Course on Medicines Policy Analysis in Health and Insurance Systems

Participant Guide

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Contributors and Acknowledgments

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Table of Contents

Monday, September 24

Overview and Gallery of Experts

Objectives

The main objectives of this session are to provide an overview of the course and to introduce participants and facilitators to each other. The gallery of experts will also begin to build a foundation for experience sharing and group development.

Outline

- Brief overview of course
- Activity to create a Gallery of Experts to introduce participants and facilitators.

Readings

None

Discussion Questions

None

Learning Points

- Each participant and facilitator comes to the course with a different perspective, background, experience, and skills.
- Participants can be valuable resources for each other in the learning environment of this course, and also in collaborative work in their own setting after the course.

Session 1: Medicines access and use: Significance, problems, and determinants

Objectives

This session will introduce the crucial role of medicines in curing disease and preventing morbidity and mortality. We will discuss a behavioral framework for thinking about use of medicines and describe several common intervention strategies to improve their use. These issues will be discussed in the context of the complex political, social, economic, and ethical aspects of health and health care. We will also present some key policy recommendations from the 2004 International Conference on Improving Use of Medicines.

Outline

- Roles of medicines in society
- Case discussion of consumer access to prescription medicines in pharmacies and potential policy problems
- Pharmaceutical sector framework and behavioral perspective
- Determinants of medicines use by health providers and consumers
- Overview of intervention strategies to change medicines use behavior

Readings

Laing RO, Hogerzeil HV, Ross-Degnan D. Ten recommendations to promote improved use of medicines in developing countries. Health Policy Plan 2001; 16(1): 13-20.

Policies and Programmes to Improve Use of Medicines: Recommendations from ICIUM 2004 (http://www.icium.org/icium2004/ Accessed September 2007). See especially the following sets of recommendations: 8. Economic issues: pricing; 11. Generic prescribing and dispensing; 14. Insurance coverage; 18. Medicines use in the private sector 25. Improving hospital prescribing.

Discussion Questions

1. What major factors influence the way medicines are used in your country and what are major problems in the way they are used?
2. How effective are current policies and programs to influence prescribing and dispensing by health providers and use of medicines by consumers?
3. What opportunities exist in your system for implementing tailored interventions to improve key problems in medicines use?

Learning Points

- Medicines play important clinical, public health, economic, and political roles in societies.
- Access to and appropriate use of medicines are determined by a complex network of individual and system-related factors.
- Many types of educational, managerial, economic, and policy interventions can be used to try to influence the way medicines are used by prescribers, dispensers, and patients. Interventions that combine multiple components in a coordinated way tend to be more successful.

- Health systems and insurance programs may design interventions to address specific problems among known groups of health providers or patients. These tailored interventions generally use educational outreach as a central approach, combined with managerial supports like standard treatment guidelines and formularies. To address other more generalized problems like unnecessary use of expensive brand medicines, intervention approaches are often less targeted and more systems-oriented, combining restrictive policies, positive and negative financial incentives, management systems strengthening, and some supportive education.
- In general, interventions have greater long-term impact on behavior when the economic incentives of institutions, providers, and patients can be aligned. Economic incentives provide continuous reinforcement of the desired behaviors.

Activity 1: Determinants of medicines access and use

Format: Large group case discussion (30 minutes)

Read the following excerpt from a 2001 article in the Wall Street Journal and be prepared to discuss the questions that follow.

Drug Firms' Incentives Fuel Abuse by Pharmacists in India

® By Daniel Pearl and Steve Stecklow, The Wall Street Journal, August 16, 2001

BOMBAY -- Pharmacy owner Ranjit Ranawat smiles as he recalls how he surprised his wife one day with a new, 29-inch color television, courtesy of GlaxoSmithKline PLC India. How did he get it? He ordered 600 vials of Fortum, an antibiotic, and 100 boxes of Ceftum, a drug for urinary tract and respiratory infections. That's 10 times as much as he normally would stock.

Incentives to buy large quantities of prescription drugs have become commonplace in India, where thousands of drug manufacturers compete for shelf space and the country's half-million pharmacists wield an unusual amount of clout. Pharmacists in the U.S. and other developed countries have little influence over the volume of prescription-drug sales. There, the marketing push usually targets doctors, the main legal conduit for prescription drugs. In India, many patients are too poor or too busy to see a doctor and often rely on local pharmacists for medical advice. As a result, powerful drugs are routinely, and illegally, sold over the counter…

As in the U.S., pharmaceutical companies had long courted Indian doctors with gifts and junkets. But as the number of Indian companies proliferated and their representatives began descending on doctors' offices in droves, they often were given scant time to promote their products. So the drug makers began paying more attention to pharmacists…

Despite Indian regulations that require a licensed pharmacist to dispense all prescription drugs, untrained counter assistants often perform that role. And even when pharmacists are on hand, they often don't provide printed information about a drug's possible adverse reactions or explain the proper dosage…

Some prescription drugs promoted by pharmaceutical companies are mild cough medications or skin creams. But many of the more lucrative incentive plans promote a powerful array of antibiotics, anti-inflammatories, sedatives and painkillers, some of which must be injected…

Nearly half of all bonus deals feature antibiotics, which are overused and misused in India, according to health experts. "For any condition, a patient gets antibiotics over the counter," says Sujeet K. Bhattacharya, director of the National Institute of Cholera and Enteric Diseases in Calcutta. Frequently, those patients don't complete the full course of treatment, he adds. That has led to a number of serious diseases in India, including cholera, typhoid and gonorrhea, growing resistant to common antibiotics in recent years.

Discussion Questions

1. How is this situation similar to or different from the situation in private retail outlets in your own country?
2. What are some key problems in access to and use of medicines illustrated here and what factors cause these problems?
3. What policy options exist to improve the way that medicines are recommended and sold in this setting?

Session 2: An insurance framework for influencing medicines access and use

Objectives

The first objective of this session is to discuss the economic impact of medicines on overall health expenditures and on catastrophic household expenditures for the poor. We will then summarize medicines financing options and highlight the role of medicines coverage in health insurance systems. We will present a framework of the structures and processes that can be used to manage medicines coverage within an insurance system, and discuss how this framework applies to participating organizations.

Outline

- Importance of medicines in health care and risk protection
- Medicines financing options
- Medicines coverage in insurance programs
- Functional framework for designing and managing medicines coverage policies

Readings

Academy of Managed Care Pharmacy. Maintaining the affordability of the prescription drug benefit: How managed care organizations secure price concessions from pharmaceutical manufacturers. (http://www.amcp.org/amcp.ark?p=AAAC630C Accessed September, 2007)

Academy of Managed Care Pharmacy. Academy of Managed Care Pharmacy. Pharmacy benefit communication grid. (http://www.amcp.org/amcp.ark?p=AA8CD7EC Accessed September, 2007).

Goff VV. Pharmacy benefits: New concepts in plan design. National Health Policy Forum Issue Brief No.772. Washington, DC; George Washington University: 2002.

Kaiser Family Foundation. Prescription drug trends. May 2007. (http://www.kff.org/rxdrugs/upload/3057_06.pdf. Accessed September, 2007)

McIntyre D, Thiede M, Dahlgren G, Whitehead M. What are the economic consequences for households of illness and of paying for health care in low- and middle-income country contexts? Social Science & Medicine 2006; 62: 858–865.

Seiter A, Lakshminarayanan R. Pharmaceuticals: Cost containment, pricing, reimbursement. HNP Brief. No. 7. Washington DC; The World Bank: August 2005.

Discussion Questions

1. How are medicines financed in your health care system?
2. Are the poor able to obtain access to essential medicines in your health system?
3. How are medicines covered in your health system or insurance program?
4. What structures and processes does your health system or insurance program use to manage medicines coverage?
5. Which are the key medicines coverage issues facing your health care system or insurance program?

Learning Points

- Medicines play important economic roles in societies. In many developing countries, medicines often represent the majority of health care costs (compared with about 10%-15% in OECD countries).
- Ensuring access to essential medicines offers important advantages for individuals, health care organizations, governments, and society as a whole. Medicines can cure or control diseases that have negative economic impacts on the entire population, such as malaria; they can prevent costly complications of chronic illnesses like diabetes; and they can reduce or prevent use of costly health services such as inpatient surgery for peptic ulcers.
- Higher levels of spending on medicines may not always result in better health outcomes and economic benefits.
- Containing medicines expenditures is an important issue in all health systems and insurance programs that cover medicines. Escalating medicines expenditures result from increases in the total volume of medicines purchased, changes in the mix of products selected, and increases in the price of those medicines. Many supply-side and demand-side factors influence the volume, selection, and price of medicines.
- Key supply-side factors that contribute to high medicines costs include: (a) market entry of innovative but costly treatments that meet unsatisfied clinical needs; (b) marketing pressure to shift prescribing and sales to more costly products, regardless of clinical need; (c) lack of leverage in negotiating medicines prices; (d) lack of competition in the generic medicines marketplace; (e) lack of transparency and accountability in price setting and supply; (f) economic incentives for individual providers or health institutions to prescribe and dispense more profitable high-cost medicines; (g) inability to ensure the quality of medicines in the marketplace.
- Key demand-side factors that drive medicines costs include: (a) aging populations with chronic illnesses like cardiovascular diseases and spreading epidemics like HIV/AIDS and malaria; (b) increasing purchasing power and demand for health care; (c) lack of trust in locally produced generic products and demand for costly imported products; (d) patient demand for specific products as a result of advertisement or other types of drug promotion; (e) lack of health provider adherence to evidence-based standard treatment guidelines; (f) lack of organizational capacity to assess quality or cost-effectiveness of treatment; (g) lack of coordination between inpatient and outpatient care.
- Health systems and insurance programs have a wide array of options for managing medicines benefits to achieve clinical objectives and contain costs. Key opportunities for managing medicines coverage include deciding which medicines to cover; procuring or reimbursing for those medicines at fair prices; building performance standards into provider accreditation or contracting; monitoring both the cost and quality of pharmaceutical care; actively facilitating use of generic medicines; and implementing programs to assist patients in using medicines in a clinically effective way.
- Health systems and insurance programs need to communicate about medicines benefits policies and programs to payers, providers, institutions, and consumers. The Academy for Managed Care Pharmacy suggests a variety of strategies that health plans can use to communicate with employees, purchasers, providers, and patients about details of pharmacy coverage (see http://www.amcp.org/amcp.ark?p=AA8CD7EC).

Activity 1: A functional framework for medicines coverage in insurance systems

Format: Small mixed group discussion then large group debriefing (1 hour)

The table below lists some key functions that health or insurance systems may undertake to develop medicines coverage or manage a pharmacy program. Please discuss in your group how your systems handle each function listed. Which departments, committees, or people are involved? Which data systems are used? Does your system carry out this function efficiently? Which functions are coordinated? What are current problems?

Key Function	Implementation in Health Insurance System
1. Determining needs for medicines	
2. Allocating resources for pharmacy services and financial monitoring	
3. Formulary or essential drug list decision making and management	
4. Accrediting/certifying suppliers (providers, hospitals, pharmacies, manufacturers, products)	
5. Contracting (clinicians, hospitals, pharmacies, manufacturers, government, employers, etc.)	
6. Negotiating medicines prices	
7. Procuring or purchasing medicines	

Key Function	Implementation in Health Insurance System
8. Delivering pharmacy services: running pharmacy outlets, mail-order pharmacy	
9. Processing claims for medicines payments	
10. Communicating with members and providers about medicines benefits, limitations, costs, etc.	
11. Marketing medicines benefits to payers and members	
12. Providing medicines-related clinical care: adherence monitoring, disease management	
13. Monitoring utilization of clinicians, hospitals, pharmacies, manufacturers (including fraud/abuse)	
14. Reporting utilization to providers, members, accreditation organizations, government, public	
15. Evaluating, monitoring, reporting effects of coverage policies	
16. Other?	

Activity 2: Identification of key medicines policy issue

Format: Small country group discussion then large group debriefing (30 minutes)

During the course, small groups (usually from the same country) will work together on developing a policy analysis or intervention on an important issue in their health systems or insurance programs.

This exercise is the first step in this activity. Form small groups (4-5 people) who would like to work together on this exercise. You will have opportunities to change groups as the course proceeds if necessary.

Select an important issue or problem related to access to or appropriate use of medicines in your health system or insurance program. Try to select an issue or problem that you think you might be able to use data available in your system to explore. Discuss the issue in the group and write brief answers to the following questions on flip charts to present to the large group.

1. What is the issue or problem?
2. Why is this an important issue or problem to address in your system at this time?
3. What is currently known (prevalence, providers or members involved, cost, clinical consequences)?
4. Have there been any past efforts in your system to address this issue?
5. What studies or activities are currently planned?
6. At this point in the course, what do you think could potentially be done to address the issue?

Tuesday, September 25

Session 3: Availability and use of data in health systems and insurance programs

Objectives

The objectives of this session are to characterize the types of data that often exist in health systems and insurance programs. Existing data may include information on enrollees, patients, providers, medicines, episodes of hospital care, outpatient visits, and procedures. To illustrate the ways in which these types of data can be employed for policy analysis, we will use data from a health insurance program to explore utilization patterns and costs of care for members hospitalized to treat hypertension.

Outline

- Comparison of data available in the systems of course participants with a comprehensive list of possible data elements
- Use of data to quantify problems in medicines coverage and use
- Example: Analysis of inpatient claims data to quantify a potential medicines coverage problem
- Collecting ad hoc data to study a problem in depth

Readings

Chan KA et al. Development of a multipurpose dataset to evaluate potential medication errors in ambulatory care settings. AHRQ 2005.

Description of the ATC/DDD System. WHO Collaborating Center for Drug Statistics Methodology, Oslo. Available at http://www.whocc.no/atcddd/.

International Network for Rational Use of Drugs. How to use applied qualitative methods to design drug use interventions (draft). Chapter 1: Overview of Methods. (http://www.inrud.org/documents/How_to_Use_Applied_Qualitative_Methods.pdf)

Jollis JG, Ancukiewicz M, DeLong ER, Pryor DB, Muhlbaier LH, Mark DB. Discordance of databases designed for claims payment versus clinical information systems: Implications for outcomes research. Ann Intern Med. 1993; 119: 844–850.

Strom BL. Overview of Automated Databases in Pharmacoepidemiology. In Strom BL, ed. Pharmacoepidemiology, Fourth Edition. Chichester: John Wiley & Sons Ltd, 2005, 219-222.

Unauthorized Guide to Multum's Lexicon. Cerner Corporation, 2005. Available at http://www.multum.com/LexGuide.pdf.

Zhao Y, Ash AS, Ellis RP, et al. Predicting pharmacy costs and other medical costs using diagnoses and drug claims. Med Care 2005;43:34-43.

Discussion Questions

1. Which types of data tend to exist in most health and insurance systems? What are their strengths and weaknesses?

2. Which coding systems are commonly used to classify medicines, diseases, and procedures? Which systems are currently used in the systems of course participants?
3. Which data would be needed to describe a key medicines problem in your system? Could you obtain these data?

