Course in Pharmaceutical Policy Analysis

Participant Guide

Beijing, China

22-31 March 2009

An activity of the

Medicines and Insurance Coverage (MedIC) Initiative

Sponsored by

WHO Collaborating Center in Pharmaceutical Policy at the Department of Ambulatory Care and Prevention of Harvard Medical School and Harvard Pilgrim Health Care

Harvard China Fund

Xuan-wu Hospital of Capital Medical University

Contributors and Acknowledgments

The MedIC Course in Pharmaceutical Policy Analysis in Health Care Delivery and Insurance Systems was developed by Anita Wagner and Dennis Ross-Degnan of the WHO Collaborating Center in Pharmaceutical Policy (WHO CCPP) in Boston, USA. The WHO CCPP consists of the Drug Policy Research Group at the Department of Ambulatory Care and Prevention of Harvard Medical School and Harvard Pilgrim Health Care and the Center for International Health and Development at Boston University School of Public Health.

The following colleagues at the WHO CCPP and elsewhere contributed to the development of Participant Guides for MedIC Courses:

Jeffrey Brown, João Carapinha (PharmaLogica, South Africa), Joyce Cheatham, Amy Johnson, Richard Laing (WHO, Switzerland), Michael Law, Sarah Lewis, Connie Mah Trinacty, Sauwakon Ratanwijitrasin (Pharmaceutical System Research and Development Foundation, Thailand), Michael Reich (Harvard School of Public Health, USA), Sheila Reiss, Jim Sabin, Tienie Stander (Northwest University, South Africa), Russell Teagarden (MedCo Health Solutions, Inc., USA), Brenda Waning, Catherine Vialle-Valentin, Alexander Walker (Harvard School of Public Health, USA), Frank Wharam, Fang Zhang, and Lan Zhang (Xuan-wu Hospital, China).

We gratefully acknowledge the support of the WHO Programme in Medicines Policy and Standards and the Department of Ambulatory Care and Prevention of Harvard Medical School and Harvard Pilgrim Health Care for the development of the original course materials; and the Harvard China Fund for the adaptation of materials for the 2009 Bejing MedIC Course.

Comments and suggestions should be directed to:

Anita K. Wagner, PharmD, MPH, DrPH
Assistant Professor
Director, MedIC Courses in Pharmaceutical Policy Analysis
Co-Director, MedIC Initiative
WHO Collaborating Center in Pharmaceutical Policy
Department of Ambulatory Care and Prevention
Harvard Medical School and Harvard Pilgrim Health Care
133 Brookline Avenue, 6th Floor
Boston, MA 02215 USA

Phone: +1 617 509 9956
Fax: +1 617 859 8112
E-mail: awagner@hms.harvard.edu

Table of Contents

Sunday, March 22

Course 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 (key readings in bold)

None

Discussion Questions

None

Learning Points

- Each participant and facilitator comes to the course with his/her own perspective, background, experiences, and skills.
- The learning in this course happens through discussion of information, experiences, and perspectives among participants and facilitators.
- Participants are valuable resources for each other in the learning environment of this course and in collaborative work in their settings 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 a framework for 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
- Pharmaceutical sector framework and behavioral perspective
- Determinants of medicines use by health care providers and consumers
- Overview of intervention strategies to change medicines use behavior

Readings (key readings in bold)

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://archives.who.int/icium/icium2004/recommendations.html). 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 factors influence medicines use in China and what are major problems in the way medicines are used?
2. How effective are current policies and programs to influence prescribing and dispensing by health care 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 medicines and their appropriate use are determined by a complex network of individual and system-related factors.
- Many types of educational, managerial, economic, and policy interventions can 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 care delivery systems and insurance programs can design interventions to address specific problems among specific groups of health care 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. These approaches can combine 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.

Session 2: Medicines management in participating organizations

Objectives

The objective of this session is for participants to describe the hospitals and health insurance system they represent to course participants and facilitators. Participant presentations should focus on processes, frameworks, and policies in their organizations that influence medicines use. Presenters should also pose key questions on medicines access and use which senior administrators in their organizations would wish to answer.

Outline

- Presentations (10 minutes each) by participating hospitals and the Beijing Public Health Insurance
- Discussion of key questions

Readings (none)

Discussion Questions

1. Which are key structures, processes and policies related to medicines in your organization?
2. What are key medicines issues your system is facing?

Monday, March 23

Session 3: Structures, processes, and policy options to manage medicines in health care delivery and insurance systems

Objectives

The first objective of this session is to discuss the economic impact of medicines on overall health care and individual household expenditures. We will then present frameworks of structures, processes, and policy options that can be used to manage medicines in health care delivery and insurance systems. We will apply a behavioral framework to understanding policy interventions to improve access to and use of medicines in health care delivery systems or insurance programs and discuss the rationales for, strengths, and unintended effects of various policies and program options.

Outline

- Importance of medicines in health care and risk protection
- Functional frameworks for managing medicines in health care delivery and insurance systems
- Medicines policy options to improve access to and use of medicines

Readings (key readings in bold)

Aaserud M, Dahlgren 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.

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).

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

Austvoll-Dahlgren A, Aaserud M, Vist G, Ramsay C, Oxman AD, Sturm H, Kösters JP, Vernby A. Pharmaceutical policies: effects of cap and co-payment on rational drug use. Cochrane Database Syst Rev 2008;1:CD007017.

Chen Y, Schweitzer SO. Issues in drug pricing, reimbursement, and access in China with references to other Asia-Pacific region. Value Health 2008;11(Suppl1):S124-S129.

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

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

Kaiser Family Foundation. Prescription drug trends. September 2008. (http://www.kff.org/rxdrugs/upload/3057_07.pdf)

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.

Meng Q, Cheng G, Silver L, Sun X, Rehnberg C, Tomson G. The impact of China's retail drug price control policy on hospital expenditures: a case study in two Shandong hospitals. Health Policy Plan 2005; 20: 185-96.

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.

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

Sun Q, Santoro MA, Liu C, Eggleston L. Pharmaceutical policy in China. Health Aff 2008;27:1042-1050.

van Doorslaer E, O'Donnell O, Rannan-Eliya RP, et al. Catastrophic payments for health care in Asia. Health Econ 2007; 16:1159-1184.

Vermeulen LC, Rough SS, Thielke TS, Shane RR, Ivey MF, Woodward BW, Pierpaoli PG, Thomley SM, Borr CA, Zilz DA. Strategic approach for improving the medication-use process in health systems: the high-performance pharmacy practice framework. Am J Health Syst Pharm 2007; 64(16):1699-710.

Wang H, Zhang L, Hsiao W. Ill health and its potential influence on household consumptions in rural China. Health Policy 2006;78:167-177.

Wagner AK, Ross-Degnan D. The potential for insurance systems to increase access to and appropriate use of medicines in Asia Pacific countries. In: Eggleston K, ed. Prescribing Cultures and Pharmaceutical Policy in the Asia-Pacific. Walter H. Shorenstein Asia-Pacific Research Center, Stanford University, forthcoming in 2009 from Brookings Press.

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 (http://www.euro.who.int/eprise/main/WHO/Progs/OBS/Publications/20040527_2).

Discussion Questions

1. How are medicines financed in your organization?
2. What structures and processes does your organization use to manage medicines?
3. Are the poor able to obtain access to essential medicines in your health care delivery or insurance system?
4. How can a health care delivery system or insurance program influence medicines access, use, and costs?
5. What challenges do systems face in determining which medicines to allow for prescribing or reimbursement?

Learning Points

Session 3: Structures, processes, and policy options to manage medicines in health care delivery and insurance systems

- Medicines play an important economic role in societies. In many developing countries, medicines account for more than 20% of health care expenditures (compared with about 10% in OECD countries).
- Medicines also play an important economic role in individual households. In many developing countries, health care expenditures account for a large proportion of household expenditures; and medicines account for a major part of household health care expenditures.
- Ensuring access to essential medicines benefits 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 or HIV/AIDS; 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 care delivery 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 medicines prices. 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 care 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 advertising or other types of drug promotion; (e) health care providers failing to follow 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.
- Medicines policies in health delivery systems and pharmacy benefit policies in insurance systems influence access to, cost of, and quality use of medicines.
- Health care delivery systems and insurance programs have a wide array of options 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 the cost and quality of pharmaceutical care; actively promoting use of high-quality generic medicines; and implementing programs to assist patients in using medicines in a clinically effective way.

Session 3: Structures, processes, and policy options to manage medicines in health care delivery and insurance systems

- The American Society for Health-System Pharmacists develops official professional policies, in the form of policy positions and guidance documents (statements and guidelines), for the continuum of pharmacy practice settings in integrated systems (http://www.ashp.org/practice-policy/).
- Medicines policies can be broadly grouped into those related to formulary controls, other types of utilization management, medicines pricing, and regulation. Tables 3.1 to 3.4 list some common approaches in each of these areas.
- Strategies to control escalating medicines costs fall into three major categories: (1) *supply-side* measures that target pharmaceutical manufacturers and purchasers, (2) *proxy demand-side* measures that target physicians and pharmacies, and (3) *demand-side* measures that target patients.
- Reference-pricing for medicines involves an insurance program reimbursing up to a specified price per group of generic medicines, with patients paying additional co-payments for more expensive generics or brand name medicines. Reference pricing can reduce cost inflation and overall medicine expenditures.
- 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. Restrictions in access to or failure to use medicines correctly can result in higher downstream costs for outpatient and inpatient care to deal with uncontrolled health problems.
- 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 timely decision making.
- Health care delivery systems and insurance programs must continually update their medicines policies due to: (1) availability of new and more expensive products; (2) escalating prices for medicines; (3) increasing patient and prescriber demand, in part due to effective marketing; continuously evolving standards of care; (4) increasing resistance to anti-infective medicines; and (5) changing population demographics and disease burden.
- Health care delivery systems and insurance programs need to communicate clearly about medicines benefits policies and programs to a variety of individuals and institutions in order to achieve the desired objectives. The Academy for Managed Care Pharmacy suggests several strategies that health plans can use to communicate with industry, employers, purchasers, providers, and patients about details of pharmacy coverage (see http://www.amcp.org/amcp.ark?p=AA8CD7EC).
- 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 3.1: 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 care delivery 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.

Policy Approach	Description
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.
Tiered copayments	Copayments that vary by medication, often with generic products being free or having low copayments, preferred brand products having higher copayments, and non-preferred brands with the highest copayments 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 insurance, sometimes with different coinsurance percentages by formulary tier.
Reference pricing	A health insurance 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 3.2: 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.

Session 3: Structures, processes, and policy options to manage medicines in health care delivery and insurance systems

Policy Approach	Description
Contracting: Health care delivery 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 care 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.
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 care delivery and insurance systems 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 3.3: Policy Approaches – Medicines Pricing

Policy Approach	Description
Pricing strategies available to governments, health care delivery 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.
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 3.4: 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.

Session 3: Structures, processes, and policy options to manage medicines in health care delivery and insurance systems

Activity 1: A functional framework for managing medicines in health care delivery and insurance systems

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

The table below lists key functions that health care delivery and insurance systems may undertake to manage a pharmacy program. Briefly review the functions listed. We will assign two or three specific functions to each small group. Please discuss how your system handles each of these functions. Is the function carried out directly by your system or indirectly through another organization? Which departments, committees, or people are involved? Which data are used? Are the processes efficient? Is there sufficient coordination? What are current problems?

Key Function	Implementation in 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	

Session 3: Structures, processes, and policy options to manage medicines in health care delivery and insurance systems

Key Function	Implementation in System
8. Delivering pharmacy services: running pharmacy outlets, mail-order pharmacy	
9. Submitting (health care delivery organization) or processing (insurance system) claims for medicines payments	
10. Communicating with insured members/patients and providers about medicines benefits, limitations, costs, etc.	
11. Marketing medicines benefits to payers and members (insurance organization)	
12. Providing medicines-related clinical care: adherence monitoring, disease management, adverse drug reaction and medication error reporting	
13. Monitoring utilization by clinicians, hospitals, pharmacies, manufacturers (including fraud/abuse)	
14. Reporting utilization patterns, economic, clinical impacts to organization board, providers, members, accreditation organizations, government, public	
15. Evaluating, monitoring, reporting effects of medicines policies	

Activity 2: Expanding medicines coverage – policy goals and potential effects

Format: Large group discussion (1 hour)

Based in part on: Feng S, Yang Q, Liu M, Li W, Zhang S, Wu B, Yuan W. Edaravone for acute ischaemic stroke (Protocol). *Cochrane Database of Systematic Reviews* 2008, Issue 3.

