

Technical Assistance for the Reform of Pharmaceutical Supply Management Curriculum at the Hanoi University of Pharmacy in Vietnam: SIAPS Technical Report

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ACRONYMS AND ABBREVIATIONS

ARV	antiretroviral
ART	antiretroviral therapy
DAV	Drug Administration of Vietnam (Regulatory Authority)
Global Fund	Global Fund to Fight AIDS, Tuberculosis, and Malaria
HIV/AIDS	human immunodeficiency virus /acquired immunodeficiency syndrome
HUP	Hanoi University of Pharmacy
M&E	monitoring and evaluation
MDR	multidrug-resistant
MIS	Management Information System
MoH	Ministry of Health
MSA	Medical Services Administration
NTP	National Tuberculosis Program
PEPFAR	President's Emergency Plan for AIDS Relief
PLMIS	Pharmaceutical Logistics Management Information System
PMP	Performance Monitoring Plan
PSM	pharmaceutical supply management
PV	pharmacovigilance
SCMS	Supply Chain Management System
SIAPS	Systems for Improved Access to Pharmaceuticals and Services [Program]
SOP	Standard Operating Procedure
TB	tuberculosis
USAID	US Agency for International Development
VAAC	Vietnam Administration of AIDS Control
WHO	World Health Organization

EXECUTIVE SUMMARY

The Hanoi University of Pharmacy (HUP) has initiated a process of reforming their undergraduate and postgraduate curricula to ensure appropriate coverage of Pharmaceutical Supply Management (PSM) elements in their preservice pharmacy training courses. With support from US President's Emergency Plan for AIDS Relief, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is assisting the HUP to facilitate this process.

This report is submitted as a combined report for the in-country visit made in September 2012 by a SIAPS principal technical advisor and a SIAPS consultant, and a technical report of activities and progress achieved in assisting HUP undertake PSM curriculum reform.

Since January 2012, when this PSM curriculum reform activity formally began getting implemented, SIAPS has collaborated with the HUP counterparts to help review the existing curriculums; map PSM-related competencies expected from the graduates; develop a curriculum for both postgraduate and undergraduate levels including aim, learning objectives, topic areas, contact times, pedagogical techniques, and detailed content summaries; and carrying out a stakeholder workshop to obtain and address feedback on the reformed curriculums. SIAPS has also assisted HUP in producing teaching slides for all the nine modules of the new curriculum—introduction and contextualization of PSM/governance; product selection; forecasting/quantification and supply planning; procurement; quality assurance; storage and distribution; inventory management; logistics management information system; and rational use of medicines.

BACKGROUND

In the recent changing environments for pharmacy practice, including huge increases in the supply of essential medicines for priority public health programs such as HIV/AIDS, tuberculosis (TB), and malaria, a pharmacy taskforce is expected to have sound knowledge and competencies relating to pharmaceutical supply management (PSM). Preservice learning is a sustainable intervention which provides a critical foundation of knowledge and skills to students, developing their competency for practice in the real world after graduation. Effectively designed and implemented preservice training reduces the future need for large-scale and expensive in-service trainings.

In this context, the Hanoi University of Pharmacy (HUP) has initiated a process of reforming their undergraduate and postgraduate curricula to ensure appropriate coverage of PSM elements in their pharmacy training course. With support from US President's Emergency Plan for AIDS Relief (PEPFAR) and the US Agency for International Development (USAID), the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is assisting the HUP to facilitate this process.

STRATEGIC APPROACH

Problem Statement

In Vietnam, as in many other developing and newly industrialized countries, the current preservice pharmacy education does not adequately expose the students to the practical aspects of PSM, and especially to the development and implementation of public health concepts. The consensus amongst the major stakeholders involved in pharmaceutical activities is that the graduates are often not adequately prepared to effectively manage pharmaceutical supply chain functions, apply basic public health concepts, and subsequently require long and laborious in-service orientation and training in order to gain competence in PSM functions.

Portfolio Vision/Goal

The SIAPS/Vietnam program goal is to bring about positive patient and health outcomes through improved availability and use of pharmaceuticals. The pivotal approach taken to achieve this end will be to work closely with in-country partners to strengthen their capacity and health systems, leading to sustainable health improvements.

SIAPS works to support this vision by focusing specifically on preservice training to strengthen the pharmaceutical supply management component in the pharmacy academic curriculum of HUP. This activity will directly help address the issues indicated in the Problem Statement section above by producing local pharmacy graduates with appropriate competencies to manage pharmaceutical supply chain in a standardized and uniform manner.

Preservice learning is a sustainable intervention which provides critical foundational knowledge and skills to students, preparing them to be competent in advance for practice in the real world after graduation. Effectively designed and implemented preservice training reduces the future need for large-scale and expensive in-service trainings.

OVERALL CURRICULUM DEVELOPMENT WORKPLAN

Technical Objective

The technical objective is to provide in-country human resource capacity for pharmaceutical services strengthened leading to improved patient outcomes.

Proposed Activity to Support the Objective—

The SIAPS team was to provide technical assistance activity to assist Hanoi University of Pharmacy to develop preservice curriculum on pharmaceutical supply management (annexes A, B, C, D).

Overall Activity

Based on the discussion with HUP's academic leadership, the following two curricular reform activities are being undertaken—

- Reform HUP's undergraduate pharmacy curriculum to strengthen the PSM component.
- Reform HUP's postgraduate pharmacy curriculum to strengthen the PSM component.

A systematic and step-wise process has been adopted to ensure that the resulting curricula for both undergraduate and postgraduate levels are tailored to suit the specific needs of Vietnam. SIAPS is working with HUP and other relevant stakeholders to—

- Map the existing gaps and the required competencies
- Develop a draft of the curriculum including the contents and instructional plans
- Finalize the draft of the curriculum through review and consultative process

Expected Result

Customized preservice PSM curricula for both postgraduate and undergraduate levels developed and implemented by HUP, thus providing a cost-effective and sustainable local approach to human resource development and health system strengthening.

PROGRESS REPORT

The SIAPS team has made good progress and activities are generally on schedule.

Results Framework

Reported progress in the Performance Monitoring Plan (PMP) is shown in annex E and progress in the Activity Monitoring Matrix is contained in annex F.

Key Progress Developments

- Gathered PSM and other supply chain curricula from various universities from elsewhere and created a comparative analysis of the various supply components included in them.
- Reviewed the existing curriculum document of HUP to identify the PSM topics that are currently covered.
- Using a structured questionnaire, members of HUP teaching faculty and the students who have already undergone exposure to PSM topics identified the details of the PSM topics which were already covered in various parts of the existing Pharmacy degree courses, along with their allocated times and teaching-learning methods.
- Using a method of self-administered questionnaire and open discussions with the various key informant groups, helped identify the PSM-related competencies expected of today's pharmacy graduates at both undergraduate and postgraduate levels. The key groups consulted were Drug Administration of Vietnam (DAV), Medical Services Administration (MSA), chief pharmacists of six public sector hospitals, private sector pharmaceutical enterprises, and HUP's Department of Pharmaceutical Management and Economics.
- Used the findings of the existing situation and expected competency analysis exercise to identify the existing strengths and areas requiring strengthening relating to PSM topics.
- Drafted, discussed, and agreed on an outline of the PSM curricula for both under- and postgraduate levels, including contact times for both theory and practical exposures in key topic areas (introduction and contextualization of PSM/governance; product selection; forecasting/quantification and supply planning; procurement and quality assurance; storage and distribution; inventory management; logistics management information system; and rational use of medicines). Outline curriculum summaries for all the modules are contained in annex G.
- Based on the planned outline and time allocations, SIAPS and HUP's Department of Pharmaceutical Management and Economics collaborated to develop detailed curriculum drafts of all the nine modules for both postgraduate and undergraduate courses, including—

- Aim
 - Learning objectives
 - Topic areas
 - Pedagogical techniques
 - Detailed content summaries
- To achieve wider consultation and feedback, HUP and SIAPS distributed summaries of these modules to key local stakeholders and then conducted a full-day Curriculum Review Workshop in Hanoi on September 26, 2012. The workshop was attended by a total of 45 stakeholders representing HUP, DAV, MSA, 108 Hospital, Friendship Hospital, E Hospital, Thanh Nhan Hospital, Thanh Hoa Pediatric Hospital, Hai Phong Obstetrics Hospital, Venus Pharmaceutical Joint Stock Company, CPC1, MNPG Commercial Joint Stock Company, Anper Company, Da Nang Pharmaceutical and Medical Equipment Joint Stock Company, Traphaco Company, Clinton Foundation HIV/AIDS Initiative, USAID, Vietnam Pharmaceutical Cooperation, VAAC, MSH/SCMS and SIAPS. HUP and SIAPS obtained more than 50 comments and suggestions from the majority of the stakeholders attending the workshop. Details of the workshop activities including feedback received and follow-up actions agreed with HUP are contained in annexes B, C, and D.

HUP and SIAPS are currently revising and finalizing the curriculum by incorporating all the relevant suggestions and feedback obtained during the above Curriculum Review Workshop. Additionally, SIAPS is supporting HUP by providing technical assistance to develop a detailed set of teaching slides for all the modules of the PSM curriculum. A sample of the draft slides developed so far is contained in Annex H.

TECHNICAL ACTIVITIES REPORT

Curriculum Reform Process

- A systematic process was adopted to ensure that the resulting curriculum is tailored to suit Vietnam’s needs.
- Key steps in the process included—
 - Mapping the gaps in the existing curriculum (table 1 and 2)
 - Developing curriculum draft including the topic areas, instructional plans, and technical content summaries
 - Consulting key stakeholders and obtaining feedback
 - Revising and finalizing the curriculum

Competencies Mapping

- Methods
 - Curriculum document review
 - Consultation with key stakeholders

Table 1. Existing PSM Courses Mapping

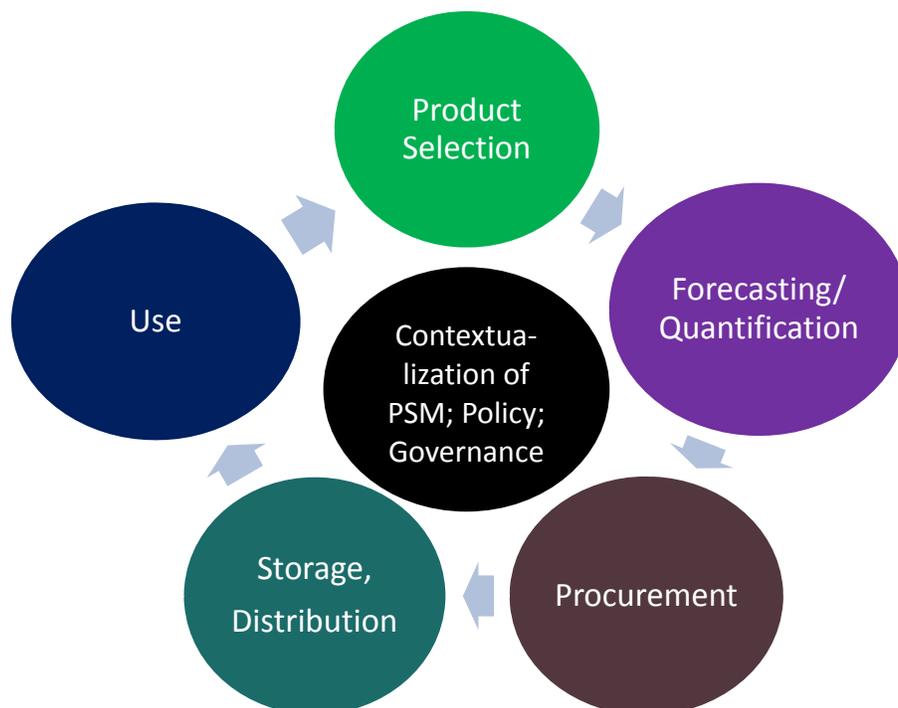
Description	Undergraduate Course	Postgraduate Course
Course duration	5-year course	2-year, full-time (master’s course) OR 3-year, part-time (Special Level 1 Course)
Training center	HUP, Hanoi	1 in Hanoi, 2 centers in Ho Chi Minh City, 1 in Quang Ninh, 1 in Khanh Hoa
No. of students (studying Pharmaceutical Mgmt. and Economics)	50 to 60	About 100 (about 20 in each training site)
PSM topics currently taught	Yes	No
PSM topics taught when	Fourth year of the course	Unknown
Total time for PSM topics	15 hours of classroom lectures and 3 half-day observational hospital visits followed by Pharmacy Practical Training in Hospital Departments	Unknown
Pharmacy “stream” teaching PSM topics	Pharmaceutical Management and Economics	Pharmaceutical Management (proposed for future inclusion)
No. of teachers	10	5

Table 2. Existing PSM Content and Identified Gaps

Existing Coverage	Areas that Require Strengthening
Product selection	Topics relating to inventory management, transportation, LMIS, and policy/regulation/governance and connection to rational use poorly covered
Forecasting/quantification	Time allocated insufficient even for the topics that are covered
Procurement	Inadequate variety of teaching-learning methods: Theory teaching is based only on classroom lectures and practical exposure is only “observational” hospital visit. No hands-on exposure. No case studies/problem-based learning.
Storage	Need to introduce Good Storage Practice concepts and practice
At least some degree of practical exposure through hospital field visits	Need for more structured practical exercises

Outline of New Curriculum

Based on the findings of the mapping, a curriculum overview following the classic PSM elements and flow patterns has been produced



^aHealth Systems Strengthening

Adapted from: Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health. Chapter 37.