Learning Points

- Data on patients/enrollees, health providers, and medical services frequently exist in systems that provide or finance medical care. We refer to these as administrative data. In some systems, administrative data originate from computerized records that identify members and document encounters between patients and health care providers. In other systems, records on patients and services provided are only recorded manually and are usually kept in medical records or treatment logs at the point of care.
- Administrative data are most useful for policy analysis if they are accurate, complete, identify unique members of a well-defined population, and contain the key data elements (e.g., visits, diagnoses, procedures, medicines, costs) needed to evaluate a specific policy.
- Insurance systems routinely collect data to enroll members and reimburse claims. These data are not designed for research purposes, but they can often be very useful to evaluate and monitor the effects of medicines coverage policies.
- Insurance data systems capture utilization of services delivered to or paid for insurance system members. Generally, the data elements needed for financial transactions (e.g., the type, amount, and cost of a prescription drug dispensed) are more complete and reliable than data that are not used for specific business purposes (race, ethnicity, weight, smoking status, etc.).
- Administrative data are useful for policy analysis because they are often readily available at low cost; without interference in the care process; cover defined populations for long periods of time; are often already in electronic format; and avoid recall bias inherent in survey data.
- Limitations of administrative data include lack of information on non-members, services delivered outside the system, clinical outcomes not associated with a diagnosis (e.g., pain, blood pressure, and mood changes), health status (functioning and well-being), quality of care, or satisfaction with care. Another potential bias of insurance systems data is the tendency to shift diagnoses to those with higher reimbursements. Using administrative data, it is also difficult to assess severity of illness and certain comorbidities (such as mental health conditions).
- The validity of administrative data to identify patients with specific diseases or utilization patterns depends on the data source and the disease of interest. For example, information on procedures performed (e.g., hip fracture repair) which are specific to a disease can be used to accurately identify patients with such diseases in administrative data. Information on procedures performed can be combined with inpatient and outpatient visit diagnoses to create a "claims history" that can identify patients with specific diseases.
- Administrative data often contain data on professional services provided, diseases treated, procedures performed, and medicines dispensed. Coding and classification systems are needed to organize data on service types, diseases, procedures, and medicines. Wherever possible, administrative systems should use existing classification systems rather than developing their own.
- Classification systems for medicines are particularly complex for several reasons: large numbers of medicines exist and many have similar names; chemically equivalent

medicines are marketed under different trade names; new products enter the market frequently; and medicines differ from country to country. Because of this complexity, there is no universally adopted classification system for medicines. To be useful, a medicines coding system must allow for new medicines and new therapeutic classes; be updated frequently; be organized so that medicines used to treat a particular condition are easily retrievable together; and allow for medicines to be assigned to more than one therapeutic class.

- Routine insurance system data are limited in scope. Questions about access to medicines and affordability of medicines require ad-hoc collection of data through population and/or member surveys.
- Once a medicines use problem has been identified, many health programs jump ahead to implementing targeted interventions or policy changes without fully understanding the reasons for the problems. This can lead to ineffective interventions or unexpected negative results. To avoid unsuccessful approaches, a variety of quantitative an qualitative methods can be used to explore an identified problem in more detail in order to design a strategy to address it efficiently and effectively. Common exploratory methods include focus groups, in-depth interviews, structured observations of provider or patient behavior, and attitude questionnaires.

Activity 1: Availability of data in insurance systems

Format: Large group discussion (30 minutes)

The table below presents a comprehensive list of data on medicines use, cost, diagnoses, and procedures that are frequently available in health or insurance systems. Which are routinely available in your system (column 2) and which ones you might be able to collect from other sources (column 3). We will present summaries of data availability in the systems represented in the course for comparison.

Type of data	Have in my system? (yes/no)	Could get from other source? (yes/no, how?)	No. of systems with these data
Enrollee data			
Age			
Gender			
Employment status			
Socio-economic group			
Enrollment period			
Details of benefit package			
Medicines data			
Unique drug identifying code			
Generic name			
Brand name			
Generic vs. brand indicator			
Dosage form			
Strength			
Dose prescribed per treatment			
Prescriber identification			
Date prescribed			
Dispenser identification			
Date dispensed			
Quantity dispensed			
Total charge			
Amount paid by patient			
Hospitalization data			
Admission date			
Admission diagnosis description			

Availability and use of data in health systems and insurance programs

Type of data	Have in my system? (yes/no)	Could get from other source? (yes/no, how?)	No. of systems with these data
Admission diagnosis code (ICD)			
Admission diagnosis code (non-ICD)			
Discharge date			
Discharge diagnosis description			
Discharge diagnosis code (ICD)			
Discharge diagnosis code (non-ICD)			
Total hospital charges			
Hospital charges by type of service			
Amount paid by patient			
Outpatient visit data			
Outpatient visit diagnosis description			
Visit diagnosis code (ICD)			
Visit diagnosis code (non-ICD)			
Visit date			
Total visit charges			
Amount paid by patient			
Procedure data			
Procedure description			
Procedure code (ICD/CPT)			
Procedure code (non-ICD, non-CPT)			
Procedure date			
Procedure provider identification			
Procedure place of service			
Total procedure costs			
Amount paid by patient			
Provider data			
Provider name			
Unique provider code			
Provider type (e.g. physician, facility)			
Provider address			
Age (for individual providers)			
Gender (for individual providers)			
Specialty (for individual providers)			

Activity 2: Impact of providing only inpatient coverage for hypertension

Format: Small (across system) groups then large group debriefing (2 hours)

The Philippine Health Insurance Corporation (PhilHealth) currently covers primarily inpatient care (except for adult tuberculosis treatment, maternity care, and malaria treatment). For many diseases, the lack of outpatient medicines coverage can lead to unnecessary use of costly inpatient care.

Evaluating the extent to which outpatient benefits might be a cost-effective approach for a given health problem requires some or all of the following analyses:

- Examine the current extent of payments for inpatient services for patients with the target health problem;
- Identify subgroups of patients who experience potentially preventable hospitalizations and estimate the costs involved;
- Examine the adequacy of outpatient use of medicines for the target condition;
- Estimate the degree to which inability to pay for medicines is a reason for poor adherence to recommended medications;
- Assess ability and willingness to pay for outpatient medicines at possible levels of an outpatient medicines benefit;
- Evaluate the logistical and economic feasibility of implementing an outpatient medicines benefit for specific subgroups of patients.

You have an Excel data set that was created to explore the patterns and cost of inpatient hypertension care for PhilHealth members. The data set contains the variables listed in the data dictionary below. Please refer to the section "Working with Excel" to find instructions on how to aggregate data in Excel using formulas and pivot tables.

Using these data, assess the extent of current PhilHealth expenditures on hypertension inpatient care by age and gender. Create pivot tables for cost by age, cost by gender, cost by hypertension diagnosis category by age and cost by hypertension diagnosis category by gender. Examine whether patterns of inpatient care differ by patients with different severity of hypertension.

Based on the results, discuss the following questions:

1. Which groups of patients might be appropriate candidates for an outpatient medicines benefit for hypertension?
2. What additional information would you need on these patients to decide if such a benefit would be feasible and cost-effective?
3. If a benefit was to be implemented, what administrative and clinical systems would need to be developed in order to monitor the effectiveness of the benefit?

Data Dictionary for PhilHealth Hypertension Inpatient Claims Data

Variable Name	Variable Description and Data Summary
PATIENTID	Patient identification number Number of observations, n=1000 Number missing, n=0 Min=5000495, Max=5601856
AGEGRP	Patient age group Number of observations, n=1000 Number missing, n=0 0-39, n=90 40-59, n=385 60-79, n=451 80+, n=74
PATAGE	Patient age Number of observations, n=1000 Number missing, n=0 Min=18, Max=93, Mean=59.5
PATSEX	Patient gender Number of observations, n=1000 Number missing, n=0 Male, n=571 Female, n=429
HTNCAT	Hypertension diagnosis category Number of observations, n=1000 Number missing, n=0 Primary or secondary hypertension, n=404 Hypertensive heart or renal disease, n=226 Potential consequences of hypertension, n=370
MONDIS	Discharge month Number of observations, n=1000 Number missing, n=0 January, n=110 February, n=92 March, n=79 April, n=83 May, n=70 June, n=76 July, n=76 August, n=71 September, n=87 October, n=85 November, n=90 December, n=81

Variable Name	Variable Description and Data Summary
B_TOTAL	PhilHealth reimbursement as written on check Number of observations, n=1000 Number missing, n=0 Min=100, Max= 62890.00, Mean=6039.36
B1_PHIC	Total computed allowable amount for room and board Number of observations, n=891 Number of missing, n=109 Min=0, Max=18000.00, Mean=1436.11
B2_PHIC	Total computed allowable for drugs and medicines Number of observations, n=923 Number missing, n=77 Min=0, Max=18986.60, Mean=2132.69
B3_PHIC	Total computed allowable amount for X-Ray/Lab Number of observations, n=922 Number missing, n=78 Min=0, Max=14000.00, Mean=1838.84
B4_PHIC	Total computed allowable amount for O.R. Number of observations, n=64 Number missing, n=936 Min=0, Max=3490.00, Mean=1093.72
Tot_PF_PHIC	Total computed allowable amount for physician care Number of observations, n=1000 Number missing, n=0 Min=0, Max=15900.00, Mean=620.79

Activity 3: Exploring determinants of medicines problems (optional)

Format: Small (within system) groups then large group debriefing

Think of the specific priority medicines problem in your health delivery or insurance system that you described in Session 2. Working with your colleagues, answer the following questions:

1. How could you explore the problem in more detail?
2. Which specific questions would you ask about the populations, health problems, or medicines involved?
3. Which data sources and methods would be most useful in this exploration process?
4. If you have already explored this problem in your system, how did you do it?
5. How would you identify the patients, health providers, or system managers who would be the best sources of information?

Session 4: Medicines coverage policy options

Objectives

In this session, we will apply a behavioral framework to understand interventions to improve access to and use of medicines in health delivery systems or insurance programs. We will discuss the rationale, strengths, and unintended effects of various policies and program options.

Outline

- Case discussion of expanding antibiotic coverage for pneumonia treatment in the Philippines
- Insurance policy and program options to improve access to and use of medicines
- Studying intended and unintended policy effects

Readings

Aaserud M, Dahkgren AT, Kösters JP, Oxman AD, Ramsay C, Sturm H. Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies. Cochrane Database of Systematic Reviews 2006, Issues 2. Art. No.: CD005979.

Goff V. Pharmacy Benefits: New Concepts in Plan Design. NHPF Issue Brief No.772. National Health Policy Forum. Washington DC; George Washington University: March 8, 2002.

Hoadley J. Cost-containment strategies for prescription drugs: Assessing the evidence in the literature. Kaiser Family Foundation, March 2005. Available at: http://www.kff.org/rxdrugs/7295.cfm.

Nguyen A. What is the range of policy options that can be used to promote the use of generic medicines in developing and transitional countries? Draft for review and comment, 2007.

Schneeweiss S. Reference drug programs: Effectiveness and policy implications. Health Policy 2007; 81:17-28.

Shojania KG, Grimshaw JM. Evidence-based quality improvement: the state of the science. Health Aff (Millwood). 2005 Jan-Feb;24(1):138-50.

Walley T, Mossialos E. Chapter 10: Financial incentives and prescribing. In: Mossialos E, Mrazek M, Walley T, editors. Regulating pharmaceuticals in Europe: Striving for efficiency, equity and quality. European Observatory on Health Systems and Policies Series. Open University Press: 2004, 177-196. Available at http://www.euro.who.int/eprise/main/WHO/Progs/OBS/Publications/20040527_2.

Discussion Questions

1. What are some key issues in your system in access to or use of medicines?
2. What challenges do systems face in determining which medicines to cover and how to reimburse for medicines?
3. How can a health system or insurance program influence medicines access, use, and costs?

Learning Points

- Medicines policies in health delivery systems and the design of pharmacy benefits in insurance systems influence access to, cost of, and quality use of medicines.
- Health systems and insurance programs must continually update their medicines policies due to: availability of new and more expensive products; escalating prices for medicines; increasing patient and prescriber demand, in part due to effective marketing; continuously evolving standards of care; and changing population demographics and disease burden.
- Development of effective and cost-effective medicines policies requires: (1) Strong clinical expertise; (2) Well-developed processes for managing formularies and benefits; (3) Good communication with members/patients, providers (prescribers, pharmacists), employers, the government, and the pharmaceutical industry; (4) Information systems that can support efficient benefit administration.
- Medicines policies can be broadly grouped into those related to: formulary controls; other types of utilization management, medicines pricing, and regulation. Tables 4.1 to 4.4 that follow list some common approaches in each of these areas.
- Evidence is limited on the potential positive and negative impacts of most medicines policies. Efforts to contain medicines expenditures can make it more difficult for patients to get access to needed medicines and adhere to therapy due to administrative barriers and higher out-of-pocket costs. Lack of access and failure to use medicines correctly can result in higher downstream costs for outpatient and inpatient care to deal with uncontrolled health problems. Health and insurance systems should monitor both expected and unintended effects of medicines policies and develop procedures that are transparent and manageable for providers and patients.

Table 4.1: Policy Approaches – Formulary Controls

Policy Approach	Description
Coverage Limits: Limits on medicines that are provided or reimbursed, usually without regard to specific patient circumstances.	
Limiting coverage to specific medicines or therapeutic classes	Health system or insurance program identifies specific products or therapeutic classes to be covered (e.g., through a positive list) or excluded (negative list), leaving patients to pay the full cost of uncovered products.
Dispensing limits on the quantity of particular medicines received	Some programs limit how much of a specific medicine (quantity of tablets or number of days supply) can be dispensed or reimbursed during a given visit or time period.
Dispensing limits on the number or value of medicines received	Some programs limit the number or total value of medicines that can be dispensed or reimbursed in a given visit or time period.
Formulary Management: Formulary structures that promote the use of specific medicines or classes, usually based on economic or clinical criteria.	
Preferred drug list	Specific medicines are listed as preferred and these are promoted to physicians and patients using a variety of educational managerial, and economic approaches.
Step therapy/fail first requirement	To receive access to or be reimbursed for specific expensive medicines, patients must first have tried and failed on less expensive therapeutic alternatives, usually for chronic illnesses like hypertension or depression.
Mandatory generic substitution	Dispensers are required by regulation or coverage policy to dispense a generic product unless no generic equivalent is available, although some systems allow prescribers to override by writing “dispense as written” or “no substitution” on the prescription.
Therapeutic substitution	Some systems encourage dispensers to switch patients from the prescribed medication to a more preferred one, usually in the same therapeutic category, but dispensers usually need to contact the prescriber to authorize the change.
Provider incentives	Some health plans offer financial incentives to prescribers who meet explicit performance criteria, like rates of use of generic or preferred medications, or pharmacists who offer value-added services like adherence monitoring.
Cost-Sharing: Approaches that require patients to pay all or some of the cost of all medicines or specific medicines.	
Copayments in general	A charge (usually fixed) for each medication or for each medical consultation, paid by the patient and intended to discourage unnecessary utilization.

