prevent medication errors	35 min	At the end this session, the student 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
		• Burden of substandard and counterfeit products, and the impact of low	<b>2.3. Other Factors for Adverse Drug Events</b> • Brief overview of the burden of	15 min	At the end this session, the student will be able to: - Briefly describe the burden of

Existing curriculum		Gaps/ deficiencies/ redundancies / need for modifications	Recommended revised curriculum		
Topic covered	Contact time		Suggested topic areas	Suggested contact time	Key behavioral objectives
		quality medicines • Therapeutic ineffectiveness and the factors contributing to it, including drug resistance	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		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
		• Assessing severity of ADRs (mild, moderate, severe, fatal)	<b>2.4. Adverse Drug Events: Assessment of Severity and Causality</b> • Assessing severity of ADRs (mild, moderate, severe, fatal) • Method of assessing causality of ADRs: WHO-UMC scale and Narainjo Algorithm	50 min	At the end this session, the student will be able to: - Distinguish ADRs of various severity (mild, moderate, severe and fatal) - Briefly explain the WHO-UMC scale and Narainjo Algorithm for assessing causality of ADRs
<b>3. Risk Evaluation and Reporting</b>					
• 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	300 min	<del>Delete</del> statistical methods with regard to assessing causality	<b>3.1. Passive and Active Methods of Surveillance</b> • 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,	200 min	At the end this session, the student will be able to: - 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

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Topic covered	Contact time		Suggested topic areas	Suggested contact time	Key behavioral objectives
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			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)		understanding by telling that spontaneous reporting and active surveillance approaches are complementary methods - Describe strategies to improve ADE reporting
<b>4. Risk Communication, Risk Management, and Risk Minimization</b>					
• PV communications to healthcare professionals and in public healthcare mission • Principles and methods of risk-benefit assessment	150 min	• The Erice Declaration on effective communication • Role of the National DI&ADR Center, DAV, hospital DTCs and DIUs and other stakeholders in communicating medicine safety information; relevant	<b>4.1. Strategies to improve risk communications, and principles of risk management and risk minimization</b> • 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	150 min	At the end this session, the student will be able to: - 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

Existing curriculum		Gaps/ deficiencies/ redundancies / need for modifications	Recommended revised curriculum		
Topic covered	Contact time		Suggested topic areas	Suggested contact time	Key behavioral objectives
		circulars from MOH relating to such roles for key MOH bodies <ul style="list-style-type: none"> <li>• Examples from other countries and organization on communicating messages about medicine safety</li> <li>• Examples from other countries and organizations regarding strategies and tools for risk management and minimization</li> </ul>	stakeholders in communicating medicine safety information; relevant circulars from MOH relating to such roles for key MOH bodies <ul style="list-style-type: none"> <li>• 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)</li> <li>• Selected examples from other countries and organizations regarding strategies and tools for risk management and minimization</li> </ul>		countries or organizations to promote and support risk communication, management and minimization <ul style="list-style-type: none"> <li>- 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</li> </ul>
<b>5. Pharmacovigilance in public health programs</b>					
Implementing PV in public health care	30 min	<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> <ul style="list-style-type: none"> <li>• Importance of PV in public health programs (PHPs); strengths, challenges and mutual benefits</li> <li>• Epidemiology of adverse events and drug-related morbidity and mortality in PHPs (HIV/AIDS, TB, Malaria, Immunization); problem of treatment failure in PHPs</li> </ul>	<b>5.1. Importance of PV in PHPs, burden of ADEs in PHPs, strategies to improve adverse events reports in PHPs</b> <ul style="list-style-type: none"> <li>• Importance of PV in PHPs (HIV/AIDS, TB, Malaria, Immunization): strengths, challenges and mutual benefits</li> <li>• Epidemiology of adverse events and drug-related morbidity and mortality in PHPs (HIV/AIDS, TB, Malaria, Immunization); problem of treatment failure in PHPs</li> <li>• Improving adverse event reporting within PHPs (HIV/AIDS, TB, Malaria, Immunization)</li> </ul>	50 min	At the end this session, the student will be able to: <ul style="list-style-type: none"> <li>- 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</li> <li>- Show awareness of the significant problem of ADEs in PHPs by describing the burdens of ADRs and treatment failures</li> <li>- Describe locally feasible measures that can help improve adverse event reporting within PHPs</li> </ul>

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Topic covered	Contact time		Suggested topic areas	Suggested contact time	Key behavioral objectives
		<ul style="list-style-type: none"> <li>Improving adverse event reporting within PHPs (HIV/AIDS, TB, Malaria, Immunization)</li> </ul>			

### Seminars, assessment and teaching-learning methods

Area	Existing curriculum	Recommended curriculum
<b>Seminar topic (and contact hours)</b>	<ul style="list-style-type: none"> <li>Spontaneous reporting (200 min)</li> <li>Causality assessment (200 min)</li> <li>Risk management (200 min)</li> </ul>	<ul style="list-style-type: none"> <li>Spontaneous reporting (200 min)</li> <li>Causality assessment (200 min)</li> <li>Risk management and risk minimization (200 min)</li> </ul>
<b>Assessment</b>	<ul style="list-style-type: none"> <li>Seminar-related and in-class tests (approx. 30% of the final score) – group discussion followed by individual student reporting</li> <li>Final test after the completion of 16-hr theory and seminars (approx. 70% of final score) – short answer questions or SAQs</li> </ul>	<p>Keep multiple and flexible options for student assessments, including objectively structured tests.</p> <ul style="list-style-type: none"> <li>Seminar-related and in-class tests – group discussion followed by individual student reporting; SAQs, multiple choice questions (MCQs), true and false (T/F) questions, objectively structured practical examination (OSPE)</li> <li>Final test – Short report writing assignments, SAQs</li> </ul>
<b>Learning Experiences (Teaching-Learning Methodologies)</b>	<ul style="list-style-type: none"> <li>Large group teaching (# of students – 80 to 100) – Lectures</li> <li>Seminars (# of students &lt; 20) – Group discussions</li> </ul>	<ul style="list-style-type: none"> <li>Large group teaching (# of students – 80 to 100) – PowerPoint presentations, lectures</li> <li>Seminars (# of students &lt; 20) – Brainstorming, interactive discussions, problem-based learning (PBL), group work and presentation, video clips</li> </ul>