Stroke is a frequent cause of death and disability. Most strokes are ischemic, due to blockage of an artery in the brain. Much effort has been focused on developing drugs to limit brain damage following an ischemic stroke. Edaravone is a novel drug. It was first reported to have a beneficial effect in animals in the late 1980s. In June 2001, Japanese regulatory authorities approved edaravone as the first free radical scavenger for clinical use in the management of acute stroke. A multicenter, randomized, placebo-controlled, double-blind trial showed that edaravone significantly improves functional outcome in patients with acute ischemic stroke. However, a systematic review of eight trials of edaravone for acute ischemic stroke, published before 2005, found no conclusive evidence of the efficacy of edaravone. Since then, few small trials have been conducted in China. There have been reports of fatal adverse events (due to acute renal failure) associated with the use of edaravone. A Cochrane review of the evidence for efficacy of edaravone is ongoing. (http://mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD007230/frame.html)

Edaravone is widely used in Chinese hospitals. It does not at the moment constitute treatment according to guidelines and is 3-times more expensive than the standard treatment guideline recommended treatment, ozagrel. Although listed on the hospital formulary, edaravone is not on the formulary of the urban health insurance system; insured patients treated with edaravone need to pay for the medicine out-of-pocket.

Hospital administrators would like to see edaravone listed on the health insurance formulary, to decrease the financial burden on patients and their families associated with edaravone treatment

Be prepared to discuss in the plenary group the rationale for expanding an insurance formulary to include edaravone as reimbursable treatment for patients with acute ischemic stroke. The discussion will address the following questions:

1. What are expected positive and negative effects of including edaravone on the insurance program formulary from the perspectives of patients, hospitals, and the health insurance?
2. What could hospitals and insurance organizations do to increase the positive effects of the formulary inclusion policy while minimizing its potential negative effects?
3. What would be the feasibility and likely outcomes of implementing such a policy in your setting?

Session 3: Structures, processes, and policy options to manage medicines in hospitals and insurance systems

Expanded Coverage Discussion Notes

Group	Positive Effects	Negative Effects	Policy Strategies to Maximize Positive and Minimize Negative Effects
Patients and community			
Hospital			
Health insurance			

Session 4: Standard treatment guidelines and formularies

Objectives

The objectives of this session are to describe the rationales for and uses of two key policy tools: standard treatment guidelines and formularies. We will outline steps for developing a standard treatment guideline. 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 and apply criteria to a formulary decision example.

Outline

- Rationale for implementing standard treatment guidelines
- A process for developing a standard treatment guideline
- Formulary policy options and their expected effects
- Processes for formulary decision making
- Case discussion of an insurance program's formulary decision and a pharmaceutical manufacturer's reaction

Readings (key readings in bold)

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.

American Society of Health System Pharmacists. ASHP guidelines on the pharmacy and therapeutics committee and the formulary system. Am J Health-Syst. Pharm 2008; 65: 1272-83. (http://www.ashp.org/Import/PRACTICEANDPOLICY/PolicyPositionsGuidelinesBestPractices/BrowsebyTopic/FormularyManagement.aspx)

Martin DK, Hollenberg D, MacRae S, Madden S, Singer P. Priority setting in a hospital drug formulary: a qualitative case study and evaluation. *Health Policy 2003; 66*(3): 295-303. doi: 10.1016/S0168-8510(03)00063-0.

Holloway K, Green, T. Managing the formulary process. Chapter 3 in Drug and Therapeutics Committees: A Practical Guide. World Health Organization, 2003.

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.

Chapter 10. Managing drug selection. In: Quick JD, ed. Managing drug supply: The selection, procurement, distribution, and use of pharmaceuticals. West Hartford, CT: Kumarian Press, 1997; 121-136.

Session 4: Standard treatment guidelines and formularies

Savelli A, Schwarz H, Zagorski A, Bykov A. Stage II. Develop Drug Formulary List. In: Manual for the Development and Maintenance of Hospital Drug Formularies. Management Sciences for Health, 1996.
http://erc.msh.org/mainpage.cfm?file=2.2.htm&module=dtc&language=English

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.

Discussion Questions

1. What are the clinical and economic benefits of standard treatment guidelines?
2. What information and practical steps are needed to develop and implement an evidence-based standard treatment guideline?
3. What are the clinical and economic benefits of formularies?
4. How are formulary decisions made in your system?

Learning Points

- Standard treatment guidelines are statements developed with clinical evidence that support decisions of health care providers about diagnosing and treating clinical conditions, including prescribing medicines. A standard treatment guideline for a specific clinical condition may include clinically relevant features of the condition, factors to consider in correctly diagnosing the condition, pharmaceutical and non-pharmaceutical treatments, and whether referrals are required between health care professionals.
- Standard treatment guidelines aim to: guide health care workers in managing specific clinical conditions; establish acceptable standards for patient management; set criteria by which to measure compliance with these standards; and assist in identifying resource requirements for managing the condition.
- Adherence to treatment guidelines is essential not only for the delivery of quality health care but also, in infectious diseases, to slow the development of drug-resistance.
- The development of a standard treatment guideline should be a consultative, data-intensive, multi-stakeholder process that requires careful planning (see Table 4.1). To enhance widespread acceptance of guidelines, leading clinicians and professional societies should be involved in their development.
- Standard treatment guidelines need to be reviewed regularly to ensure that recommendations are still consistent with scientific and clinical knowledge.
- Evidence shows that many health care providers in both the public and private sectors fail to adhere to evidence-based treatment guidelines. Consensus building, information dissemination, targeted training, and supportive community sensitization are needed to increase adherence to guidelines in all sectors.
- Cost will always be an important issue when countries decide about national treatment policies. The largest cost components and biggest challenges in changing a treatment policy are likely to be the cost of training, monitoring practices, and the higher costs of newer medications. When decisions are made to change a policy, all costs associated with implementing and monitoring adherence to the policy change should be addressed .

- Standard treatment guidelines should form the basis for selecting medicines for essential medicines lists and formularies.
- Essential Medicines Lists (EMLs), have been introduced in many countries to encourage and guide rational drug prescribing and purchasing. An EML should contain those medicines that satisfy a population's primary care needs.
- Essential Drugs Programs often include policies and programs to promote use of generic medications rather than brands, which keeps costs low and helps to increase patient access to and compliance with treatment.
- To be effective within a health care system, EMLs must be accompanied by regular education for prescribers and dispensers, guaranteed availability of essential medicines, adequate time for patient consultation and dispensing, adequate labeling of dispensed medicines, and effective communication to patients about how to administer medications properly.
- A formulary is a list of medicines approved for use within a health care setting. 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 in the system. 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. Restricted 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 list all products that cannot be prescribed or reimbursed.
- The World Health Organization promotes use of a certain type of restricted formulary known as an Essential Medicines List [EML], which is intended to contain all the medicines needed to address important public health problems in a given setting; WHO maintains a Model Essential Medicines List to use as a starting point for developing EMLs in national or institutional settings. The WHO Model Formulary refers to the compiled information on indications, dosage, adverse effects, contraindications and warnings for all of the medicines on the Model EML.
- Formularies are vital to the successful management of a hospital pharmacy program and a health insurance prescription drug benefit. Formularies guide 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 delivery or insurance organization. P&T Committee 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. Table 4.1 below lists some of the factors that a P&T Committee may choose to consider when making decisions about the formulary status of a medicine. 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.
- Having explicit guidelines for formulary submissions supports the formulary decision making process by: (1) standardizing the information required from the manufacturer; (2) formalizing the formulary decision process; and (3) making explicit and transparent the assumptions, evidence, and rules that influence formulary choices.
- Guidelines exist for the types of information that formulary committees 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 process.
- Conducting medication class reviews and creating a draft formulary list is the most important step in the formulary development process. Drug class reviews help to improve patient care by introducing new drugs and removing less effective or harmful drugs from the formulary. Medication class reviews can also have economic impacts by emphasizing the most cost-effective medications, which can improve hospital budgets.
- Managing a formulary, which includes the addition and deletion of medications after the list has been developed, is as important as the initial development process. Adding new medications to a formulary requires careful evaluation of whether a candidate medication has sufficient efficacy, effectiveness, safety, quality, superiority to current medications on the formulary, and adequate cost-effectiveness to warrant inclusion on the formulary.
- The UK National Institute for Health and Clinical Excellence (http://www.nice.org.uk/) provides guidance documents on preferred treatment practices. The Cochrane Library (http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME?CRETRY=1&SRETRY=0) is another source of comparative drug information for formulary decision making.
- Economic analysis during formulary decisions has traditionally focused on the acquisition cost of a medication. However, economic analyses now include other economic factors, such as the cost of an entire course of therapy, the cost of associated medical supplies, the cost of storage, and the costs of educating patients and providers about the use of newly listed medicines.
- Formularies and standard treatment guidelines are crucial for pharmaceutical management and cost-effective prescribing; neither alone is sufficient to ensure quality health care. Standard treatment guidelines inform providers of how to properly use the medications contained in a formulary. Without Standard Treatment Guidelines, inappropriate and/or inefficient prescribing may occur even in the presence of an excellent formulary. Without ensuring that recommended medicines are listed on a health care system's formulary and available to patients, prescribers cannot practice according to Standard Treatment Guidelines.

Table 4.1: The Process of Developing Standard Treatment Guidelines (adapted from Holloway, 2003)

Step	Process
1	Create a team to develop the required standard treatment guidelines (STGs) - Wide representation – pharmacists, physicians, hospital management
2	Develop a plan for creating and implementing the STGs - Data collection, data analysis, drafting, reviewing, editing - Budget: allocate resources
3	Prioritize which diseases require a STG - Identify priority diseases within the hospital (prevalence, severity, impact on general health, cost to treat) - Identify areas in clinical practice where evidence of wide variation in diagnosing and prescribing occurs
4	Establish the appropriate treatment - Review evidence, consult and reach consensus - Consider: non-medicinal interventions; cost-effectiveness of medicines; dose, duration, side-effects, and contraindications; and available resources
5	Discuss and decide what information should be included in the STG - description of the clinical condition - diagnostic criteria - treatment objective - pharmaceutical and non-pharmaceutical interventions - expected outcomes - when to refer - information that patients may need - cost of treatment
6	Create the first draft of the STG and consult - Consult widely and reach consensus - Consider pilot testing the STG
7	Implement the STG - Print and distribute the finalized STG - Consider: an official launch of the STG, training staff, and mechanisms to monitor its implementation
8	Schedule regular reviews and updates of the STG - Review current and emerging evidence that would warrant an update of the STG - Update and actively disseminate revised guidelines

Table 4.2: Factors to consider 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 (when 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 and national essential medicines list 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 country?
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? Which advantages does it have in obtaining lower prices and influencing more appropriate use of medicines?
4. Which challenges does hospital face in determining which drugs to admit to its formulary? Which options does it have in influencing appropriate use of medicines?

Activity 2: Formulary decision about an expensive medication

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?

Tuesday, March 24

Session 5: Pharmacoeconomics in hospital and insurance policy decision making

Objectives

The objectives of this session are to explore and discuss pharmacoeconomic principles as tools to assist in policy decision making.

Outline

- Describe pharmacoeconomic principles
- Discuss the rationale and purposes for their use in hospital and insurance policy decision making, and when their use would not be appropriate
- Outline challenges in generating quality pharmacoeconomic data
- Share international examples of using pharmacoeconomic data in decision making
- Apply key pharmacoeconomic concepts to a formulary decision process

Readings (key readings in bold)

Bao Peng L, Qing Tan C, Min Wan X, Cui W. Cost-Utility China: Differences and difficulties compared with developed countries. Pharmacoeconomics 2007;25:619.