Policy Approach	Description
Tiered copayments	Copayments that vary by medication, often with generic products free or low copays, preferred brand products with higher copays, and non-preferred brands with the highest copay or paid completely out of pocket.
Coinsurance	A percentage of the medication cost that patients need to pay which will not be reimbursed by the health plan, sometimes with different coinsurance percentages by formulary tier.
Reference pricing	A health plan establishes a reference price as the basis for reimbursing medicines in a specific therapeutic class, usually the price of a low-cost effective generic, with patients responsible for any differences in price between a higher cost medication in the category and the reference price.

Table 4.2: Policy Approaches – Other Types of Utilization Management

Policy Approach	Description
Utilization Review: Strategies that focus on reviewing patterns of use for the system as a whole or for particular patients, physicians, health facilities, or regions.	
Physician, health facility, or regional profiling	Health plans give feedback to prescribers, facilities, or regions about their patterns of use overall, for specific diagnoses, or specific medicines, usually in comparison to peers or to theoretical evidence-based practice.
Disease management	Health plans identify patients with specific chronic conditions who are (potential or actual) high users of health care and medications, and offer them additional services to better manage their conditions, including education, careful monitoring, and adherence counseling interventions.
Contracting: Health systems or insurance programs can contract with providers as a mechanism to contain costs or improve quality.	
Preferred provider networks	Contracts with a network of health providers to provide care for health plan members, in return for lower fees, bundled services (e.g., disease management, adherence monitoring), or agreement to achieve performance standards.
Performance-based contracts	Provider contracts incorporating economic incentives that reward achievement of target rates of recommended practices (e.g., generic prescribing, guideline-based care) or use withholds to penalize failure to achieve target rates.

Policy Approach	Description
Education: Approaches based on providing information in a persuasive way to prescribers, dispensers, or patients as a strategy to influence medication use.	
Continuing education	Health plans frequently provide many types of traditional continuing education (printed materials, clinical guidelines, seminars), although reviews have shown these approaches may increase knowledge but do not change practice.
Educational outreach (academic detailing)	Health plans provide unbiased persuasive education to individual prescribers or small practice groups about comparative efficacy or cost in a format similar to the one used by the pharmaceutical industry (called detailing).
Tailored patient education	Print materials, audiovisual programs at treatment sites, group or individual educational sessions can inform patients about treatment of acute and chronic illness, medicines use and cost, or details of health plan benefits.
Promotion of generics	Programs to promote use of generics can include direct communication, information provided in pharmacies or health facilities, or media campaigns that aim to educate prescribers, dispensers, and patients about the quality and cost-effectiveness of using generic products.

Table 4.3: Policy Approaches – Medicines Pricing

Policy Approach	Description
Pricing strategies available to governments, health systems, or insurance programs: Policy options that can lower the costs of medicines to the system or to patients.	
Purchasing pools	Purchasers (for example, regions, hospitals) procure medicines jointly to increase purchasing power through higher volume and shared expertise
Rebates	Manufacturers return a percentage of the purchase price of specific medicines based on quantities used over a specified time period in order to gain access to a formulary or to have their products become preferred medicines. Rebate information is often proprietary, which limits the ability of other purchasers to negotiate the best prices for products.
Differential dispensing fees	To encourage generic dispensing, health plans can pay pharmacists a higher dispensing fee for generic products than for brand-name products, thus overcoming the disincentive inherent in percentage based mark-ups.
Preferred pharmacy networks	Health plans contract with a network of pharmacies to dispense to their members, either exclusively or on a preferred basis (with lower out-of-pocket costs at network pharmacies), in return for lower dispensing fees, generic dispensing, or other utilization management programs.

Policy Approach	Description
Discount cards	Health plans offer reduced prices to members who enroll in a discount card program for medicines from specific manufacturers or for prescriptions filled in a preferred pharmacy network.
Pricing strategies available only to governments: Government policies that can lower the costs of medicines throughout the pharmaceutical system.	
Price controls	Governments can fix prices paid to manufacturers, using defined formulas to set market entry prices, approve price increases, or in some cases, regulate profits.
Distribution mark-up controls	Governments can set the maximum mark-ups allowable to importers, wholesalers, or retailers as medicines pass through the distribution system, usually on a percentage basis.
Transparent pricing	Governments can mandate that manufacturers and distributors disclose specific information about prices or mark-ups so that purchasers or consumers can make more informed choices about medicines.

Table 4.4: Policy Approaches – Market Controls

Policy Approach	Description
Government policy options beyond pricing policies that can increase the availability and appropriate use of essential medicines.	
Promoting generic competition	Governments facilitate market entry and use of generic products by shortening approval times, lowering registration fees, establishing quality control mechanisms, and implementing pricing strategies that favor generics.
Importation of essential medications	Governments implement laws and establish systems to facilitate importation of less expensive pharmaceutical products from other countries, including taking advantage of the TRIPS flexibilities for parallel importation and compulsory licensing.
Regulating promotion	Governments implement regulations to control marketing activities of manufacturers and distributors, including ethical standards in promotion, allowable incentives for prescribers or dispensers, truth in promotional claims, quality of package information, and direct-to-consumer advertising.

Activity 1: Expanding medicines coverage – policy goals and potential effects

Format: Large group discussion (45 minutes)

Since the late 1990s, a clinical practice guideline for diagnosing and treating pneumonia has existed in the Philippines. Multidisciplinary teams of clinical experts from leading professional societies and hospitals developed the guideline, which the Philippine Health Insurance Corporation (PHIC) endorsed in 1999.

The pneumonia treatment guideline recommends specific antibiotics for the management of different types and severities of pneumonia based on strong research evidence supporting the efficacy of the drugs. At the time the guideline was developed, several of the recommended drugs still under patent were not included in the Philippine National Drug Formulary (PNDF), which lists only generic medicines. PHIC reimburses hospitals only for drugs that are listed on the PNDF (i.e., a positive list). Thus, PHIC was not reimbursing for specific medicines used in pneumonia treatment that was delivered according to its recommended treatment guidelines.

To correct this disconnect between evidence-based practice and reimbursement and to provide an incentive for guideline-based treatment, PHIC expanded its list of reimbursable antibiotics for pneumonia treatment to include 14 brand antibiotics that were recommended in the treatment guidelines but not included in the PNDF. These antibiotics included injectable and oral cephalosporins, dirithromycin, roxithromycin, and levofloxacin. Drugs on the Expanded Positive List were to be covered by PHIC only if prescribed for the indicated condition, pneumonia. The Expanded Positive List went into effect on October 1, 2000.

Please be prepared to discuss in the plenary group the rationale for the Expanded Positive List policy and its possible strengths and weaknesses. The discussion will address the following questions:

1. What were the expected positive impacts of the policy change for different stakeholders in the system (patients, physicians, hospitals, manufacturers, PHIC)?
2. What were some possible unintended effects for the different stakeholders?
3. What could PHIC have done to increase the positive impacts of the policy while minimizing its potential unintended effects?
4. What would you need to know to assess the actual impacts of the policy?
5. What would be the feasibility and likely outcomes of implementing a similar policy in your setting?

Expanded Positive List Discussion Notes

Group	Intended Effects	Possible Unintended Effects
Patients		
Providers		
Hospitals		
Manufacturers		
PHIC		

Activity 2: Possible approaches to address identified medicines problems

Format: Small (within system) group discussion then large group debriefing (1 hour)

Using the medicines problem in your setting that you identified in Session 2, describe possible approaches to addressing the problem, and discuss both desired impacts and possible unintended effects. Refer to the tables of potential approaches included in the session notes so that you can consider a range of possible approaches. Consider how you might combine approaches to create a multi-faceted intervention program.

Fill in the following template for each approach discussed.

Description of Intervention Approach	Rationale and Desired Positive Effects	Possible Unintended Impacts

Wednesday, September 26

Session 5: Medicines coverage policy objectives and performance evaluation

Objectives

This session explores the key objectives of medicines coverage policies and programs, and considers strategies for measuring the performance of a health delivery or insurance system in relation to these objectives. Possible performance domains may include equitable access to medicines, affordable medicines cost for patients and systems, clinical appropriateness of prescribing, adherence to therapy, achievement of clinical targets, or patient and provider satisfaction.

Outline

- Case study: Building the case for coverage of outpatient medicines for patients with hypertension in the Philippines
- Identifying the domains of intended policy effects
- Defining criteria for useful performance measures
- Mapping performance measures within policy domains
- Identifying data and operationalizing performance measures
- Uses of performance measures for policy evaluation, routine monitoring, or performance-based contracting

Readings

Friedman YM, Hanchak NA. Chapter 9. Pharmacy program performance measurement. In Navarro RP. Managed Care Pharmacy Practice. Gaithersburg, MD: Aspen Publishers, 1999.

Katz A, Soodeen R-A, Bogdanovic B, De Coster C, Chateau D. Can the quality of care in family practice be measured using administrative data? HSR: Health Services Research 2006; 41(6): 2238-54.

Selected sections from The Health Plan Employer Data and Information Set (HEDIS®) Volume 2, Technical Specifications, NCQA, 2008.

NCQA. Desirable attributes of HEDIS® measures. NCQA, 1998. Available at http://www.ncqa.org/programs/hedis/desirable%20attibutes.html.

Discussion Questions

1. In your system, which stakeholders would be interested in assessing system performance in the area of medicines coverage, and why?
2. Which policy domains and performance areas related to medicines coverage would be the most important to assess in your system?
3. Which aspects of medicines coverage could you assess using routinely collected data in your system?
4. Which performance measures might be the most useful to compare across different health systems and insurance programs?

Learning Points

- Managing a medicines benefit efficiently and effectively should involve: (1) periodically establishing meaningful long-term goals and short-term objectives; (2) assessing whether goals and objectives are achieved using standard performance indicators, (3) and implementing and evaluating policy and program changes to improve performance.
- Medicines coverage policies and programs often have goals and objectives in the following domains: (1) increasing equitable access to medicines, especially for vulnerable populations (poor, children, elderly, rural populations); (2) ensuring affordable medicines for patients (3) containing system costs for pharmacy and overall; (4) improving quality of prescribing; (5) encouraging patient adherence to prescribed treatment; (6) improving provider and patient satisfaction; and (7) improving health outcomes..
- Objectives in different domains can compete. For example, improving access to medicines for more members can increase overall system costs, requiring increased premiums that make health insurance less affordable. On the other hand, efforts to contain system costs may decrease access to medicines and reduce appropriate use.
- Performance indicators must be practical, reliable, valid, and sensitive to change. The most useful indicators can be calculated from routinely available data, often contained in an electronic data base. Technical definitions of performance indicators usually consist of a numerator (number of patients or prescriptions meeting the performance criterion) and a denominator (all observations that could possibly meet the performance criterion). Observations in the numerator must be part of the observations in the denominator. The table below includes examples of commonly used performance indicators.
- Some important performance indicators cannot be calculated from existing data, including measures of affordability of medicines at the household level; provider and patient satisfaction with care; and equitable access to medicines in different population groups. These indicators generally need to include data collected in member, patient, and provider surveys.
- Some health plans evaluate member satisfaction as an important pharmacy benefit performance area. In phone or mail surveys, they ask members about factors that contribute to satisfaction including: waiting time for prescription filling; courtesy of staff; ease of access to a pharmacy; accuracy of prescriptions filled; and quality of consultation by pharmacy staff.
- Quality of care affects long-term health care costs. Quality/cost measurement is complex. Low costs may indicate effective patient management or they may indicate lack of coverage for necessary care, including under-utilization of medicines. Conversely, high costs may indicate poor patient management, such as poly pharmacy, drug-induced diseases, or under-utilization of medicines, or they may indicate appropriate utilization of necessary and cost-effective care.
- A pharmacy benefits program should monitor quality of care by reviewing utilization on a regular basis to identify opportunities for improving medicines benefit policies or mounting interventions to improve the appropriateness of prescribing or dispensing. In advanced electronic data systems, real-time messages can be delivered to alert prescribers or dispensers to potential problems associated with the medicine for the given patient.
- Few standard performance measures exist for medicines benefits. In the US, the Health Plan Employer Data and Information Set (HEDIS®) was developed by the National Committee for Quality Assurance (http://web.ncqa.org/) to assess which health plans offer the best quality of care, but it includes only a few pharmacy-based measures. The

Australian National Prescribing Service (http://www.nps.org.au/) has developed a full range of pharmacy program performance measures to assess the effectiveness of the Australia National Medicines Policy. Table 5.1 provides some examples of commonly used pharmacy performance measures and their operational definitions.

Table 5.1: Examples of commonly used pharmacy performance measures and their operational definitions

Measure	Operational Definition
Utilization per member per month (PMPM)	Total number of prescriptions filled in a month divided by the total number of members enrolled in that same month (calculated overall and by age, gender, chronic illness group)
Pharmacy cost PMPM	Total cost for prescription medicines (minus member co-payments) in a month divided by the total number of members enrolled in that month (calculated overall and by age, gender, chronic illness group, therapeutic categories)
Average prescription cost	Total prescription cost divided by the number of prescriptions dispensed (overall, by generic and brand products, and within therapeutic categories)
Formulary compliance	Total number of prescriptions dispensed using drugs on the formulary divided by the total number of prescriptions filled
Generic utilization rate	Total number of prescriptions filled as generic divided by the total number of prescriptions filled
Adherence to clinical guidelines	Total number of patients treated with first-choice medicines on the clinical guideline for a particular condition divided by the number of patients treated for that condition
Patient adherence to recommended therapy	Total number of patients dispensed more than 90% of the medicines needed to treat a specific chronic illness over a defined period divided by the number of patients treated for that condition
Equitable access to medicines	Proportion of patients living in rural areas treated with first-choice medicines on the clinical guideline for a particular condition divided by proportion of patients in urban areas treated with first-choice medicines for that condition
Member satisfaction	Total number of members with a specific chronic illness reporting that they are very satisfied or satisfied with the quality of care for their illness divided by the number of member surveyed

Activity 1: Outpatient coverage for hypertension medicines – policy domains

Format: Small (across system) group discussion then large group debriefing (1 hour)

Hypertension is a major contributor to morbidity, mortality, and increased health care expenditures in the Philippines. Two out of 10 Filipinos above 20 years of age, an estimated 7.76 million in 2003, have diagnosed hypertension. If not properly treated, hypertension leads to strokes, heart attacks, heart failure, or kidney disease (see www.webmd.com). Hypertension can be treated by lifestyle changes for some patients, but often requires long-term treatment with one or more antihypertensive medications. Outpatient medication treatment of hypertension has been shown to reduce stroke (by 35%-40%), heart attack (by 20%-25%), and heart failure (by more than 50%), and thus can prevent costly inpatient care for complications due to disease progression.