## ANNEX 2. PHARMACOVIGILANCE CURRICULUM FOR TRAINING OF HEALTH CARE PROFESSIONALS (IN-SERVICE TRAINING) IN VIETNAM

Module	Key Topic Areas	Outline of the Key Contents for Each Key Topic Area	Key Behavioral Objectives	Instructional Methods (Teaching-Learning Methods)	Contact period
Module 1: Overview of PV and Medication Safety	<p><b>1.1. General Overview of PV and Medication safety</b></p> <p>1.1.1. Definition and History of PV and medication safety</p> <p>1.1.2. The importance of PV and medication safety</p> <p>1.1.3. PV information for regulatory actions and decisions</p>	<ul style="list-style-type: none"> <li>• Definition of PV</li> <li>• History of PV</li> <li>• Goals of PV (rational medicine use, communication of risk and benefit of medicines, health worker and patient education)</li> <li>• Widening scopes of PV—adverse drug reaction (ADR), medication error, product quality, therapeutic ineffectiveness</li> <li>• Need and importance of PV (burden of ADRs; morbidity and mortality, cost burden of ADRs, benefits of PV.</li> <li>• Various phases of clinical trials of medicines and post-marketing surveillance, and how PV fits in all these steps (life-cycle approach)</li> <li>• PV information influencing medicines policy and regulation: recall, labeling changes, reschedule withdrawal, policy change.</li> </ul>	<p>At the end this session, the participant will be able to:</p> <ul style="list-style-type: none"> <li>-define PV and emphasize that its scope includes not only ADRs but also medication errors, product quality issues, and therapeutic ineffectiveness</li> <li>- explain the burden and impact of adverse drug events (ADE) and use this context to articulate the need to support PV activities</li> <li>- link PV as a key ingredient to achieving the broader goals of rational medicine use and pharmaceutical care</li> <li>- emphasize that monitoring the safety of a medicine is an ongoing process, and needs to happen both during pre-marketing and post-marketing periods</li> <li>- tell how PV information provides evidence for and influences regulatory decision, giving one example of such a decision taken by drug regulatory authority</li> </ul>	<ul style="list-style-type: none"> <li>- Brainstorming</li> <li>- PowerPoint slides</li> <li>- Show pictures of thalidomide babies while discussing the brief history of PV</li> <li>- Interactive mini-lecture</li> <li>- Video clip</li> <li>- Flash rosiglitazone removal circular from DAV and any newspaper clipping related to this removal</li> <li>- Similarly, show the circular related to removal of the brand product, “Duxil”</li> </ul>	90 minutes
	<p><b>1.2. PV Program in Vietnam</b></p> <p>1.2.1. Overuse and misuse of drugs</p> <p>1.2.2. Legal basis of PV activities in Vietnam</p> <p>1.2.3. The</p>	<ul style="list-style-type: none"> <li>• 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</li> <li>• Overview of the legal basis for PV system and framework of the PV system in Vietnam</li> <li>• PV roles and activities the Ministry</li> </ul>	<p>At the end this session, the participant will be able to:</p> <ul style="list-style-type: none"> <li>- Describe the legal basis of PV activities in Vietnam</li> <li>-List the key national stakeholders with regard to PV in Vietnam</li> <li>- Analyze and explain how these stakeholders are interlinked for an effective and coordinated PV “system” in Vietnam</li> <li>- Articulate how and in what roles</li> </ul>	<ul style="list-style-type: none"> <li>- Brainstorming</li> <li>- PowerPoint slides</li> <li>- Interactive mini-lecture</li> <li>- Graphic presentation of who the national PV stakeholders are and how they are linked</li> <li>- Show legal document, decrees relating to PV</li> <li>- Slides of adverse events caused by herbal</li> </ul>	90 minutes

*Annex 2. Pharmacovigilance (PV) Curriculum for Training of Health Care Professionals (In-service Training) in Vietnam*

<b>Module</b>	<b>Key Topic Areas</b>	<b>Outline of the Key Contents for Each Key Topic Area</b>	<b>Key Behavioral Objectives</b>	<b>Instructional Methods (Teaching-Learning Methods)</b>	<b>Contact period</b>
	framework of the PV system in Vietnam 1.2.4. Roles of MOH bodies, hospitals and other stakeholders 1.2.5. PV of herbal medicines used in Vietnam 1.2.6. Setting up PV programs in hospitals	of Health (MOH), especially the National DI&ADR Center, Drug Administration of Vietnam (DAV), and Medical Services Administration (MSA) of Vietnam • Other PV stakeholders in Vietnam, including hospitals (and their DTCs and DIUs) • Importance of stakeholder coordination and collaboration for conducting PV activities effectively • Role of hospitals, including Drug & Therapeutics Committees (DTCs) and Drug Information Unit (DIU), in promoting PV and medicine safety in Vietnam • Minimum requirements for setting up PV programs in hospitals in Vietnam	his/her hospital (including its DTC and DIU) fits as a stakeholder in the overall PV system in Vietnam - Describe the key problems and clinically significant toxicities associated with the use of herbal and traditional medicines in Vietnam - Describe the “basic minimum requirements” for setting up a PV program in his/her hospital	or traditional products - Display of real examples of PV-related activities or initiatives carried out by hospitals or their DTCs in Vietnam (if available) - Brainstorming on “basic minimum requirements” for setting up PV programs in Vietnam hospitals	