Chen Y, Schweitzer SO. Issues in drug pricing, reimbursement, and access in China with references to other Asia-Pacific region. Value in Health 2008; 11(Suppl 1):S124-129.

Cheung YB, Thumboo J. Developing health-related quality-of-life instruments for use in Asia: the issues. Pharmacoeconomics 2006;24: 643-650.

Cyranoski D. China's deadly drug problem. Nature 2007;446:598-599.

Lau EW, Leung GM. Is the Hospital Authority's drug formulary equitable and efficient? Hong Kong Med J 2008;14:416-417.

Marshall DA, Douglas PR, Drummond MF, Torrance GW, MacLeod S, Manti O, Cheruvu L, Corvari R. Guidelines for conducting pharmaceutical budget impact analyses for submission to public drug plans in Canada. Pharmacoeconomics 2008;26:477-495.

McCabe C, Claxton K, Culyer AJ. The NICE cost-effectiveness threshold: what it is and what that means. Pharmacoeconomics 2008;26:733-744.

Meng Q, Cheng G, Silver L, Sun X, Rehnberg C, Tomson G. The impact of China's retail drug price control policy on hospital expenditures: a case study in two Shandong hospitals. Health Policy and Planning 2005;20:185-96.

Singer ME. Cost-Effectiveness analysis. Developing nations left behind. Pharmacoeconomics 2008;26:359-361.

Wang YR. Price competition in the Chinese pharmaceutical market. International Journal of Health Care Finance and Economics 2006;6:119-129.

Xie X, Vondeling H. Cost-Utility analysis of intensive blood glucose control with Metformin versus usual care in overweight Type 2 Diabetes Mellitus patients in Beijing, P.R. China. Value in Health 2008; 11(Suppl 1):S23-32.

Yuan Y, Iloeje U, Li H, Hay J, Yao BG. Economic implications of Entecavir treatment in suppressing viral replication in chronic Hepatitis B (CHB) Patients in China from a Perspective of the Chinese Social Security Program. Value in Health 2008;11 (Suppl 1):S11-22.

Zhou B, Yang L, Sun Q, Gu H, Wang B. Social health insurance and drug spending among cancer inpatients in China. Health Affairs 2008;27:1020-1027.

Discussion Questions

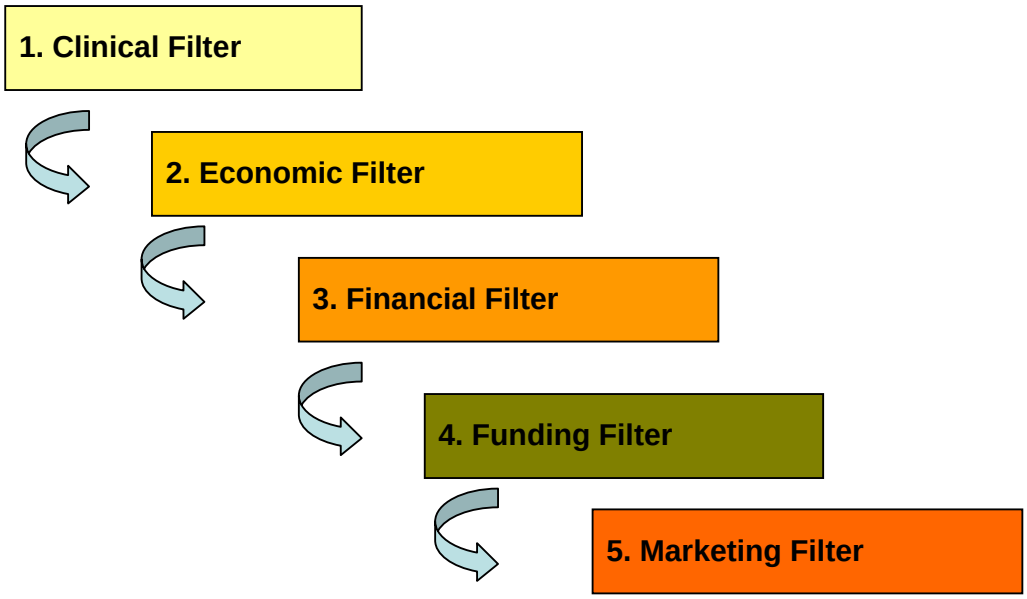
1. What could be done to improve the acceptance of pharmacoeconomics as a tool for decision making in China? (See article by Mendel E Singer)
2. How could access to local pharmacoeconomic analysis results assist decision makers in allocating scarce healthcare resources?
3. Based on the correspondence from Bao Peng et al., in your opinion, what are the barriers that affect acceptance of pharmacoeconomic studies in China. Debate the reasons given in the article by Bao Peng et al.
4. Discuss how the Five Filter approach can be used and applied in China for policy decision making.

Learning Points

- Pharmacoeconomics is a tool that can be used with other tools to allocate scarce healthcare resources in a scientific way.
- Pharmacoeconomics is the scientific discipline that assesses the overall value of pharmaceutical healthcare products, services and programs. Of necessity, it addresses the clinical, economic and humanistic aspects of health care interventions in the prevention, diagnosis, treatment and management of disease. Pharmacoeconomics thus provides information critical to the optimal allocation of health care resources (International Society for Pharmacoeconomics and Outcomes Research, ISPOR, http://www.ispor.org/).
- Utility is a quantitative expression of an individual's preference, or desirability of, a particular state of health under conditions of uncertainty. Utility measurement is a method of querying an individual to measure the strength of preference that the individual has for an outcome, and to represent that preference by a quantitative score called a utility (ISPOR).
- Quality-adjusted life year (QALY) is a universal health outcomes measure applicable to all individuals and all diseases, thereby enabling comparison across diseases and across programs. A QALY combines, in a single measure, gains and losses in both quantity of life (mortality) and quality of life (mortality (ISPOR).
- Cost-effectiveness analysis (CEA) compares incremental costs of two alternative treatments to the incremental benefits of two alternatives without considering the utility value associated with the two treatments.

- Cost-utility analysis (CUA) is methodology of economic analysis that compares two or more alternative choices in terms of both their costs and outcomes where the outcomes are measured in unit of utility or preference, often as quality-adjusted life year (ISPOR).
- Cost benefit analysis (CBA) is an analytical technique derived from economic theory that enumerates and compares the net cost of a health care intervention with the benefits that arise as a consequence of applying that intervention. For this technique, both the net costs and the benefits of the health intervention are expressed in monetary terms (ISPOR).
- Budget Impact Analysis (BIA) is a technique whereby the financial impact of a health care intervention is estimated for a particular country and patient profile taking into consideration all the direct health care costs that are applicable to that disease area and intervention over a specified period of time.
- Cost-effectiveness thresholds are benchmark values per country that can be used to adjudicate and evaluate the results from CEA and CUA studies as being either cost-effective or not cost-effective.
- The Five Filter approach to scarce resource allocation is a systematic way of structuring decision making in a rational way. The Five Filter Decision Making Model allows stakeholders to adjudicate new technologies in a scientific and holistic way.

Figure 5.1 The Fiver Filter Decision Making Model



Activity 1: Considering economics in decision making: vaccines and biologicals

Format: Small group case discussion with large group debriefing (2 hours)

You have just been appointed by the hospital (private medical insurer) as pharmaceutical therapeutic committee. You are responsible to make recommendations to the hospital board (medical insurer) with regards to formulary admission (reimbursement) of new technology drugs if and when they become available. You are expected to make recommendations based on sound scientific, economic, and financial evidence.

At your first meeting the following drugs are tabled for consideration:

- Prevanar®: a vaccine for children from 6 months old for the prevention of pneumococcal infection;
- Gardacil®: a vaccine for males and females between ages 9 and 26 for the prevention of cervical cancer;
- Pegasys®: an interferon alpha for the treatment of patients infected by hepatitis C;
- Herceptin®: a biological drug that is indicated for patients with early stage breast cancer as well as metastatic breast cancer that are HER 2 positive;
- Orencia®: a new biological drug for the treatment of moderate to severe rheumatoid arthritis.

Consider the drugs above using a well structured approach (such as the Five Filter Model) and make recommendations which drugs should be admitted to the formulary (reimbursed) in order of priority. You have at your disposal a consultant who will provide you with any information you might require to make sound and scientific recommendations. You are however welcome to do your own research; therefore, should you have access to a laptop and the internet, it is recommended that you bring it to this session.

On completion of your analysis, you will be expected to make a 3-minute executive presentation of your findings and your recommendations. Please report on a) your approach to decision making; b) the recommendations you are making; and c) the rationale for your recommendations.

Session 6: A systematic approach to evidence-based, effective, and fair policy making

Objectives

The objectives of this session are to discuss the importance of considering all stakeholders' interests when making policy decisions; to present a framework to promote evidence-based, effective, and fair policy decisions; and introduce research techniques that can inform the different policy making stages.

Outline

- Discuss the need for fair and evidence-based implementation of health policies
- Describe a framework that explores the values underlying policies and that optimizes benefits and minimizes risks to key stakeholders
- Discuss key elements needed to implement such a framework
- Discuss research techniques to identify key stakeholders and their values, to predict benefits and risks to stakeholders, and to monitor the effects of policies

Readings (key readings in bold)

Daniels N. Justice, health, and healthcare. Am J Bioeth. 2001 Spring;1(2):2-16.

Hudelson PM. Qualitative Research for Health Programmes. WHO. Available at: http://whqlibdoc.who.int/hq/1994/WHO_MNH_PSF_94.3.pdf

Rice PL, Ezzy D. Rice PL and Ezzy D. Qualitative Research Methods: A Health Focus. New York: Oxford University Press, 1999.

Sabin JE, Cochran D. Confronting trade-offs in health care: Harvard Pilgrim Health Care's organizational ethics program. *Health Aff (Millwood).* Jul-Aug 2007;26(4):1129-1134.

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.

Sturm H, Austvoll-Dahlgren A, Aaserud M, Oxman AD, Ramsay C, Vernby A, Kösters JP. Pharmaceutical policies: effects of financial incentives for prescribers. Cochrane Database Syst Rev 2007;3:CD006731.

Wharam JF, Daniels N. Toward evidence-based policy making and standardized assessment of health policy reform. *JAMA.* Aug 8 2007;298(6):676-679.

Wynia M, Cummins D, Flemig D, Karsjens K, Orr A, Sabin J, Saphine-Bernstein I, Witlin R. Improving fairness in coverage decisions: performance expectations for quality improvement. American Journal of Bioethics 4 (3): 87-100, 2004.

Discussion Questions

1. Have you encountered medicines policies that had unexpected results? Describe your experience.
2. Who are the stakeholders affected by pharmaceutical policies at your institution?
3. What techniques might you use to predict effects of new policies on these stakeholders?
4. Provide examples when the values of different stakeholders were in conflict related to a policy change? What processes were used to resolve these?
5. What systems or personnel would be needed at your institution to monitor the effects of a new policy on poor and illiterate patients?

Learning Points

- Pharmaceutical and health policies can have far-reaching consequences including effects on patients' physical and mental health, access to care, and their economic circumstances. It is challenging to predict effects of policies and difficult to maximize benefits for all stakeholders. Well-intentioned policies often have unforeseen adverse consequences.
- A policy-making framework can be a starting point for developing excellent health policies. Although each policy-making circumstance is unique and complex, there are similar potential inputs into creating sound health policies, including review of scientific literature, expert opinion and input from key stakeholders, pilot testing, and post-implementation monitoring. A policy-making framework might help organize and guide these approaches.
- A "framework" is a systematic guide to resolving a question or problem. Frameworks are general so that they are applicable to different situations in different places. A more detailed "infrastructure" can be built onto a framework depending on the local circumstances.
- In health policy decision-making, a framework could be used in several ways. It can be used like a roadmap to guide the policy-making process from start to "finish," used to analyze and improve a policy already implemented, or used to evaluate the merits of a particular policy-making process.
- Health policies should be shaped by rigorous scientific research (evidence-based), should lead to benefits for relevant stakeholders (effective), should not cause harm, and should benefit relevant stakeholders in an equitable manner (fair). Health policies should be especially protective of vulnerable individuals who have difficulty advocating for themselves.
- A given health policy may be based on fundamentally sound values, but may have unethical *consequences* that require it to be changed. Empirical research can illuminate ethics and effectiveness of these policies. The fundamental principles of other policies may conflict with the moral or ethical codes of key stakeholders and research would be insufficient to provide definitive policy guidance. However, discussions with key stakeholders can at least uncover such conflicts
- A framework for evidence-based, effective, and fair health policy-making involves utilizing research and fair processes to determine if the fundamental and guiding values of the policy are ethical and valid, identify all key stakeholders, identify benefits and

drawbacks to stakeholders, determine if adverse effects can be satisfactorily minimized, and implement standards-based monitoring of pertinent measures.