The Philippine Health Insurance Corporation (PHIC) currently only reimburses for inpatient care of hypertension. Given the low socio-economic status of most Filipinos, out-of-pocket payments for antihypertensive medicines would consume a substantial proportion of household income, so many patients fail to treat their condition or do so inconsistently. Indeed, PhilHealth spends PHP 968 million per year for patients hospitalized with hypertension and related conditions.

PhilHealth is interested in designing and implementing an outpatient prescription drug benefit for members with hypertension to be administered through large chain pharmacies. Large pharmacy chains account for over 75% of the retail pharmacy market, and in many areas chain pharmacies are the only available outlets. Mercury Drug is the largest chain, with over 500 outlets and an estimated 70% of the retail pharmacy market. An additional 5-6 medium sized chains that are currently positioning themselves to identify a market niche. Efforts are underway by the public Philippines International Trade Corporation (PITC) to expand the availability of low cost, high quality medicines, mostly imported products from Indian suppliers through a new private chain of Batik ng Munisipyo (BnM) pharmacies located in underserved areas.

Pharmacy chains offer many possibilities for implementing an outpatient medication benefit, including internal capacity to train, implement a program, supervise, and keep accurate records. Interventions within this structure could be done at large scale and relatively low cost. In addition, chains serve customers across all socio-economic strata.

In the intended program, PhilHealth members discharged from hospitals after treatment for hypertension would be referred to accredited pharmacies for hypertension management, in conjunction with their community physician. At the pharmacies, specially trained staff would fill prescriptions, counsel about adherence, and monitor blood pressure. PHIC would contract with private physicians to reimburse routine clinical visits and with pharmacies to reimburse anti-hypertensive medications, counseling, and adherence monitoring. Reimbursements would depend on monitoring performance.

Your working group will be assigned several of the policy domains in which the outpatient hypertension coverage policy may have impacts. Please discuss the following questions and fill in the table that follows.

Part One

1. What are some of the specific objectives of the proposed PhilHealth outpatient hypertension coverage policy in each of the domains listed in the table below?

2. For each objective, how would PhilHealth know if it had achieved its objectives?
3. State at least one or more important questions about the possible intended or unintended effects of the policy change for each objective you listed.
4. What types of data would you need to answer each question and where could PhilHealth get the data?

Part Two

Select two of the questions about the impact of the proposed PhilHealth policy change that you specified in Part One. Define one outcome indicator that you could construct to be able to answer each of these two questions. Please construct the outcome indicator with data that might be available in the PhilHealth system. Your definition of an indicator should allow a computer programmer to extract the correct data and perform the necessary calculations to provide the desired numbers, as in the following examples.

Example 1: An indicator to assess cost of care could be defined as: amount paid by PhilHealth per member admitted to PhilHealth accredited hospitals (defined as <give definition>) with a diagnosis of essential hypertension (defined as <give definition>) during a given time period (<specify period>).

Example 2: An indicator to assess quality use of antibiotics in primary care pediatric practices could be defined as: percentage of children age less than 5 who were seen in a primary care pediatric practice (defined as <give definition>) during a specified period (<specify period>), diagnosed with fever (defined as <give definition>), and who did not receive an antibiotic (defined as <give definition >) within 7 days of the visit.

Medicines coverage policy objectives and performance evaluation

Domain	Policy Objectives	Questions about Intended and Unintended Impacts	Data Needs to Answer Questions	Outcome Indicator
Equitable access to treatment				
Quality use of medicines				
Cost to patients and affordability				
Cost to PhilHealth				
Patient satisfaction with care				
Provider satisfaction with insurance				

Session 6: Formulary decision making

Objectives

The objectives of this session are to describe options for evidence-based formulary policies and processes. We will describe the responsibilities of those making formulary decisions, training requirements, ways to minimize conflicts of interest, and processes to make sound formulary decisions. We will also describe methods to make transparent the values that underlie formulary decisions.

Outline

- Case discussion of an insurance program's formulary decision and a pharmaceutical manufacturer's reaction
- Formulary policy options and their expected effects
- Processes for formulary decision making
- Transparency in values underlying formulary decisions

Readings

Academy of Managed Care Pharmacy. The AMCP format for formulary submissions, version 2.1. A format for submission of clinical and economic data in support of formulary considerations by health care systems in the United States. Academy of Managed Care Pharmacy, April 2005.

Coalition Working Group. Principles of a sound drug formulary system. Academy of Managed Care Pharmacy, October 2000. Available at http://www.amcp.org/.

Dillon MJ. Chapter 6. Drug formulary management. In Navarro RP. Managed Care Pharmacy Practice. Aspen Publishers; Gaithersburg, MD: 1999, 145-165.

Sullivan, SD, Lyles A, Luce B, Grigar J. AMCP guidance for submission of clinical and economic evaluation data to support formulary listing in U.S. health plans and pharmacy benefit management organization. J Managed Care Pharmacy 2001;7:272-282.

Teagarden RJ. Pharmacists, ethics, and pharmacy benefits. Am J Pharmaceutical Education 2003;67: Article 28, 1-6.

Teagarden RJ. Prior authorization in prescription drug benefit management: An apologia. Hospital Pharmacy 2004;39:493-498.

Teagarden RJ, Daniels N, Sabin JE. A proposed ethical framework for prescription drug benefit allocation policy. J Am Pharm Assoc 2003;43:69-74.

Discussion Questions

1. How are formulary decisions made in your system?
2. What values played a role in a recent formulary decision in your system?

Learning Points

- A formulary is defined as a list of medicines approved for use within a health care setting. In the World Health Organization's terminology, such a list is called an Essential Medicines List [EML], while the WHO Model Formulary refers to the compiled

information on use, dosage, adverse effects, contraindications and warnings for all of the medicines on the EML. A formulary system refers to the process by which a formulary is continually updated.

- A formulary can be defined as open, closed, or restricted. An open formulary contains all medicines commercially available and thus allows any of these medicines to be prescribed. A closed formulary limits prescribers to a selected subset of medicines from those that are commercially available. Products that are not listed on the closed formulary may not be prescribed or would not be reimbursed. Limited formularies are hybrids, offering all available products in some therapeutic categories and only a subset in others. Instead of listing a large number of medicines that are allowed, negative formularies instead list all products that cannot be prescribed or reimbursed.
- Formularies are vital to the successful management of a prescription drug benefit. They are intended to guiding clinicians to select certain therapies and thus improve quality of care and decrease pharmacy costs. Formularies are most successful when: (1) they take account of evidence about the safety, efficacy, and quality of available products; (2) they are consistent with accepted standard treatment guidelines; (3) they are the basis for negotiating affordable prices for listed products from manufacturers and distributors; and (4) providers and patients are presented with clear incentives to adhere to the formulary.
- A formulary system is dynamic and should incorporate current pharmacological knowledge and clinical practice standards. A committee, frequently called a Pharmacy and Therapeutics (P&T) Committee, is usually responsible for developing, managing, updating, and administering the formulary within a health care organization. P&T Committees members often include a variety of health care professionals (physicians, pharmacists, nurses) from primary care and different specialties.
- Successful management of a formulary depends on the integrity of the criteria and evidence used to make approval and removal decisions. Explicit and strictly enforced conflict of interest policies should govern the selection of P&T Committee members, their voting rights, and all aspects of committee procedures. Table 6.2 below lists some of the factors that a P&T Committee may choose to consider when they make decisions about the formulary status of a medicine.
- Having explicit guidelines for formulary submissions supports the formulary decision making process by: 1) standardizing the information required from the manufacturer; 2) formalizing the importance of formulary decisions; and 3) making explicit and transparent the assumptions, evidence, and rules that influence formulary choices.
- Guidelines exist for the types of information that health plans should request from pharmaceutical manufacturers for use in evidence-based health care decision-making. Examples include guidelines of the Academy of Managed Care Pharmacy in the U.S. (http://www.amcp.org); the Canadian Agency for Drugs and Technologies in Health (http://www.cadth.ca/); the National Institute for Clinical Excellence (NICE; http://www.nice.org.uk) in England, and the Australian Pharmacy Benefit Advisory Committee (http://www.health.gov.au), which was the first authority to include pharmacoeconomic evaluations in its formulary decision making.

Table 6.1: Factors to be considered when a P&T Committee decides on formulary status of a medicine (modified from Navarro, 1999)

Domain	Factor to consider
Evidence from clinical trials	Efficacy (in relation to placebo), comparative (to other products) efficacy, and effectiveness (where available)
	Safety, including type and frequency of adverse effects, contraindicated conditions, interactions
Patient factors	Target patient population type and size and their risk factors relative to contraindications, adverse effects, warnings
	Compliance potential, depending on route, dosing frequency, ease of administration, duration of therapy
	Approved indication, off-label use, and abuse potential
	Pharmacokinetic advantages that allow for use among patients with impaired liver or renal or gastrointestinal function, among the very young, the very old
Systems management factors	Status on accepted standard treatment guidelines
	Ease of restrictions to prevent use for unintended indications or populations
	Ability to replace a formulary medicine
	Relationship to current prevalent prescribing habits and need for education of prescribers
	Source of supply and reliability of manufacturer and distributor
Economic factors	Cost, including acquisition, preparation, storage, distribution, administration
	Cost comparison relative to other medicines for the same condition(s)
	Additional support by the manufacturer in the form of patient training, subsidies for indigent, help lines
	Impact on health care costs through effects on length of stay, therapeutic monitoring costs
	Pharmacoeconomic data where available

Activity 1: Formulary decision making and the pharmaceutical industry

Format: Large group case discussion (30 minutes)

Please read the following fictitious newspaper excerpt, which is based on a real situation, and be prepared to discuss the questions that follow.

Drug Company Sues National Health Insurance

August 1, 2003

CAPITAL CITY – Blockbuster Corporation Inc., maker of the widely used cholesterol lowering drug Superstatin, has sued the country's National Health Insurance Scheme (NHIS), accusing the scheme of misrepresenting scientific information, infringing on doctors' rights, and withholding potentially life-saving treatment from patients.

Superstatin is the newest, and most expensive, member of a group of drugs called statins. Statins are the most potent cholesterol-lowering agents, lowering so-called "bad cholesterol" by 30–50%. They are essential in preventing heart disease and stroke, diseases that plague at least 1 in 20 individuals in the country.

In January 2003, the NHIS Department of Technology Assessment compared the scientific evidence of all 9 statins on the market. The published report concluded that "Superstatin lacks data on long-term clinical efficacy and is more expensive than Olderstatin", another member of the drug class. Superstatin is about twice as expensive as Olderstatin. NHIS advised doctors to prescribe Olderstatin. Responding to NHIS' report, Blockbuster's CEO Dr. Samuel Stakeholder cited scientific research data that showed that Superstatin is safe and effective in reducing total and bad (LDL) cholesterol level, and, for some patients, less costly than other statins on the market. However, NHIS maintained that the cited studies were flawed and that Superstatin was not worth the additional cost.

Superstatin remains among the top ten drugs in the country prescribed by physicians who may erroneously think that NHIS reimburses for the drug. However, Blockbuster Corporation has not yet applied for inclusion of the drug in the NHIS formulary. Because NHIS only reimburses hospitals for drugs on the formulary, hospitals that dispense Superstatin do not get paid for the drug. NHIS spokeswoman Dr. Pru Publichealth stressed that NHIS does not prevent prescribers from prescribing Superstatin, but that it advises physicians to compare scientific evidence and cost when choosing a statin.

Possible discussion questions

1. How is this similar to or different from the situation in your countries?
2. Why would an international pharmaceutical company be concerned about the recommendations of a national health insurance program?
3. Which challenges does an insurance program face in determining which drugs to reimburse?
4. Which advantages does a health insurance program have in obtaining lower prices and influencing more appropriate use of medicines?

Activity 2: Formulary decision making

Format: Small (across system) group discussion then large group debriefing (1.5 hours)

Imagine you are the P&T Committee for the National Health Insurance Scheme. Blockbuster Corporation Inc. has recently indicated its interest in submitting an application requesting inclusion of Superstatin on the NHIS formulary. At the same time, Dr. Jim Pureheart, who is the Director of the NHIS Ethics Board, has requested that the P&T Committee conduct a review of its policies and procedures for making formulary decisions with an eye toward making the decision making more transparent and equitable.

Based on what you know about the situation, decide how you will proceed with the review process for Superstatin. In your discussions, consider the following questions:

1. What information would you need to make the decision about Superstatin and how would you obtain this information?
2. In light of Dr. Pureheart's request, what procedures should the P&T Committee follow to make this decision?
3. If, after reviewing the evidence, the Committee found that Superstatin had equivalent risks and benefits to other statins already on the formulary but 25% higher cost, would you approve its inclusion on the formulary?
4. If you decide to add Superstatin to the formulary, which restrictions would you consider placing on its use?
5. Whether you decide to include or exclude Superstatin, how would you learn if your decision had positive or negative effects?

Session 7: Political aspects of implementing a medicines policy change

Objectives

The objectives of this session are to discuss how to implement a medicines policy change in a health delivery system or insurance program. We will first focus on assessing which stakeholders need to be involved, how to elicit their perspectives, and how to engage them in the process. We will also discuss system needs for implementing a policy change and mechanisms for communicating policy changes effectively to all stakeholders.

Outline

1. Political, social, and systems requirements for successful policy change
2. Discussion of systematic analysis of policy content, positions and power of major stakeholders, opportunities and obstacles to policy change, and strategies for change
3. Introduction to ***PolicyMaker*** software (http://polimap.com/)

Readings

Reich MR. The politics of health sector reform in developing countries: Three cases of pharmaceutical policy. Health Policy 1995:32:47-77.

Glassman A, Reich MR, Laserson K, Rojas F. Political analysis of health reform in the Dominican Republic. Health Policy and Planning 1999;14:115-126.

Roberts MJ, Hsiao W, Berman P, Reich MR, eds. Chapter 4. Political Analysis and Strategies. In: Roberts MJ, Hsiao W, Berman P, Reich MR, eds. Getting Health Reform Right. A Guide to Improving Performance and Equity. Oxford: Oxford University Press, 2004:61-89.

Discussion Questions

1. Who are the most important stakeholders with respect to medicines issues in your country as a whole, as well as in your health system or insurance program?
2. What concerns would your stakeholders have about changes in a specific medicines policy?
3. What systems are in place for communicating effectively with stakeholders about policy changes in your setting?

Learning Points

- Pharmaceutical policy change is not only a technical process, but is also a political process for several reasons. High pharmaceutical expenditures (usually 10%-30% of public sector health expenditures) make medicines a high priority issue for policy makers. In addition, medicines policies involve both public and private sectors, as well as a range of domestic and international actors in various political patterns of collaboration, competition, and conflict. Pharmaceutical policy decision making often elicits debate about values, including the roles of the market and the state, transparency and accountability, the relative importance of efficiency, and equity.
- Political analysis can improve the advice that policy analysts generate based on technical policy evaluation and improve the political feasibility of policy reform.