Module	Key Topic Areas	Outline of the Key Contents for Each Key Topic Area	Key Behavioral Objectives	Instructional Methods (Teaching-Learning Methods)	Contact period
Module 2: Risk Identification	<p><b>2.1. Adverse Drug Reaction as a Factor for Adverse Drug Event:</b></p> <p>2.1.1. Definition of PV-related terminologies</p> <p>2.1.2. Classification of ADRs</p> <p>2.1.3. Risk factors for ADRs</p> <p>2.1.4. ADRs in selected organ-system classes</p> <p>2.1.5. Key strategies to prevent ADRs</p>	<ul style="list-style-type: none"> <li>• Definition: Adverse drug reactions (ADR), adverse drug event (ADE), Side effect (SE), post marketing surveillance (PMS), and other PV-related terminologies</li> <li>• Classification of ADRs (e.g., Type A and B and others; immediate, delayed etc),</li> <li>• 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</li> <li>• Brief overview and listing of organ-system-based ADRs of <i>major clinical significance</i> (e.g., dermatological, gastrointestinal, hematological, hepatic, renal, and ocular)</li> <li>• Brief overview of strategies that minimize the occurrence or early detection of ADRs</li> </ul>	<p>At the end this session, the participant will be able to:</p> <ul style="list-style-type: none"> <li>-Define the various terms related to PV</li> <li>- Differentiate the various types of ADRs</li> <li>- Enumerate three ADRs of high clinical significance for each organ system</li> <li>- 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)</li> <li>- 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</li> <li>- Discuss ongoing or potential strategies feasible in his/her hospital setting that could help minimize or prevent the risk of ADRs</li> <li>- Narrate self-perception of his/her role in minimizing or preventing ADRs in his or her own hospital practice setting</li> </ul>	<ul style="list-style-type: none"> <li>- PowerPoint slides</li> <li>- Mini-lecture</li> <li>- Handout of the PV terminologies and their definitions</li> <li>- Brief interactive discussion on the participants' experiences regarding organ system related ADRs</li> <li>- Handout of a list of organ system-based ADRs of "major clinical significance"</li> <li>- Slides or video clips of teratogenic effects</li> </ul>	75 minutes

<b>Module</b>	<b>Key Topic Areas</b>	<b>Outline of the Key Contents for Each Key Topic Area</b>	<b>Key Behavioral Objectives</b>	<b>Instructional Methods (Teaching-Learning Methods)</b>	<b>Contact period</b>
	<p><b>2.2. Medication Error as a Factor for Adverse Drug Events</b>                      2.2.1. Definition Causes, and Prevention of Medication Error</p>	<ul style="list-style-type: none"> <li>• Burden of medication error; causes of medication error;</li> <li>• Overview of common problem-prone areas with regard to medication errors</li> <li>• Approaches to prevent medication errors</li> </ul>	<ul style="list-style-type: none"> <li>- Highlight, with some international data, the burden of medication error in hospitals</li> <li>- Analyze how system weakness contributes to medication errors in hospitals</li> <li>- Demonstrate awareness of the problems of medication error as also being PV issue (not just ADRs) and narrate how this issue directly impacts his/her professional practice and ability to provide “safe” care to their patients</li> <li>- Citing real examples, highlight key strategies, tools or interventions that can be used to prevent medication errors</li> <li>- Narrate self-perception of his/her role in minimizing or preventing medication errors in his or her own hospital practice setting</li> </ul>	<ul style="list-style-type: none"> <li>- Interactive mini-lecture</li> <li>- PowerPoint slides</li> <li>- Discussion of real examples of medication errors; brainstorming for causes of medication errors in hospital setting</li> <li>- Display and briefly discuss real examples of strategies and tools used locally in Vietnam or in other countries to help prevent or minimize medication errors</li> </ul>	45 minutes