Curriculum Contents Development

Curriculum Contents Flow Process

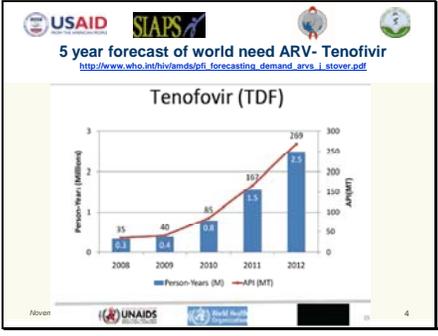
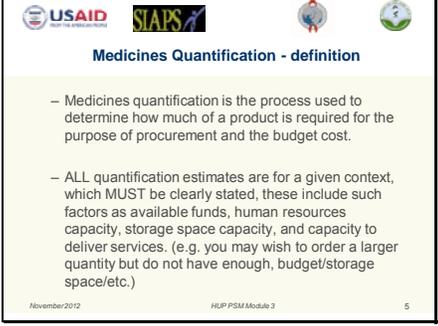
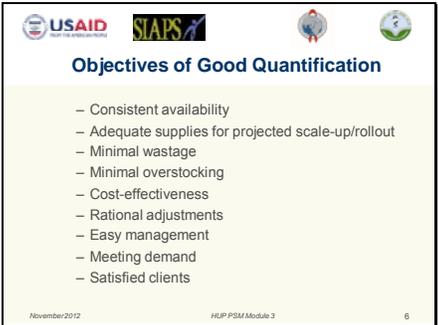
		HUP PSM CURRICULUM TIME ALLOWANCES				
		POSTGRADUATE		UNDER-GRADUATE		
		Hours				
BASIC MODULES Module structure and outline time allowance 1 page	Module	Module title	Theory	Practical	Theory	Practical
	1	Introduction/contextualization of PSM/governance	2		2	
	2	Product Selection	2	2	2	2
	3	Forecasting/quantification and supply planning	3	2	3	1 ^a
	4	Procurement	2	1.5	2	1
	9	Quality assurance	2	1.5	0	0
	5	Storage and distribution	3	3	3	3
	6	Inventory management	4	4	4	3 ^a
	7	Logistics management information system (LMIS)	3 ^a	5 ^a	3	3 ^a
	8	Rational medicines use	3	2	3	2
	9	Quality Assurance			2	1
		Total # of hours	24	21	24	16

a = The yellow-shaded areas in the table above denote changes that have been made to the time allocations from the original design made in March 2012.

<p style="text-align: center;">SAMPLE SUMMARY CONTENT OUTLINE</p> <p>Module 8 Rational Medicines Use</p> <p>Outline contents of each module (Total for all the modules is about 25 pages)</p>	Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time	
			10	Definition of rational medicine use	Didactic	
	30	20	Examples of irrational medicine use <ul style="list-style-type: none"> • Polypharmacy • No medicine needed • Wrong medicines • Ineffective medicines and medicines with doubtful efficacy • Unsafe medicines • Underuse of available effective medicines • Incorrect use of medicines 	Didactic		
	50	20	Adverse impact of irrational medicine use <ul style="list-style-type: none"> • Impact on quality of medicine therapy and medical care • Impact on antimicrobial resistance • Impact on cost • Psychosocial impact • Adverse drug reactions • Medication errors • Adverse drug events 	Didactic		

<p style="text-align: center;">SAMPLE DETAILED CONTENT</p> <p>(Total for all the modules is over 1,000 pages)</p>	<p style="text-align: center;">Hanoi University of Pharmacy (HUP) Pharmaceutical Supply Management, Draft Curriculum</p> <p>MODULE 9: UNDERGRADUATE</p> <p>Pharmaceutical Product Quality Assurance INTRODUCTION TO PHARMACEUTICAL QUALITY ASSURANCE</p> <p>AIM To gain knowledge of the total system approach required for effective pharmaceutical quality assurance.</p> <p>LEARNING OBJECTIVES At the end of this module, students should be familiar with—</p> <ul style="list-style-type: none">• The total systems approach for pharmaceutical quality assurance• The difference between pharmaceutical manufacturing quality control and supply chain quality assurance• The key parameters of quality standards needed as the basis for quality assurance <p>INSTRUCTIONAL OUTLINE</p> <ul style="list-style-type: none">• Definition: Quality assurance is a broad concept covering all matters that individually or collectively influence the quality of a pharmaceutical product. It is the totality of the arrangements made to ensure that pharmaceutical products are of the quality required for their intended use. http://whqlibdoc.who.int/publications/2004/9241546190_part1.pdf <p>Note that quality assurance in pharmaceutical supply is not the same as quality control in manufacturing. Quality Control is concerned with ensuring compliance to technical standards to statistically significant levels (3 σ or above). Quality assurance is to confirm that standards have been met, and are maintained throughout the supply chain.</p> <ul style="list-style-type: none">• The purpose of quality assurance in pharmaceutical supply systems is to help ensure that each medicine reaching a patient is safe, effective, and of acceptable quality.• A comprehensive quality assurance program includes technical, regulatory, managerial, and legal/enforcement activities, spanning the entire supply process from pharmaceutical selection to patient use. It is NOT just laboratory testing of products. It requires a complete, integrated system approach.• Established pharmaceutical quality standards are published in pharmacopoeias and pharmaceutical monographs.• For the purposes of public health, the most important characteristics of a pharmaceutical product are<ul style="list-style-type: none">○ Identity<ul style="list-style-type: none">▪ The correct active ingredient is present. This may sound obvious, but many of the medicines sold over the internet have been found to contain the wrong ingredient, e.g., oseltamivir (Tamiflu) was found to contain only paracetamol. http://www.fda.gov/forconsumers/consumerupdates/ucm048396.htm
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	<p>In the WHO review of 46 reports of drug problems, they found: products without active ingredients, 32.1%; products with incorrect quantities of active ingredients, 20.2%; and products with wrong ingredients, 21.4% were present http://www.who.int/medicines/services/counterfeit/overview/en/</p> <ul style="list-style-type: none"> ○ Purity <ul style="list-style-type: none"> ▪ Items other than the active ingredients and agreed excipients are not present. ○ Strength <ul style="list-style-type: none"> ▪ The correct amount of active ingredient is present. ○ Potency <ul style="list-style-type: none"> ▪ The active ingredient is in an active form (e.g., levo and dextro forms) ○ Uniformity of dosage form <ul style="list-style-type: none"> ▪ All the capsules/tablets contain the same amount of active ingredient
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<p>Sample PowerPoint Slides (Development in progress of estimated 3,000+ slides)</p>	Slide 4			
	Slide 5			
	Slide 6			

Based on the planned outline and time allocations, SIAPS and HUP's Department of Pharmaceutical Management and Economics collaborated to develop detailed curriculum drafts of all the modules for both postgraduate and undergraduate courses.

These module draft summaries are contained in annex G but a sample is presented below.

Module 3. Forecasting Quantification

Nominal time allowance

	Undergraduate	Postgraduate
Theory	3 hours	3 hours
Practical	1 hour	2 hours

Module Contents:

Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time
20 min	20 min	Overview of pharmaceutical quantification	Didactic	
60 min	40 min	Major methods of quantification <ul style="list-style-type: none"> • Major methods • Relative accuracies of the different methods 	Didactic	
100 min	40 min	Issues to consider in quantification <ul style="list-style-type: none"> • Action plans • Centralized or decentralized quantification manual and computerized methods • Estimating the time required • Filling the supply pipeline • Lead times • Safety stock • Adjusting for losses and other changes • Cross-checking the results • Estimating total procurement costs • Adjusting and reconciling final quantities 	Didactic	
120 min	20 min	Consumption method	< ^a Didactic Seminar > ^b	50 min
140 min	20 min	Morbidity method	< Didactic Seminar >	50 min
160 min	20 min	Proxy consumption method	<Didactic Seminar >	20 min
180	20 min	Service level projections of budgets	Didactic	

a is < = theory time; b is > = practical time

Aim

The module's purpose is for the student to be aware of the need for good forecasting quantification, which can be achieved using well established pharmaceutical management techniques. The purpose is also to practice forecasting using basic quantification calculations.

Learning Objectives

Students will gain knowledge of—

- The difference between forecasting and quantification
- The importance of quantification
- Use of well-established pharmaceutical management methods to achieve good quantification
- The four major methods of pharmaceutical quantification
- The relative strengths and weaknesses of the different methods
- The circumstances for selection of an appropriate quantification method
- The key decisions that need to be made at the outset of quantification
- The need to prepare and implement an effective action plan for the quantification process
- The need for a team approach and inclusive approach to quantification
- The preparation of medicine lists
- Methods of reconciliation of differing results obtained by different quantification methods
- Sources of medicine prices which can be used for quantification
- The steps in the process for undertaking consumption pharmaceutical quantifications
- The formula used for undertaking consumption based quantifications
- The need for morbidity data by disease type for morbidity quantifications
- The use of standard treatment guidelines to determine defined daily doses and medicine per episode requirements
- The operation of morbidity quantification methodology
- The conditions and circumstances when use of the proxy consumption quantification methodology is appropriate
- The methodology of data extrapolation based on population or patient episodes
- The operation of proxy consumption quantification methodology
- The appropriate circumstances for undertaking service level quantifications
- The use of service level quantifications
- The advantages and limitation of the service level quantification methodology

Detailed Contents Development

Following the summary contents development and their agreement by the active stakeholders, the detailed contents development was undertaken. The process to do so was threefold—

- Collect the major international reference works
- Collect existing course information from universities worldwide
- Collect specific examples and materials for Vietnam

The collected information was used in conjunction with competency mapping as the base for developing the curriculum materials.

Major International Reference Works

The Procurement and Supply Management ToolBox. Joint project of WHO and selected partners. <http://www.psmtoolbox.org/en/index.php>

Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health. <http://www.msh.org/resource-center/mds-3-digital-edition.cfm>

Management Sciences for Health. 2010. “Managing Medicines and Health Products.” Chapter 7 in *Health Systems in Action: An eHandbook for Leaders and Managers*. Cambridge, MA: Management Sciences for Health. <http://www.msh.org/resource-center/health-systems-in-action.cfm>

USAID | DELIVER PROJECT. 2011. *The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LogiHand.pdf

World Health Organization (WHO). 2006. *Handbook of Supply Management at First-Level Health Care Facilities*. Geneva: World Health Organization. <http://www.who.int/management/resources/procurement/handbookforsupplymanagement.pdf>

WHO Department of Essential Drugs and Medicines Policy. 1999. *Operational Principles for Good Pharmaceutical Procurement*. Geneva: WHO. <http://apps.who.int/medicinedocs/en/d/Jwhozip49e/9.html> (This is an interagency consensus document published by WHO.)

WHO and International Pharmacy Federation. 2010. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards For Quality Of Pharmacy Services*. - https://www.fip.org/www/uploads/database_file.php?id=331&table_id=

PSM Course Information from Other Universities and Agencies

McCarthy, T., and M. Gravier. ND. *A Multidisciplinary Approach to Implementing an Academic Supply Chain Management Program*. Lombard, IL: Council of Supply Chain Management Professionals. <http://cscmp.com/downloads/public/academics/scmec/paper1.pdf>

Commonwealth Pharmacists Association. *The Management of Pharmaceutical Supply*. Online course. Administered by the Pharmacy Training and Development Project of the School of Pharmacy at the Medunsa Campus, University of Limpopo, South Africa.
<http://www.commonwealthpharmacy.org/about/projects/distance-learning>

Chartered Institute of Purchasing & Supply. 2009. Graduate Diploma and Advanced Diploma in Purchasing and Supply (online course)
<http://www.cips.org/documents/study%20and%20qualify/level%205%20unit%20content%20guide%20web.pdf>

I+ Solutions. Procurement Management of Essential Medicines and Medical Supplies: Holland.
<http://www.iplussolutions.org/index.php?id=51>

USAID | Deliver Project. 2010. *Initiating In-Country Pre-Service Training in Supply Chain Management for Health Commodities: Process Guide and Sample Curriculum Outline*.
http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/initiatincount_preservetrain.pdf

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Dược Điển Việt Nam II – The Vietnam Pharmacopea

Circular 01/2012/Ttlt-Byt-Btc 01/19/2012 Guide to Drug Procurement in the Public Health Facilities by Ministry Health - Ministry of Finance

Regulations for Pharmaceutical Product Recall in Vietnam Contained in Circular No. 09/2010/Tt-Byt -
<http://haiquanbinhduong.gov.vn/en/vanban/thongtu09kiemtrachatluongthuoc.doc>

The Essential Medicines List Of Vietnam
Danh Mục Thuốc ThiẾT YẾu Việt Nam LẦN THỨ V (Ban Hành Kèm Theo Quyết Định Số 17/2005/QĐ-Byt Ngày 01 Tháng 07 Năm 2005 Của Bộ Trưởng Bộ Y Tế)

Vietnam National Institute of Drug Quality Control laboratory
http://apps.who.int/prequal/lists/PQ_QCLabsList.pdf

A large body of materials from VAAC and the SCMS program in Vietnam
<http://scms.pfscm.org/scms/where/vn>

Abt Associates Inc. 2010. *Assessment of Health System Performance in Six Provinces of Vietnam - Second Draft Report for Comments*. Bethesda, MD: Health Systems 20/20 Project.

WHO Country Office for Viet Nam. Medicines Prices: Make People Sicker and Poorer. Vietnam
<http://apps.who.int/medicinedocs/documents/s19220en/s19220en.pdf>

WHO Country Office for Viet Nam Medicine Prices, Availability, and Affordability in Vietnam.
<http://apps.who.int/medicinedocs/documents/s16376e/s16376e.pdf>

Nguyen, H. 2011. The Principal-Agent Problems in Health Care: Evidence from Prescribing Patterns of Private Providers In Vietnam. *Health Policy Plan* 26 (Suppl 1): i53-62.

Detailed Contents Development Methodology

Using the outline obtained from the agreed summary content structures, the detailed curriculum was written by the SIAPS consultant and underwent a review process with HUP staff.

Major Methods of Quantification

The detailed curriculum content comprises over 1,000 pages but a short extract of one section of one module is provided below as an example:

Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time
60 min	40 min	Major Methods of Quantification	Didactic	

Aim

Be aware of the four major methods of pharmaceutical quantification and their relative strengths and weaknesses.

Learning Objectives

At the end of this module, students should be able to explain—

- The four major methods of pharmaceutical quantification
- The relative strengths and weaknesses of the different methods
- The circumstances for selection of an appropriate quantification method

Instructional Outline

- The four major methods of pharmaceutical (and health products) quantification are
 - Consumption method
 - Morbidity method
 - Proxy consumption method
 - Service-level projection of budget requirements

The names of the methods are often misunderstood by non-PSM specialists, so it is important to understand the name and the method, and to be able to explain the basic methodology to non-specialists. The four methods are NOT exclusive. In the best systems, at least two different methods will be used so as to provide a check on the calculations.