- Key elements required to implement the framework include personnel such as experts, researchers, and key stakeholder; fair processes; time and money; research, measures and standards; and monitoring and feedback systems.
- Fair processes give all stakeholders the ability to be fairly represented in decision-making that may be controversial or complex. Such processes include making the policymaking process and reasons for decisions public and easily accessible (publicity), ensuring that decisions rest on reasons that stakeholders agree are relevant (relevance), allowing decisions to be revisable in light of new evidence and arguments (revisability), and having mechanisms that enforce publicity, relevance, and revisability (enforceability).
- For example, deciding which drugs should be included on a formulary inherently involves limiting access to drugs. Distrust by those affected can be minimized if people understand the rationales behind the decisions. A fair process for such decision-making could occur at four allocation decision levels: determining the health needs of the covered population, then the drugs that treat those health needs, then the indications for the drugs, then relevant restrictions. Fair processes require that at each level, a rationale, a communication strategy, and a process for appeal/revision be in place.
- Deliberative, evidence-based policy implementation is costly and time consuming but may best optimize outcomes and minimize adverse events for key stakeholders and may contribute to increased policy acceptance.
- Qualitative and quantitative research methods can be used to improve almost every aspect of the policy making process. Qualitative research aims to understand people's beliefs, experiences, attitudes, behavior, and interactions. It generates non-numerical data through interviewing individuals or discussing issues with small groups of stakeholders. Quantitative research generates numerical data that can be used to draw conclusions about the effects of policies
- Choosing measures to assess a policy as well as the levels at which to define success or failure (standards) are key elements of developing effective and fair policy-making. These measures and standards can be integrated into systems to monitor the effects of a policy at regular intervals after implementation.

Activity 1: Evaluating the fairness and effectiveness of a potential policy change: Are physician incentives for generic prescribing a "good policy option?"

Format: Small group (across systems) case discussion with large group debriefing (2 hours)

Please read the following scenario describing a health policy dilemma and a government's response. Complete the questions below in your small groups.

A Government's Response to Rising Medicines Costs

In response to rising medicines costs in your country, policy makers are reviewing options to increase prescribing of generic medicines. They are strongly considering providing financial incentives to physicians as the primary mechanism to change prescribing patterns. They have drafted an initial policy that provides physicians a year-end bonus payment equivalent to one month's salary if they issue greater than 90% of their prescriptions for patients with certain conditions per year for approved generics. The conditions include: hypertension, adult-onset diabetes, congestive heart failure, asthma, bacterial sinusitis, group A streptococcal pharyngitis, otitis media, and urinary tract infection.

You have been assigned to an advisory committee providing recommendations regarding this potential policy change. You are asked to investigate whether this would be a "good policy option" for lowering costs and increasing access to medicines.

Using Table 1 below, please:

1. List the fundamental and guiding principles of this policy.
2. Decide whether the principle in question is ethical and valid.
3. If it is unclear whether the given principle is ethical and valid, list research methods you could use (literature review, expert opinion, key informant interviews, focus groups, surveys, cross-sectional or longitudinal data analysis) to further clarify.

Using Table 2 below, please

1. Identify the key stakeholders affected by this policy?
2. Identify potential benefits and unintended effects to these stakeholders.
3. Identify research techniques (literature review, expert opinion, key informant interviews, focus groups, surveys, cross-sectional or longitudinal data analysis) that could further clarify any uncertainties regarding benefits and unintended effects of the policy.

Using Table 3 below, please

1. Imagine that the policy has been implemented without changes. Based on your analysis above, choose 3 key measures and the associated research methodologies needed to determine effects of this policy.
2. List the structures and personnel needed to monitor these outcomes.

Session 6: A systematic approach to evidence-based, effective, and fair policy making

1.a. List the fundamental and guiding principles of this policy.

1.b. Decide whether the principle in question is ethical and valid.

1.c. If it is unclear whether the given principle is ethical and valid, list research methods you could use (literature review, expert opinion, key informant interviews, focus groups, surveys, cross-sectional or longitudinal data analysis) to further clarify.

Fundamental and Guiding Principles	**Ethical and Valid? (Yes/No/Uncertain)**	**Research Methods to Use If Uncertain**

Session 6: A systematic approach to evidence-based, effective, and fair policy making

2.a. Who are the key stakeholders affected by this policy?

2.b. Identify potential benefits and unintended effects to these stakeholders.

2.c. Identify research techniques (literature review, expert opinion, key informant interviews, focus groups, surveys, cross-sectional or longitudinal data analysis) that could further clarify any uncertainties regarding benefits and unintended effects of the policy.

Key Stakeholder Potentially Affected	Potential Benefits	Potential Unintended Effects	Research Methods to Further Clarify

Session 6: A systematic approach to evidence-based, effective, and fair policy making

Key Stakeholder Potentially Affected	Potential Benefits	Potential Unintended Effects	Research Methods to Further Clarify

Session 6: A systematic approach to evidence-based, effective, and fair policy making

3.a. Imagine that the policy has been implemented without changes. Based on your analysis above, choose 3 key measures and the associated research methodologies needed to determine effects of this policy.

3.b. List the structures and personnel needed to monitor these outcomes.

Measure	Research Methodology	Structures and Personnel Needed

Wednesday, March 25

Session 7: Availability and use of data in hospitals and insurance systems

Objectives

The objectives of this session are to characterize the types of data that often exist in health care delivery systems and insurance programs. Existing data can 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 hospital to analyze costs of care for stroke patients over time.

Outline

- Comparison of data available in the systems of course participants with a comprehensive list of possible data elements
- Use of data to quantify patterns of use and cost of care
- Example: Analysis of inpatient data to quantify health care expenditures
- Collecting ad hoc data to study a problem in depth

Readings (key readings in bold)

Chapter 29. Investigating drug use. In: Quick JD. Managing drug supply: The selection, procurement, distribution, and use of pharmaceuticals. West Hartford, CT: Kumarian Press, 1997; 431-449.

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

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.

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

3. Which types of data tend to exist in most systems? What are their strengths and weaknesses?
4. 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 care 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, data 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 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.
- Health care delivery systems routinely collect data to manage patient care and seek reimbursement from insurance. 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 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 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; may already be 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 claims data is the tendency for providers to shift diagnoses to those that carry 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, administrative data on procedures performed (e.g., hip fracture repair) that are unique to a specific disease can be used to accurately identify patients with the disease. Information on procedures performed can be combined with related inpatient and outpatient visits to create a “claims history” for patients with specific diseases.
- Administrative 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 problem in use of medicines has been identified, 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 and qualitative methods can be used to explore the problem in more detail to design a strategy for addressing 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 hospitals and insurance systems

Format: Large group discussion (45 minutes)

Below is a comprehensive list of possible data on patients, medicines and other health services that may be available in health care delivery and health insurance systems. For this exercise, you will be given similar tables that shows how many participating organizations have each type of data available, based on the surveys some of you completed before the course. The first two columns show the type of data and the percentage of organizations reporting that have each data element routinely available or linkable from other sources. Please review the table and identify which data elements are available in most systems. Discuss the kinds of questions that can be answered with data that are routinely available data and which questions would require you to collect additional information.

Type of data	%of systems with data available	Total no. of systems reporting	%of systems with data collected, not filed	%of systems with data on paper	%of systems with data computer ized
Hospital data					
Demographic data for INpatients					
Demographic data for OUTpatients					
Pharmacy data for INpatients					
Pharmacy data for OUTpatients					
Clinical data for INpatients					
Clinical data for OUTpatients					
Reimbursement claims for INpatients to health insurances					
Reimbursement claims for OUTpatients to health insurances					
Reimbursement receipts for INpatients from health insurances					
Reimbursement receipts for OUTpatients from health insurances					

Session 7: Availability and use of data in hospitals and insurance systems

Type of data	%of systems with data available	Total no. of systems reporting	Available for IN-patients	Available for OUT-patients	Not available
Patient data					
Age					
Gender					
Employment status					
Socio-economic group					
Insurance provider (for insured patients)					
Specific insurance benefit information (for insured patients)					
Provider data					
Provider name					
Provider type (e.g. physician, facility)					
Level of medical training					
Age or year of medical graduation					
Gender					
Medical specialty					
Hospital department					
Hospitalization data					
Admission diagnosis description					
Admission diagnosis code (ICD)					
Admission diagnosis code (non-ICD)					
Discharge diagnosis description					
Discharge diagnosis code (ICD)					
Discharge diagnosis code (non-ICD)					
Admission date					
Discharge date					
Hospital charges to insurance					
Amount paid by patient					
Hospital total payment by insurance					
Hospital total payment by patient					
Procedure data					
Procedure description					
Procedure code (ICD/CPT)					
Procedure code (non-ICD, non-CPT)					
Procedure date					
Hospital charges to insurance for specific procedures					
Hospital charges to patient for specific procedures					

Session 7: Availability and use of data in hospitals and insurance systems

Type of data	%of systems with data available	Total no. of systems reporting	Available for IN-patients	Available for OUT-patients	Not available
Outpatient visit data					
Outpatient visit diagnosis description					
Visit diagnosis code (ICD)					
Visit diagnosis code (non-ICD)					
Visit date					
Visit charges to insurance					
Visit charges to patient					
Hospital payments by insurance for outpatient visit					
Hospital payments by patient for outpatient visit					
Medicines data					
Generic name					
Brand name					
Unique drug identifying code					
Generic or brand status					
Dosage form					
Strength					
Dose prescribed per treatment					
Quantity prescribed					
Date prescribed					
Quantity dispensed					
Date dispensed					
Prescriber name					
Prescriber identifying code					
Dispenser name					
Dispenser identifying code					
Hospital charge to insurance for individual medicines					
Total hospital charge to insurance for medicines					
Hospital charge to patient for individual medicines					
Total hospital charge to patient for medicines					
Medicine payment by insurance for individual medicines					
Medicine payment by patient for individual medicines					

Activity 2: Working with Excel

Format: Large group data activity (45 minutes)

Please see "Working with Excel" handout. Together we will work through an analysis of data on purchases of four antibiotics and illustrate how to use different Excel functions, including pivot tables and pivot charts to summarize data. The data dictionary below characterizes the data.

Data Dictionary for Purchase Data of Four Antibiotics, 2005 to 2008

Variable Name	Variable Description and Data Summary
年（Year）	Purchase year Number of observations, n=192 Number missing, n=0 Min=2005, Max=2008
月（Month）	Purchase month Number of observations, n=192 Number missing, n=0 Min=1, Max=12
药品名称（Drug name）	Abbreviated drug name Am=Amoxicillin Az=Azithromycin Le=Levofloxacin Pe=Penicillin Number of observations, n=192 Number missing, n=0
金额（Cost）	Cost per unit (yuan) Number of observations, n=192 Number missing, n=0 Min=12802, Max=14,000,684
数量（Volume）	Number of units purchased Number of observations, n=192 Number missing, n=0 Min=20900, Max= 2250134

Activity 3: Cost of care for stroke patients

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

Hypertension is increasingly prevalent in China, as are conditions that can result from untreated hypertension, which include stroke. Hospitals need to know how much they are spending on care for stroke patients; the patterns of care and expenses over time; and by payer.

Evaluating care and cost patterns for stroke patients requires some or all of the following analyses:

- Examining the trajectory of total payments for inpatient services for patients with the target health problem over time;
- Examining the trajectory of payments for specific services (Western medicines; Chinese medicines; procedures) over time;
- Identifying subgroups of patients who experience particularly high costs;

You have an Excel data set that was created to explore the patterns of cost of inpatient care for stroke patients in a teaching hospital. 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 costs of care over time and by payer. Create pivot tables for total hospitalization cost by year and payer; average hospitalization cost per patient by payer and outcome category; proportion of total hospitalization costs accounted for by Western and Chinese medicine expenditures. Examine whether patterns of cost differ over time and by payer.