Political aspects of implementing a medicines policy change

- Political analysis can facilitate the design of effective political strategies for policy change. Political analysis involves answering the following questions: (1) Who are the key groups of stakeholders that will be affected by the policy change and what are their political resources and roles in the political structure? (2) What are the consequences of the proposed change for the different stakeholders? (3) What positions of support and opposition have been taken or are likely to be taken by key stakeholders and what is the intensity of their commitment? (4) What are the primary objectives of different stakeholders? (5) What are the relationships among the various key players in a policy network map? (6) Are there transitions already underway that could create positive opportunities for policy change? (7) How can strategies for change be constructed?

Activity 1: Implementing a PhilHealth outpatient medicines benefit

Format: Small (across system) group discussion then large group debriefing

Assume that PhilHealth would like to implement its limited outpatient medicines coverage for patients with hypertension, a chronic illness that affects a high proportion of enrollees and which consumes a large share of reimbursed hospital expenditures. Different stakeholders may support or oppose the idea of implementing such a benefit, and have strong opinions about details of its implementation. Understanding how the various stakeholders align and managing the political aspects of implementation will be a critical factor in the success or failure of this policy initiative.

This exercise will involve structured thinking about stakeholder interests and likely positions in reacting to a medicines policy change. The following table lists several different stakeholder groups that may have positions related to the proposed benefit. Each working group will be assigned to think about and represent the likely positions of one or more specific stakeholder groups. Discuss the stakeholder groups, their likely attitudes and position toward the policy change, and possible processes that PhilHealth might use to engage and win support from each group. Be prepared to present a concise summary of your discussions.

Political aspects of implementing a medicines policy change

Stakeholder interests, positions, and opportunities for constructive policy engagement related to outpatient medicines benefit

Stakeholder	Key Interests	Likely Consequences	Likely Concerns and Position	Opportunities for PHIC Engagement
PhilHealth Benefits development, actuaries, public policy				
Enrollees With/without diabetes, entitled/private pay, indigent				
Department of Health Secretary, Non-communicable disease program				
Industry Multinationals, generics manufacturers				
Medical community Professional assoc., primary care/specialist, community/hospital				
Pharmacy community Professional assoc., distributors, chain/independent pharmacies				
Health facilities Public/ private hospitals, rural health units				
Employers Professional assoc., government, large/small private				

Thursday, September 27

Session 8: Detecting and solving data problems

Objectives

The objectives of this session are to identify some of the key issues that arise when extracting, organizing, and analyzing insurance program data. We will illustrate how to identify and deal with common data problems that may distort results if not taken into consideration. These data problems include changing populations; missing data; extreme values; seasonal variation in medicine use; inconsistent units of measurement; different dosage forms; pre-policy effects; lag periods following policy implementation; and changing codes. We will use spreadsheet-based analyses to assess data patterns, explore reasons for unexpected data patterns, and establish rules to deal with inconsistencies.

Outline

- Common data issues and how they influence results
- Identifying data issues using frequencies of cross-sectional data and longitudinal displays of data patterns
- Resolving common data issues

Readings

Lin CC, Lai MS, Shy CY, Chang Sc, Tseng FY. Accuracy of diabetes diagnosis in health insurance claims data in Taiwan. J Formos Med Assoc 2005; 104:157-163.

Maclure M, Nguyen A, Carney G, Dormuth C, Roelants H, Ho K, Schneeweiss S. Measuring prescribing improvements in pragmatic trials of educational tools for general practitioners. Basic Clin Pharmacol Toxicol. 2006; 98(3):243-52.

Platt R. Speed bumps, potholes, and tollbooths on the road to panacea: making best use of data. Health Aff (Millwood) 2007; 26:w153-5.

Tyree BT, Lind BK, Lafferty WE. Challenges of using medical insurance claims data for utilization analysis. Am J Med Quality 2006; 21(4): 269-75.

Discussion Questions

1. In which ways can routine data from a health care or insurance system be incorrect or misleading?
2. What are some of the known or suspected data problems in your setting and what steps have been taken to address these problems?
3. What are the potential effects of different types of data problems on interpreting policy analysis results?

Learning Points

- Health utilization data are not collected primarily for policy evaluation purposes, but rather for routine medical records or claims for insurance reimbursement. Unusual data patterns can be influenced by many factors. Analysts need to assess the quality of the

data by examining its completeness, its consistency with expected patterns, and to identify patterns that are likely to be due to other causes other than the policy in question. Table 9.1 below outlines some of the key steps in data quality checking.

- Data inconsistencies may be introduced during data collection, coding, or the data recording process, or they may reflect unusual but real variations in health services or medicines utilization and expenditures . If data inconsistencies are not accounted for appropriately, policy effects may be incorrectly estimated.
- Data inconsistencies may be due to: inclusion of denied or duplicate claims; claims for non-members; missing data; incorrectly entered data; changing coding systems; confusion in units for drugs that come in different dosage forms; or characteristics of the benefit design, such as reimbursement limits on the number of drugs, frequency of visits, or total expenditures. Inconsistencies that represent unusual but true patterns include utilization increases before a policy change; seasonal variations in use; or changes in population characteristics over time.
- Excel PivotTables and PivotCharts are a tool that allows analysts to create tabular and graphic displays of data within groups, across sites, and over time in order to assess inconsistencies in data patterns.
- Different strategies exist to account for data inconsistencies. For example, changing personal identifiers can be recoded using an algorithm that identifies individuals based on name and birthday. Table 9.2 below lists some common patterns of data inconsistencies, possible causes for those, and possible solutions specific to these types of inconsistencies.
- Data problems can be accounted for in analysis so that they are not misleading. For example, seasonal variations in use can be accounted for statistically; unusual patterns of utilization in anticipation of or immediately after a policy effect can be accounted for in analysis by assigning the respective data points “missing” values; and values of missing variables can be imputed using standard approaches.

Table 8.1: Steps in examining data quality

Check	Data Quality Issue
1. Preliminary	
Total number of records	If number of records differs from expected, data may be missing, duplicated, or incorrectly extracted.
Completeness of data codebook	Variable names, descriptions, codes, and handling of missing values should be clearly stated for all variables
2. First-level quality check	
Codes, frequencies, and number of missing values for categorical variables	Codes should match codebook and frequencies should be reasonable. For example, you would expect to see two values (female and male) for gender, and their frequency should match what you know about the population. More values than expected or unusual frequencies may indicate data problems.
Means/medians, ranges, number of zeroes and missing values for continuous variables	Mean/medians, ranges (min, max) should be reasonable. The difference between "0" and missing should be clear. For example, mean cost of expensive medicines should not be too low (may mean that missing data have been entered as 0), nor mean cost of inexpensive medicines too high (may mean high outliers).
Medicine utilization summaries	Examine key summaries of medicines use (utilization and expenditures per member/patient; % of use and expenditures accounted for by top 30 products; % dispensed as generic; market share of medicines within key therapeutic classes). Unusual patterns may indicate data capture or coding problem.
3. Differences between key subgroups	
First-level summaries stratified by key population groups	Examine summaries in Step 2 by key population groups (men/women, children/adult/elderly, patients with specific illnesses, members with different benefit packages) or administrative groups (regions, hospitals, health facilities). Patterns should be consistent and appropriate to the group.
4. Patterns over time	
Frequencies or means/medians of key variables plotted over time (months or quarters)	Plot data over time to assess consistency (changes in level, spikes, trends). Important variables to check: enrollment; # of unique patients; average expenditures overall and per member/patient; total utilization (dispensings, outpatient visits, hospitalizations) overall and per member/patient. Differences may indicate changes at a specific point in time in membership rules, policies, data systems, supply systems, etc.
Data summaries plotted over time for key subgroups	Compare patterns over time for key population and administrative subgroups. Differences may mean specific changes in policies or systems in that subgroup.

Table 8.2: Common Problems Possible Causes, and Solutions in Cross-Sectional and Longitudinal Data

Data Pattern	**Possible Causes**	**Possible Solutions** (depending on cause)
Member/patient enrollment, demographic data		
Patterns of key variables (age, gender, insurance category) at a point in time differ from what is expected (within and/or across sites)	• Populations differ across sites • Coding of age, gender, insurance category variables differs across sites • Missing or duplicate data	• Include only sites with similar populations • Stratify analyses by age, gender, insurance category • Match codes to standardized coding system • Exclude sites with large amounts of missing data • Delete patients or utilization records with missing data
Sudden change in number of members over time	• Eligibility rules changed (e.g., inclusion of dependents) • Member identifiers changed • Missing or duplicate data	• Analyze rates of use and cost by member • Match member identifiers • Remove any duplicate ("unduplicate") data by member • Exclude time periods with missing data or include only continuously enrolled members
Gradual decline in number of members over time	• Members of a closed cohort dying or leaving the system	• Limit analyses to continuously enrolled members • Stratify analyses of use and cost by member age or severity of illness • Control for changing population characteristics (age) in regression analyses
Time periods without members or utilization	• Missing data	• Exclude time periods with large amounts of missing data • Delete patients or utilization records with missing data

Detecting and solving data problems

Data Pattern	**Possible Causes**	**Possible Solutions** (depending on cause)
Utilization data (diagnoses, medicines, procedures; hospitalization episodes; outpatient visits)		
Number or types of diagnoses, medicines dispensed, procedures, hospitalizations, outpatient visits varies from what is expected per time period or per member (within or across sites)	• Populations differ across sites in age, disease patterns • Available services (including medicines) differ across sites • Coding of encounters, medicines, procedures differs across sites • Data completeness differs across sites • Data time frame differs across sites • Missing or duplicate data	• Stratify analyses by age, gender, insurance category • Stratify analyses by disease • Analyze sites with similar services • Match codes to standardized coding system • Make sure that data reflect same time frames • Exclude sites with large amounts of missing data • Delete patients or utilization records with missing data
Little variation in utilization of services or amount reimbursed per member per time period	• Other policy or external factors (economic downturn) restricting utilization, reimbursement	• Acknowledge limitation
Sudden change in number of diagnoses, medicines dispensed, procedures, hospitalizations, outpatient visits over time overall and/or per member	• Effect of known or unknown policy (e.g., product withdrawal; change in reimbursement rules; discontinued service, etc.) • Clinics/hospitals/dispensaries closed • Membership changed • Service code changed (e.g., ICD-10 code for specific hospitalization) • Missing or duplicate data	• None, if true policy change • Subset data to those from continuously serving clinics/hospitals/dispensaries • Subset data to continuously enrolled cohorts • Match codes to standardized coding system • Unduplicate data by member • Delete patients or utilization records with missing data

Detecting and solving data problems

Data Pattern	**Possible Causes**	**Possible Solutions** (depending on cause)
Gradual or seasonal change in number of diagnoses, medicines dispensed, procedures, hospitalizations, outpatient visits over time overall and/or per member	• Policy change with delayed effect (e.g., prescribed education regarding preferred product) • Policy with annual utilization limits • Seasonal needs (e.g., malaria treatment during rainy season; increased antibiotics during outbreak, antihistamines in allergy season)	• Account for lag of policy effects in analysis • Account for seasonal effect in analysis
Very high or very low numbers of diagnoses, medicines dispensed, procedures, hospitalizations, outpatient visits per time period overall and/or per member	• Anticipatory policy effect • Double-counting of services provided, prescriptions dispensed • Missing or duplicate data	• Assess effects of extreme values on results and possibly exclude extreme values from analysis • Unduplicate records by member • Delete patients or records with missing data

Activity 1: Identifying and solving problems in dispensing data

Format: Small (across system) group work then large group debriefing (2 hours)

Your group will be assigned to work with one of three different Excel data sets that are included in your course materials. Each data set of dispensings contains the following variables: Date, month, region, site, patient identifier, drug code, and cost of the prescription,

Using the data set assigned to your group, please do the following:

1. Assess the completeness and consistency of the data (check the total number of records, look for missing data, and summarize the frequencies/distributions of each of the variables);
2. Create a PivotTable and a PivotChart (see section on Working with Excel) to work with and display the data;
3. Summarize the data by month of dispensing by site/region, and by drug code by site/region;
4. Look for any irregularities in the data patterns;
5. Look if use by patient is consistent within sites;
6. Explore and suggest possible reasons for these irregularities;
7. Suggest how you might try to correct or account for any data problems that you identify in your analyses.

Friday, September 28

Session 9: Evaluating changes in medicines coverage policies

Objectives

The objectives of this session are to discuss methods that can be used to evaluate the effects of medicines policy changes over time. We will illustrate the strengths and weaknesses of different policy evaluation designs.

Outline

- Discussion of policy evaluation designs – pre-post versus longitudinal studies, use of different types of control groups
- Designing and implementing a policy evaluation – defining study objectives; study group selection; data collection; study time frame; planning for analysis

Readings

Cook TD, Campbell DT. Chapter 5. Quasi-Experiments: Interrupted time-series designs. In Cook TD, Campbell DT. Quasi-Experimentation. Design and Analysis Issues for Field Studies. Boston: Houghton Mifflin Company, 1979.

Kanavos P, Ross-Degnan D, Fortess E, Abelson J, Soumerai SB. Chapter 5. Measuring, monitoring and evaluating policy outcomes in the pharmaceutical sector. In: Mossialos E, Mrazek M, Walley T, editors. Regulating pharmaceuticals in Europe: Striving for efficiency, equity and quality. European Observatory on Health Systems and Policies Series. Open University Press: 2004, 177-196. Available at http://www.euro.who.int/eprise/main/WHO/Progs/OBS/Publications/20040527_2.

O'Malley AJ, Frank RG, Kaddis A, Rothenberg BM, McNeil BJ. Impact of alternative interventions on changes in generic dispensing rates. HSR: Health Services Research. 2006; 41(5): 1876-94.

Shojania KG, Grimshaw J. Evidence-based quality improvement: The state of the science. Health Affairs. 2005; 24(1): 138-150.

Soumerai SB, Ross-Degnan D, Fortess EE, Abelson J. A critical analysis of studies of state drug reimbursement policies: Research in need of discipline. Milbank Quarterly 1993; 71(2): 217-252.

Ray W. Policy and program analysis using administrative databases. Ann Intern Med 1997;127:712-718.

Discussion Questions

1. What is the structure (administrative, geographical, different member populations) of your insurance system and of its routine data systems?
2. What is the potential for designing controlled or longitudinal policy evaluation studies in your setting?
3. Who would be the audience for a policy evaluation in your system and what would they most like to know about the impact of medicines policies?