- The **consumption method** uses records of past consumption of individual medicines (adjusted for any stock-outs and projected changes in medicine use) to project future need, e.g., last year we dispensed 1,250 bottles, no stock-outs, and this year we expect to dispense 5 percent more so $1,250 * 1.05 = 1,313$ bottles required.
- The **morbidity method** estimates the need for specific medicines based on the expected number of attendances, the incidence of common diseases, and standard treatment patterns for the diseases considered. In effect, the estimated number of patients multiplied by the amount of medicine needed per patient.

For example, Vietnam's population is 86,206,000. National TB incidence of sputum smear (ss) positive cases: 85 per 100,000 population. Detection/treatment level of ss TB is 85 percent. So $86,206,000 * 85/100,000 * 85\% = 62,383$ patient requiring treatment. Then use standard treatment guidelines for amount for medicine needed.

<http://www.stoptb.org/assets/documents/countries/acsm/Viet%20Nam.pdf>

- The **proxy consumption method** uses data on disease incidence, medicine consumption, demand, or use, and/or pharmaceutical expenditures from a "standard" supply system and extrapolates the consumption or use rates to the target supply system, based on population coverage or service level to be provided.

For example, for the treatment of candida esophagitis in People Living with HIV/AIDS, no reliable morbidity or consumption data for Vietnam. Thailand treats around 30 percent of AIDS patient before starting antiretroviral therapy (ART). Treatment is fluconazole 150mg, bid for 14 days. Vietnam had around 26,828 Patient on ART (2007). So, $26,828 * 30\% * 2 * 14 = 225,355$ tablets of 150 mg fluconazole required.

http://www.unaids.org.vn/index.php?option=com_content&task=view&id=28&Itemid=72&lang=en).

- **Service-level projection of budget requirements** uses the average medicine cost per attendance or bed-day in different types of health facilities in a standard system to project medicine costs in similar types of facilities in the target system. This method does not estimate quantities of individual medicines, but is exceedingly useful for providing a 'reality check' on calculations made by the other methods and really should be made on all major quantifications.

For example, the per patient year medicine cost for first-line ART in Vietnam is US dollars (USD) 102. In 2007, 26,828 patient on treatment, so medicine cost should be around $USD 102 * 26,828 = USD 2,736,456$.

- Relative predictive accuracy of the different quantification methods
 - All quantification of pharmaceutical requirements is inherently imprecise because of the many variables involved. It can only ever be as accurate as the data available, and often

in public sector systems little accurate data is available. Quantifications are always estimates, and should never be viewed as exact requirements.

- Good quantification requires a balance of art, or human judgment, and science, because—
 - The base data is inaccurate or incomplete
 - There is irrational use of medicines (not following the Standard Treatment Guidelines)
 - There are seasonal (malaria only during rainy season) or migratory or erratic usage patterns
- Each of the four quantification methods has particular strengths and weakness and selecting which method(s) to use will often be dictated by the availability of good quality data.
- Consumption method is generally considered to have the greatest potential to be the most accurate of the different methods provided that the source data are complete, accurate, and properly adjusted for stock-out periods and anticipated changes in demand and use.
 - Uses data on medicines consumption (dispensed to patient or inventory)
 - Predicts future needs most accurately when current usage patterns will continue
 - Requires reliable consumption data
 - Consumption data may or may not reflect rational prescribing or rational use of medicines, e.g., if there is high use of antibiotics for viral infections, this method will continue supplying large quantities of antibiotics
 - Comparison with morbidity-based method allows an estimate of the extent to which current consumption—
 - Addresses priority health needs
 - Reflects rational use of medicines
 - If stock-outs have been widespread for long periods, applying this method accurately may be impossible.
- Morbidity-based quantification is the most complex and time-consuming method. In many countries, assembling valid morbidity data is very difficult.
 - Used for new programs or for programs where consumption data are not available/reliable
 - Forecasts the quantity of medicines needed for prevention/treatment of specific diseases based on projections of the incidence of those diseases
 - Requires accurate information on the population and morbidity as well as clinic attendances, and uses standard treatment guidelines to project needs

- Most complex and time-consuming of all four methods
- Calculations can be complex
- Best alternative for—
 - A new program with no previous consumption history, such as HIV/AIDS programs rolling out antiretroviral therapy (ART)
 - Changes in standard treatment guidelines
 - A limited range of health problems accounts for virtually all medicine consumption, such as a small primary care system
 - A special-purpose hospital
- Proxy consumption is the method generally used if neither the consumption-based nor the morbidity-based method is feasible.
 - Used for new sites or new programs
 - Can be population-based or service-based
 - Uses data from an existing system to extrapolate requirements for a new system based on population coverage or the service level to be provided
 - Can be difficult to match/adjust for all variables—for example, prescribing practices
 - Useful for cross-checking projections made with other methods.
- Service-level projection of budget requirements produces a rough estimate of financial needs for pharmaceutical procurement and not the quantity of products.
 - Used for estimating budget needs
 - Does not estimate quantities of medicines needed
 - Uses the average medical supply procurement cost per attendance or bed-day or year in different types of health facilities in one system to project needs for similar types of facilities in another system
 - Limitations: variations in facility use, attendance, treatment patterns, supply system efficiency
 - Despite its limitations, this method is very useful in providing a quick and easy method of budget estimates, and in providing a quick check on calculations made by the other methods.

End of detailed curriculum content extract.

Stakeholder Consultation Curriculum Review Process

Following the detailed curriculum development and reiterative review process with HUP staff, a major stakeholder consultation workshop was held in Hanoi on September 26, 2012, to review the developed curriculum and obtain feedback from the major stakeholders.

As mentioned above, the agenda for the workshop is contained in annex B, the list of participants in the review workshop is provided in annex C, and the detailed review feedback comments received from the delegates and agreed actions are contained in annex D. The draft detailed curriculum is now being finalized in light of the stakeholder feedback received.

COMMENTS AND OBSERVATIONS ON THE PSM CURRICULUM DEVELOPMENT PROCESS

The logical and systematic approach to the curriculum development and especially the high level of stakeholder consultation, has been well received by HUP staff and other stakeholders, and drew considerable favorable comments at the stakeholder curriculum review workshop. It is clear from the active involvement in the stakeholder workshop by major units and senior staff within the MoH that the time spent in early stages on the curriculum development in defining and establishing the curriculum development process, and the inclusive nature of consultation, has yielded a substantive level of active participation by the major stakeholders.

A key issue which has required active management throughout the development process has been that of time allocations for delivery of the curriculum—in effect around a total of 25 hours of theory time. While all stakeholders have vocalized their understanding of the recognition of the time constraints inherent in any curriculum, nearly all stakeholders have also demanded ever more material to be included in their section of the course.

The detailed curriculum content—currently 9 training modules—has around 1,000 pages of content. For some modules, this will require presenting to students at the rate of one slide every 90 seconds throughout a 2-hour training session.

Coupled with the overall time issue, there have been continuous requests for ever greater practical/interactive time, and yet further additional content in the postgraduate course which would greatly added to the volume of presentational materials which has been provided.

While such competing requirements of available time and materials content, are by no means unusual in curriculum development, the extent of pressure for greater material content has, at times, bordered on extreme, and probably reflects the very great need felt throughout the stakeholder community for a much greater knowledge base for all pharmacy graduates in PSM matters.

The final detailed curriculum is therefore the result of much compromise and discussion and revision of time elements. Indeed, it is a tribute to the HUP staff that they have been able to actively engage stakeholders within an environment of the competing requirements, and produce acceptable compromises.

The latest iteration of the summary time allowances is presented below. The Quality Assurance module will be presented in a different order for the postgraduate and undergraduate courses. Areas shaded in yellow were changed during the development of the detailed curriculum contents.

Module	Module Title	Postgraduate		Undergraduate	
		Theory	Practical	Theory	Practical
1	Introduction/Contextualization of PSM/Governance	2	0	2	0
2	Product Selection	2	2	2	2
3	Forecasting/Quantification and Supply Planning	3	2	3	1 ^a
4	Procurement	2	1.5	2	1
5	Quality Assurance	2	1.5	Later	
6	Storage and Distribution	3	3	3	3
7	Inventory Management	4	4	4	3 ^a
8	Logistics Management Information System	3 ^a	5 ^a	3 ^a	3 ^a
9	Rational Use of Medicines	3	3	2	2
	Quality Assurance	Earlier		2	1
	Total # of hours	24	21	24	16

a = The yellow-shaded areas in the table above denote changes that have been made to the time allocations from the original design made in March 2012.

ANNEX A. TECHNICAL ASSISTANCE VISIT REPORT AND REQUEST FOR COUNTRY CLEARANCE

A SIAPS Principal Technical Advisor visited Hanoi in March 2012 and worked with HUP and other stakeholders to review the existing curriculum, analyze the required competencies, and develop outlines of undergraduate and postgraduate PSM curricula. A technical report of this visit was prepared and disseminated.¹

Subsequently, the SIAPS technical team made a second visit to Hanoi in September 2012. The approved Request for Country Clearance for this September visit follows. The prime purpose of the visit was to review the curriculum developed to that date to assist HUP arrange and conduct the stakeholder consultation workshop, and agree on follow-up actions following the feedback received from the workshop.

The agenda for the stakeholder workshop is contained in annex B of this report. A list of the stakeholders present is contained in annex C. The feedback received with follow-up actions agreed with HUP is contained in annex D. A debriefing meeting was held with USAID on September 27, 2012. Following this visit, the SIAPS team is finalizing the detailed curriculum and producing the teaching materials (PowerPoint slides).

¹Joshi, 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.

Request for Country Clearance

TO: Dao Nguyen, HANOI/OH

FROM: Management Sciences for Health (MSH)/Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, Cooperative Agreement number AID-OAA-A-11-00021

SUBJECT: Request for country clearance for travel to Hanoi, Vietnam for Andy Barraclough and Mohan Joshi for the period September 20 to 28, 2012

COPY: Ngoc Nguyen Thi Minh, HANOI/OH
Minh Pham Huy, HANOI/OH
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Jonathan Ross, HANOI/OH
Anthony Boni, GH/HIDN/HS, CTO SIAPS and Strengthening Pharmaceutical Systems
Maria Miralles, GH/HIDN/HS, Senior Pharmaceutical Management Advisor
Juanita Folmsbee, SCMS Vietnam Country Director, MSH
Ned Heltzer, Vietnam Portfolio Manager, MSH/SIAPS
Francis Aboagye-Nyame, Director, MSH/SIAPS
SamehSaleeb, Deputy Director, MSH/SIAPS
Gladys Tetteh, Deputy Director, MSH/SIAPS
Mohan Joshi, Principal Technical Advisor, MSH/SIAPS

1. The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program wishes to request country clearance for the proposed travel to Hanoi, Vietnam for Dr. Mohan Joshi, Principal Technical Advisor and Cluster Lead for Pharmaceutical Services, MSH/SIAPS, and Mr. Andy Barraclough, SIAPS Consultant, from September 20 to 28, 2012.

2. Background:

In the recent changing environments for pharmacy practice, including huge increases in the supply of essential medicines for priority public health programs such as HIV/AIDS, TB, and malaria, a pharmacy taskforce is expected to have sound knowledge and competencies relating to pharmaceutical supply management (PSM). Preservice learning is a sustainable intervention which provides a critical foundation of knowledge and skills to students, developing their competency for practice in the real world after graduation. Effectively designed and

implemented preservice training reduces the future need for large-scale and expensive in-service trainings.

The Hanoi University of Pharmacy (HUP) in Vietnam is currently reforming their preservice curriculum on PSM. The US Agency for International Development-funded SIAPS Program to provide technical assistance to the University in this reform initiative. A systematic process is being adopted to ensure that the resulting curriculum is tailored to suit Vietnam's specific needs. Major steps in the process include (1) mapping the existing gaps and the required competencies; (2) developing a draft of the curriculum including the topic areas, contact time, and content summaries; and (3) finalizing the draft of the curriculum (including the content summaries) through a review and consultative process.

To support the curriculum reform process, SIAPS initially conducted a desk review to gather relevant information regarding the existing PSM curricula available on the Internet and through contacts. Following this preparatory work, SIAPS technical staff Dr. Joshi conducted a technical assistance visit to Vietnam from March 10 to 27, 2012 to work with the national HUP counterparts to help perform curricular analysis and competency mapping relating to PSM using a structured questionnaire tool. The key informant groups consulted were Drug Administration of Vietnam (DAV), Medical Services Administration (MSA), chief pharmacists of six public sector hospitals, private sector pharmaceutical enterprises, and HUP's Department of Pharmaceutical Management and Economics in addition to the HUP students that have undergone exposure to PSM topics. Drawing on the findings of the existing situation and expected competency analysis exercise, Dr. Joshi and the national colleagues helped develop and agree on an outline of the PSM curricula for both under- and postgraduate levels, including contact times for both theory and practical exposures in key topic areas. These areas included introduction and contextualization of PSM/governance, product selection, forecasting/quantification and supply planning, procurement and quality assurance, storage and distribution, inventory management, logistics management information system (LMIS), and rational medicines use.

Following this ground work, SIAPS helped draft most of the modules of the curriculum. These drafts are currently undergoing preliminary review by the teaching faculty members of the Department of Pharmaceutical Management and Economics at HUP. The task of drafting the remaining modules is also expected to be completed very soon.

A critical next step in the curriculum development and finalization process is to hold a curriculum review and feedback workshop. The date of this workshop has already been agreed and fixed by HUP and SIAPS counterparts. It will be a full-day workshop in Hanoi on the 26th of September 2012. Besides HUP staff, other expected stakeholders attending this workshop will be those from DAV, MSA, public sector hospitals, private sector pharmaceutical enterprises, PEPFAR, VAAC-GF, WHO and Clinton Foundation. Mr. Barraclough and Dr. Joshi will be traveling to Hanoi to work with the national counterparts to facilitate this workshop.