<b>Module</b>	<b>Key Topic Areas</b>	<b>Outline of the Key Contents for Each Key Topic Area</b>	<b>Key Behavioral Objectives</b>	<b>Instructional Methods (Teaching-Learning Methods)</b>	<b>Contact period</b>
	<p><b>2.3. Other Factors for Adverse Drug Events</b></p> <p>2.3.1. Product Quality Problem</p> <p>2.3.2. Therapeutic Ineffectiveness</p>	<ul style="list-style-type: none"> <li>• Brief overview of the burden of substandard and counterfeit products, and the impact of low quality medicines</li> <li>• Brief overview of therapeutic ineffectiveness and the factors contributing to it, including drug resistance</li> </ul>	<ul style="list-style-type: none"> <li>- Demonstrate awareness of the problems of poor product quality and therapeutic ineffectiveness as also being PV issues (not just ADRs and medication errors) and narrate how these issues directly impact their professional practice and their abilities to provide “safe” and “effective” care to their patients</li> <li>- Differentiate drug “efficacy” (in clinical trial settings) from “effectiveness” (during use in the real world)</li> <li>- Articulate that appropriate record-keeping of the burden of treatment failure can inform subsequent revision of the national guidelines</li> </ul>	<ul style="list-style-type: none"> <li>- Brief discussion on the burden sub-standard and counterfeit products, citing some real local and international examples</li> <li>- Slides or pictures of counterfeit or poor quality products</li> <li>- Brief discussion on the issues of treatment failure in the public health programs such as HIV/AIDS, TB, and malaria</li> </ul>	30 minutes
	<p><b>2.4. Adverse Drug Events: Assessment of Severity and Causality, and Prevention in Day-to-Day Practice</b></p> <p>2.4.1. Severity of adverse drug reactions</p> <p>2.4.2. Assessing causality of ADRs</p>	<ul style="list-style-type: none"> <li>• Assessing severity of ADRs (mild, moderate, severe, fatal)</li> <li>• Method of assessing causality of ADRs: WHO-UMC scales.</li> </ul>	<p>At the end this session, the participant will be able to:</p> <ul style="list-style-type: none"> <li>- Based on presentations and findings in a patient, demonstrate ability to evaluate and classify the severity of ADR</li> <li>- Demonstrate competence to practically apply the WHO-UMC causality scale and assess causality of a reported ADR</li> </ul>	<ul style="list-style-type: none"> <li>- PowerPoint presentation</li> <li>- Interactive mini-lecture</li> <li>- Brainstorming</li> <li>- Display of examples of real educational materials or tools developed and used in hospital settings for preventing or minimizing ADRs and medication errors</li> <li>- Demonstration of the causality assessment of a real case, followed by opportunity to practice on other cases in small groups</li> </ul>	120 minutes

Module	Key Topic Areas	Outline of the Key Contents for Each Key Topic Area	Key Behavioral Objectives	Instructional Methods (Teaching-Learning Methods)	Contact period
<b>Module 3: Risk Evaluation and Reporting</b>	3.1.1. Sources of data relating to adverse drug events (ADEs) 3.1.2. Passive surveillance methods (spontaneous reporting) 3.1.3. Active surveillance methods	<ul style="list-style-type: none"> <li>• Sources of ADE data: premarket safety data, spontaneous reports, Phase IV studies, scientific literature, product inquires and complaints, unpublished manuscripts, internet</li> <li>• <i>Detailed coverage</i> on 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</li> <li>• <i>Brief introduction to active surveillance methods:</i> case control study, cohort study, prescription events monitoring, registries, sentinel surveillance (<i>more extensive coverage of this topic in trainings designed for health care workers from public health programs</i>)</li> <li>• 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)</li> </ul>	At the end this session, the participant will be able to: <ul style="list-style-type: none"> <li>- Explain strengths and limitations of spontaneous reporting</li> <li>- Demonstrate competence and confidence in filling the various fields of the spontaneous reporting form currently used in Vietnam</li> <li>- Through a personal narrative, demonstrate enthusiasm and conscientiousness (in his/her role as a health care worker) toward filling and sending spontaneous reporting form when an ADE is suspected in his/her work setting</li> <li>- Demonstrate correct understanding by telling that spontaneous reporting and active surveillance approaches are complementary methods</li> <li>- Describe practically feasible strategies for improving ADE reporting in his/her practice setting</li> </ul>	<ul style="list-style-type: none"> <li>- PowerPoint presentation</li> <li>- Interactive mini-lecture</li> <li>- Inputs by participants on their experiences in filling out the spontaneous reporting forms</li> <li>- Demonstration of some real spontaneous reports, followed by opportunity to practice filling out blank forms in small groups based on case scenarios</li> <li>- Brief small group discussions and reporting on locally feasible strategies to improve ADR reporting</li> </ul>	150 minutes

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<b>Module 4: Risk Communication, Risk Management, and Risk Minimization</b>	4.1.1. Erice Declaration and strategies to improve risk communications 4.1.2. Principles of risk management and risk minimization	<ul style="list-style-type: none"> <li>• The Erice Declaration on effective communication in PV</li> <li>• Role of the National DI&amp;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</li> <li>• Communicating messages about medicine safety (e.g., “Dear Doctor” letters, medicine alerts, media statements, patient information leaflets, newsletters, and personal feedback to reporters)</li> <li>• Strategies and tools for risk management and minimization</li> </ul>	<ul style="list-style-type: none"> <li>- Through a personal narrative, demonstrate commitment to communicating drug safety information ethically and effectively</li> <li>- Cite actual examples of strategies, approaches or tools used by stakeholders in Vietnam to promote and support risk communication, management and minimization</li> <li>- Cite examples of risk management and minimization initiative such as FDA’s “risk management framework”, “risk minimization action plans” and “risk evaluation and mitigation strategies”</li> <li>- 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 in his/her work setting</li> </ul>	<ul style="list-style-type: none"> <li>- PowerPoint presentation</li> <li>- Interactive mini-lecture</li> <li>- Video clips</li> <li>- Demonstration of examples of real messages used to communicate medicine safety information</li> <li>- Distribution of a copy of Erice Declaration and discussion on its salient statements</li> <li>- Display and discussion of real examples of risk communication, management and minimization strategies that have been utilized in Vietnam, and by other countries and organizations such as FDA and ISMP</li> </ul>	120 minutes
<b>Module 5: PV in public health programs</b>	5.1.1. Importance of PV in public health programs (PHP) 5.1.2. Burden of ADEs in PHPs	<ul style="list-style-type: none"> <li>• Importance of PV in PHPs: strengths, challenges and mutual benefits</li> <li>• Epidemiology of adverse events and drug-related morbidity and mortality in PHPs; problem of treatment failure in PHPs</li> </ul>	<ul style="list-style-type: none"> <li>- 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</li> <li>- Show awareness of about the significant problem of ADEs in PHPs by describing the burdens of ADRs and treatment failures</li> </ul>	<ul style="list-style-type: none"> <li>- Brainstorming</li> <li>- Interactive mini-lecture</li> <li>- Brief practical talks by experts from PHPs (if available)</li> <li>- Slide shows of ADRs</li> <li>- Video clips</li> <li>- Display of the national guidelines</li> <li>- Display of national IEC/BCC materials prepared by PHPs relating to ADR and</li> </ul>	60 minutes

