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The signs are all around us, spring is almost here! I always look forward to the first sign of spring around my house, which typically begins with the blooming of a 30-foot flowering pear tree in our front yard. The beautiful array of white blossoms is the first indicator that we have turned the corner into one of my favorite seasons. My children refer to it as the ‘popcorn tree’ because of the unique cluster of white blooms that adorn each branch.

Spring is also a time to look forward to the annual rituals that affect our profession, namely the beginning of the legislative session in Sacramento. Unfortunately, this year, spring has roared into the Sacramento political landscape like a lion and brought a series of stormy events that could have a detrimental impact on pharmacists’ patients and practices alike.

Specifically, Governor Brown proposed a state budget that includes significant cuts to patient prescription benefits, as well as a 10% reduction in pharmacist provider reimbursements. Additionally, the Department of Health Care Services introduced a budget trailer bill that would change the fundamental reimbursement model from Average Wholesale Price (AWP) to Actual Acquisition Cost (AAC), much like we witnessed in Alabama, only without any promise of an increase in the dispensing fee for a pharmacist’s services. Together, the cumulative effects of these two proposals could result in a very real economic disaster for pharmacists in that each prescription they fill would be at a loss to their practice. It would not take long for pharmacists’ practices to become financially unviable, or worse, they would be forced into the ethically difficult dilemma of having to stop accepting Medi-Cal insurance benefits. Both options would leave California’s poorest, most underserved patients with few or no options for getting their prescriptions filled.

CPhA has been proactive in working with allied pharmacy organizations and other health care provider groups to bring these important issues to light. Just as important, CPhA is proactively developing alternative cost-saving strategies and proposing them to the state for saving money in areas that will have less impact on patients and the profession.

This edition of California Pharmacist is dedicated to a look at CPhA’s legislative program as well as the important aspects of pharmacoeconomics from a clinical and practice setting. Clearly with all the changes being proposed at the Capitol for pharmacy reimbursement, both these subjects are important considerations for practitioners going forward.

Best Regards,

Jon R. Roth, CAE
Executive Editor
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Looking Forward to the Opportunity to Serve as President of CPhA

A Message from Kenny Scott

As I begin my Presidency, I'm looking forward to a very exciting year for CPhA as we move into a new era of leadership under Jon Roth, our new CEO, and as we prepare ourselves to take advantage of the opportunities offered to pharmacists under the Accountable Care Act (ACA).

The time is now for us to organize ourselves as “One Profession, One Voice” and to ensure that we are at the table to influence new laws and regulations that will govern our profession and determine how we practice pharmacy.

The health care landscape is changing and the window of opportunity for pharmacists has opened as policymakers discuss how the various services will be delivered under the new ACA. We have an opportunity to expand our scope of practice as we work with policymakers to define our role with the implementation of Medication Therapy Management (MTM), Community Based Care Transition Programs, Accountable Care Organizations (ACO), Independence at Home and the Medical Home. As we strive to be a catalyst to facilitate a paradigm shift in the practice of pharmacy and blaze new trails for the profession under the ACA, we must not lose sight of the primary responsibilities we have to the Association and the goals given to us by our membership.

CPhA must take the lead as the pharmacy organization that prides itself as being the voice of the profession in the State of California. We must serve as a convener to bring pharmacists together from all practice settings and members from other professional organizations/associations that historically may have had opposing views. We must convene the groups with the purpose of finding the common ground that defines the role of the pharmacist under the Accountable Care Act with the focus on the patient—not based on our own personal and/or association interests. We must work together, collectively and in partnership, to become a powerful force in defining the future role of pharmacists in the State of California and across the country.

As we strive to be a catalyst to facilitate a paradigm shift in the practice of pharmacy and blaze new trails for the profession under the ACA, we must not lose sight of the primary responsibilities we have to the Association and the goals given to us by our membership.

The foundation has been laid by those before me to ensure that I have a successful and prosperous presidency. We have a new, highly qualified CEO to lead the daily operations of our organization; we have reaffirmed our vision and mission statements and have developed a new strategic plan. My vision for the Association is your vision, and as President I will hold myself accountable for operationalizing CPhA’s strategy: to represent the interests and desires of the membership, to hold the organization accountable to achieve its strategic goals and operational objectives; to enhance the value of the organization and to advocate and promote the profession.