3. **Purpose of Proposed Visit:**

The purpose of this visit is to work together with the counterparts at HUP and other stakeholders to help finalize preparations and then facilitate the curriculum review workshop in Hanoi on September 26, 2012.

4. **Scope of Work for Andy Barraclough and Mohan Joshi for the Visit**

- Working with HUP counterparts, finalize preparations for the workshop, including presentations and other technical materials that will be distributed and reviewed at the workshop. Also ensure that the key workshop materials are translated into Vietnamese.
- Along with HUP counterparts, co-facilitate the one-day stakeholder workshop on curriculum review on the 26th of September.
- Compile all the relevant feedback and suggestions obtained during the workshop
- Work with HUP's Department of Pharmaceutical Management and Economics to identify and agree on the required actions and timelines for integrating all the relevant comments/suggestions emerging out of the workshop
- Debrief the HUP academic leadership on the accomplishments and next steps
- Provide inbriefing and/or debriefing to USAID/Vietnam, as requested.

5. **Deliverables**

- Curriculum review workshop successfully completed
- A Trip Report produced and disseminated, including:
 - A brief summary of the feedback and recommendation on the curriculum development to date, received at the workshop
 - A list agreed with HUP of curriculum adjustments and amendments to be made in light of the workshop feedback
 - Expected timeline chart for completing final version of curriculum, contents summaries, and any other supporting technical documents

6. **Anticipated Contacts:**

- Representatives of USAID/Vietnam
- HUP/Academic authorities and Postgraduate Training Department
- HUP/Department of Pharmaceutical Management and Economics
- Representative of VAAC/Global Fund to Fight AIDS, Tuberculosis and Malaria
- Representative of PEPFAR and Clinton Foundation
- Representative of WHO Country Office

7. **Logistics:** Dr. Joshi will arrive in Hanoi on or about the 20th of September and Mr. Barraclough on or about the 22nd of September. Both will stay at Hotel Nikko and depart from Hanoi on the 28th of September.

8. **Funding:** The funding for this visit will be covered through SIAPS Vietnam field support funds.

9. **Action:** Please advise if there are any reasons why Mr. Barraclough and Dr. Joshi should not arrive as planned. Please reply via e-mail to the attention of Tony Boni, USAID/G/PHN/HN/HPSR, e-mail: aboni@usaid.gov, tel (202) 712-4789, fax (202) 216-3702. Please send carbon copies to Maria Miralles at mmiralles@usaid.gov, Juanita Folmsbee at jfolmsbee@msh.org, Ned Heltzer at nheltzer@msh.org, Francis Aboagye-Nyame at fnyame@msh.org, SamehSaleeb at ssaleeb@msh.org, Gladys Tetteh at gtetteh@msh.org, Mohan Joshi at mjoshi@msh.org, Andy Barraclough at ajarnandybarraclough@gmail.com, and Nicolette Regis at nregis@msh.org.

Thank you for Mission cooperation

**ANNEX B. HUP PSM CURRICULUM REVIEW STAKEHOLDER WORKSHOP –
AGENDA**

Hanoi University of Pharmacy (HUP)

Pharmaceutical Supply Management, Curriculum Development

WORKSHOP FOR REVIEW OF PSM CURRICULUM MATERIALS

Date: 26 September 2012

Location: Army hotel, 33 Pham Ngu Lao St., Hanoi

AGENDA

Time	Topic	Presenter	Comments
8.30 – 9.00	Registration		
9.00 – 9.15	Official Welcome of Delegates Opening Speech		HUP Dignitary
9.15 – 9.30	Why PSM is important	Ministry of Health	
9.30 – 10.00	Overview of the PSM Curriculum Development process	Mohan Joshi	
10.00 – 10.15	<i>Coffee break</i>		
10.15 – 11.15	Curriculum overview, methodology, sources and challenges in compiling the curriculum materials	Andy Barraclough	Original profile, MDS, Time restrictions
11.15 – 11.45	Overview of the curriculum materials produced so far	Dept. of Pharmaceutical Management and Economics/ HUP	
11.45 – 12.15	Review of Module 1 Introduction	Moderator Chairs Discussion HUP/Andy Barraclough Chiefly Responses from delegates	Senior, well respected Person to act as moderator for the discussion HUP/ Andy Barraclough respond to points raised
12.15 – 13.00	Lunch		
13.00 – 13.20	Review of Module 2 – Product Selection		
13.20 – 13.40	Review of Module 3 – Forecasting Quantification		
13.40 – 14.00	Review of Module 4 - Procurement		
14.00 – 14.20	Review of Module 5 – Storage and Distribution		
14.20 – 14.40	Review of Module 6 – Inventory Management		

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14.40 - 15.00	Review of Module 7 Logistics Management Information System		
15.00 – 15.20	Review of Module 8 Rational Medicine Use		
15.20 – 15.40	Review of Module 9 Quality Assurance		
15.40– 15.50	Coffee break		
15.50 – 16.10	Summary of review comments and major points		
16.10 – 16.25	Next steps		
16.25 – 16.40	Closing remarks	HUP/Andy Barraclough	Brief summary of key points provided by delegates
		HUP/Mohan Joshi	

ANNEX C. HUP PSM CURRICULUM REVIEW STAKEHOLDER WORKSHOP – PARTICIPANTS LIST

No	Full name	Title	Organization
1.	Ms. Nguyen Thi Hien Luong	International Relation Department	Hanoi University of Pharmacy
2.	Mr. Le Phan Tuan	General Administration Department	Hanoi University of Pharmacy
3.	Ms. Bui Bich Thuy	Department of Pharmaceutical Administration and Economics	Hanoi University of Pharmacy
4.	Ms. Vu Thi Anh	Department of Pharmaceutical Administration and Economics	Hanoi University of Pharmacy
5.	Mr. Nguyen Dang Hoa	Vice Rector	Hanoi University of Pharmacy
6.	Mr. Nguyen Thanh Binh	Vice Rector	Hanoi University of Pharmacy
7.	Ms. Tran Lan Huong	Training Department	Hanoi University of Pharmacy
8.	Ms. Nguyen Thi Phuong Thuy	Post Graduate Department	Hanoi University of Pharmacy
9.	Mr. Nguyen Manh Tuyen	Quality Check Department	Hanoi University of Pharmacy
10.	Ms. Nguyen Thi Song Ha	Department of Pharmaceutical Administration and Economics	Hanoi University of Pharmacy
11.	Ms. Nguyen Thi Thanh Huong	Department of Pharmaceutical Administration and Economics	Hanoi University of Pharmacy
12.	Ms. Tran Thi Lan Anh	Department of Pharmaceutical Administration and Economics	Hanoi University of Pharmacy
13.	Ms. La Thi Quynh Lien	Department of Pharmaceutical Administration and Economics	Hanoi University of Pharmacy
14.	Mr. Nguyen Vinh Nam	Department of Pharmaceutical Administration and Economics	Đại học Dược Hà Nội
15.	Ms. Nguyen Phuong Chi	Department of Pharmaceutical Administration and Economics	Đại học Dược Hà Nội
16.	Ms. Le Thu Thuy	Department of Pharmaceutical Administration and Economics	Đại học Dược Hà Nội
17.	Ms. Kieu Thi Tuyet Mai	Department of Pharmaceutical Administration and Economics	Đại học Dược Hà Nội
18.	Mr. Chu Quoc Thinh	Deputy Head of Price Management	DAV
19.	Mr. Nguyen Tat Dat	Head of Price Management	DAV
20.	Ms. Le Kim Dung	Specialist	MSA
21.	Mr. Nguyen Trung Ha	Vice Head of Pharmaceutical Department	108 Hospital
22.	Ms. Hoang Thi Minh Hien	Head of Pharmaceutical Department	Friendship Hospital
23.	Ms. Vu Thi Thu Huong		E Hospital
24.	Ms. Be Ai Viet	Head of Pharmaceutical Department	Thanh Nhan Hospital
25.	Ms. Dang Thi Hoa	Head of Pharmaceutical Department	Thanh Hoa Pediatric Hospital
26.	Ms. Nguyen Thi Hoang Hoa		Hai Phong Obstetrics Hospital
27.	Mr. Nguyen Tuan Anh	Branch Director – HCM city	Venus Pharmaceutical Joint Stock company
28.	Mr. Nguyen Nhat Hai	Branch Director – Bac Giang	CPCI
29.	Mr. Nguyen Ngoc Hanh	Director	MNPG Commercial Joint Stock Company
30.	Mr. Khong Duc Manh		

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31.	Mr. Nguyen Truong Thanh	Director	Anper Company
32.	Mr. Dinh Minh Tuan	Hanoi Branch Director	Da Nang Pharmaceutical and Medical equipment Joint stock company
33.	Mr. Nguyen Huy Van	Vice Director	Traphaco Company
34.	Mr. Mohan P. Joshi		SIAPS
35.	Mr. Andy Barraclough		SIAPS
36.	Ms. Le Thi Lan Phuong	Interpreter	MSH/SCMS
37.	Ms. Nguyen Kim Chi	Accountant	MSH/SCMS
38.	Mr. Nguyen Viet Anh	IT	MSH/SCMS
39.	Ms. Trinh Thu Thuy	Admin Coordinator	MSH/SCMS
40.	Mr. Nguyen Anh Dao		USAID
41.	Mr. Luu Ho Thanh Tuan		CHAI
42.	Mr. Nguyen Duc Thinh		Vietnam Pharmaceutical Cooperation
43.	Ms. Pham Lan Huong		VAAC
44.	Ms. Juanita Folmsbee	SCMS Vietnam Country Director	MSH/SCMS
45.	Mr. Ned Heltzer	Principal Technical Advisor	MSH/SCMS

ANNEX D. HUP PSM CURRICULUM REVIEW STAKEHOLDER WORKSHOP— STAKEHOLDER COMMENTS AND PROPOSED ACTIONS

Stakeholder Workshop Consultation on PSM Curriculum Development

Stakeholder Consultative Workshop

Name	Institution	Position	Comment	Response	Proposed Action
<i>Module 1. Introduction comments</i>					
Mr. Van	Traphaco Joint Stock company	Deputy Managing Director	<ul style="list-style-type: none"> - Clarify the concept of drug supply - Supplement the drug role to doctors and patients 	<p>The concept is reasonably well covered in the technical material developed for Module 1 and clear definitions are provided.</p> <p>The role of pharmacists in the overall provision of health care is covered in other parts of the pharmacy training, but adding a small flowchart/diagram to emphasize the role in PSM appears reasonable</p>	<p>Move glossary to front of module. Move definitions to front of module.</p> <p>Add flowchart/diagram to show role of pharmacists within overall PSM provision.</p>
Mr. Think	Management of drug price department –DAV	Deputy head	<ul style="list-style-type: none"> - Clarify the concept of drug supply and drug supply role. - Drug supply situation in the world and in Vietnam today - Essential drug is mentioned in Module 2, so whether essential drug is in Module 1 again. (suggestion: give an overview of the national drug policy) 	<p>The concept is reasonably well covered in the technical material developed for Module 1 and clear definitions are provided.</p> <p>Some comparisons between Vietnam and the world and SE Asia countries have been included but more can be added if time permits.</p> <p>The essential medicine concept is included in Module 1 while essential medicine lists are included in Module 2. National medicine policy is also included. It is possible to move essential medicines self- study from Module 1 to Module 2 and increase module 1 time NMP</p>	<p>Move glossary to front of module. Move definitions to front of module.</p> <p>Add more comparison charts/graphs of world situation</p> <p>Move essential medicine self-study from Module 1 to Module 2. Increase NMP time in Module 1</p>

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Name	Institution	Position	Comment	Response	Proposed Action
Mr. Tuyen	Quality control department – HUP	Head	<ul style="list-style-type: none"> - Supplement the importance and location of the PSM subject. - Supplement aim, learning objective, learning outcomes, and assessment of PSM subject before starting Module 1. - In each module, not mention the aim, just mention learning objective. 	<p>The importance of PSM is reasonably well covered in the technical material developed for Module 1.</p> <p>These are provided in the curriculum summary and are covered in the technical material provided for each section of each module.</p> <p>We believe the aim is the learning objective.</p>	
Mrs. Viet	Pharmacy department - Thanh Nhan Hospital	Head	<ul style="list-style-type: none"> - Section 3 (What is the role for pharmacists): agree that this section will be taught for undergraduate students, however this section should be lightly reviewed. - For undergraduate students, focus on the role for pharmacists in drug supply system and the role of other participants. For postgraduate students, focus on the role of other participants, lightly review the role of pharmacists 	<p>The role of the pharmacist is already very short— just 15 minutes and 3 pages which we believe provides only a short overview.</p> <p>For postgraduate students the role could be expanded slightly to include other health care workers.</p>	Postgraduate –expand role to include other health care workers
Hạnh	MN Joint Stock company	Director	Supplement personal factors in PSM	It is difficult to see how personal and HR issues can be incorporated into the course in a meaningful way.	No immediate action
<i>Module 2. Medicines Selection comments</i>					
Mrs. Ha	Pharmaceutical Administration and Economics	Deputy head	- Clarify the drug selection process and process of building drug list (the steps taken and the selection criteria).	The technical materials do clearly list the steps but it could be useful if it were customized specifically for the process in Vietnam	Further information needs to be gathered on process undertaken in Vietnam and then module to be revised.