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				safety of medicines used in their program	
	5.2.1. PV in the Antiretroviral Therapy Program	<ul style="list-style-type: none"> <li>• ADRs of clinical significance with ARVs and OI drugs included in the national guidelines recommended by the Antiretroviral Therapy (ART) Program in Vietnam; measures to reduce ARV- and OI-related morbidities; improving adverse event reporting within the ART Program</li> </ul>	<ul style="list-style-type: none"> <li>- List clinically significant adverse effects and drug interactions associated with the ARVs and OIs included in the national guideline</li> <li>- Explain measures that are locally feasible to reduce ARV- and OI-related morbidities</li> <li>- Describe locally feasible measures that can help improve adverse event reporting within the ART Program</li> <li>- Explain how an effectively functioning system to collect ADR and treatment failure information can inform an evidence-based revision or change in the guideline</li> </ul>	<ul style="list-style-type: none"> <li>- Brainstorming</li> <li>- Interactive mini-lecture</li> <li>- Brief practical talk by expert from the ART Program (if available)</li> <li>- Slide shows of ART and OI-related ADRs</li> <li>- Video clip</li> <li>- Display of the national guideline</li> <li>- Display of national IEC/BCC materials prepared by the ART Program relating to ADR and safety of medicines used in their program</li> </ul>	90 minutes
	5.2.2. PV in the National Tuberculosis Program	<ul style="list-style-type: none"> <li>• ADRs of clinical significance with anti-TB drugs included in the national guidelines recommended by the National TB Program (NTP) in Vietnam; measures to reduce anti-TB agents-related morbidities; improving adverse event reporting within NTP</li> </ul>	<ul style="list-style-type: none"> <li>- List clinically significant adverse effects and drug interactions associated with the anti-TB drugs included in the national guideline</li> <li>- Explain measures that are locally feasible to reduce anti-TB drugs-related morbidities</li> <li>- Describe locally feasible measures that can help improve adverse event reporting within the NTP</li> <li>- Explain how an effectively functioning system to collect ADR and treatment failure information can inform an evidence-based revision or change in the guideline</li> </ul>	<ul style="list-style-type: none"> <li>- Brainstorming</li> <li>- Interactive mini-lecture</li> <li>- Brief practical talk by expert from the NTP (if available)</li> <li>- Slide shows of anti-TB drug-related ADRs</li> <li>- Video clip</li> <li>- Display of the national guideline</li> <li>- Display of national IEC/BCC materials prepared by the NTP relating to ADR and safety of medicines used in their program</li> </ul>	90 minutes

<b>Module</b>	<b>Key Topic Areas</b>	<b>Outline of the Key Contents for Each Key Topic Area</b>	<b>Key Behavioral Objectives</b>	<b>Instructional Methods (Teaching-Learning Methods)</b>	<b>Contact period</b>
	5.2.3. PV in the National Malaria Control Program	<ul style="list-style-type: none"> <li>• ADRs of clinical significance with antimalarial agents included in the national guidelines recommended by the National Malaria Control Program (NMCP) in Vietnam; measures to reduce antimalarial drugs-related morbidities; improving adverse event reporting within NMCP</li> </ul>	<ul style="list-style-type: none"> <li>- List clinically significant adverse effects and drug interactions associated with the antimalarials included in the national guideline</li> <li>- Explain measures that are locally feasible to reduce antimalarial agents-related morbidities</li> <li>- Describe locally feasible measures that can help improve adverse event reporting within the NMCP</li> <li>- Explain how an effectively functioning system to collect ADR and treatment failure information can inform an evidence-based revision or change in the guideline</li> </ul>	<ul style="list-style-type: none"> <li>- Brainstorming</li> <li>- Interactive mini-lecture</li> <li>- Brief practical talk by expert from the NMCP (if available)</li> <li>- Slide shows of antimalarial agents-related ADRs</li> <li>- Video clip</li> <li>- Display of the national guideline</li> <li>- Display of national IEC/BCC materials prepared by the NMCP relating to ADR and safety of medicines used in their program</li> </ul>	90 minutes
	5.2.4. PV in the National Immunization Program	<ul style="list-style-type: none"> <li>• Adverse events following immunization (AEFI) with vaccines included in the national guidelines provided by the National Immunization Program in Vietnam; measures to reduce vaccine-related adverse events; improving adverse event reporting within the National Immunization Program; strategies for integrating vaccine adverse event reporting (VAER) into the national ADR database</li> </ul>	<ul style="list-style-type: none"> <li>- List clinically significant AEFI that could possibly be associated with the nationally recommended vaccines and immunizations</li> <li>- Explain measures that reduce vaccine and immunization-related adverse events</li> <li>- Describe locally feasible measures that can help improve adverse event reporting within the National Immunization Program</li> </ul>	<ul style="list-style-type: none"> <li>- Brainstorming</li> <li>- Interactive mini-lecture</li> <li>- Brief practical talk by expert from the National Immunization Program (if available)</li> <li>- Slides of AEFI</li> <li>- Video clip</li> <li>- Display of the national immunization schedule</li> <li>- Display of national IEC/BCC materials prepared by the National Immunization Program relating to safe use of vaccines and immunizations (if available)</li> </ul>	90 minutes