Based on the results, discuss the following questions:

1. Which groups of patients account for the highest percentage of costs in a given year?
2. How do high-cost patients differ from others in terms of diagnoses and treatment received? What additional information would you need on these patients to decide if cost differences are related to differences in severity of illness?
3. What data would you need to assess appropriateness of care given?

Data Dictionary for Stroke Inpatient Data

Variable (Chinese)	Variable (English)	Variable Description
病案号	PID	Patient ID Number of observations, n=6850 (2004-2008)
性别	SEX	Gender 1=male, n=4,754 2=female, n=2,096
年龄	AGE	Age (years)
入院日期	ADMISSION	Admission date (mm/dd/yyyy), n=6,850
出院日期	DISCHARGE	Discharge date (mm/dd/yyyy), n=6,850
付费方式	PAYER	1=BPHI, n=3,468 3=Out of pocket, n=1,475 4=Government, n=850 6=Other payer, n=1,057
主要诊断	DIAGNOSIS	Major Diagnosis (Chinese characters), n=6,850
主要手术名称	PROCEDURE	Major Procedure (Chinese characters), n=1,220
主要诊断出院情况	OUTCOME	Outcome at discharge 1=cured, n=401 2=improved, n=5,928 3=unchanged, n=160 4=dead, n=309 5=?, n=52
住院费总计	CHARGE	Total cost of hospitalization (yuan), n=6,850
西药费	W-DRUG	Western drug cost (yuan), n=6,850
中成药费	C-DRUG	Chinese drug cost (yuan), n=6,850
中草药费	H-DRUG	Traditional Chinese herb cost (yuan), n=6,850
放射费	RADIATION-C	Radiation cost (yuan), n=6,850
治疗费	TREATMENT-C	Other treatment cost (yuan), n=6,850
手术费	OPERATION-C	Operation cost (yuan), n=6,850

Friday, March 27

Session 8: Medicines policy objectives and performance evaluation

Objectives

This session explores the key objectives of medicines policies and programs, and considers strategies for measuring the performance of a health care 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
- 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 (key readings in bold)

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.

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

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

World Health Organization. How to measure drug use in health facilities: Selected drug use indicators. EDM Research Series No. 07. Geneva: WHO/DAP, 1993 (http://www.who.int/medicinedocs/en/d/Js2289e/1.html).

Yip W, Hsiao WC. Non-evidence-based policy: How effective is China's new cooperative medical scheme in reducing medical impoverishment? Soc Sci Med. 2009 Jan;68(2):201-9.

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 care delivery systems and insurance programs?

Learning Points

- Improving quality use of medicines requires appropriate action in several areas of a health care system, including regulation (e.g., the National Medicines Policy), quality improvement (e.g., continuous quality improvement processes), market competition (e.g., based on quality of care performance metrics) and incentives (e.g., align pay with increases in quality).
- Quality use of medicines can be improved through incremental introduction of quality improvement interventions, accompanied by regular and relevant assessments. This should be carried out with the participation of key stakeholders (e.g., health care program administrators, insurance program managers, health care personnel, and patients).
- Managing a pharmacy program or insurance medicines benefit 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 can have objectives in many domains: (1) increasing equitable access to medicines, especially for vulnerable populations like the poor, children, elderly, or rural populations; (2) ensuring affordable access to medicines for patients; (3) optimize the health value for the money spent, for the pharmacy program and the overall system; (4) improving quality of prescribing; (5) encouraging patient adherence to prescribed treatment; (6) improving provider and patient satisfaction; and (7) improving health care outcomes.
- Policy 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 are ones calculated from routinely available data, especially data 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.

- The International Network for Rational Use of Drugs and the World Health Organization developed standardized indicators to assess prescribing practices and supervise medicines utilization in health care facilities (see Table 8.1). Assessments in many countries have indicated that often medicines costs are unnecessarily high because of prescribing clinically unnecessary medicines, limited prescribing of generic drugs, and prescribing inappropriately large numbers of medicines per patient. Targeting these issues will not only reduce costs, but increase quality of patient treatment.
- Some important performance measures 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 measures are generally computed from data collected in member, patient, or 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 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 program should review utilization on a regular basis to identify opportunities for improving policies or for mounting interventions to improve prescribing or dispensing. In advanced electronic data systems, real-time messages can be delivered to alert prescribers or dispensers to potential problems associated with a particular medicine for a 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 8.2 provides some examples of commonly used pharmacy performance measures and their operational definitions.

Table 8.1: List of selected medicine use indicators

WHO/INRUD medicine use indicators for primary health care facilities
Prescribing indicators
Average number of medicines prescribed per patient encounter
Percentage of medicines prescribed by generic name
Percentage of encounters with an antibiotic prescribed
Percentage of encounters with an injection prescribed
Percentage of medicines prescribed from an EML or formulary
Patient care indicators
Average consultation time
Average dispensing time
Percentage of medicines actually dispensed
Percentage of medicines adequately labeled
Percentage of patients with knowledge of correct dose
Facility indicators
Availability of EML or formulary to practitioners
Availability of clinical guidelines
Percentage of key medicines available in a facility
Complementary medicine use indicators
Average medicine cost per encounter
Percentage of prescriptions in accordance with clinical guidelines
Disease-specific medicine use indicators
ARI treatment indicators
Percentage of pneumonia cases treated with recommended antibiotics
Percentage of cases of upper respiratory tract infections treated with antibiotics
Percentage of cases of acute respiratory infections treated with cough syrups
Diarrhea treatment indicators
Percentage of cases of diarrhea treated with antibiotics
Percentage of cases of diarrhea treated with antidiarrheals
Percentage of cases of diarrhea treated with oral rehydration therapy
Malaria treatment indicator
Percentage of cases of malaria treated with recommended antimalarials
Additional indicators
Percentage of patients receiving medicines without prescription
Percentage of cases prescribed multivitamins/tonics
Percentage of injections prescribed inappropriately
Percentage of patients prescribed antibiotics inappropriately
Percentage of antibiotics prescribed in too low dose
Percentage of cases of pregnant woman treated with iron and/or folic acid

Table 8.2: 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

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

Hypertension is a major contributor to morbidity, mortality, and increasing health care expenditures. If not properly treated, hypertension leads to strokes, heart attacks, heart failure, or kidney disease. 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 the risk of 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.

Most of the plans of the New Rural Cooperative Medical Scheme (NRCMS) currently reimburse for inpatient care. Given the low socio-economic status of most rural Chinese, the cost of antihypertensive medicines may be unaffordable and many patients may fail to treat their condition or do so inconsistently and may need to be hospitalized with conditions related to untreated hypertension.

Assume that the NRCMS were interested in designing and implementing an outpatient prescription drug benefit for members with hypertension and that efforts were underway by the government to expand the availability of low cost, high quality medicines through community health centers located in underserved areas.

Challenges for such a program could include potential lack of internal capacity to train, implement a program, supervise, and keep accurate records.

In the intended program, NRCMS members discharged from hospitals after treatment for hypertension would be referred to community health centers for hypertension management, in conjunction with community physicians at the centers. At the community outlet, trained staff would fill prescriptions, counsel about adherence, and monitor blood pressure. The NRCMS would contract with health centers to reimburse routine clinical visits and with outlets to reimburse anti-hypertensive medications, counseling, and adherence monitoring. Reimbursements would depend on monitoring performance.

Your working group will be assigned one or more of the policy domains in the following table. Please discuss the following questions in relation to each domain and fill in the table.

1. What are the specific objectives of the proposed outpatient hypertension coverage policy in relation to each policy domain: equity in access, quality use, affordability for patients and systems, satisfaction, health care outcomes?
2. State one or more important questions about possible intended or unintended effects of the policy change for each objective you listed.
3. What data would you need to answer each question and where could NRCMS get the data?
4. What would be a key outcome indicator to measure in order to answer each question?

Session 8: Medicines policy objectives and performance evaluation

Domain	Policy Objectives	Questions about Intended and Unintended Impacts	Data Sources Needed to Answer Questions	Outcome Indicator
Access to treatment				
Quality use of medicines				
Affordability for patients				
Affordability for systems				
Patient satisfaction				
Provider satisfaction				
Health care outcomes				

Session 9: Designing studies to evaluate change in medicines policies

Objectives

The objective of this session is 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 (key readings in bold)

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.

Perera R, Heneghan C, Yudkin P. A graphical method for depicting randomised trials of complex interventions. British Medical Journal 2007; 334:7585 (127-129). (reading for Activity 1)

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

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.

Discussion Questions

1. What is the potential for designing controlled or longitudinal policy evaluation studies in your setting?
2. 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 (patients, 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 for practical, political, logistic, and economic reasons.
- Whenever possible, non-randomized evaluations should include comparisons which 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 policy (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) Identifying and measuring specific outcomes that the policy was intended to change; (2) Measuring both intended and unintended outcomes; (3) Measuring changes in process (how the system behaves) as well as changes in outcomes (what the system achieves); (4) Focusing on carefully defined groups in whom the intervention should have the greatest impact; (5) Considering not only if the objectives of the policy intervention are achieved, 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 policy 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 observed changes would have occurred anyway without the intervention due to previous trends or to external changes.
- Adding a comparison group greatly increases 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 before 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 an outcome 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 in the absence of the intervention 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 visual nature of time series makes them an excellent way to present findings to policy makers.

- Graphical methods can be used to display the exact timing and nature of exposure of different study groups to specific components of a policy change or intervention. Depicting an intervention in this way makes clear: (1) specific differences between study groups; (2) ways to evaluate the success in implementing an intervention as planned and the intensity of exposure of different groups to individual intervention components; and (3) practical aspects of intervention implementation and evaluation.
- 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 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.

Session 9: Designing studies to evaluate change in medicines policies

Activity 1: Designing a policy evaluation in your system

Format: Small (within system) group discussion then large group debriefing (2 hours)

Please refer back to the priority medicines policy problem and the potential policy interventions that you have discussed in earlier in the course. Agree on one policy change or 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. Describe in detail the components of the specific policy intervention you have in mind.
2. Who would be included in the study (i.e. which regions, health care facilities, health care providers, patients), and why?
3. Referring to the reading by Perera et al for this session, create a graphical display of the policy intervention as it applies to each of the proposed study groups.
4. What would be the study design to evaluate the policy change or intervention? What would be strengths and weaknesses of your study design?
5. How would you measure the impacts of the intervention? Which desired and undesirable outcomes would you want to measure? Which indicators would you use? Would you use routine or ad hoc data, or a combination? Which time periods would the data span?

Saturday, March 28

Session 10: 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 health care delivery system and 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 (key readings in bold)

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 delivery 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 care 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 completeness, consistency with expected patterns, and to identify patterns that are likely to be due to other causes other than the policy in question. Table 10.1 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 care 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 or duplicate records; 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 insurance 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 tools that allow analysts to create tabular and graphic displays of data within groups, across sites, and over time 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 11.2 below lists some common patterns of data inconsistencies, possible causes for those, and possible solutions specific to these types of inconsistencies.
- Some data problems can be accounted for during data analysis. For example, seasonal variations in utilization can be identified graphically and adjusted for statistically; unusual patterns of utilization in anticipation of or immediately after a policy change can be accounted for in analysis; values of missing variables can be imputed using standard approaches.

Table 10.1: 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 10.2: Common Data Patterns, 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

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

Session 10: Detecting and solving data problems

Data Pattern	**Possible Causes**	**Possible Solutions** (depending on cause)
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
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)

You are interested in conducting an analysis that examines the types and cost of medicines prescribed for specific diagnoses in 22 hospitals, and how these patterns vary by age, sex, and hospital. The first step is to check the quality and comparability of the data.