Stakeholder Comments and Proposed Actions

Name	Institution	Position	Comment	Response	Proposed Action
	department – HUP		<ul style="list-style-type: none"> - It is necessary to teach product selection for both undergraduate students and postgraduate students. However, undergraduate curriculum need to be specific theory and postgraduate curriculum should be focused on practical section. (After finishing course, postgraduate students can choose drug list for their institution.) - Supplement list of main drug (In Vietnam, there are two lists of drug: essential drug list and main drug list.) 	<p>Postgraduate practical for Module 8 RMU does include taking part in a DTC but practical exercise for Module 2 could be changed to direct selection.</p> <p>Noted and module will be revised accordingly.</p>	<p>Change postgraduate practical to direct selection example.</p> <p>Further information on 2 list system is needed and module to be revised.</p>
Mr. Tuyen	Quality control department – HUP	Head	<ul style="list-style-type: none"> - Theoretical approach: increase self-study - In practical section: 60 minutes self-study is not effective because students will not work (based on fact in Vietnam). 	The key aim of the self-study is for students to learn to access pharmaceutical information from the internet— especially specifications and standards.	Sessions will be monitored and supervised.
Mrs. Hoa	Pharmacy department - Children’s Hospital of Thanh Hoa province	Head	<ul style="list-style-type: none"> - It is divided into two parts: drug selection in hospital and in the company. Clarify product selection base on pharmacological effect group or name of active ingredient - There are difficulties and challenges when doctors use INN in prescribing in Vietnam. 	<p>Describing drug selection in companies is problematical and only rarely undertaken systematically. The technical materials describe selection in layers starting at group and moving to specific active ingredient.</p> <p>Noted. Perhaps linkage with development of hospital formulary using INN can be introduced to promote INN.</p>	<p>Drug selection will focus on public sector.</p> <p>Further information on hospital formulary linkage and incorporate into the course if appropriate.</p>
Mr. Van	Traphaco	Deputy	- Merge Module 2 and Module	This does not appear appropriate —	No action

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Name	Institution	Position	Comment	Response	Proposed Action
	Joint Stock company	managing director	4 into one module because product selection comes with a choice the supplier.	selection is only one aspect of procurement	
<i>Module 3. Forecasting and Quantification comments</i>					
Mrs. Huong	Pharmacy department - E hospital	Deputy head	Only consumption method is clear and can be applied after learning while the other methods (morbidity method, proxy consumption method, and service-level projection of budget requirements) can be covered as general principles. Therefore, it should be build three methods such as consumption method	It is possible that the morbidity interactive calculation session could be removed from the undergraduate course giving more time for practice of consumption method calculations.	Not accepted 4 methods required
Mr. Thanh	Anper Joint Stock company	Director	<ul style="list-style-type: none"> - Undergraduate students: overview of methods - Postgraduate students: teach detailed methods (e.g., calculation) 	<p>This is currently provided at the postgraduate—key issue is time.</p> <p>Detailed methods can only be taught if time allocation is increased.</p>	Increase time allocation
Mr. Hai	CPC1	Branch Director	Supplement state laws on procurement (e.g., circular)	Noted – key restraint is time allocations	List of documents will be provided.
Mr. Hoa	Pharmacy department - Children's Hospital of Thanh Hoa province	Head	Prepare for forecasting quantification: determine inventory (<i>product that is in stock and will be used</i>), unused inventory (<i>product that is in stock but not used</i>), instability product (<i>number of drug changes, for example, last year the hospital use A drug in large numbers and this year hospital use A drug small numbers</i>), considering replacement (<i>when B drug is not available, find alternative drug</i>)	<ul style="list-style-type: none"> - This is covered in Module 5 Storage and Module 6 Inventory. - Postgraduate course includes real graphs (Quantimed) of such variability - Substitution is a major area and would require a significant additional time allocation 	Revise time allocations for more calculations.

Stakeholder Comments and Proposed Actions

Name	Institution	Position	Comment	Response	Proposed Action
<i>Module 4. Procurement comments</i>					
Mr. Tuyen	Quality control department –HUP	Head	<ul style="list-style-type: none"> - The practice: that interactive Q/A and discussion with invited external expert is very difficult because experts are busy and it is not easy to invite them to participate the practice with students - Need to provide specific criteria of expert - Suggestion: Group discussion practice, then presentation 	<p>Noted but this area is of such importance that experts have indicated they will be available.</p> <p>More than 3years of pharmaceutical procurement worth considering if experts not available</p>	Replace with hospital visit
Mr. Van	Traphaco Joint Stock company	Deputy managing director	In Vietnam, there are two typical forms of procurement: procurement at hospital and at company. Therefore, the practice should be organized for students to visit to the company and hospital to find out procurement SOPs	While we would fully support a company visit, time is very limited.	Focus must remain on hospitals
Mr. Hai	CPC1	Branch Director	Clarify who is selling, who is buying in the procurement system	Noted. We will try to include a small chart of buyer seller interactions.	Add chart of buyer seller interactions.
Mr. Ha	Pharmacy department - 108 Hospital	Deputy Head	<ul style="list-style-type: none"> - In Vietnam, the procurement activities comply with the law documents, such as circular - For postgraduate students: reduce the theory, increase the practice - There should be regular efforts to to visit to company and hospital. Question for the experts should focus on 	<p>Circulars are referenced in the technical material.</p> <p>Difficult to reduce theory – at present it covers only the basic elements</p> <p>While we would fully support a company visit, time is very limited.</p>	HUP to advise on practicality of increasing time to include company visit

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Name	Institution	Position	Comment	Response	Proposed Action
			procurement at hospital and company because TB or malaria program procurement is not typical.		
<i>Module 5. Storage and Distribution comments</i>					
Mr. Tuyen	Quality control department – HUP	Head	The practical: observe at stock what achieve GSP and combine with watching video.	A reasonable recommendation considering the time restrictions.	Combine practicals for Modules 5 and 6 so as to allow enough time for a warehouse visit
Mr. Manh	ManhDuc Company	Director	- Move Module 6 ahead of Module 5 - Restructure: all resources for drug supply support merge into one module (human, financial, LMIS)	Largely a decision on flow sequence – hard to see any significant advantage. Appears impractical given current Module structure and time limitations	No action
Mrs. Hoa	Children’s Hospital of Thanh Hoa province	Head of Pharmacy department	- Merge storage and inventory management into one module and separate module for only distribution - The aim of section 1 (Introduction to Pharmaceutical Storage and Distribution) and section 2 (Goals of distribution management) should be merged into one aim – the importance and the need for storage and distribution.	Largely a decision on flow sequence Largely a decision on flow sequence - hard to see any significant advantage	No action
Mr. Binh	HUP	Vice rector	Supplement the interaction between the pharmacist and the patient	Difficult with time restraints but a reasonable request	Expand interactions section
<i>Module 6 Inventory Management comments</i>					
Ms. Mai	Pharmaceutical	Lecturer	- For the different types of storage (storage at hospital,	The formula factors, especially lead time, do vary but hard to explain all in time	Add note into formula calculation that factors do

Stakeholder Comments and Proposed Actions

Name	Institution	Position	Comment	Response	Proposed Action
	Administrati on and Economics Department – HUP		at pharmacies and so on), the adjustment factors in formula should be included. - IMAT: take students to the pharmacy warehouse of hospital to practice	available. Excellent proposal	Vary depending on level. Amend practical to hospital level.
Mr. Hai	CPC1	Branch Director	Distinguish the concept between inventory and unused inventory	Good point	Expand explanation of distinction between working stock and dead stock.
Mrs. Huong	Pharmacy department - E hospital	Deputy head	Need to link between stock record, standard reports, and regulation of GSP.	It is very hard to include more than a cursory reference to GSP in the time allocations available.	No action included in other parts of pharmacy course
<i>Module 7 LMIS comments</i>					
Mr. Binh	HUP	Vice rector	- Teaching Module 7 for only postgraduate students	It is recommended that some knowledge of LMIS is necessary for undergraduate students, but it is possible that it could be much reduced if there was strong feeling that this would be beneficial.	Undergraduate theory only, postgraduate theory and practical
Mr. Tuan	Danaphar Company	Branch director	- Supplement regulation of GDP - Merge section 5 and section 8 into one section The implementation of LMIS in the world, provide examples In Vietnam, LMIS is not strong. Some company or project are invested for LMIS, for example, TB program, CPC1, Diethelm Keller Siber Hegner (DKSH). For undergraduate student : teach only theory, not practice	It is difficult to include more than a cursory reference to GDP in the time allocations available. Hard to see any significant benefit It is very hard to include more examples in the time allocations available. Agreed and examples from TB program have been included Hard to see relevance of theory only but could be done if considered beneficial.	no action
<i>Module 8 Rational Medicine Use comments</i>					

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Name	Institution	Position	Comment	Response	Proposed Action
Mrs. Lien	Pharmaceutical Administration and Economics Department – HUP	Lecturer	The practice for postgraduate students should be a discussion because some postgraduate students are head of the pharmacy department and they are members of the DTC	Would help time allocations	Change practical to internal discussion
Mr. Think	Management of drug price department - DAV	Deputy head	<ul style="list-style-type: none"> - The theory: supplement indicators of rational medicine use - The practice of undergraduate students: act as members of the DTC. - Supplement report ADR process. undergraduate students can observe the operation of the DI&ADR national center. - Link regulation of GPP 	<p>Indicators are included</p> <p>Reasonable proposal—hard to include in current time allocations and no further practical time available</p> <p>It is very hard to include more than a cursory reference to GDP in the time allocations available.</p>	<p>No action required</p> <p>Change undergraduate practical to DTC</p>
Mrs. Hoa	Children’s Hospital of Thanh Hoa province	Head of Pharmacy department	Specifying the pharmacist role in each stage of drug use. For example, clinical pharmacist has a role in consulting with doctors on prescription pharmacist role in the drug dispensation to patients and so on	Difficult to include in current time allocations but a flow chart might be possible	Include flow chart of interactions
Module 9 Quality Assurance comments					
Mr. Think	Management of drug price department - DAV	Deputy head	The theory: supplement process when detecting poor quality drugs (how to deal with receiving poor quality drugs). In Vietnam, there are many cases that the hospital director	Important point —must be moderated by time restraints but an action chart should be possible	Include action chart for sub-standard drugs

Stakeholder Comments and Proposed Actions

Name	Institution	Position	Comment	Response	Proposed Action
			<p>does not know to solve when suspecting poor quality drugs: How to seal drug or what appropriate authorities they need to send suspected drugs and so on.</p> <ul style="list-style-type: none"> - The practice for undergraduate students: observation at agencies what achieve GLP - Ensure the students understand how to implement a comprehensive QA and role of appropriate authorities in ensuring QA 	<p>Probably not possible within current time constraints</p> <p>Is included in technical material</p>	No action required
Mr. Van	Traphaco Joint Stock company	Deputy managing director	<ul style="list-style-type: none"> - Clarify concept of QA and quality control (QC) because QC is clearly taught by other department of HUP - In Vietnam, the agencies continue to check the quality of drug in all stages: transport, storage and so on. 	<p>Is included in Technical materials</p> <p>Full supply chain QA is included in the technical materials</p>	No action required

ANNEX E. PERFORMANCE MONITORING PLAN PROGRESS STATUS AT END NOVEMBER 2012

Result Area	Related SIAPS sub-IR*	Performance Indicators	Means of Verification	Frequency of Collection	Baseline	FY1	Status at end November 2012
Objective: <i>In-country human resource capacity for pharmaceutical services strengthened leading to improved patient outcomes</i>	2.1 5.1	HUP's postgraduate (postgraduate) pharmacy curriculum reformed to include PSM concepts	Based on evidences seen from the completed deliverables listed in Annex B of the SIAPS/Vietnam workplan	Annual	Minimal PSM content in the existing curriculum	Postgraduate curriculum reformed adequately addressing PSM topic (n = 1)	In Progress. Outline curriculum for all the PSM modules has been developed, revised, agreed and finalized. Detail curriculum content (technical summaries) for all the modules have been developed. Development of teaching materials (PowerPoint Presentations) has started.
		HUP's undergraduate (undergraduate) pharmacy curriculum reformed to include PSM concepts	Based on evidences seen from the completed deliverables listed in Annex B of the SIAPS/Vietnam workplan	Annual	Inadequate PSM topics in the existing curriculum	Undergraduate curriculum reformed adequately addressing PSM topic (n = 1)	In Progress. Outline curriculum for all the PSM modules has been developed, revised, agreed and finalized. Detail curriculum content (technical summaries) for all the modules have been developed. Development of teaching materials (PowerPoint Presentations) has started.

*Intermediate results

ANNEX F: ANNUAL ACTIVITY MONITORING MATRIX

Result Area	Associated Activities	Technical Area	Deliverables and Outputs	Status at end November 2012	Original Timeline					
					Q3			Q4		
					A	M	J	J	A	S
<p>Objective: In-country human resource capacity for pharmaceutical services strengthened leading to improved patient outcomes (contributes to IR2.1 and 5.1)</p> <p>Activity: Provide Technical Assistance to Hanoi University of Pharmacy to Develop Pre-Service Curriculum on Pharmaceutical Supply Management</p>	Map the existing gaps and the required competencies	Pharmaceutical Management Capacity Building	<ul style="list-style-type: none"> Curriculum reviewed and existing pharmaceutical supply management (PSM) topics listed Desired PSM competencies in pharmacy graduates identified in collaboration with local stakeholders & listed Curricular deficiencies and gaps identified and listed 	Completed						
	Develop a draft of the curriculum including the contents and instructional plans	Supply Chain Management	<ul style="list-style-type: none"> Revised preservice PSM curriculum drafted 	Completed. Approximately 1,000-page long detailed curriculum content produced.	X	X	X	X		

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Result Area	Associated Activities	Technical Area	Deliverables and Outputs	Status at end November 2012	Original Timeline						
					Q3			Q4			
					A	M	J	J	A	S	
	Finalize the draft of the curriculum through a wide review and consultative process	Supply Chain Management	<ul style="list-style-type: none"> • Draft curricula finalized through a stakeholder review and meeting • Final curricula submitted to the academic section of HUP • Trip/technical report developed and disseminated 	In progress. Draft detailed curriculum completed. Stakeholder consultative workshop completed. Final version of curriculum content now being produced in light of stakeholder feedback, including PowerPoint Presentations for all the modules. Technical/trip report produced.						X	X

ANNEX G: PSM CURRICULUM COURSE MODULES SUMMARIES

Hanoi University of Pharmacy (HUP)

Pharmaceutical Supply Management, Draft Curriculum

COURSE MODULE OVERVIEWS

Background Information

Recognizing: that in the recent changing environments for pharmacy practice, including the pharmaceutical management demands placed by huge increases in the supply of essential medicines for priority public health programs such as HIV/AIDS, TB and malaria, pharmacy students are expected to acquire sound pharmaceutical supply management (PSM) knowledge and skills by the time they graduate and join the workforce; The Hanoi University of Pharmacy (HUP) has initiated a process of reforming the curriculum to ensure appropriate coverage of PSM elements in their pharmacy training courses.