**ANNEX 3. LIST OF PARTICIPANTS WHO ATTENDED THE HALF-DAY  
PHARMACOVIGILANCE CURRICULUM REVIEW MEETING HELD AT HUP ON  
AUGUST 19, 2011**

<b>No</b>	<b>Name</b>	<b>Department/Organization</b>
1	Nguyen hoang Anh	DI&ADR Center
2	Vo Thu Thuy	DI&ADR Center
3	Do Thu Giang	DI&ADR Center
4	Tran Ngan Ha	DI&ADR Center
5	Cao Thu Huyen	DI&ADR Center
6	Tran Thu Hang	DI&ADR Center
7	Nguyen Mai Hoa	DI&ADR Center
8	Nguyen Van Anh	DI&ADR Center
9	Le Thi Kim Dung	Medical Services Administration (MoH)
10	Nguyen Dang Hoa	Hanoi University of Pharmacy
11	Nguyen Thi Thanh Huong	Hanoi University of Pharmacy (Pharmacoeconomics Management Dept)
12	Nguyen Thanh Binh	Hanoi University of Pharmacy (Pharmacoeconomics Management Dept)
13	Do Xuan Giang	Hanoi University of Pharmacy (Post graduate Dept)
14	Nguyen Thi Ngoc Thanh	Hanoi Medical University (Pharmacology Dept)
15	Nguyen Hong Ha	Central Pediatric Hospital (Pharmacological Dept)
16	Pham Thuy Van	Hanoi University of Pharmacy (Clinical Pharmacy Dept)
17	Nguyen Vinh Nam	Hanoi University of Pharmacy (Pharmacoeconomics Management Dept)
18	Nguyen Thi Hien Luong	Hanoi University of Pharmacy (International Cooperation Dept)
19	Dinh Thi Hien Van	Hanoi University of Pharmacy (International Cooperation Dept)
20	Nguyen Thi Vu Thanh	Vietnam Administration of HIV/AIDS Control
21	Nguyen Thi Lien Huong	Hanoi University of Pharmacy (Clinical Pharmacy Dept)
22	Mohan Joshi	Management Sciences for Health (MSH)/SPS
23	Michael Wilson	MSH
24	Mehmood Anwar	MSH
25	Trinh Thu Thuy	MSH

## ANNEX 4. SPS PRESENTATION AT THE HALF-DAY PHARMACOVIGILANCE CURRICULUM REVIEW MEETING HELD AT HUP ON AUGUST 19, 2011



**Pre-service and in-service curricula on pharmacovigilance**

**Mohan P. Joshi, MBBS, MSc, MD**  
Senior Technical Manager for Antimicrobial Resistance, and SPS Country Program Manager for Jordan and Vietnam

Pharmacovigilance Curriculum Review Meeting organized by Hanoi University of Pharmacy (HUP) in technical collaboration with MSH/SPS Hanoi, Vietnam, August 19, 2011

For better health worldwide

### Outline of the presentation

- Brief overview of the need to support pharmacovigilance (PV)
- Brief overview on curriculum reform
- The process of developing an in-service training on PV for health care professionals
- The process of developing a pre-service training on PV for post graduate pharmacy students



## To reflect.....

- There are some patients that we cannot help; there are none whom we cannot harm.”

▪ Attributed to Arthur L. Bloomfield  
[Quoted in: BMJ 2004; 329:1-2 (3 July 04)]



## Why effective pharmacovigilance is urgent in resource-constrained countries?

- ADRs, medication error, drug quality problems, and therapeutic ineffectiveness are common
- Large increases in the availability and use of relatively new medicines (for HIV/AIDS, malaria, TB)
- Systems to implement pharmacovigilance (PV) are often weak
- Lack of resources and expertise for PV
- Recent global mishaps on quality and safety of medicines
- Lack local evidence-based information to guide treatment and safety-related regulatory decisions
- Safety issues with traditional and herbal medicines

ADR = Adverse drug reaction



## Effective PV efforts will help...

- Avoid preventable adverse events ( $\approx 70\%$  of ADRs) and promote medicines safety
- Strengthen medicines regulation and enforcement capacities
- Promote government stewardship in safeguarding public health
- Improve public trust in the safety of public health program medicines



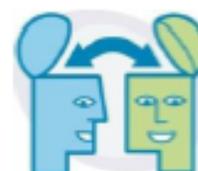
## Pre-service and in-service education on pharmacovigilance

- Training and education on PV is a key investment for strengthening the PV system
- Both pre-service education (training of students) and in-service education (training of health care professional) are important
- PV-related topics are often not covered adequately at both pre- and in-service levels
- Recognizing this gap, HUP and the National DI&ADR Center are developing/revising PV-related curriculum



## Curriculum.....

- is a dynamic and living document
- Needs periodic review and revision
- Requires continuous improvement