Learning Points

- Randomized controlled trials (RCTs), in which individual study units (members, clinicians, hospitals, pharmacies) are randomly assigned to receive or not receive a policy intervention, are the gold standard for policy evaluation. However, RCTs of policy changes are rarely conducted, because of practical, political, logistic, and economic reasons.
- Whenever possible, non-randomized evaluations should include other kinds of comparisons that increase confidence that observed changes are due to the policy intervention in question, not to some other factor. These might include comparisons to: (1) other groups of facilities, providers, or patients that were not affected by the intervention; (2) other types of medicines use not expected to be affected by the intervention (e.g., use of antihypertensive medications for an intervention that targeted diabetes medications); (3) similar practices at a previous point in time, especially shortly before the policy change.
- Some principles that can strengthen the evaluation of a policy intervention include: (1) Evaluate the intervention by identifying and measuring the specific outcomes it was intended to change; (2) Try to measure changes in process (how the system behaves) as well as changes in outcomes (what the system achieves); (3) Focus on carefully defined groups in whom the intervention should have the greatest impact; (4) Try to measure both intended and unintended outcomes; (5) Consider not only if the objectives of the policy intervention are met, but why or why not.
- Many evaluations take place only after a policy change or intervention has already occurred. This "post-only" design is very weak and there are many reasons why evaluation results may be incorrect. Even if outcomes in the intervention group are compared to another group, there is no way to know if they would have been different anyway. People's memories and perceptions about how they felt and acted prior to the intervention are easily distorted.
- Measuring outcomes in a single group before and after a policy intervention (a "pre-post" design) is very common in evaluation studies, especially for changes that affect an entire system. However, this is also a weak design, since there is no way to know whether any observed changes would have occurred anyway without the intervention in question due to previous trends or to external changes.
- Adding a comparison group can greatly increase the strength of a pre-post design. However, it is important to show that the intervention and comparison groups were similar on a variety of factors prior to the intervention and that they differed afterwards in ways that would be expected if the intervention achieved its expected impacts. There are statistical methods (e.g., propensity scores) that are sometimes used to adjust for pre-intervention differences, but analyses that depend on these types of statistical adjustment are usually less convincing to policy makers.
- One strong quasi-experimental design is the "interrupted time series" design, which consists of several measures of the outcome in question taken at regular intervals of time (e.g., monthly or quarterly) both before and after a policy intervention that occurs at a defined point in time. In a time series, the post-intervention outcomes that might have occurred if the intervention had not taken place can be predicted based on pre-intervention trends, so it is possible to get more valid and accurate measures of intervention effects. Adding a comparison series from another group of facilities, providers, or patients ("interrupted time series with comparison series") makes this an

especially strong evaluation design. The strong visual nature of time series makes them an excellent way to present data to policy makers.

- Evaluations are usually stronger if they combine several quantitative and qualitative methods to look at changes, since the findings from one method can complement and help to explain the findings from another. For example, an intervention might consist of an educational program to promote generics use, feedback to physicians about their rates of generic prescribing, increased pharmacy dispensing fees for generic medicines, and increased copayments for patients for brand products with a generic alternative. Claims data could be used to compare overall rates of generics use in the year before and after the intervention. Patient interviews might be used to determine if patients who are better informed about the policy have the larger changes in rates of generics use. And finally, prescriptions retained in pharmacies could be analyzed to examine rates of generic substitution after the policy compared to before.

Activity 1: Designing a policy evaluation in your system

Format: Small (within system) group discussion then large group debriefing (1 hour)

Please refer back to the priority medicines policy problem and the potential policy interventions that you discussed in Session 4. Agree on one policy intervention (or a combination intervention) that will be the focus for this exercise. You will design a study to evaluate the effects of the proposed policy intervention, including evaluating both desired and potentially undesirable impacts. Please answer the following questions:

1. What would be the study design?
2. Who would be included in the study (i.e. regions, health facilities, health providers, patients), and why?
3. How would you measure the impacts of the intervention (routine or ad hoc data, which time periods, which indicators of desired and undesirable impacts)?
4. What would be strengths and weaknesses of your study design?

Session 10: Analyzing data and disseminating policy findings

Objective

The objective of this session is to describe the process for conducting a longitudinal policy evaluation, interpreting the results, and disseminating key information to decision making to policy makers.

Outline

- Setting up longitudinal data for analysis
- Using excel-based pivot charts and tables to create visual displays and summaries of data over time
- Interpreting results in light of design strengths and weaknesses
- Summarizing results and making evidence-based recommendations for policy change

Readings

Brufsky JW, Ross-Degnan D, Calabrese D, Gao X, Soumerai SB. (1998) Shifting physician prescribing to a preferred histamine-2-receptor antagonists. Medical Care, 36, 321-332.

Ross-Degnan D, Soumerai SB, Fortess EE, Gurwitz JH. (1993) Examining product risk in context. Market withdrawal of zomepirac as a case study. JAMA, 270, 1937-1942

Soumerai SB, Avorn J, Ross-Degnan D, Gortmaker S. (1987) Payment restrictions for prescription drugs under Medicaid. Effects on therapy, cost, and equity. N Engl J Med, 317, 550-556.

Soumerai SB, Ross-Degnan D, Gortmaker S, Avorn J. (1990) Withdrawing payment for nonscientific drug therapy. JAMA, 263, 831-839.

Wagner AK, Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Therapeutics 2002; 27:299-309.

Wagner AK, Ross-Degnan D, Gurwitz JH, Zhang F, Gilden DB, Cosler L, Soumerai SB. Effect of New York State regulatory action on benzodiazepine prescribing and hip fracture rates. Ann Intern Med 2007; 146:96-103.

Weinberg M, Fuentes JM, Ruiz AI, et al. Reducing infections among women undergoing cesarean section in Colombia by means of continuous quality improvement methods. (2001) Arch Intern Med, 161, 2357-2365.

Discussion Questions

1. What questions arise when conducting policy analyses?
2. Who should be involved in interpreting findings from policy evaluations?
3. What are the most useful strategies for communicating results to policy makers?

Learning Points

- Visual displays of policy effects are important for policy makers and can easily be created using aggregated data in Excel pivot charts.

- Confidence in interpreting policy evaluation results increases with adequate evaluation design. Quasi-experimental studies with control or comparison groups have a lower chance of bias by common confounders.
- High variability in outcomes over time can make it difficult to detect policy effects. Different techniques exist to smooth highly variable data.
- Policy makers need concise data briefs with figures displaying results and specific recommendations based on the results.

Activity 1: Analyzing the effects of a generic dispensing policy

Format: Small (across system) group work then large group debriefing (2 hours)

Siriraj hospital in Bangkok is a 2,324 bed tertiary care teaching hospital, where more than 3,000 outpatient prescriptions per day are filled. As in many other hospitals, preferred prescribing of brand name products contributes to large and increasing drug expenditures. In October 2001 (period 13 in the data), the hospital administration implemented a generic dispensing regulation to lower medication expenditures by authorizing pharmacists to automatically dispense a generic product unless the prescriber specifically requests dispensing of a brand name product. They combined this with an educational program in the hospital to increase the confidence of physicians in the quality of generic products stocked by the hosptial pharmacy. To estimate the impact of the hospital-wide generic dispensing policy on prescribing patterns and cost of medications, pharmacists at Siriraj Hospital conducted a retrospective, interrupted time series study of monthly computerized in-patient and out-patient dispensing records, from one year before to one year after policy implementation.

Assume you have been asked to do a 3-minute briefing for the Minister of Public Health about the generic dispensing policy at Siriraj Hospital and its implications for the MoPH pharmacy program, the national health insurance program, and other Thai hospitals.

You have an excel sheet with n=30,000 dispensings for different drugs and their costs, by date dispensed. We aggregated the dispensings for you by generic and brand subclass into which each drug code belongs. The data dictionary below explains the variables. Using these longitudinal, please do the following:

1. Create a pivot table and chart of the cost of dispensed products by group over time to examine the policy impacts. Look especially at products dispensed as brand but for which there is a generic substitute (group 1) and products dispensed as generic but for which there is a brand substitute (group 2).
2. Visually inspect the data for consistency and identify possible data inconsistencies
3. Evaluate the impact of the generic substitution policy
    a. For all medicines together, assess changes in the four groups of medicines (brand products with generic substitutes, generic products with brand substitute, brand-only products, generic-only products)
    b. Examine whether any observed changes differed by pharmacologic category (e.g., cardiovascular medicines (category 2), neuromuscular (4), antibiotics (7), vitamins and minerals (11), etc)
    c. For medicines with high levels of use where there is a brand-generic trade-off (e.g., lorazepam, simvastatin, furosemide, folic acid), examine whether there were notable differences in shifts from brand to generic, and whether differences have anything to do with differences in the relative treatment cost of brand and generic.
4. Suggest possible interpretations of the results
5. Consider limitations of the data that may impact interpretation of results
6. Identify 3-4 key policy recommendations
7. Prepare one figure or table that communicates the most important results
8. Be prepared to present the graphic summary and policy recommendations

Data Dictionary for Siriraj Generics Dispensing Data

Variable Name	Variable Description and Data Summaries
date	Date using Thai year format (yyyymmdd)
period	Period Number of observations, n=30,000 Number missing, n=0 Number of observations by period: 3 = 1183 4 = 1295 5 = 1270 6 = 1297 7 = 1100 8 = 1343 9 = 1295 10 = 1406 11 = 1480 12 = 1359 13 = 1476 14 = 1520 15 = 1335 16 = 1505 17 = 1272 18 = 1448 19 = 1154 20 = 1373 21 = 1348 22 = 1578 23 = 1536 24 = 1427
pharm_code	Drug code Number of observations, n=30,000 Number missing, n=0
category	Code indicating broad pharmacologic category 1 = alimentary system 2 = cardiovascular, hematopoietic 3 = respiratory 4 = neuromuscular 5 = hormones 6 = depot contraceptives 7 = antibiotics 8 = other anti-infective, antineoplastic 9 = genitourinary 10 = endocrine, lipid lowering 11 = vitamins, minerals 14 = antihistamines, antipruritics 15 = anesthetics 17 = antihistamines, antiallergics 18 = antidotes & detoxifying agents\ 19 = intravenous and sterile solutions\ 20 = contrast media

Variable Name	Variable Description and Data Summaries
	23 = miscellaneous 24 = opiate analgesics
class	Code indicating class within broad pharmacologic category
class_name	Name of pharmacologic class
group	Group code describing generic/brand availability Number of observations, n=30,000 Number missing, n=0 1 = products dispensed as brand but for which there is a generic substitute, n= 5115 2 = products dispensed as generic but for which there is a brand substitute, n= 12,909 3 = brand-only products, n= 5870 4 = generic-only products, n= 6106
trade_name	Trade name under which product is marketed
generic_name	Name of equivalent generic product
amt	Cost per dispensing Number of observations, n = 30,000 Number missing, n=0 Mean: 346.21 Median: 62.00 Minimum: 0; Maximum 66,900

Session 11: Preparing country presentations

Objective

During this session, participants will finalize the preparation of presentations on a key medicines policy issue in their insurance systems, a plan for studying the policy issue in more depth, and the design of a study to evaluate a possible intervention or policy change to address the issue.

Please use the following framework in preparing your group's presentation. The slide template provided in the course materials will allow you to present your project in this framework.

Table 11.1. Framework for Presentations on Key Medicines Policy Issues

Domain	Questions to Consider
Problem	What is the key medicines policy problem you have decided to address?
Causes	What are possible causes for the problem?
Stakeholders	Who has an interest in the problem and what are their positions?
Previous Actions	What has been done about the problem so far? What have been the outcomes?
Proposed Policy Change	Which policy change(s) do you suggest?
Evaluation of Proposed Policy Change	How would you evaluate the proposed policy change(s)? • Which evaluation design would you use and why? • Which are the most important data elements you would need, and where would you obtain them? • How would you define key outcome indicators?
Implementation Plan	How would you implement the policy (approach, timing, duration)? How would you consider stakeholder interests?
Disseminating Results	How, to whom, and when would you disseminate the results of your policy evaluation?

Saturday, September 29

Session 12: Routine monitoring systems in insurance programs

Objectives

The objectives of this session are to discuss the rationale for and design of monitoring systems using routine data on medicines and other health services use in health systems or insurance programs. Participants will identify possible domains of performance measurement, how to operationalize performance indicators, data needs, and use of performance data for management decisions

Outline

1. Reasons for routine monitoring, including strategic planning, performance assessment, and fraud detection
2. Discussion of which performance indicators to monitor, which data can contribute to these indicators, and how, for whom, and how frequently the resulting monitoring data should be presented
3. Templates to report data from routine monitoring systems

Readings

Friedmann YM, Hanchak NA. Chapter 9. Pharmacy Program Performance Measurement. In Navarro RP. Managed Care Pharmacy Practice. Gaithersburg, MD: Aspen Publishers, 1999, 199-220.

Selected sections from The Health Plan Employer Data and Information Set (HEDIS®) Volume 2, Technical Specifications, NCQA, 2008.

Sokol L, Garcia B, Rodriguez, J, West M, Johnson K. Using data mining to find fraud in HCFA health care claims. Top Health Inf Manage 2001;22:1-13.

Discussion Questions

1. Which performance indicators would be relevant to different stakeholders in your system?
2. In which format would they need to see performance data to be able to act on them?