With support from PEPFAR/USAID, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program of Management Sciences for Health (MSH) is assisting the HUP to facilitate this curriculum revision process. The review group has already helped accomplish the following:

- Gathered PSM and other supply chain curricula from various universities from elsewhere and created a comparative analysis of the various PSM components included in them.
- Reviewed the existing curriculum document of HUP to identify the PSM topics that are currently covered.
- Using a structured questionnaire administered to the HUP teaching faculty members and the students who have already undergone exposure to PSM-topics, identified the details of the topics covered along with allocated times and teaching-learning methods.
- Using a method of self-administered questionnaire and open discussions with the various key informant groups, helped identify the PSM-related competencies expected of today's pharmacy graduates at both under- and postgraduate levels. The key informant groups consulted were: Drug Administration of Vietnam (DAV), Medical Services Administration (MSA), chief pharmacists of six public sector hospitals, private sector pharmaceutical enterprises, and HUP's Department of Pharmaceutical Management and Economics.
- Used the findings of the existing situation and expected competency analysis exercise to identify the existing strengths and areas requiring strengthening relating to PSM topics.

- Drafted, discussed, and agreed on an outline of the PSM curricula for both under- and postgraduate levels, including contact times for both theory and practical exposures in key topic areas (introduction and contextualization of PSM/governance; product selection; forecasting / quantification and supply planning; procurement and quality assurance; storage and distribution; inventory management; logistics management information system; and rational use of medicines).

HUP PSM CURRICULUM TIME ALLOWANCES					
		POSTGRADUATE		UNDERGRADUATE	
		Hours			
Module	Module Title and link to Detailed Content	Theory	Practical	Theory	Practical
1	Introduction/Contextualization of PSM/Governance	2	0	2	0
2	Product Selection Product Selection	2	2	2	2
3	Forecasting/Quantification and Supply Planning	3	2	3	1
4	Procurement	2	1.5	2	1
9	Quality Assurance	2	1.5		
5	Storage and Distribution	3	3	3	3
6	Inventory Management	4	4	4	3
7	Logistics Management Information System(LMIS)	3	5	3	3
8	Rational Use of Medicines	3	2	3	2
9	Quality Assurance			2	1
	Total # of hours	24	21	24	16

At the present time, the PSM curriculum being developed is exceedingly intensive and contains a greater volume of materials/information that can realistically be presented in the agreed time allocations.

All reviewers are asked to bear in mind that:

- Any requests for additional materials/topics to be covered should be accompanied by suggestions for which material/topics should be cut from the courses so as to maintain the time envelope
- Requests for additional practical/interactive sessions should similar be accompanied by suggestions for which material/topics should be cut from the courses to accommodate the greater time requirements required by non-didactic sessions

Module 1. Introduction/Contextualization of PSM/Governance

Introduction	Product Selection	Forecasting Quantification	Procurement and Quality Assurance	Storage Distribution	Inventory Management	LMIS	Rational Use of Medicines
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Nominal Time allowance:

	Undergraduate	Postgraduate
Theory	2 hours	2 Hours
Practical	0	0

Module Contents:

Elapsed Time	Section Time	Topic	Pedagogical technique
10 min	10 min	Summary	Didactic
40 min	30 min	Why worry about medicines?	Didactic
55 min	15 min	What is the role for Pharmacists?	Didactic
85 min	30 min	Public Health Objectives and Essential Medicines Concept	Didactic
100 min	15 min	Pharmaceutical Supply Management – What works	Didactic
110 min	10 min	Challenges for Pharmaceutical Supply Management	Didactic
120 min	10 min	Managing Pharmaceutical Supply Improvements	Didactic
30 min for students alone, using internet and references		Questions on National Medicines Policy of Vietnam	Self-Study
		Questions on Essential Medicines List of Vietnam	Self-Study
		Questions on Financial level of medicines in Vietnam	Self-Study
Start of Module 2 10 minutes		Discuss Questions and answers	Interactive

AIM:

This module aims to provide a general overview of the Pharmaceutical Supply Management approach, seeks to define basic terminology, and introduce the fundamental concepts of Essential Medicines and the principles behind effort to improve access and effective management of medicines supply at all levels

LEARNING OBJECTIVE:

To increase knowledge and develop the ability to explain to non-pharmacists:

- Why Medicines are important
- Why it is necessary, and how, to explain to non-pharmacists why medicines are important
- That Access to medicines is a key requirement for effective healthcare, and wellbeing
- The four parameters of the definition of ‘access to medicines’
- That it is possible to improve the situation, and ALL pharmacists are capable of contributing to these improvements
- How medicines contribute to major disease treatment and control
- How medicines contribute to overall health services and their importance
- An overview of the ‘big numbers’ - per capita medicine spends in countries
- The concept of the therapeutic benefit of medicines
- The realization that therapeutic benefit can be improved
- The essential role pharmacists play through the procurement supply management cycle in: Selection; Procurement; Distribution and Use of medicines.
- The Public Health Approach to Medicines
- Essential Medicines Lists
- Essential Medicines Concept
- The need and value for a National Medicine Policy
- The need for effective management and good governance
- Effective methods of rational medicine use
- The difficulties in changing public perceptions of medicines

Module 2. Product Selection

Introduction	Product Selection	Forecasting Quantification	Procurement and Quality Assurance	Storage Distribution	Inventory Management	LMIS	Rational Use of Medicines
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Nominal Time allowance:

	Undergraduate	Postgraduate
Theory	2 hours	2 hours
Practical	2 hours	2 hours

Module Contents:

Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time
		Review Answers from Module 1 Self Study	Interactive	15 min
	10 min	Introduction to Product Selection	Didactic	
25 min	15 min	Practical implications of the essential medicines concept	Didactic	
45 min	20 min	Selection criteria	Didactic	
65 min	20 min	Use of International Nonproprietary (generic) Names	Didactic	
85 min	20 min	Essential medicines lists in context/ Lists of registered medicines	Didactic	
95 min	10 min	Formulary manuals/Treatment guidelines	Didactic	
105 min	10 min	Therapeutic classification systems	Didactic	
120	15 min	Operating Selection/what works	Didactic	
		Assessment of Current Status of National essential Medicine list Management in Vietnam	Practical Session	2 hours total
		Form into Groups of 5 persons, Review assessment table, split questions between group members	Interactive	10 min
		Individuals reference information to answer questions	Self-study	60 min
		Group collates answers, discusses and formulates overall assessment of status	Interactive	15 min
		Group elects spokesperson and prepares brief presentation on findings	Interactive	10 min
		Selected groups present findings	Interactive	25 min

AIM:

General overview of the reasons and mechanism for undertaking good medicine selection. Strengthening of understanding of the essential medicines concept and developing knowledge of the mechanisms used for National Essential Medicine Lists.

LEARNING OBJECTIVES:

To increase knowledge and develop the ability to explain:

- Basic economics of medicines in public health systems
- Characteristics of the world medicines market
- The benefits that good medicines selection can bring
- Definition of Essential Medicines
- Rationale for using Essential Medicine concept
- The range of application of Essential Medicine Lists
- The importance of the Essential Medicine approach in addressing growing anti-microbial resistance
- Become familiar the criteria to be used for medicine selection:
- The concept and use of INN, Why the use of INN is important and Price effects of INN
- Generic substitution issues
- The potential opposition to the use of INN
- The misuse of quality and bioequivalence issues to oppose the use of INN
- The need and value for a National Medicine Policy
- Medicines selection processes and essential medicines lists
- The need for effective management and good governance in medicines selection
- The interdependence of the different types of medicines lists
- Methodologies for developing treatment guidelines and essential medicines lists
- The need to keep all lists up to date
- The need for the use of therapeutic systems of classification of pharmaceuticals
- The need for a therapeutic system which can be used by non-pharmacists
- The WHO recommended ATC classification system
- Transparent procedures in developing EML
- Key factors in implementation of EML programs
- The need for high level technical and political involvement in disseminating EML information

Module 3. Forecasting Quantification

Introduction	Product Selection	Forecasting Quantification	Procurement and Quality Assurance	Storage Distribution	Inventory Management	LMIS	Rational Use of Medicines
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Nominal Time allowance:

	Undergraduate	Postgraduate
Theory	3 hours	3 hours
Practical	1 hours	2 hours

Module Contents:

Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time
20 min	20 min	Overview of Pharmaceutical Quantification	Didactic	
60 min	40 min	Major methods of quantification <i>Major Methods</i> <i>Relative accuracies of the different methods</i>	Didactic	
100 min	40 min	Issues to consider in Quantification <i>Action plans</i> <i>Centralized or decentralized quantification</i> <i>Manual and computerized methods</i> <i>Estimating the time required</i> <i>Filling the supply pipeline</i> <i>Lead times</i> <i>Safety stock</i> <i>Adjusting for losses and other changes</i> <i>Cross-checking the results</i> <i>Estimating total procurement costs</i> <i>Adjusting and reconciling final quantities</i>	Didactic	
120 min	20 min	Consumption Method	< Didactic Seminar >	50 min
140 min	20 min	Morbidity Method	< Didactic Seminar >	50 min
160 min	20 min	Proxy Consumption Method	<Didactic Seminar >	20 min
180	20 min	Service Level projections of budgets	Didactic	

AIM:

To be aware of the need for good forecasting quantification and that it can be achieved using well established pharmaceutical management techniques. To practice using basic quantification calculations.

LEARNING OBJECTIVES:

For students to gain knowledge of:

- The difference between forecasting and quantification
- The importance of quantification
- That good quantification can be achieved using well established pharmaceutical management methods
- The four major methods of pharmaceutical quantification
- The relative strengths and weaknesses of the different methods
- The circumstances for selection of an appropriate quantification method
- The key decisions that need to be made at the outset of quantification
- The need to prepare and implement an effective action plan for the quantification process
- The need for a team approach and inclusive approach to quantification
- The preparation of medicine lists
- Methods of reconciliation of differing results obtained by different quantification methods
- Sources of medicine prices which can be used for quantification
- The steps in the process for undertaking consumption pharmaceutical quantifications
- The formula used for undertaking consumption based quantifications
- The need for morbidity data by disease type for morbidity quantifications
- The use of standard treatment guidelines to determine defined daily doses and medicine per episode requirements
- The operation of morbidity quantification methodology
- The conditions and circumstances when use of the Proxy consumption quantification methodology is appropriate
- The methodology of data extrapolation based on population or patient episodes
- The operation of Proxy Consumption quantification methodology
- The appropriate circumstances for undertaking Service Level Quantifications
- The use of Service Level Quantifications
- The advantages and limitation of the Service Level Quantification methodology

Module 4. Procurement

Introduction	Product Selection	Forecasting Quantification	Procurement	Storage Distribution	Inventory Management	LMS	Rational Use of Medicines	Quality Assurance
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Nominal Time allowance:

	Undergraduate	Postgraduate
Theory	2 hours	2 hours
Practical	1 hour	1.5 hours

Module Contents:

Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time
20 min	20 min	Introduction and The procurement cycle	Didactic	
40 min	20 min	Factors influencing pharmaceutical prices and total costs <i>Unit prices</i> <i>Reorder frequency</i> <i>Total cost of purchasing</i> <i>Visible and hidden costs</i>	Didactic	
60 min	20 min	Overview of procurement methods	Didactic	
90 min	30 min	Good pharmaceutical procurement practices <i>Reliable payment and good financial management</i> <i>Procurement by generic name (International Nonproprietary Name)</i> <i>Procurement limited to essential medicines list</i> <i>Increasing procurement volume by aggregating demand</i> <i>Formal supplier qualification and monitoring</i> <i>Competitive procurement</i> <i>Monopsony and pooled procurement</i> <i>Order quantities based on reliable estimate of actual need</i> <i>Transparency and written procedures</i> <i>Separation of key functions</i> <i>Product quality assurance program</i> <i>Annual audit with published results</i> <i>Regular reporting on procurement performance</i>	Didactic	
110 min	20 min	Organization and management of the procurement	Didactic	

		<p>functions</p> <p><i>Supervision by senior management</i></p> <p><i>Responsibilities in the procurement process</i></p> <p><i>Procurement office staffing and management systems</i></p>		
120 min	10 min	<p>Financial sustainability</p> <p><i>Sources of funds for pharmaceutical procurement</i></p> <p><i>Access to foreign currency exchange</i></p> <p><i>Reliable payment mechanism</i></p> <p><i>Financial support for the procurement office</i></p>	Didactic	
		Procurement System Assessment	<p>Interactive Q/A Discussion session with invited external expert</p>	90 min

Procurement:

AIM:

To have knowledge of the procurement cycle and the and role of pharmacists in ensuring Good Procurement Practice as part of overall Good Pharmacy Practice. To be familiar with the different procurement techniques and the practical requirements for their effective implementation.

LEARNING OBJECTIVES:

To gain knowledge of:

- The definition of procurement
- The Procurement Cycle
- Good Procurement Practice
- The role of pharmacists in ensuring Good Procurement Practice as part of overall Good Pharmacy Practice
- The main factors effecting pharmaceutical pricing
- Hidden costs of procurement
- Total costs of acquisition
- The main procurement routes used for pharmaceuticals
- The relative merits of the different procurement methods
- The requirements for Good Pharmaceutical Procurement

- The practical implications for the implementation of Good Pharmaceutical Procurement Practices
- The five main types of supply chain systems
- Centralized and decentralized procurement systems
- The different sections and units required for effective procurement management
- The needs for financing of medicines
- The potential sources of medicine financing

Module 5.Storage and Distribution

Introduction	Product Selection	Forecasting Quantification	Procurement and Quality Assurance	Storage Distribution	Inventory Management	LMIS	Rational Use of Medicines
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Nominal Time allowance:

	Undergraduate	Postgraduate
Theory	3 hours	3 hours
Practical	3 hours	3 hours

Module Contents:

Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time
0	20	Introduction to Pharmaceutical Storage and Distribution	Didactic	
40	20	Goals of distribution management	Didactic	
60	20	The distribution cycle	Didactic	
100	40	Distribution system design <i>Basic design features</i> <i>Distribution network</i> <i>Push and pull systems</i> <i>Resupply interval</i> <i>Storage</i> <i>Delivery systems versus collection systems</i> <i>Transport</i> <i>Delivery schedules</i>	Didactic	
120	20	Resources for distribution management <i>Logistics managers</i> <i>Staffing levels</i> <i>Information systems</i> <i>Communication</i>	Didactic	
150	30	Cost analysis and performance monitoring <i>Calculating costs</i> <i>Collecting and analyzing cost and performance data</i>	<<<< Didactic Seminar Cost Performance Analysis	90
165	15	The private-sector option	Didactic	

180	15	Considering improvement and replacement	Didactic	
		<i>Systems review and improvement considerations</i>	Interactive	90

AIM:

To gain knowledge of the key elements involved storage and distribution of pharmaceuticals and the importance of cost analysis techniques in guiding decision making for effective and efficient systems.