## Framework for Curriculum Revision and Implementation



Source: International Journal of Pharmacy, 25 (2), Dec. 2009, pg 16



## Emphasis shifting from.....

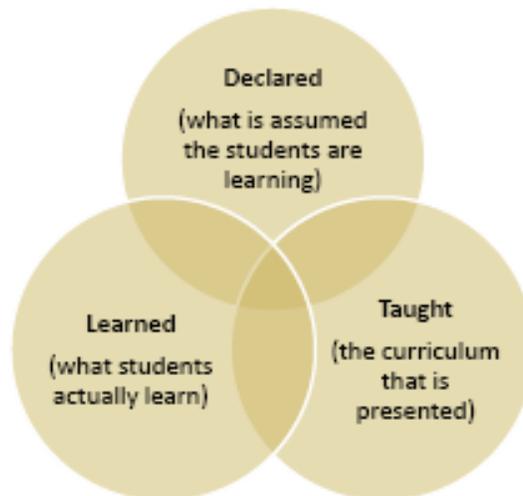
- What is “taught” to what is “learned” (curriculum)
- “Teacher-centered” to “learner-centered” (instruction)
- “subjective tests” to “precise criteria” (assessment)

Source: Reed D. Designing Curriculum and Instruction for Extended Periods, 22 Feb 2011



## Curriculum: seen in three ways

- Declared (intended) curriculum
- Taught (enacted) curriculum
- Learned (tested) curriculum



Source: Harden, R. M. (2001). AMEE guide no. 23: Curriculum mapping: A tool for transparent and authentic teaching and learning. *Medical Teacher*, 23(2), 123-137.



## The process of curriculum review and revision

- What are the **learning outcomes** ? (What the students or trainees will be able to do in real world practice, as a result of this training)
- What is currently being done ? (**curriculum mapping** or course stocktaking)
- Review, analyze **gaps and deficiencies**, and revise followed by further refinement based on **wider consultations** (curriculum reform)
- Implement, review and revise cyclically (**continuous curriculum improvement**)



## Curriculum Mapping



Mapping helps to identify:

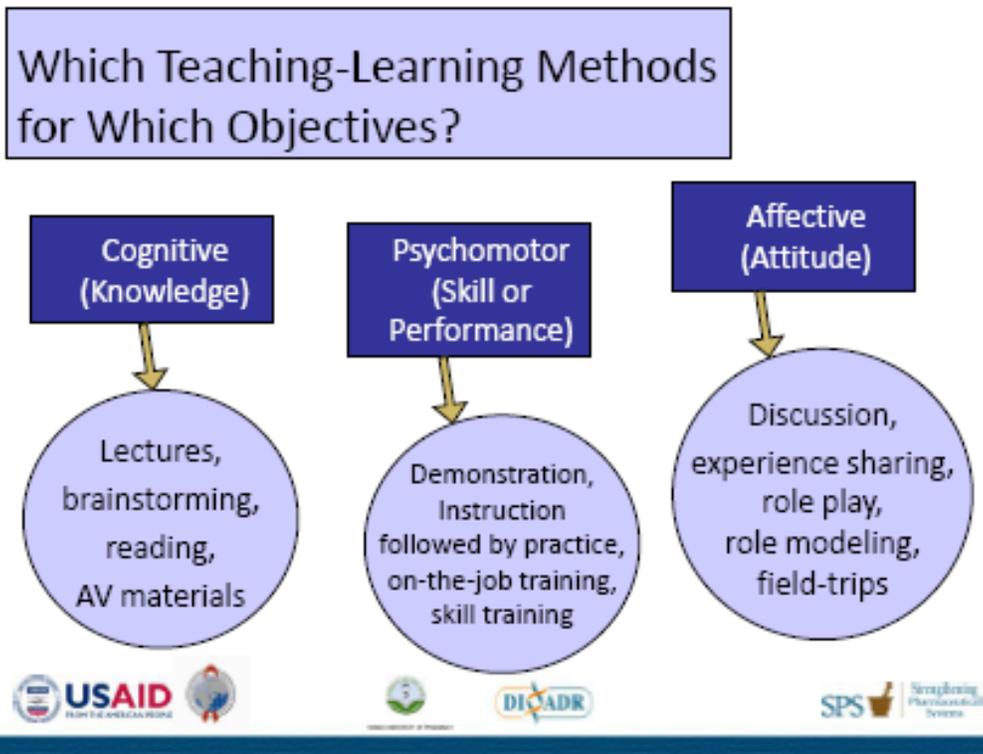
- what taught
- how taught
- when taught
- learning outcomes (assessment)

Mapping

- Identifies gaps and redundancies
- Shows where knowledge, skills and values are introduced and assessed
- helps in better sequencing in introducing contents
- Links and integrates curriculum by showing relationship between different content areas
- Makes the curriculum more transparent to the stakeholders

Source: Nicholson K. Brief #3: Mapping Outcomes Through Courses. McMaster University, 3 January 2011





## Theory and Practice to go Together



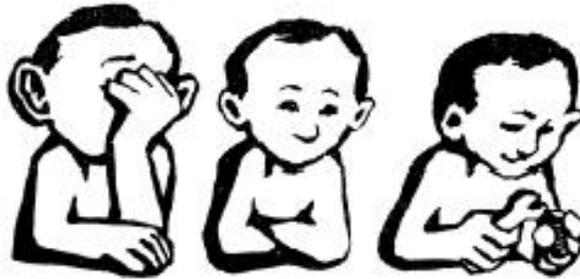
“Ideally theory and practice should be taught together.”

Source: Abbat FR. Teaching for better learning. Geneva: WHO, 1980



Chinese Proverb:

Hear & forget.....See & remember  
.....Do & understand



"Hear and forget ..."