Examine each of the following variables in the dataset:

Visit data: sex, age, number of diagnoses, primary diagnosis, number of drugs dispensed

Drug data: money, pay, usage

a. Which fields have data quality problems (e.g., blanks, wild codes, unusual patterns)? Do these data problems vary by hospital? Keep track of the hospitals in which you discover problems and make a decision about how to deal with the problem (e.g., eliminate the hospital from analysis, eliminate certain patients, avoid using certain variables).

b. How would you decide which hospitals and cases to include in the analysis? What would be the final sample size if you included only the hospitals and patients you judge to have adequate data?

c. What percent of medicines are reimbursed by health insurance, completely or in part? Do these percentages differ by hospital? Do you believe these percentages? What could be possible problems with this field?

Data Dictionary for Dispensing Data from Hospitals

Variable name	Variable Description	Located in Visit Data	Located in Drug Data
VISIT_ID	Unique code for each patient visit	×	×
HN	Hospital code	×	×
DATE	Visit date, mmdd	×	×
PCODE	Patient ID number	×	×
DEPT	Department identifier	×	×
SEX	Gender, 1=male, 2=female	×	×
ICD-9	First three digits of the ICD code	×	×
CONDITION	Description of the ICD9 code	×	×
PLACE	Prescription site, C=outpatient clinic	×	×
FCODE	Therapeutic category code		×
CODE	Individual drug code		×
CONTENT	Product strength		×
MONEY	Money charged		×
QU	Quantity dispensed		×
PAY	Source of drug payment, 0=entirely reimbursed by insurance, 1=patient out of pocket, 7=partly reimbursed		×
USAGE	Dosing frequency, 1=qd, 2=bid, 3=tid,….		×
DOSAGE	Dosage each time (number)		×
ROUTE	Administration route		×

Variable name	Variable Description	Located in Visit Data	Located in Drug Data
AGE	Patient age	×	×
NUM_DIAG	Number of diagnoses	×	
DIAG_1	First diagnosis that appears for each patient	×	
DIAG_2	Second diagnosis that appears, if any	×	
DIAG	Diagnosis code		×
VISIT_MONEY	Total cost of prescription	× (subset data)	
NUM_DRUG	Number of drugs used per patient	×	

Session 11: Using data from different systems

Objectives

The objectives of this session are to (a) describe some of the practical aspects and problems of assembling data from different sources within a health care delivery or insurance system for use in pharmaceutical policy analysis; and (b) highlight the need for standardized coding of medicines, diagnosis, and procedure data. Standardized codes are required to organize the data conveniently for defining problems, evaluating the impacts of interventions, and for routine monitoring. We will show examples of how to organize medicines into chemical groups and therapeutic categories, and how to classify diagnoses and symptoms into meaningful health problem groups. We will also discuss strategies to sample data when data need to be abstracted from paper records or a subset selected from large electronic administrative databases.

Outline

- Brief description of data sources, data collection processes, and resulting data structures
- Challenges in assembling, cleaning, analyzing, and interpreting data
- Sampling data from health care systems
- Rationale and requirements for coding systems of medicines, diagnoses, and procedures
- Description of commonly used coding schemes
- Linking text information to standardized codes

Readings (key readings in bold)

Chapter 46. Computers in drug management. In: Quick JD, ed. Managing drug supply: The selection, procurement, distribution, and use of pharmaceuticals. West Hartford, CT: Kumarian Press, 1997; 728-746.

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

INRUD and WHO Action Programme on Essential Drugs. How to investigate drug use in health facilities: selected drug use indicators. (DAP Research Series N°7. WHO/DAP/93.1) World Health Organization; Geneva: 1993. Chapter 3: Study design and sample size, pp.25-31.

Tamblyn R, Lavoie G, Petrella L, Monette J. The use of prescription claims databases in pharmacoepidemiological research: The accuracy and comprehensiveness of the prescription claims database in Quebec. Journal of Clinical Epidemiology 1995; 48 (8): 999-1009.

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

Discussion Questions

1. What are key issues in assembling data from various data sources in your systems?
2. What are the implications of missing data (e.g., diagnosis, individual medicine cost, amount dispensed) and lack of precise codes for diagnoses, medicines, and procedures?

3. What recommendations about data recording and quality checking would you make for health care delivery systems and insurance programs for using data for policy evaluation?
4. Which coding systems are commonly used to classify medicines, diseases, and procedures? Which systems are currently used in the systems of course participants?
5. How would you identify cases of diabetes if you had only medicines data; only diagnosis data; and medicines, diagnosis, and procedure data?

Learning Points

- Health insurance systems collect data for business purposes. Until insurance systems are concerned about efficient use of resources, the data collected will often focus primarily on the reimbursed costs of services.
- Health care delivery organizations collect data for patient care management. Different data are important for different departments. Pharmacy department data may focus on medicines information and may not include diagnostic information. Medical department data may include diagnoses but not whether a brand or generic product was dispensed.
- The most useful data for understanding utilization patterns are at the patient level (i.e., medicines used by a patient at a particular time for a specific condition). It is only possible to assess the appropriateness of prescribing and the efficiency of pharmacy costs using such detailed patient-specific data.
- Routine data systems in pharmacy programs or insurance organizations may not have patient-specific data on patient-specific medicines and diagnoses readily available at the central or regional level. Frequently, only aggregate data are available at these levels summarizing the amounts reimbursed for medicines and other services during a given period. Even if patient-specific data are reported as part of the reimbursement process, they may not be computerized. Or, in large systems, computerized data bases may contain more records than needed for analysis.
- When records are not computerized, small sample research methods can be used to gather targeted samples of patient-level data from reimbursement claims or from records at health facilities. Careful thought needs to be given to the specific purposes of a study to minimize the amount of data to be collected and computerized.
- Sampling is a process by which we study a smaller part of a population to make judgments about that population. To get a representative sample we need to ensure that all facilities or patients can be included in the study. We sample by selecting a number of study units from a defined study population. A study unit may be a person, a health facility, a prescription, or another such unit. The study population, sometimes called the reference population, is the collection of all possible study units. This population may be people, health facilities, prescriptions or other such units. A representative sample has all the important characteristics of the population from which it is drawn. A sampling frame is a list of all of the available units in the study population. If a complete listing is available, the sampling frame is identical to the study population.
- There are two broad types of sampling methods: Non-probability sampling and probability sampling. The type of sampling depends whether a sampling frame is available. If a sampling frame exists, or if it can be created, probability sampling is used. If there is no sampling frame available, probability sampling cannot be used. A sample drawn using non-probability methods is likely to be less representative than a probability sample.

- There are two common methods of non-probability sampling: Convenience sampling and quota sampling. Convenience sampling is a method by which, for convenience sake, the study units that happen to be available at the time of data collection are selected in the sample. This is the least representative sampling method. Quota sampling is a method by which different categories of sample units are included to ensure that the sample contains units from these categories. For example, a quota sample of patients from a health center might include 10 patients with diabetes, 10 with cardiovascular disease, and 10 with stroke.
- When measuring prescribing and dispensing times or in assessing patient understanding, a convenience sample of patients may be the only practical method. A quota sample may be used for males and females to ensure that both genders are observed or interviewed. This may be important since men are often treated with more respect and have higher literacy rates. Also, men may be given priority over women or children and receive more thorough care.
- If a sampling frame (a list of the population units) exists then probability sampling may be used: We select each sample unit randomly through one of the following methods: Simple random sampling; systematic sampling; stratified sampling; cluster sampling; multistage sampling.
- The appropriate sample size depends on expected variation of the data (the more variation the larger the sample required); the expected rate of the variable (a smaller sample will be required to obtain the same degree of accuracy if the rate of antibiotic prescribing further away from 50% than if it is closer to 50% (i.e., a smaller sample for a expected rates of 20% and 80% than for a rate of 50%); and the degree of accuracy required (more certainty with a larger the sample. This certainty is measured in terms of a 95% confidence interval.)
- 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.
- A list of the data elements commonly included in medicines coding systems appears in Table 46.1 in the reading for this session from Managing Drug Supply, copied below.
- 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.
- Many health facilities develop their own "home-grown" codes or conventions to handle specific problem situations, such as dispensing of medicines not included on the formulary (and therefore without a defined code) or medicines not yet included in drop-down lists in prescribing software. These conventions must be accounted for when combining data from multiple facilities.

Table 11.1: Standard Information in a Master Drug Data File (from Quick JD, ed. Managing drug supply: The selection, procurement, distribution, and use of pharmaceuticals. West Hartford, CT: Kumarian Press, 1997; 728-746.)

Description	Example	Explanation
Product code	AMP250C	Each entry in the drug data file must have a unique code. (See reference for discussion of coding options.)
Generic name	Ampicillin	The official international nonproprietary name (INN) is generally preferred. The WHO *Model List of Essential Drugs*, which is regularly updated, uses the INN.
Strength	250 mg	The International System of Units (SI), with related SI abbreviations, should be used. "Strength" can be split into "strength number" (250, for example) and "strength unit" (such as mg), but this often creates unnecessary confusion and coding difficulties.
Route of administration	PO	Standard abbreviations should be used. For example, PO = per os (oral), IV = intravenous, TOP = topical.
Dosage form	CAP	Standard abbreviations should be used. For example, CAP = capsule, TAB = tablet.
Issue unit	CAP	The smallest unit by which a drug can be conveniently distributed. (See reference for further explanation.)
Defined daily dosage (DDD)	4	The usual total daily therapeutic dosage for an adult. In computer systems, this is best defined in terms of issue unit per DDD.
DDD unit	gm	The unit in which the DDD is measured.
National essential drugs list (EDL)/formulary status	Y	Is the drug listed in the national EDL or formulary? Y = yes, N = no.
Therapeutic class	44:29	It is useful to categorize drugs by therapeutic or pharmacologic class. Several systems exist, including the ATC, BNF, AFHS, and PAHO systems, and that used for the WHO *Model List of Essential Drugs*. (See Chapter 30 in reference for further discussion of therapeutic category systems.)
Prescription status	POM	Status for retail sales. For example, POM = prescription-only medicine, OTC = over-the-counter.
Level of care	A	National EDLs may categorize drugs according to level of care. For example, A= all levels, B = all levels except dispensary, and so forth.
ABC classification	A	Classification of a drug as A, B, or C according to the volume consumed and unit cost. (See Chapter 41 in reference for discussion of ABC analysis.)
VEN classification	V	Classification of a drug as V, E, or N, according to its therapeutic value as vital, essential, or nonessential. (See Chapter 41 in reference for discussion of the VEN system.)
WHO status	M	Is the drug on the WHO *Model List of Essential Drugs?* This can be listed as Y (yes) or N (no). It can also be listed as M (main), C (complementary), E (therapeutically equivalent), or N (not on the list).

Activity 1: Diagnosis, therapeutic class, and medicines identifiers in policy analysis

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

Using the visit data subset provided to you (a subset of the data set you used in Session 10), please focus first on the outpatient visit file. The file contains the subset of visits with more complete and reliable data. Please conduct analyses to answer the following questions:

1. Are the cost of medicines dispensed for a visit similar in all hospitals? Are there any outliers? What could explain the patterns observed?

2. Do hospitals see the same diagnostic mix of patients? Could variations in diagnostic mix explain some variations in cost? How would you deal with that in analyses of visit cost?

Create diagnosis groups for the most common diagnoses. These include acute respiratory illness (ICD 460-466), cancer (ICD 140-238), eye infections (ICD 372-373), diabetes (ICD 250), hypertension (ICD 401), and other heart disease (ICD 411-429).

3. What are the average and total costs of drugs dispensed for the most common diagnosis groups? Do these costs differ by diagnosis group?

4. Overall, does the average cost of medicines per visit vary by age and sex? Does average cost of medicines vary by age and sex within the six main diagnosis groups?

Now focus on the file containing prescription of individual medicines.

5. Which are the most common therapeutic groups of medicines prescribed (FCODE)? What percentage of prescribing is accounted for by each therapeutic group?

6. Which are the most common therapeutic groups of medicinies prescribed for diabetes? Does the percentage of prescribing of different therapeutic groups vary by hospital? Does the percentage of prescribing of different therapeutic groups vary by hospital for acute respiratory infections (ARI)?

7. Does the choice of products within therapeutic group I052 for patients with ARI vary by hospital? What could explain these patterns?

8. Does the choice of products within therapeutic group I052 for patients with ARI vary by age and sex? What could explain these patterns?

If you have time, explore patterns of prescribing by hospital or age/sex for other diagnosis and therapeutic groups.