LEARNING OBJECTIVES:

To gain knowledge of:

- The prime goals of storage and distribution management
- The distribution cycle including
 - Port clearing (for imported products)
 - Receipt and inspection
 - Inventory control
 - Storage
 - Requisition of supplies
 - Delivery
 - Dispensing to patients
 - Reporting consumption
- The basic characteristics of distribution systems-degree of centralization, and the number of levels in the system,
- The four major elements which define the different types of distribution systems
- The value and use of a cost analysis approach to decision making for storage and distribution
- Examples of conducting cost analysis of distribution systems
- Centralized distribution systems
- Collaboration between private and public systems
- The necessary steps in planning a distribution system
- Private and parastatal distribution options
- Needs for contracting out elements of the storage and distribution systems

Module 6. Inventory Management

Introduction	Product Selection	Forecasting Quantification	Procurement and Quality Assurance	Storage Distribution	Inventory Management	LMIS	Rational Use of Medicines
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Nominal Time allowance:

	Undergraduate	Postgraduate
Theory	4 hours	4 hours
Practical	3 hours	4 hours

Module Contents:

Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time
0	20	Introduction to Inventory Management	Didactic	
40	20	The context of an inventory management system	Didactic	
70	30	Stock records and standard reports <i>Stock records</i> <i>Activity reports</i> <i>Performance Monitoring</i>	Didactic	
90	20	Selection of items to be held in stock	Didactic	
110	20	Service level and safety stock <i>Service level to operating units</i> <i>Methods for setting safety stock levels</i>	<<<< Didactic Seminar >>>>	30
170	60	Inventory control models and reorder frequency <i>Annual purchasing</i> <i>Scheduled purchasing</i> <i>Perpetual purchasing</i> <i>Drawing down from framework contracts</i> <i>Combinations of annual, scheduled, and perpetual purchasing</i>	Didactic	
190	20	Factors to consider in calculating reorder quantity <i>Factors in the reorder formula</i> <i>Projecting demand</i> <i>Integrating experience and other factors</i>	<<<<< Didactic Seminar >>>>>	30
210	20	Standard reordering formulas	<<<<< Didactic	60

		<i>Minimum and maximum stock-level formula Consumption-based reordering formula</i>	Seminar >>>>	
240	30	Mathematical models for reordering <i>Economic order quantity Economic order interval Exponential smoothing Standard deviation of consumption and lead time</i>	<<<< Didactic Seminar >>>>	60
		<i>Inventory Operational Review</i>	Seminar	60

AIM:

To gain knowledge of the need for a systematic, cost based approach to Inventory Management and how the use of Management data and basic cost calculations can greatly improve system efficiency and cost effectiveness.

LEARNING OBJECTIVES:

To gain knowledge of:

- The seven basic issues for effective, efficient inventory management
- Need to consider the inventory operation within the overall supply chain context
- The requirements for accurate and current stock records
- The use and value of key inventory management indicators
- Value of VEN and ABC approaches and expansion of their use to order frequency as well as value
- Service levels and safety stocks
- Methods for calculating safety stocks
- Common inventory management examples
- Formulas for calculating order levels and quantities
- Key factors and data requirements in Inventory calculations
- Relative merits of different kinds of inventory formulae
- Methods of minimizing total inventory costs
- Use on Inventory indicators – especially cost levels for performance evaluation

Module 7. Logistics Management Information System

Introduction	Product Selection	Forecasting Quantification	Procurement and Quality Assurance	Storage Distribution	Inventory Management	LMIS	Rational Use of Medicines
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Nominal Time allowance:

	Undergraduate	Postgraduate
Theory	4 hours	4 hours
Practical	2 hours	4 hours

Module Contents:

Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time
	20	Importance of a pharmaceutical logistics management information system	Didactic	
60	40	<i>Definition of a pharmaceutical logistics management information system</i> <i>Functions of a pharmaceutical logistics management information system</i> <i>Data and information</i> <i>The information systems pyramid</i>	Didactic	
80	20	Meeting the information needs of users with different requirements	Didactic	
140	60	Typical components of a pharmaceutical management information system <i>Record-keeping documents</i> <i>Data compilation/aggregation tools</i> <i>Data-reporting forms</i> <i>Feedback reports</i>	<<<< Didactic Seminar >>>	60
170	30	Steps in designing or revising a pharmaceutical logistics management information system	Didactic	

190	20	Key issues in designing or revising a pharmaceutical logistics management information system	Didactic	
210	20	Implementing a pharmaceutical logistics management information system	<<<< Didactic Seminar >>>>	30
240	30	From information to action <i>Processing data</i> <i>Presenting information</i> <i>Interpreting information</i> <i>Taking action</i>	<<<<<< Didactic Seminar >>>>>>	60
		Systems Overview and analysis	Seminar	90

AIM:

To gain knowledge of the importance of LMIS/PLMIS, how data requirements can be established, and effective information flow systems implemented. The practical requirements for data collation, analysis and presentation across the different levels of the supply chain

LEARNING OBJECTIVES:

To gain knowledge of:

- The importance of LMIS as the key data provider
- Definition of LMIS/PLMIS.
- Establishing information needs at each level of the system
- Use of participatory process in establishing information collection and dissemination needs
- Selection and use of PLMIS indicators
- Integration of PLMIS with PMIS and HMIS and other systems
- Considerations for computerization at the different levels of the system
- Data processing requirements
- Processed data presentation and analysis
- Value of trend analysis – Pipeline examples
- Introduction of new technologies such as e-mail, websites, on-line reporting, strategic monitoring systems text
- Feedback mechanisms

Module 8: Rational Medicine Use

Introduction	Product Selection	Forecasting Quantification	Procurement and Quality Assurance	Storage Distribution	Inventory Management	LMIS	Rational Use of Medicines
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Nominal Time allowance:

	Undergraduate	Postgraduate
Theory	3 hours	3 hours
Practical	2 hours	2 hours

Module Contents:

Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time
	10	Definition of rational medicine use	Didactic	
30	20	Examples of irrational medicine use <i>Polypharmacy</i> <i>No medicine needed</i> <i>Wrong medicines</i> <i>Ineffective medicines and medicines with doubtful efficacy</i> <i>Unsafe medicines</i> <i>Underuse of available effective medicines</i> <i>Incorrect use of medicines</i>	Didactic	
50	20	Adverse impact of irrational medicine use <i>Impact on quality of medicine therapy and medical care</i> <i>Impact on antimicrobial resistance</i> <i>Impact on cost</i> <i>Psychosocial impact</i>	Didactic	
70	20	Factors underlying irrational use of medicines at various levels of the health system <i>Health system</i> <i>Prescriber</i> <i>Dispenser</i> <i>Patient and community</i>	Didactic	
90	15	Strategies to improve medicine use	Didactic	

125	35	<p>Developing a strategy</p> <p><i>Step 1. Identify the problem and recognize the need for action</i></p> <p><i>Step 2. Identify underlying causes and motivating factors</i></p> <p><i>Step 3. List possible interventions</i></p> <p><i>Step 4. Assess resources available for action</i></p> <p><i>Step 5. Choose an intervention or interventions to test</i></p> <p><i>Step 6. Monitor the impact and restructure the intervention</i></p>	<p><<< Didactic</p> <p>Seminar Case Study</p> <p>>>></p>	60
160	30	<p>Promoting treatment adherence and appropriate medicine use by patients</p> <p><i>Communication between providers and patients</i></p> <p><i>Inadequate counseling</i></p> <p><i>Lack of resources for medicines and treatment</i></p> <p><i>Complexity and duration of treatment</i></p> <p><i>Availability of information</i></p>	<p><<< Didactic</p> <p>Seminar Case Study</p> <p>>>>></p>	60
180	20	<p>What is pharmacovigilance and why is it important?</p> <p><i>Adverse drug reactions</i></p> <p><i>Medication errors</i></p> <p><i>Adverse drug events</i></p>	<p>Didactic</p>	

AIM:

To gain knowledge of the importance of LMIS/PLMIS, how data requirements can be established, and effective information flow systems implemented. The practical requirements for data collation, analysis and presentation across the different levels of the supply chain

LEARNING OBJECTIVES:

To gain knowledge of:

- Definition of Rational Medicines Use
- Effects of Polypharmacy and irrational use
- Effects of dispensing process on RMU
- Strategies to address irrational medicine use
- Need to focus on targeted messages
- Practical approaches to selecting strategies and implementing program of RMU
- Communication with Patients and patient counseling
- Role of pharmacovigilance

Module 9: Quality Assurance

Introduction	Product Selection	Forecasting Quantification	Procurement and Quality Assurance	Storage Distribution	Inventory Management	LMIS	Rational Use of Medicines
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Nominal Time allowance:

	Undergraduate	Postgraduate
Theory	2 hours	2 hours
Practical	1.5 hours	1.5 hours

Module Contents:

Elapsed Time	Section Time	Topic	Pedagogical technique	Practical Time
0	20 min	Introduction to Pharmaceutical Quality Assurance	Didactic	
50	30 min	Pharmaceutical quality <i>Defining and assessing pharmaceutical quality</i> <i>Consequences of poor pharmaceutical quality</i> <i>Determinants of pharmaceutical quality</i> <i>Prevalence of poor-quality pharmaceuticals</i> <i>Global quality-monitoring options</i>	Didactic	
60 min	10 min	Practical approaches to quality assurance	Didactic	
80 min	20 min	Obtaining good-quality pharmaceutical <i>Careful product selection</i> <i>Careful supplier selection</i> <i>Product certification</i> <i>Product pedigrees</i> <i>Batch certificates</i> <i>DRA's and the procurement market today</i> <i>Contract specifications</i>	Didactic	
100	20 min	Verifying the quality of shipped products <i>Product identification technology</i> <i>Inspection of shipments</i> <i>Tiered pharmaceutical quality assessments</i> <i>Laboratory testing</i>	Didactic	

110	10 min	Maintaining pharmaceutical quality <i>Appropriate storage and transport</i> <i>Appropriate dispensing and use</i>	Didactic	
120	10 min	Monitoring pharmaceutical quality <i>Product problem reporting system</i> <i>Product recalls</i>	Didactic	
		Practical observation and demonstration of Quality Assurance activities	Demonstration at NIDQC/interactive session with DDA	90 min

Quality Assurance:

AIM:

To gain knowledge of the total system approach require for effective pharmaceutical Quality Assurance. To be aware of the different key elements within an effective medicines QA program.

LEARNING OBJECTIVES:

To gain knowledge of:

- The total systems approach for pharmaceutical Quality Assurance
- The difference between pharmaceutical manufacturing Quality Control and supply chain Quality Assurance
- The key parameters of quality standards needed as the basis for Quality Assurance
- Techniques for defining and assessing pharmaceutical quality
- The consequences of poor pharmaceutical quality
- The determinants of pharmaceutical quality
- The prevalence of poor quality pharmaceuticals
- The four key components of a pharmaceutical quality assurance program
- The difference between pharmaceutical manufacturing Quality Control and supply chain Quality Assurance
- The key parameters of quality standards needed as the basis for Quality Assurance
- The need for careful product selection
- The critical role that careful supplier selection and secure sourcing plays in quality assurance
- The need for product certifications
- The role of WHO format certifications and their very real limitations
- The need for clear contract specifications
- Product Identification technology
- Visual Inspections of shipments

- The effects of therapeutic windows and the tiered approach to Quality Assurance product assessments
- The role of laboratory testing in the overall QA program
- The requirements for appropriate storage and transport
- The needs for appropriate dispensing and patient interactions
- Systems for reporting product problems
- The requirements for undertaking product recalls
- The different types of product recalls which can be made

ANNEX H: SAMPLE OF POWERPOINT TRAINING MATERIALS






Pharmaceutical Supply Management

Module 3: Forecasting Quantification

Introduction	Product Selection	Forecasting Quantification	Procurement and Quality Assurance	Storage Distribution	Inventory Management	LMIS	Rational Use of Medicines
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OVERVIEW OF PHARMACEUTICAL QUANTIFICATION

AIM:

- To be aware of the need for good forecasting quantification and that it can be achieved using well established pharmaceutical management techniques.

LEARNING OBJECTIVES:

At the end of this Session, students should be aware of:

- The difference between forecasting and quantification
- The importance of quantification
- That good quantification can be achieved using well established pharmaceutical management methods

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Forecasting vs Quantification

- Definitions:
 - **forecasting** refers to the (long term) projection of future needs (beyond the next purchase order),
 - **quantification** refers to the imminent medicine needs for the next procurement activity.
 - (e.g.: Vietnam undertakes a 5 year forecast for anti-retroviral medicines, with annual quantifications for procurement).
- www.who.int/hiv/amds/vietnam.ppt

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5 year forecast of world need ARV- Tenofovir

http://www.who.int/hiv/amds/pfi_forecasting_demand_arvs_i_stover.pdf

Tenofovir (TDF)

Year	Person-Years (M)	API (MT)
2008	0.3	35
2009	0.4	40
2010	0.8	85
2011	1.5	167
2012	7.5	269

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Medicines Quantification - definition

- Medicines quantification is the process used to determine how much of a product is required for the purpose of procurement and the budget cost.
- ALL quantification estimates are for a given context, which **MUST** be clearly stated, these include such factors as available funds, human resources capacity, storage space capacity, and capacity to deliver services. (e.g. you may wish to order a larger quantity but do not have enough, budget/storage space/etc.)