Source: Abbat FR. Teaching for better learning.  
Geneva: WHO, 1980



## Learning Pyramid



Source: <http://www.acu.edu/cte/activelearning/whyuse12.htm>



## Perspectives to consider for PV curriculum reform

- Traditionally, PV is approached in health curriculums from ADR and reactive management perspectives.
- Bringing in safety, system and economic viewpoints, along with public health and programmatic considerations at both pre- and in-service levels, ensures that graduates enter or return to clinical practice with the right skills and attitudes to be both effective practitioners and committed stewards of pharmacovigilance.



## Process of drafting the PV curriculum for HCPs

- The DI&ADR Center staff and SPS reviewed the existing situation and identified that no fully developed local curriculum existed for training HCPs
- Brainstormed on appropriate competencies and organization of the modules
- Developed details of the draft curriculum along with key behavioral objectives



## Salient features of the new PV curriculum for training Health Care Professionals (HCPs)

- Mainly for hospital staff (doctors, pharmacists and nurses)
- Modular in nature, so possible to give the “full training”, or customize and deliver only selected modules depending on the specific needs of the participating audience and the time available for the training.
- Possible to piggy-back one or two modules on trainings organized for other purposes
- Altogether 5 modules, totaling 19 hours
- Emphasis on providing practical and competency-building learning experiences



## The suggested modules and sequence of the PV curriculum for HCPs

- *Module 1:* Overview of PV and Medication Safety
- *Module 2:* Risk Identification
- *Module 3:* Risk Evaluation and Reporting
- *Module 4:* Risk Communication, Risk Management, and Risk Minimization
- *Module 5:* PV in public health programs



## The draft curriculum for HCPs contains the following set of information

- Module Number and Title
- Key Topic Areas within the module
- Outline of the Key Contents for the Various Topic Areas
- Key Behavioral Objectives
- Instructional Methods (Teaching-Learning Methods)
- Contact Time for Each Module/Session
- References and Resources for the Key Contents



## DI&ADR Center's plan for implementing PV trainings for HCPs

- Initially provide training of trainers (TOT) in a few provinces based on the new PV curriculum
- Use the lessons learned from these field tests to further refine the curriculum
- Then roll-out the TOT to other provinces to help develop a “core” cadre of local trainers
- These core trainers will then lead the technical process of implementing further trainings in their respective local hospital settings

HCPs = Health care professionals



## Process of drafting the PV curriculum for post-graduate pharmacy students at HUP (for pre-service training)

- Clinical Pharmacy Dept and Post-graduate Dept of HUP reviewed their existing PG level curriculum in collaboration with MSH/SPS
- Identified gaps/deficiencies/need for modifications regarding PV contents
- Took the draft of the new in-service (HCP training) curriculum as the basis for identifying the required competencies after graduation of the students
- Drafted the revised PV curriculum along with key behavioral objectives and contact hours
- Then 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



## Salient features of the revised pre-service PV curriculum (1)

- The pre-service training topics are organized in a manner similar to those for in-service training for HCPs
  - This allows opportunities for leveraging of efforts, collaboration, resource-sharing, and other complementarities between the DI&ADR Center (for in-service training) and the Clinical Pharmacy Dept (for pre-service training)
- No additional contact hour burden compared to the existing curriculum
  - For theory, 825 minutes in the existing curriculum, and 800 minutes in the newly recommended curriculum
  - For seminar, contact hour remained the same (600 minutes)



## Pre-service PV curriculum: Seminar topics and contact hours

Existing curriculum	Revised curriculum
<ul style="list-style-type: none"> <li>• Spontaneous reporting (200 min)</li> <li>• Causality assessment (200 min)</li> <li>• Risk management (200 min)</li> </ul>	<ul style="list-style-type: none"> <li>• Spontaneous reporting (200 min)</li> <li>• Causality assessment (200 min)</li> <li>• Risk management &amp; risk minimization (200 min)</li> </ul>



## Pre-service PV curriculum: Teaching-Learning Methods

Existing curriculum	Revised curriculum
<ul style="list-style-type: none"> <li>• Large group teaching (# of students – 80 to 100) – Lectures</li> <li>• Seminars (# of students &lt; 20) – Group discussions</li> </ul>	<ul style="list-style-type: none"> <li>• Large group teaching (# of students – 80 to 100) – PowerPoint presentations, lectures</li> <li>• Seminars (# of students &lt; 20) – Brainstorming, interactive discussions, problem-based learning (PBL), group work and presentation, video clips</li> </ul>



## Pre-service PV curriculum: Student Assessment Methods

Existing curriculum	Revised curriculum
<ul style="list-style-type: none"><li>• Seminar-related and in-class tests (approx. 30% of the final score) – group discussion followed by individual student reporting</li><li>• Final test after the completion of 16-hr theory and seminars (approx. 70% of final score) – short answer questions or SAQs</li></ul>	<p>Keep multiple and flexible options for student assessments, including objectively structured tests.</p> <ul style="list-style-type: none"><li>• <i>Seminar-related and in-class tests</i> – group discussion followed by individual student reporting; SAQs, multiple choice questions (MCQs), true and false (T/F) questions, objectively structured practical examination (OSPE)</li><li>• <i>Final test</i> – Short report writing assignments, SAQs</li></ul>



## Conclusion

- HUP and the National DI&ADR Center are revising and standardizing their PV curricula at both pre- and in-service levels, and trying to maximize harmony between the two levels of training
- This effort will contribute to safety of medicines in the country and better patient outcomes
- MSH/SPS will continue to collaborate in this process and help develop a detailed trainers' guide for implementing the trainings