Data Dictionary for Dispensing Data from Hospitals

Variable name	Variable Description	Located in Visit Data	Located in Drug Data
VISIT_ID	Unique code for each patient visit	×	×
HN	Hospital code	×	×
DATE	Visit date, mmdd	×	×
PCODE	Patient ID number	×	×
DEPT	Department identifier	×	×
SEX	Gender, 1=male, 2=female	×	×
ICD-9	First three digits of the ICD code	×	×
CONDITION	Description of the ICD9 code	×	×
PLACE	Prescription site, C=outpatient clinic	×	×
FCODE	Therapeutic category code		×
CODE	Individual drug code		×
CONTENT	Product strength		×
MONEY	Money charged		×
QU	Quantity dispensed		×
PAY	Source of drug payment, 0=entirely reimbursed by insurance, 1=patient out of pocket, 7=partly reimbursed		×
USAGE	Dosing frequency, 1=qd, 2=bid, 3=tid,….		×
DOSAGE	Dosage each time (number)		×
ROUTE	Administration route		×

Variable name	Variable Description	Located in Visit Data	Located in Drug Data
AGE	Patient age	×	×
NUM_DIAG	Number of diagnoses	×	
DIAG_1	First diagnosis that appears for each patient	×	
DIAG_2	Second diagnosis that appears, if any	×	
DIAG	Diagnosis code		×
VISIT_MONEY	Total cost of prescription	× (subset data)	
NUM_DRUG	Number of drugs used per patient	×	

Monday, March 30

Session 12: 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 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 (key readings in bold)

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

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

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

Soumerai SB, Ross-Degnan D, Gortmaker S, Avorn J. Withdrawing payment for nonscientific drug therapy. JAMA 1990; 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. Arch Intern Med 2001; 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?

Session 12: Analyzing data and disseminating policy findings

Learning Points

- Visual displays of policy effects are important for policy makers and can easily be created using aggregated data in Excel pivot charts. These graphs display the data in ways that are easy to interpret.
- 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.
- Statistical analysis of policy evaluation data is needed to assess the role of chance in creating the observed effects. Segmented regression analysis with control for auto-correlated errors is a powerful statistical method to analyze interrupted time series data.
- 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 analysis 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 hospital 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 subclass over time to examine the policy impacts
2. Visually inspect the data for consistency and identify possible data inconsistencies
3. Suggest possible interpretations of the graphical results
4. Consider limitations of the data that may impact interpretation of results
5. Identify 3-4 key policy recommendations
6. Prepare one figure or table that communicates the most important results
7. Be prepared to present the graphic summary and policy recommendations

Data Dictionary for Siriraj Hospital Generics Dispensing Data

Variable Name	Variable Description and Data Summaries
pharm_code	Drug code Number of observations, n=30,000 Number missing, n=0
subclass	Subclass of generic/brand availability Number of observations, n=30,000 Number missing, n=0 Subclass 1, brand products with generic substitutes, n= 5115 Subclass 2, generic products with brand substitute, n= 12909 Subclass 3, brand-only products, n= 5870 Subclass 4, generic-only products, n= 6106
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
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 13: Routine monitoring

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 care services utilization in health care delivery 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

Brown JS, Kulldorff M, Petronis KR, et al. Early adverse drug event signal detection within population-based health networks using sequential methods: key methodologic considerations. Pharmacoepidemiol Drug Saf 2009 Jan 15;18(3):226-234.

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 13.1: 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/

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, 220.

Figure 13.2: 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 13.3: 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 13.1: 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

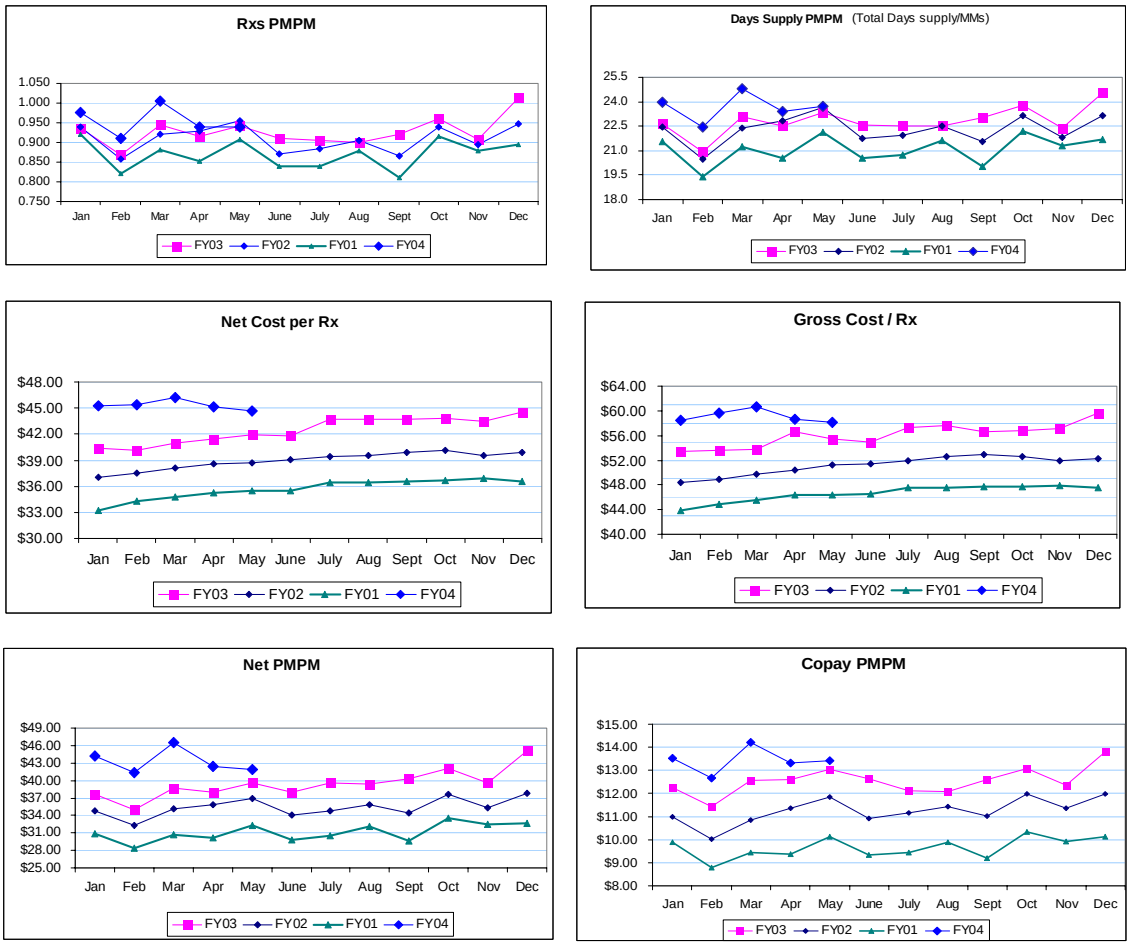
[2] Percentage of formulary medicines prescribed to total number of formulary and non-formulary medicines

[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

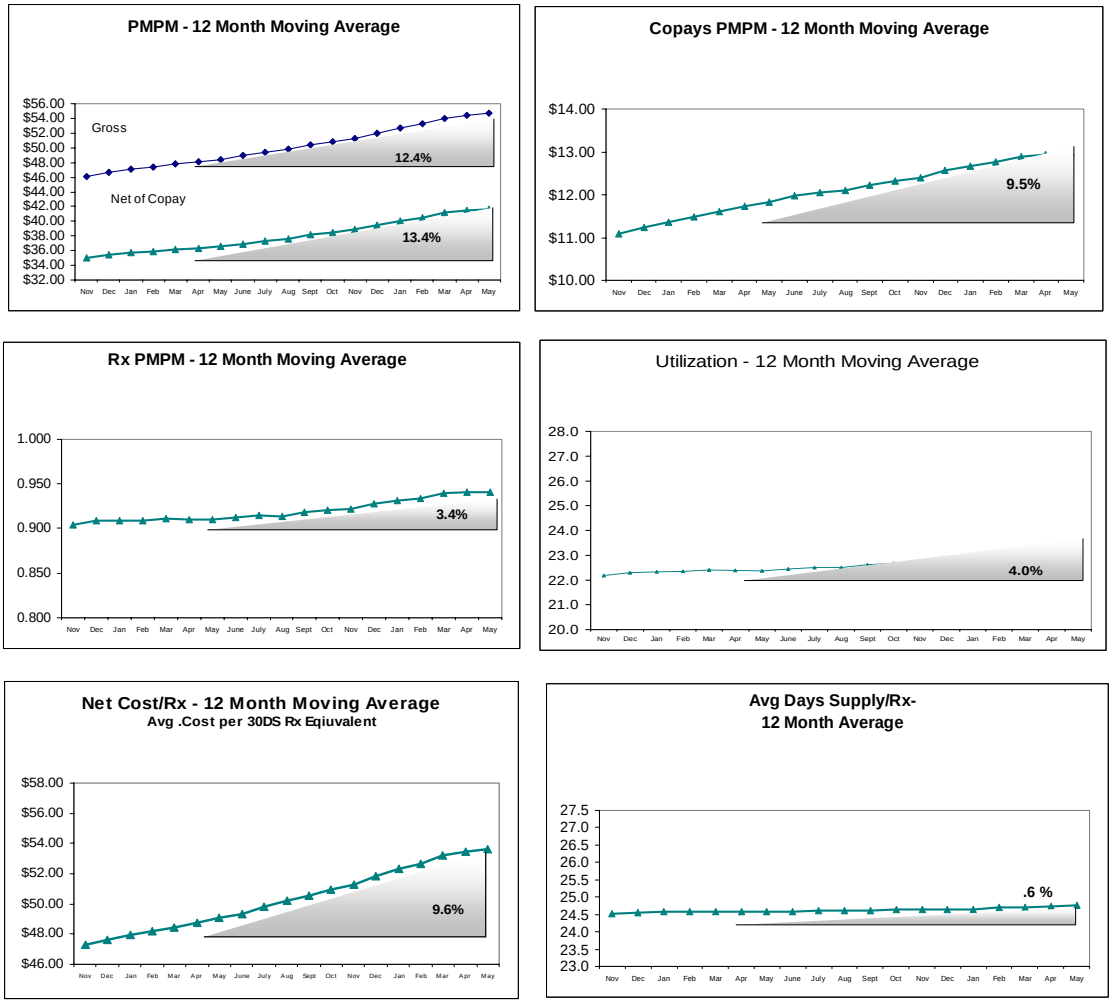
[5] Percentage of preferred HMGA Co A (atorvastatin) prescribed to all HMGA Co A medicines

Figure 13.4: Sample graphs tracking basic monthly utilization and cost monitoring indicators of pharmacy program performance



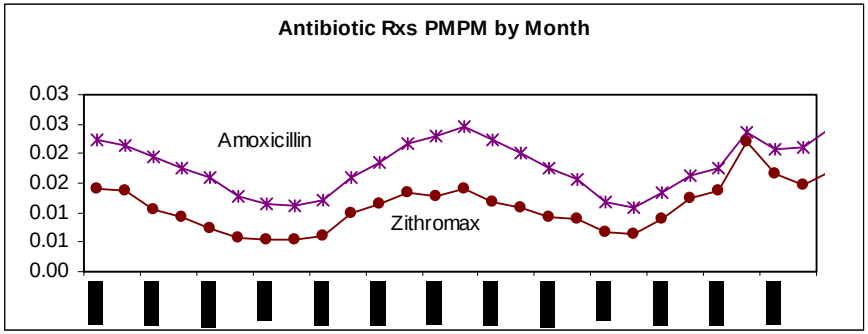
Source: Pharmacy management templates developed by Harvard Pilgrim Health Care. All rights reserved.