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Objectives of Good Quantification

- Consistent availability
- Adequate supplies for projected scale-up/rollout
- Minimal wastage
- Minimal overstocking
- Cost-effectiveness
- Rational adjustments
- Easy management
- Meeting demand
- Satisfied clients

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Applications of Quantification

- Prepare and justify a pharmaceutical budget
- Plan for new and expanding programs
- Optimize pharmaceutical budgets based on priority health problems to be treated and the most cost effective treatment approaches
- Calculate emergency needs for disaster relief and epidemics
- Resupply an existing supply network that has become depleted of products

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Why is Quantification so important ?

- Good quantification, contributes to saving lives, reducing morbidity, and saving money.
- E,g, Uganda: *“Records of 27 essential medicines and 11 medical supplies were reviewed over two-year periods **Results:** The median number of days out-of-stock for drugs and medical supplies was 94*
- *Lack of adequate training in medicines quantification was cited as one of the reasons affecting availability*
- <http://www.bioline.org.br/request?pr10067> “

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Example Medicines Quantification in Vietnam

- The PEPFAR supported provision of HIV/AIDS medicines to Vietnam provides over 30 different anti-retroviral (ARV) medicine formulations for use in other 30 different treatment protocols, to over 29,000 people living with HIV/AIDS; with a budget of US \$ 9 million.
- It is a highly complex system of medicines, further complicated by rapidly changing ratios of treatment protocols.

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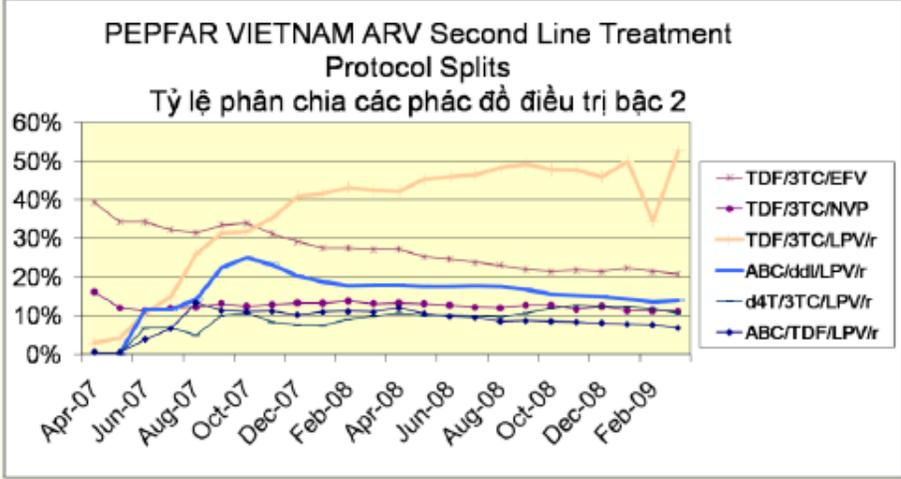





Changing ARV Treatments over time in Vietnam

PEPFAR VIETNAM ARV Second Line Treatment Protocol Splits

Tỷ lệ phân chia các phác đồ điều trị bậc 2



Month	TDF/3TC/EFV (%)	TDF/3TC/NVP (%)	TDF/3TC/LPV/r (%)	ABC/ddI/LPV/r (%)	d4T/3TC/LPV/r (%)	ABC/TDF/LPV/r (%)
Apr-07	38	15	2	0	0	0
Jun-07	35	12	5	10	0	0
Aug-07	32	10	15	15	5	0
Oct-07	35	12	25	25	10	0
Dec-07	30	12	40	20	10	0
Feb-08	28	12	45	18	10	0
Apr-08	27	12	48	18	10	0
Jun-08	25	12	50	18	10	0
Aug-08	23	12	52	18	10	0
Oct-08	22	12	50	18	10	0
Dec-08	22	12	50	18	10	0
Feb-09	22	12	55	18	10	0

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Potential Effects of Incorrect Quantification – ARVs Vietnam

A 5% error in the quantification could result in:

- Wastage of medicines (many ARVs have a shelf life of only 2 or 3 years) with a value of over **US \$ 450,000**

AND

- Interruption of treatment through stock outs to over **1,500 patients**, which could result in increased patient morbidity, and **even death**.

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Successfully Quantification is Achievable

- In practice, the PEPFAR program in Vietnam has consistently achieved a less than 1% wastage rate with no stock outs, in over 7 years of operation, through the use of well managed quantification techniques.
- Although donor funded, this is a Vietnamese program operated by Vietnamese pharmacists.
- Good quantification, even of highly complex medicine systems, is possible **using existing well established pharmaceutical management techniques**.
- It requires a systematic and good management approach but is not especially complex or difficult.

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Major Methods of Quantification

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Major Methods of Quantification

AIM:

- Be aware of the four major methods of pharmaceutical quantification and their relative strengths and weaknesses.

LEARNING OBJECTIVES:

At the end of this Module, students should, be able to explain:

- The four major methods of pharmaceutical quantification
- The relative strengths and weaknesses of the different methods
- The circumstances for selection of an appropriate quantification method

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Methods of Quantification

There are four major methods of pharmaceutical product quantification.

- The names of the methods are often misunderstood by non-PSM specialists, so it is important that you understand the name, the method, and are able to explain the basic methodology to non-specialists.
- The four methods are **NOT exclusive**. In the best systems, **at least two different methods** will be used so as to provide a check on the calculations.

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The 4 Major Methods of Quantification

The four major methods of pharmaceutical (and health products) quantification are:

- Consumption method
- Morbidity method
- Proxy consumption method
- Service-level projection of budget requirements

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Consumption Method Overview

The **consumption method** uses records of past consumption of individual medicines (adjusted for any stockouts and projected changes in medicine use) to project future need.

E.g last year we dispensed 1,250 bottles, no stock outs, and this year we expect to dispense 5% more so:

$$1,250 * 1.05 = 1,313 \text{ bottles required.}$$

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Morbidity Method Overview

- The **morbidity method** estimates the need for specific medicines based on the incidence of common diseases, and standard treatment guidelines
- In effect, the estimated number of patients multiplied by the average amount of medicine needed per patient.
- *E.g. Vietnam Population 86,206,000. National TB incidence of sputum smear (ss) positive cases: 85 per 100,000 population. Detection/Treatment level of ss TB 85%. So: $86,206,000 * 85/100,000 * 85\% = 62,323$ patient requiring treatment. Then use Standard Treatment Guidelines for amount for medicine needed.*

<http://www.stoptb.org/assets/documents/countries/acsm/Viet%20Nam.pdf>

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Proxy Consumption Overview

- The **proxy consumption method** uses data on medicine consumption, demand, or use, from a “standard” supply system and extrapolates the consumption or use rates to the target supply system, based on population coverage or service level to be provided.
- *E.g. Treatment of Candida Esophagitis amongst People Living with HIV/AIDS. No reliable morbidity or consumption data for Vietnam. Thailand treats around 30% of AIDS patient before starting ART. Treatment is Fluconazole 150mg, bid for 14 days. Vietnam has around 26,828 Patient on ART (2007*
http://www.unaids.org.vn/index.php?option=com_content&task=view&id=28&Itemid=72&lang=en) So, $26,828 * 30\% * 2 * 14 = 225,355$ tablets of 150mg Fluconazole required.

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Service Level Projection Overview

- **Service-level projection of budget requirements** uses the average medicine cost per patient or attendance in different types of health facilities in a standard system to project medicine costs in similar types of facilities in the target system. This method **does not** estimate quantities of individual medicines, but is exceedingly **useful for providing a ‘reality check’** on calculations made by the other methods and **really should be made on all major quantifications.**
- *E.g The per patient year medicine cost for first line ART in Vietnam is US \$ 102. In 2007, 26,828 patient on treatment so medicine cost should be around $\$ 102 * 26,828 = \$ 2,736,45$*

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Accuracy of Quantification - General

- All quantification of pharmaceutical requirements is inherently imprecise because of the many variables involved.
- It can only ever be as accurate as the data available, and often in public sector systems little accurate data is available.
- Quantifications are always estimates, and should never be viewed as exact requirements.

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Quantification – Art and Science

Good quantification requires a balance of “art,” or human judgment, and science, because:

- the base data is inaccurate or incomplete,
- there is irrational use of medicines (not following the Standard Treatment Guidelines),
- there are seasonal (malaria only during rainy season) or migratory or erratic usage patterns

Experience is important

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Relative Accuracies of the Different Methods

- Each of the four quantification methods has particular strengths and weakness and selecting which method(s) to use will often be dictated by the availability of good quality data.
- There is no one 'Best Method'
- There can be a 'better method' for the particular combination of circumstances and data

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Consumption Method Accuracy 1

- Consumption Method is generally considered to have the **greatest potential to be the most accurate** of the different methods provided: the source data are complete, accurate, and properly adjusted for stockout periods and anticipated changes in demand and use.
 - Uses data on medicines consumption (dispensed to patient or inventory)
 - Predicts future needs most accurately when current usage patterns will continue
 - **Requires reliable consumption data**

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Consumption Method Accuracy 2

- Consumption data may not reflect rational prescribing or rational use of medicines (e.g if there is high use of antibiotics for viral infections, this method will continue supplying large quantities of antibiotics)
- Comparison with morbidity-based method allows an estimate of the extent to which current consumption—
 - Addresses priority health needs
 - Reflects rational use of medicines
- If stockouts have been widespread for long periods, applying this method accurately may be impossible.

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Morbidity Method Accuracy 1

- Morbidity-based quantification is the most complex and time-consuming method. In many countries, assembling valid morbidity data is very difficult.
 - Used for new programs or for programs where consumption data are not available/reliable
 - Forecasts the quantity of medicines needed for prevention/treatment of specific diseases based on projections of the incidence of those diseases
 - Requires accurate information on the population and morbidity as well as clinic attendances, and uses standard treatment guidelines (STGs) to project needs

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Morbidity Method Accuracy 2

- Most complex and time-consuming of all four methods
- Best alternative for:
 - a new program with no previous consumption history, such as HIV/AIDS programs rolling out antiretroviral therapy (ART);
 - or changes in standard treatment guidelines.
 - a limited range of health problems accounts for virtually all medicine consumption, such as a small primary care system;
 - a special-purpose hospital;

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Proxy Consumption Method Accuracy

- Proxy consumption is the method generally used if neither the consumption-based nor the morbidity-based method is feasible.
 - Used for new sites or new programs
 - Can be population based or service based
 - Uses data from an existing system to extrapolate requirements for a new system based on population coverage or the service level to be provided
 - Can be difficult to match/adjust for all variables—for example, prescribing practices
 - **useful for cross-checking** projections made with other methods.

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SERVICE Level Projections

- Service-level projection produce a rough estimate of financial needs for pharmaceutical procurement
 - Used for estimating budget needs
 - **Does not estimate quantities** of medicines
 - Uses the average medical supply cost per attendance in different types of health facilities in one system to project needs for similar types of facilities in another system
 - Useful in providing a **quick and easy method of budget estimates**, and in providing a **quick check on calculations made by the other methods.**

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Comparisons of Quantification Methods

Method	Uses	Essential Data	Limitations	Application
Consumption	First choice, IF reliable data is available	Reliable dispensed to patient/inventory records	Must have accurate consumption data	Mature/stable programs with accurate and complete 'dispensed to patients' records
	Most reliable predictor of future consumption	Projected pharmaceutical prices	Can perpetuate irrational use	

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Comparisons of Quantification Method 2

Method	Uses	Essential Data	Limitations	Application
Morbidity	Estimating need in new and scaling-up programs or disaster assistance	Population and patient attendances	Morbidity data not available for all diseases	New programs, or no or unreliable consumption data or rapid scale ups. Measuring irrational medicine use/system accuracy/efficiency
		Actual or projected incidence of health problems	Standard treatments may not really be used	
	Comparing use with theoretical needs	Standard treatments (ideal, actual)		
	Developing and justifying budgets	Projected pharmaceutical prices		

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Comparisons of Quantification Method 3

Method	Uses	Essential Data	Limitations	Application
Proxy consumption	Procurement quantification when other methods are unreliable	Comparison area or system with good per capita data on consumption, patient attendance, service levels, and morbidity	Questionable comparability of patient populations, morbidity, and treatment practices, between sites/countries	No or only unreliable consumption or morbidity data available
		Number of local health facilities by category		
	Comparing use with other supply systems	Estimates of local user population		

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Comparisons of Quantification Method 3

Method	Uses	Essential Data	Limitations	Application
Service-level projection of budget requirements	Estimating budget needs	Use by service levels and facility type	Variable facility use, attendance, treatment patterns, supply system efficiency	Quick budget estimate Reality check on calculations from other methods
	Reality check on calculations by other methods	Average medicine cost per attendance/year		

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Examples of Usage of Different Quantification Methods

Vietnam ARV program.

- Year 2004 started on Morbidity method, because:
 - New program, no consumption data available,
 - Rapid scale-up (doubling patient numbers every year,
 - Rapidly changing standard treatment guidelines (one new treatment regimen every month).
- Year 2008, after 4 years when:
 - reliable consumption data was available,
 - stable treatment protocols established
- : changed to using Consumption method for quantification with Service Level as a check.
- Still uses Morbidity method for long term (5 year) forecasting.

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Examples of Usage of Different Quantification Methods

- Vietnam Opportunistic Infection (OI) medicines program for People Living with HIV/AIDS
- Year 2005 started using Proxy Consumption method with morbidity data from USA because:
 - New program no consumption data available
 - No morbidity data available for Vietnam or any regional country
- Year 2009, clear that USA data was not valid for Vietnam
 - No reliable consumption data because of lack of reporting
 - Clear indications of large over and under stocks
 - Massive regional/provincial variations in usage patterns

- -: changed to using Service Level Projection of US \$ 40 per patient year for Provinces to procure their own medicine requirements within the budget allowance.

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