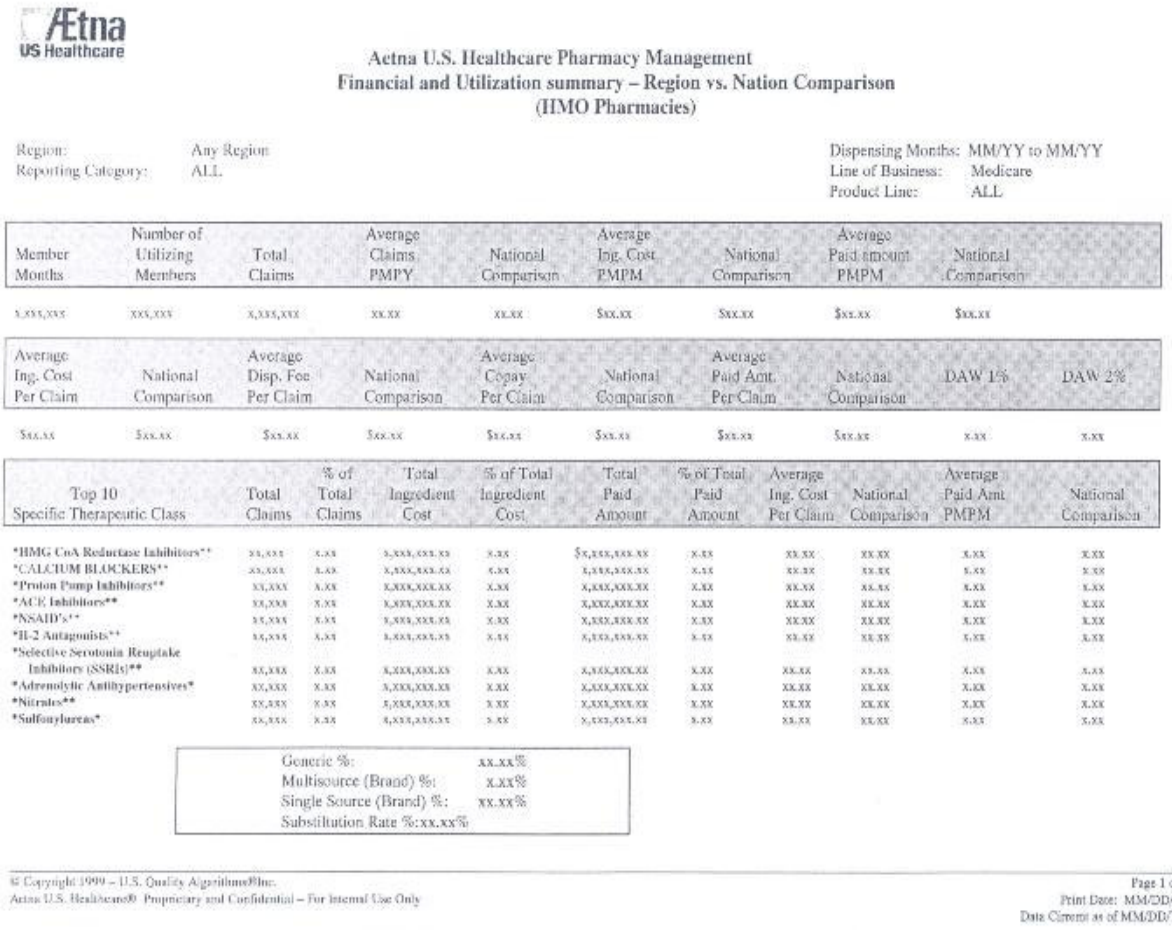
Learning Points

- Pharmacy program performance should be evaluated routinely to identify opportunities for program improvement. The frequency of reporting (quarterly, monthly, or yearly) depends on the performance measure and the purpose of reporting. For example, measures of the quality of medicines use to evaluate policy changes for better prescribing would usually be assessed less frequently than pharmacy program cost measures because potential changes in quality of care measures (depending on change in prescriber and patient behavior) take time.
- Reporting can occur at aggregate (e.g., total, by region, by hospital) or detailed (e.g., by individual prescribers, for high cost patients) levels. Aggregate reports can provide trends in overall indicators such as PMPM cost or utilization. Aggregate reports can also be

quite detailed, focusing on specific patient populations, geographic areas, types of providers, therapeutic classes and medications and help identify the causes and potential solutions for undesirable aggregate outcomes.

- Monitoring to detect fraud and abuse requires accurate and timely data to be useful, in part because the negative consequences of delay in detection and data error could be substantial. Monitoring to assess routine system performance is more tolerant of messiness in data and depending on the purpose, performance monitoring systems can tolerate greater lag times in the production of reports.
- The tables and figures below show examples of some of the routine pharmacy system financial and utilization summary reports used by large managed care insurance companies in the United States.

Figure 12.1: Example of financial summary and utilization statistics report with region vs. national comparison statistics



Aetna US Healthcare

Aetna U.S. Healthcare Pharmacy Management
Financial and Utilization summary – Region vs. Nation Comparison
(HMO Pharmacies)

Region: Any Region
Reporting Category: ALL

Dispensing Months: MM/YY to MM/YY
Line of Business: Medicare
Product Line: ALL

Member Months	Number of Utilizing Members	Total Claims	Average Claims PMPY	National Comparison	Average Ing. Cost PMPM	National Comparison	Average Paid amount PMPM	National Comparison
x,xxx,xxx	xxx,xxx	x,xxx,xxx	xx.xx	xx.xx	$xx.xx	$xx.xx	$xx.xx	$xx.xx

Average Ing. Cost Per Claim	National Comparison	Average Disp. Fee Per Claim	National Comparison	Average Copay Per Claim	National Comparison	Average Paid Amt. Per Claim	National Comparison	DAW 1%	DAW 2%
$xx.xx	$xx.xx	$xx.xx	$xx.xx	$xx.xx	$xx.xx	$xx.xx	$xx.xx	x.xx	x.xx

Top 10 Specific Therapeutic Class	Total Claims	% of Total Claims	Total Ingredient Cost	% of Total Ingredient Cost	Total Paid Amount	% of Total Paid Amount	Average Ing. Cost Per Claim	National Comparison	Average Paid Amt PMPM	National Comparison
*HMG CoA Reductase Inhibitors**	xx,xxx	x.xx	x,xxx,xxx.xx	x.xx	$x,xxx,xxx.xx	x.xx	xx.xx	xx.xx	x.xx	x.xx
*CALCIUM BLOCKERS**	xx,xxx	x.xx	x,xxx,xxx.xx	x.xx	x,xxx,xxx.xx	x.xx	xx.xx	xx.xx	x.xx	x.xx
*Proton Pump Inhibitors**	xx,xxx	x.xx	x,xxx,xxx.xx	x.xx	x,xxx,xxx.xx	x.xx	xx.xx	xx.xx	x.xx	x.xx
*ACE Inhibitors**	xx,xxx	x.xx	x,xxx,xxx.xx	x.xx	x,xxx,xxx.xx	x.xx	xx.xx	xx.xx	x.xx	x.xx
*NSAID's**	xx,xxx	x.xx	x,xxx,xxx.xx	x.xx	x,xxx,xxx.xx	x.xx	xx.xx	xx.xx	x.xx	x.xx
*IL-2 Antagonists**	xx,xxx	x.xx	x,xxx,xxx.xx	x.xx	x,xxx,xxx.xx	x.xx	xx.xx	xx.xx	x.xx	x.xx
*Selective Serotonin Reuptake Inhibitors (SSRIs)**	xx,xxx	x.xx	x,xxx,xxx.xx	x.xx	x,xxx,xxx.xx	x.xx	xx.xx	xx.xx	x.xx	x.xx
Adrenolytic Antihypertensives	xx,xxx	x.xx	x,xxx,xxx.xx	x.xx	x,xxx,xxx.xx	x.xx	xx.xx	xx.xx	x.xx	x.xx
*Nitrates**	xx,xxx	x.xx	x,xxx,xxx.xx	x.xx	x,xxx,xxx.xx	x.xx	xx.xx	xx.xx	x.xx	x.xx
Sulfonylureas	xx,xxx	x.xx	x,xxx,xxx.xx	x.xx	x,xxx,xxx.xx	x.xx	xx.xx	xx.xx	x.xx	x.xx

Generic %:	xx.xx%
Multisource (Brand) %:	x.xx%
Single Source (Brand) %:	xx.xx%
Substitution Rate %:	xx.xx%

Page 1
Print Date: MM/DD
Data Current as of MM/DD/

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Figure 12.2: Example of routine monitoring report focused on indicators of quality and appropriateness of pharmaceutical care in a specific provider practice

Pharmacy Performance Report

Anytown Family Practice Office

Practice Type:	Family Practice	Overall Quality Score:	2.6
Region:	Southeastern Pennsylvania	Mean of Overall Scores:	2.5
Office #:	999999	Range of Overall Scores:	1.3 to 3.7
Office Address:	1000 Main Street, Anytown, PA 19000	Reporting Period:	7/1/97 - 6/30/98

Members with a pharmacy plan throughout reporting period: 539

	Actual	Aetna U.S. Healthcare Rank
QUALITY MEASURES		
1. Members with congestive heart failure taking an ACE inhibitor	64.3%	2
2. Overall medication compliance rate for members with congestive heart failure	93.6%	4
3. Thiazides and/or beta-blocker use in members under age 65 with uncomplicated hypertension	37.8%	2
4. Overall medication compliance rate for members with hypertension	68.6%	3
5. Use of lipid-lowering agents for secondary prevention of ischemic heart disease	58.8%	2
6. Asthmatics receiving inhaled antiinflammatory agents	NA	
7. Female members age 50-64 with sustained hormone replacement therapy	24.6%	2
8. Members with otitis media taking a preferred antibiotic	NA	
APPROPRIATENESS OF PHARMACEUTICAL THERAPY		
9. Members with selected medications having potential for drug interactions**	25.0%	2
10. Members with COPD/asthma taking a beta-blocker	0.0%	4
11. Percentage of all inhaled medications in asthmatics that are short-acting beta agonists	44.4%	3
12. Members with BPH taking a potentially contraindicated medication	5.9%	4
13. Members age 65+ taking a drug potentially contraindicated for age group	18.0%	3
14. Members taking drugs having potential for subetance abuse/addiction	21.1%	3
15. Members taking six or more drugs simultaneously	7.6%	2
16. Extended use of H-2 antagonists and/or proton pump inhibitors	37.3%	2
TREATMENT PATTERNS		
17. Average number of antibiotic prescriptions per member	0.73	3
18. Average antibiotic cost per prescription	$33.68	2
19. Members with prescriptions for a fluoroquinolone	8.3%	2
20. Percentage of multisource prescriptions written as "Do Not Substitute"	1.5%	3
21. Overall formulary compliance rate	83.8%	2
22. Total number of prescriptions per member per month	0.84	2
23. Total cost of prescriptions per member per month	$41.45	2

* Aetna U.S. Healthcare average adjusted for age, gender, office type, line of business and disease severity level

** See Appendix

NA Not Available

Rank Key		% of Aetna U.S. Healthcare Providers
4	Best Practices	10%
3	Equal to or Above Average	40%
2	Below Average	40%
1	Outlier	10%

Source: © 1999 Aetna US Healthcare. Reprinted in: Friedmann YM, Hanchak NA. Pharmacy Program Performance Measurement. In Navarro RP. Managed Care Pharmacy Practice. Gaithersburg, MD: Aspen Publishers, 1999, 218.

Figure 12.3: Example of routine monitoring report focused on indicators of patient satisfaction, appropriateness of pharmaceutical care, and prescribing volume in a specific provider practice

USQA

Pharmacy Performance Report
<<Anytown Pharmacy>>

Practice Type: ABC Pharmacy
Region: Massachusetts
Office #: 3333333
Office Address: 250 Pleasant St., Anytown, PA 01845

Overall Quality Score: 2.6
Mean of Overall Scores: 2.6
Range of Overall Scores: 1.6 to 3.6
Reporting Period: 7/1/97 to 6/30/98

Aetna U.S. Healthcare* Inc. members with pharmacy plan throughout reporting period: 517

	Actual	Rank
MEMBER SATISFACTION		
1. Overall appearance of your pharmacy	8.7	3
2. Waiting area in your pharmacy	6.7	3
3. Customary waiting time in your pharmacy	6.4	2
4. Ability to consult with your pharmacist	8.4	3
5. Personal concern of your pharmacist	7.8	3
6. Courtesy of pharmacy staff	8.2	3
7. Ability to have prescriptions filled on same day	8.6	3
8. Availability of the pharmacist after hours	5.4	2
9. Availability of the pharmacist by telephone	7.6	2
10. Overall quality of care of pharmacy	8.4	3
11. Would you recommend this pharmacy to a friend or relative?	9.5	3
USE OF PHARMACEUTICAL THERAPY		
12. Members with congestive heart failure taking an ACE inhibitor	NA	
13. Overall medication compliance rate for members with congestive heart failure	83%	3
14. Thiazides and/or beta-blocker use in members under age 65 with uncomplicated hypertension	41.9%	2
15. Overall medication compliance rate for members with hypertension	87.3%	3
16. Use of lipid-lowering drugs for secondary prevention of ischemic heart disease	73.6%	3
17. Asthmatics receiving inhaled antiinflammatory drugs	50.0%	3
18. Female members age 50-64 with sustained hormone replacement therapy	32.4%	2
19. Members with otitis media taking a preferred antibiotic	73.3%	3
20. Members with selected medications having potential for drug interactions**	25.0%	2
21. Members with COPD/asthma taking a beta-blocker	0.0%	4
22. Percentage of all inhaled medications in asthmatics that are short-acting beta agonists	55.2%	2
23. Members with BPH taking a potentially contraindicated medication	NA	
24. Members age 65+ taking a drug potentially contraindicated for age group	20.5%	3
25. Members taking drugs having potential for substance abuse/addiction	29.6%	2
26. Members taking six or more drugs simultaneously	5.8%	2
27. Extended use of H_2 antagonists and/or proton pump inhibitors	38.5%	2
DISPENSING PATTERNS		
28. Average number of antibiotic prescriptions per member	1.48	2
29. Average cost per antibiotic prescription	$30.41	2
30. Average cost of prescriptions	$34.32	3
31. Members with prescriptions for a fluoroquinolone	7.0%	3
32. Percentage of multisource prescriptions written as "Do Not Substitute"	4.7%	3
33. Overall formulary compliance rate	86.1%	3

* Aetna U.S. Healthcare average is adjusted for age, gender, office type, line of business, and disease severity level
** See Appendix
NA Not Available

Rank Key		% Aetna U.S. Healthcare Providers
4	Best Practice	10%
3	Equal to or Above Average	40%
2	Below Average	40%
1	Outlier	10%

Source: © 1999 Aetna US Healthcare. Reprinted in: Friedmann YM, Hanchak NA. Pharmacy Program Performance Measurement. In Navarro RP. Managed Care Pharmacy Practice. Gaithersburg, MD: Aspen Publishers, 1999, 219.

Table 12.1: Sample template for reporting quarterly and annual cost and utilization information by individual prescribers or practices

Date (date of report):
Date Range (time period of utilization):
Prescribing Physician name and ID:
Physician Specialty:
Practice Name and Location:

Performance Measure	Quarter / year	Quarter / year	Quarter / year	Quarter / year	Previous year	Year-to-date
Total number of prescriptions dispensed						
Total paid amount for all prescriptions [1.]						
Average paid per prescription						
Percent compliance with formulary [2.]						
Percent generic utilization [3.]						
Percent first line antibiotic utilization [4.]						
Percent preferred HMGA Co A [5.]						
Etc.						