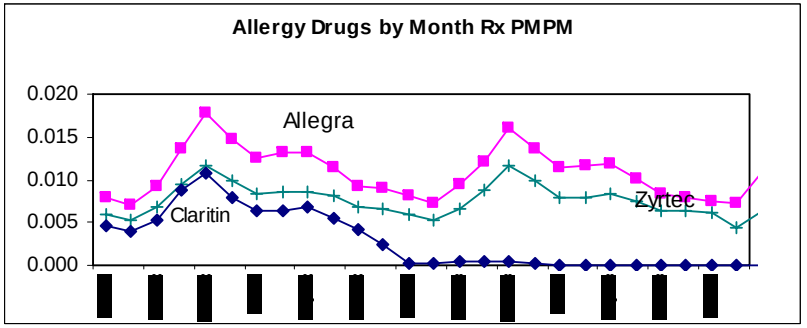
Figure 13.5: Sample graphs tracking 12-month moving averages and annual changes in basic utilization and cost monitoring indicators of pharmacy program performance

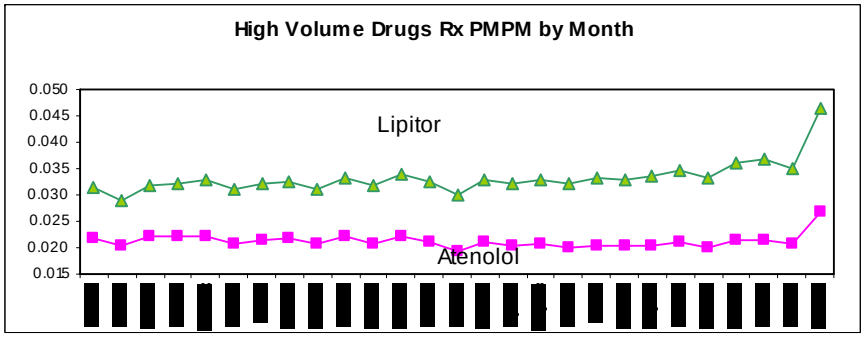


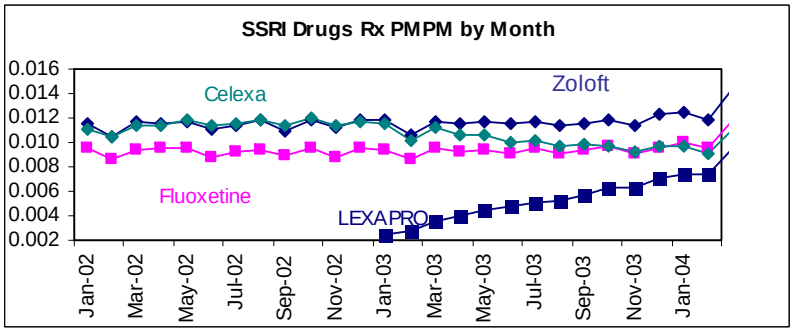
Source: Pharmacy management templates developed by Harvard Pilgrim Health Care. All rights reserved.

Figure 13.6: Sample graphs tracking volume prescribed per member per month for high cost or high utilization medicines









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

Table 13.2: 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%

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

Activity 1: Designing routine medicines policy monitoring in your system

Format: Small (within system) group discussion then large group debriefing (2 hours)

Assume that the P&T Committee in your hospital or insurance system has decided to implement guidelines for treatment of hypertension following the Seventh Report of the Joint National Committee of Prevention, Evaluation, and Treatment of High Blood Pressure (JNC 7, http://www.nhlbi.nih.gov/guidelines/hypertension/). The JNC 7 treatment algorithm is depicted in Figure 1 below.

You have been asked by the head of the pharmacy program to monitor the effectiveness of the policy roll-out and to report on the clinical and economic impacts of the policy change.

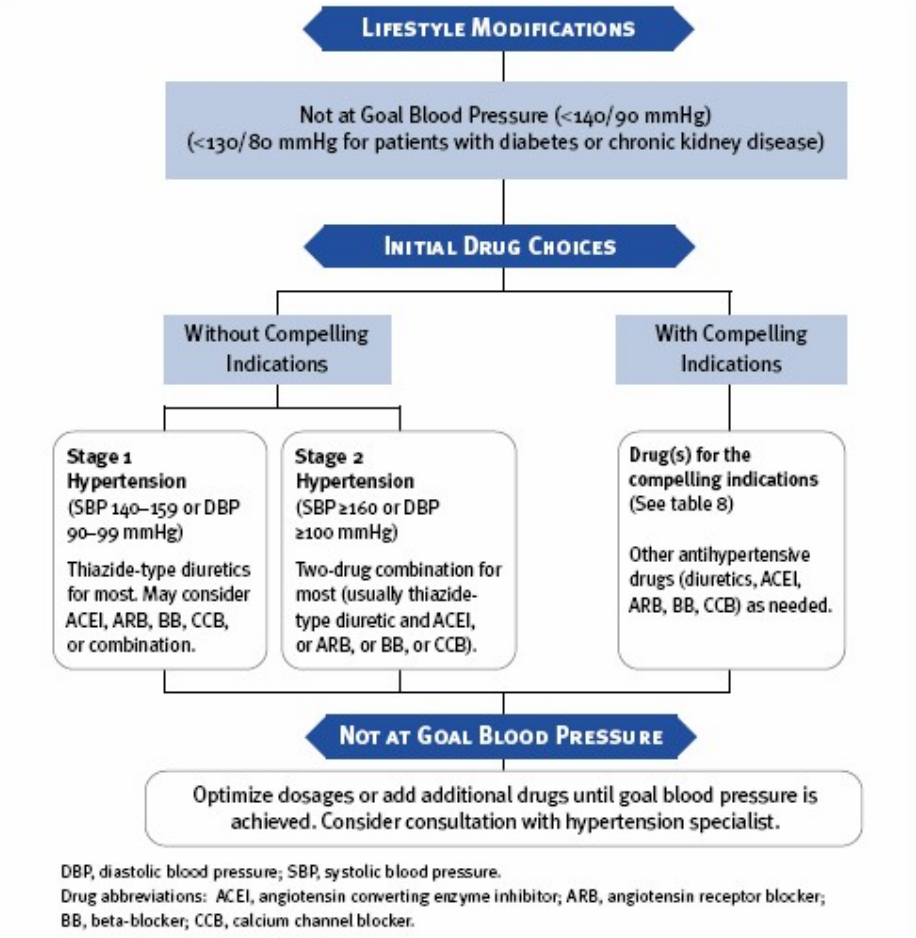
Keeping in mind the limitations of data within your system, design one or more performance monitoring reports that you think would be able to communicate key aspects of the policy change. You may wish to refer to some of the layouts and indicators in the sample reports above to generate ideas about design for your monitoring system.

Please address the following questions:

1. What information would you want to know on a regular basis about the performance of your policy, and why? How frequently would you produce these regular reports?
2. Which reports would you generate? From where would you obtain the data needed to produce the report? How would you collect the data?
3. In order to fully understand the impacts of the policy, you feel that more in-depth studies will be needed every year. Which information would you include in these annual studies that is not in your regular monitoring reports, and why? How would you obtain the necessary data for the annual studies?

4.

Figure 1. Algorithm for treatment of hypertension



DBP, diastolic blood pressure; SBP, systolic blood pressure.
Drug abbreviations: ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; BB, beta-blocker; CCB, calcium channel blocker.

Tuesday, March 31

Session 14: Implementing policy change - potential next steps among participating organizations

Objectives

The first objective of this session is to discuss how to implement medicines policy changes in a health care delivery system or insurance program. We will focus on understanding which stakeholders need to be involved, how to elicit their perspectives, and how to engage them in the process. The second objective is for participants to discuss options for potential collaboration around important medicines policy topics within and across their institutions, system needs for implementing a policy change, and mechanisms for communicating policy changes effectively to all stakeholders.

Outline

- Political, social, and systems requirements for successful policy change
- Discussion of systematic analysis of policy content, positions and power of major stakeholders, opportunities and obstacles to policy change, and strategies for change
- Identifying options for collaborations on medicines policy issues within and across participating institutions

Readings (key readings in bold)

Bengzon AR. Chapter 4. The national drug policy. In: Bengzon RA. Programs, process, politics, people: The story of the DOH under the Aquino administration: 1986-1992. <Publisher, year>;138-182.

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.

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

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 key stakeholders with respect to medicines issues in your country as a whole, as well as in your health care delivery system or insurance program?
2. What concerns would your stakeholders have about changes in the specific medicines policy you have been considering in this course?
3. What systems are in place for communicating effectively with stakeholders about policy changes in your setting?
4. How could course participants collaborate on policy changes and evaluation?

Session 14: Implementing policy change - potential next steps among participating organizations

Learning Points

- Pharmaceutical policy change is not only a technical process, but a political process as well. 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 a range of domestic and international actors in various degrees of collaboration, competition, and conflict. Pharmaceutical policy changes often elicit debate about the roles of the market and the state, transparency and accountability, efficiency, and equity.
- Political analysis can facilitate the design of effective 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 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? (7) What strategies are available for achieving positive change?
- Passing legislation and issuing regulations are not always sufficient to create meaningful changes in practice. Potential barriers to change include such things as inequitable representation of stakeholders in official policy making committees; political agendas taking precedence over technical issues; and interest groups bypassing official policy making processes to promote specific policies.
- Strategies to overcome opposition to a desired policy change include: (1) convincing key stakeholders that the policy is of interest and benefit to them; (2) presenting the proposed policy change to key players in their own language and relating it to their values and goals; (3) finding ways to group together proponents who would not have sufficient power to influence the policy decision by themselves; (4) developing and articulating a shared vision to coordinate interested stakeholders; and (5) seeking to divide and differentiate stakeholders who hold opposing opinions.
- Health care providers can strongly induce demand for care and increase costs in the health care system. Including health care providers as part of a health insurance program's management creates a unique structure that gives providers an incentive to control health care utilization and costs. Creating alliances that align the interests of physicians interested in patient welfare and technical quality of care with the interests of insurance organizations that finance health care may be a successful strategy for national health insurance programs.

Session 14: Implementing policy change - potential next steps among participating organizations

Activity 1: Ideas for collaboration on medicines policy issues

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

Since the beginning of the course, we have assembled a list of specific topics of interest to several of the organizations represented. These topics may include the following:

- How to establish standard guidelines to establish a formulary in tertiary care hospitals in China?
- How to adapt guidelines for pharmacoeconomic decision making to the context in China?

We will assign the specific topics of interest to one or more groups. In your group, please brainstorm ideas on how you would establish collaborations across institutions to achieve a common goals.

Please consider the following questions for discussion:

1. What is the key issue that you would like to address collaboratively?
2. What is the desired outcome or product of your collaboration?
3. Who are your stakeholders? How will you convince them of the need for collaboration?
4. What kind of support and resources will you need?
5. What is the proposed time line to achieve the goal of the collaboration?

Session 15: Review of course

Objective

The objective of this session is for participants and facilitators to summarize key learning points of the course and next steps for continued collaboration on medicine policy questions. Next steps may include collaborating on developing tools, guidelines, and protocols for decision making; and implementing and evaluating the policy intervention projects described in the previous session.

Participants will also complete a formal evaluation of the course.

Outline

- Summary of key learning points
- Summary of potential next steps for within and across system collaboration
- Summary of which aspects of the course worked well and which could be improved

Readings (key readings in bold)

None

Discussion Questions

1. What are the main points that the course has highlighted for you?
2. How will what was discussed in the course influence your work after the course?
3. What changes should course organizers make to the course?

Learning Points

- Medicines policy is multi-factorial and takes time. A key prerequisite is generating evidence for change by informing policy decision makers about current patterns of equity in medicines access, affordability, utilization, costs, and satisfaction with pharmaceutical care.
- During the MedIC course, participants discussed key medicines policy issues, policy tools that systems can use to improve the medicines situation, and the need for, and ways to use system data to generate evidence for medicines policy decision making.
- A step-wise, collaborative policy evaluation process using system data is one way to generate information for policy decision making within and across systems.

Session 16: Team project presentations

Objective

The objective of this session is for participants to present the projects developed during the course on a priority medicines issue facing their health care delivery or insurance system, and to receive constructive input from other participants, facilitators, and senior policy makers.

Please use the framework outlined below and the slide template provided for the presentation of your group project.

Framework for Presentations on Key Medicines Policy Issues

Domain	Questions to Consider
Problem	What is the key medicines policy issue you have decided to address?
Causes	What are possible causes for the medicines 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 project (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?