[1.] Total amount paid to pharmacies for filled prescriptions

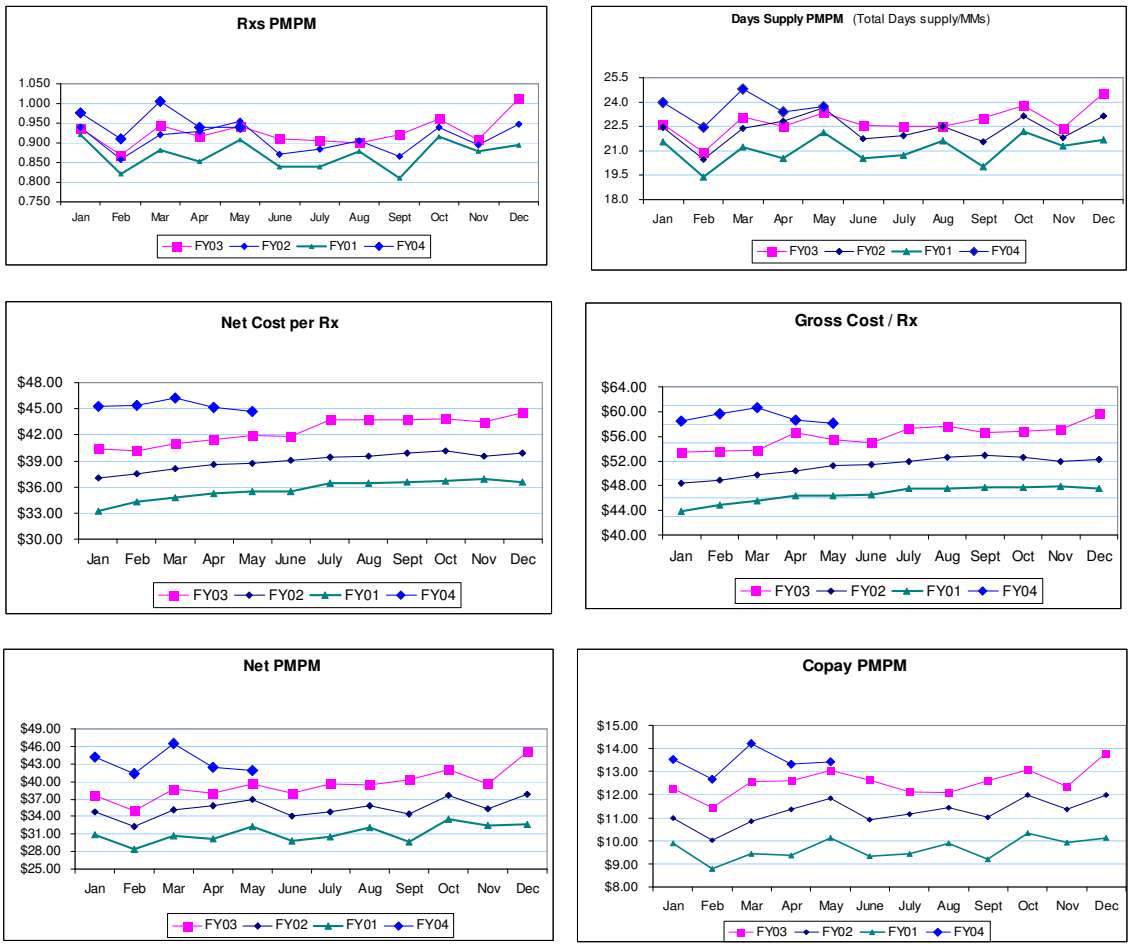
[2.] Percentage of formulary medicines prescribed to total number of formulary and non-formulary medicines

[3.] Percentage of generic medicines prescribed to total number of brand and generic medicines

[4.] Percentage of 1st line antibiotics (amoxicillin, ampicillin, erythromycin, penicillin) prescribed to total amount of 1st and 2nd line antibiotics

[5.] Percentage of preferred HMGA Co A (atorvastatin) prescribed to all HMGA Co A medicines

Figure 12.4: Sample graphs tracking basic monthly utilization and cost monitoring indicators of pharmacy program performance



Source: Pharmacy management templates developed by Harvard Pilgrim Health Care. All rights reserved.

Figure 12.5: Sample graphs tracking 12-month moving averages and annual changes in basic utilization and cost monitoring indicators of pharmacy program performance

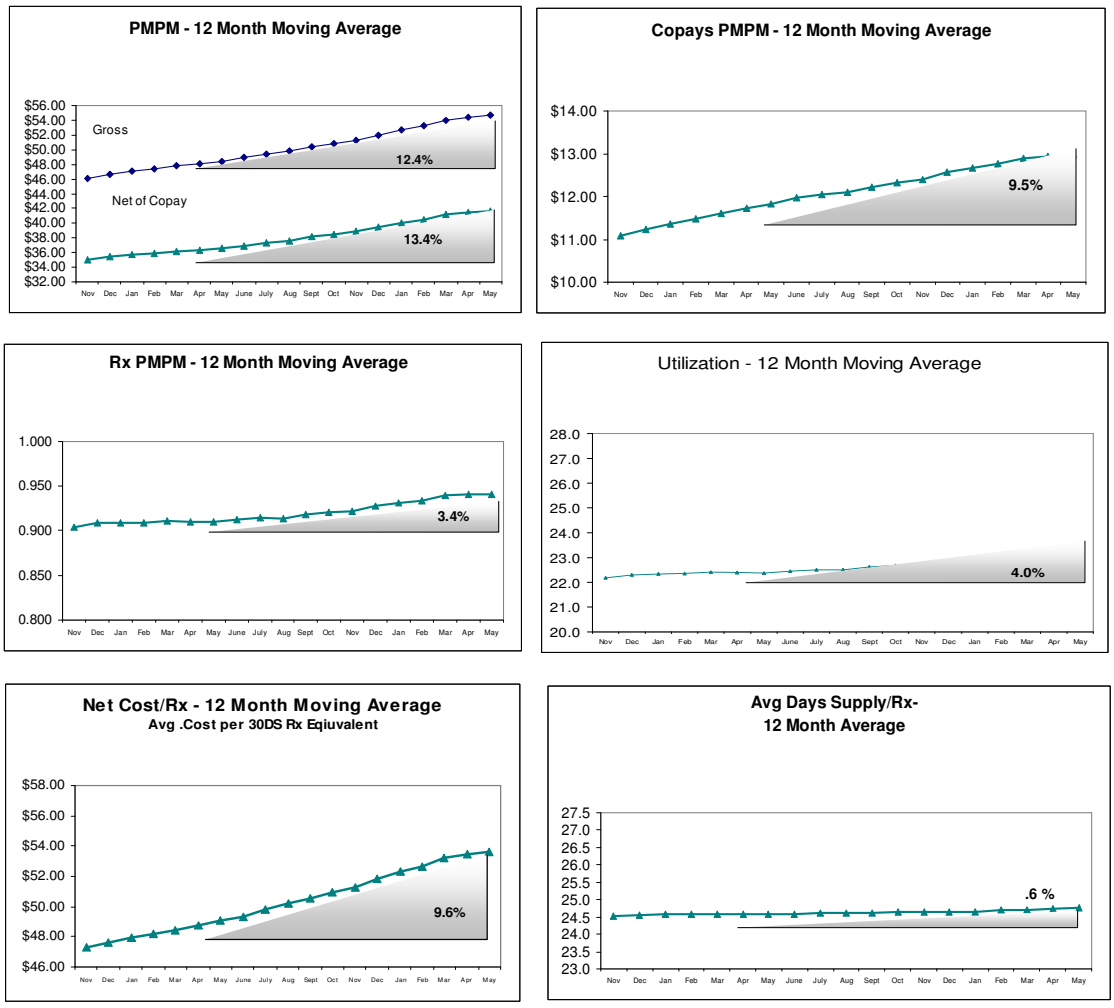


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Figure 12.6: Sample graphs tracking volume prescribed per member per month for key individual high cost or high utilization medicines

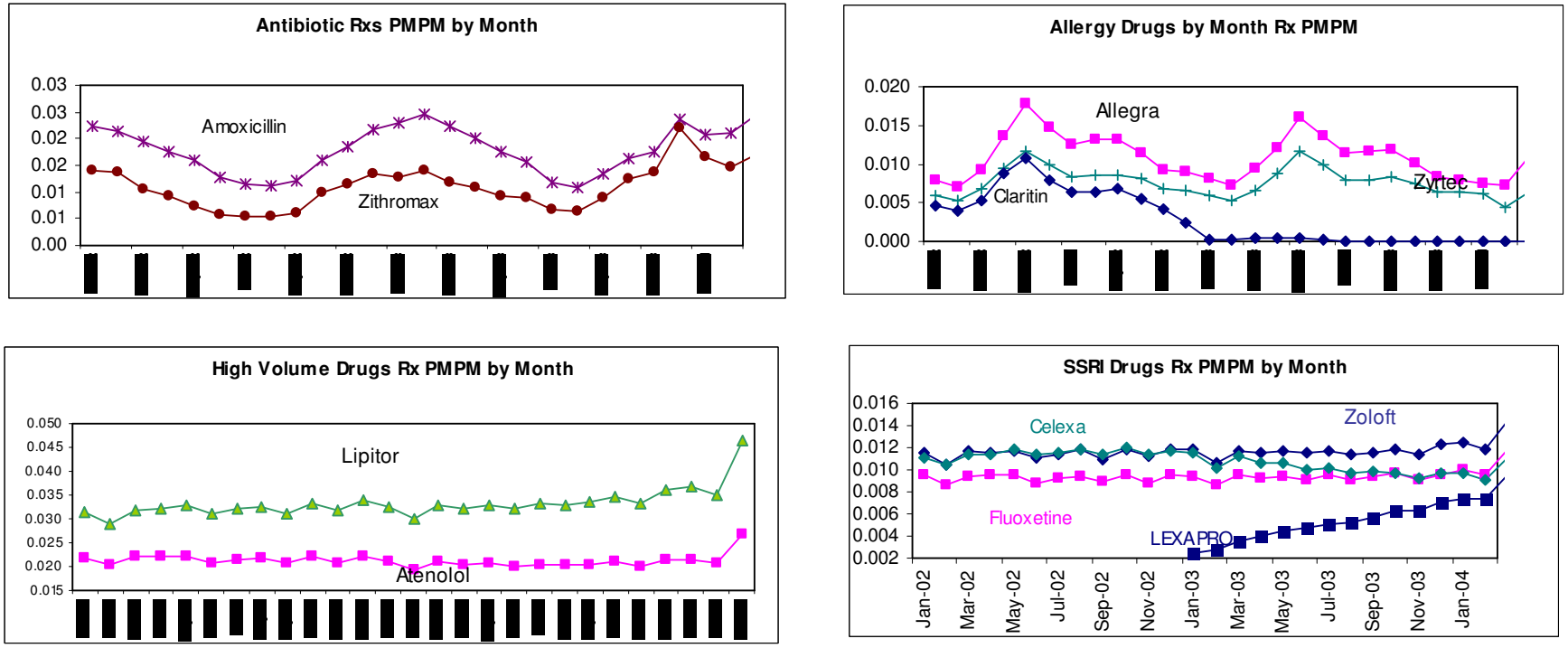

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Table 12.2: Sample template for reporting per member cost and utilization trends by therapeutic category, year on year

Top Therapeutic Categories Cost and Utilization Trend YTD'04 vs. YTD'03 **May-04**

2004 Cost Rank	Drug Class	Dominant Drugs in Category	2004 PMPM	2004 Rx PMPM	2004 Cost/Rx	2003 PMPM	2004 Rx PMPM	2003 Cost/Rx	change PMPM	Change Rx PMPM	Change Cost/rx
1	lipotropics	Lipitor, Pravachol, Zocor	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	18.6%	13.2%	4.8%
2	anti-ulcer preparations	Omeprozole, Nexium, Prilosec, Protonix	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	0.9%	2.2%	-1.3%
3	selective serotonin reuptake inhibitor (ssris)	Celexa, Paxil, Zoloft, Fluoxetine	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	2.9%	3.7%	-0.7%
4	anticonvulsants	Neurontin, Topamax, Lamictal, Clonazepam	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	21.3%	3.9%	16.7%
5	agents to treat multiple sclerosis	Avonex, Betaseron, Copaxone, Rebif	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	24.4%	7.1%	16.2%
6	analgesics,narcotics	Oxycontin	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	42.0%	5.8%	34.3%
7	follicle stim./luteinizing hormones	Gonal-F, Follistim	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	-3.1%	-1.3%	-1.8%
8	serotonin-norepinephrine reuptake-inhib (snris)	Effexor	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	40.7%	17.3%	20.0%
9	antipsychotics,atypical,dopamine,& serotonin antag	Risperdal, Zyprxa, Seroquel	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	10.1%	4.2%	5.6%
10	norepinephrine and dopamine reuptake inhib (ndris)	Wellbutrin	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	14.4%	13.5%	0.7%
11	antihistamines	Allegra, Zyrtec	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	-20.1%	-15.6%	-5.3%
12	anti-inflammatory tumor necrosis factor inhibitor	Embrel	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	62.3%	48.4%	9.4%
13	contraceptives,oral	Necon, Aviane, Apri, Microgestin	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	20.6%	1.2%	19.1%
14	beta-adrenergics and glucocorticoids combination	Advair Diskcus	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	38.0%	30.3%	5.9%
15	antimigraine preparations	Imitrex	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	2.3%	-0.6%	2.9%
16	nsaids, cyclooxygenase inhibitor - type	Celebrex. Vioxx	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	16.4%	1.9%	14.2%
17	nasal anti-inflammatory steroids	Flonase, Rhinocort, Nasonex	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	6.3%	-1.6%	8.1%
18	bone resorption inhibitors	Fosamax	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	14.7%	5.3%	8.9%
19	tx for attention deficit-hyperact(adhd)/narcolepsy	Concerta, Provigil	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	27.0%	10.5%	14.9%
20	insulins	Humalog, Humulin, Novolin, Lantus	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	23.3%	0.4%	22.7%
21	hypoglycemics, insulin-response enhancer (n-s)	Actos, Avandia	$ x.xx	0.0xx	$ xxx.xx	$ y.yy	0.0yy	$ yyy.yy	23.4%	14.0%	8.3%

Activity 1: Designing routine medicines policy monitoring in your system

Format: Small (within system) group discussion then large group debriefing (90 minutes)

Assume that you are about to implement the policy change in your system that you have been designing during this course. You have been asked by the head of the pharmacy program to monitor and report on the impact of the policy change. Please design one or more routine performance monitoring reports that you think would be able to communicate key aspects of the policy change. You may wish to refer to some of the layouts and indicators in the sample reports above to generate ideas about design for your monitoring system.

Please address the following questions:

1. What information would you want to know regularly about the performance of your policy, and why?
2. What reports would you generate, which data you would need to generate to create the report, and how could you capture the data?
3. How would you disseminate these monitoring reports, how frequently, and to which individuals or groups of stakeholders?
4. How would this report fit into the overall monitoring framework of the pharmacy program?

Session 13: Finalizing country presentations

Objective

The objective of this session is for working groups to finalize their presentations of a priority medicines issue, suggested policy change, and evaluation strategy to address in their health or insurance systems.

Please use the slide template provided for the presentation of your group project.

Session 14: Country group presentations

Objective

The objective of this session is for participants to present their work on a priority medicines issue facing their health or insurance system, and to receive constructive input from other participants.

Please use the slide template provided for the presentation of your group project.

Course wrap-up, evaluation, and next steps

Objective

The objectives of this session are for participants and facilitators to summarize key learning points of the course and to identify next steps for continued collaboration on medicine policy questions. Next steps may include collaborating on protocols to implement and evaluate the policy interventions described in the previous session. Participants will also complete a formal evaluation of all course sessions and facilitators.