The areas of focus for CPhA in 2011 are as follows:
• Support the transition of the new CEO
• Operationalize the strategic plan
  ° Execute the goals and objectives from Synergy 2010
  ° Promote ownership and engagement of the strategic plan through the use of dashboards and progress reports of local associations, academies, committees and the Board of Trustees
• Define the role of the pharmacists in the Affordable Care Act by
  ° Holding a leadership summit
  ° Convening pharmacy associations and opposing organizations
• Identify opportunities to promote and demonstrate the value of pharmacists through:
  ° Demonstration projects for medical home, ACO and/or community-based care transition teams
• Revitalize, enhance and support local associations
• Promote volunteerism
• Leverage the knowledge and experience of past presidents and key leaders across the state by establishing a “Past Presidents Council”
• Promote and enhance grassroots advocacy and government relations
• Identify opportunities for revenue
• Support the pharmacy reimbursement lawsuit
• Create a framework to ensure continuity of CPhA’s strategic plan from year to year.
Governor Brown Makes the Budget His Top Priority

CPhA on Top of All Pharmacy-Related Legislation

by Jon R. Roth, CAE

The first of a two-year legislative session began with a flurry of activity, beginning with the inauguration of Governor Jerry Brown’s third term in office, the arrival of freshman lawmakers into Sacramento, and the state facing a seemingly never-ending $26.5 billion deficit.

Governor Brown immediately went to work making the budget his top priority, with everything else taking a distant lower priority. Governor Brown is receiving strong accolades for his attempt to honestly deal with the budget deficit. No matter your political position, insiders who have been in budget discussions with the Governor report that he is serious about resolving the budget issue.

As of this writing, the Assembly and Senate Budget Committees reached relatively quick consensus on budget terms. However, the political wrangling between Democrats and Republicans threatened to derail Governor Brown’s proposal for placing a tax increase extension on the June special election ballot. The tax extension is the Governor’s revenue proposal to counter having to make additional dramatic cuts to programs and services, beyond the $12.5 billion in cuts contained in his proposed budget.

Medi-Cal Billing
As it relates to pharmacists and Medi-Cal prescriptions, the Department of Health Care Services (DHCS) introduced a budget trailer bill which eliminates the AWP reimbursement schematic and replaces it with Actual Acquisition Cost (AAC). While CPhA understands the need to find a replacement for the soon-to-expire AWP cost formula, we are concerned about a number of provisions contained in the DHCS trailer bill and are working diligently to mitigate those factors that are harmful to pharmacists and their patients.

2011 Bills
Although the budget is looming over California and casting a menacing shadow on the psyche of lawmakers, hundreds of legislative bills covering a gamut of issues were introduced in time for the mid-February bill introduction deadline.

Early in the process it appeared that few issues related to pharmacists and pharmacy practice would be raised this legislative year. However, once all the dust settled in the final days of the bill introduction cycle, we found ourselves facing 45 legislative bills that were flagged to potentially impact pharmacists and pharmacy practice. While this is an extremely large number of bills for CPhA’s Legislative Committee to review, analyze and get working on, the positive news is that roughly a third of the bills introduced were “spot bills,” or placeholders, where the legislator simply indicated intent to introduce a bill related to the subject matter. History tells us that a number of these will be pulled and used for other, non-pharmacy, issues. Nonetheless, we are mindful to monitor all of these bills because a number of them may have a direct impact on pharmacy once the author populates the bill with its substantive language.

Third-Party Audits
In addition to monitoring, taking a position, and advocating for, or against, the multitude of legislative bills introduced by others, CPhA is also looking to proactively move forward on an issue related to pharmacy third-party payer audits that is extremely important to the profession. CPhA is convening stakeholder discussions to understand current audit practices to determine the best possible method for providing relief to pharmacists facing third-party audits.

How to Track Legislative Issues
The CPhA website contains all of the substantive legislative bills related to pharmacists or pharmacy practice that CPhA has engaged in thus far in the legislative cycle. It is important to note that bill language changes frequently based on input from CPhA, committee hearings and interests from other parties. CPhA members should refer to www.cpha.com and click the ‘Government Affairs’ tab, which provides a link to the “Bill Tracker” where all of the legislative bills can be found.

Fortunately, CPhA is the voice for pharmacists in Sacramento in dealing with the Legislature and has an important role in monitoring, advocating for or against, and attempting to promote or quash all of the legislative bills in favor of your patients, your practice, and your profession. We invite members to take an active role in their profession by reviewing the legislative bills that have an impact on your practice, and then contacting your legislator to communicate your perspective.
CPhA hosted over 1,200 participants at its annual conference and policy-setting meeting in Palm Springs, February 10-13, 2011. As the premiere meeting of pharmacists on the west coast, Outlook once again served as an important forum for pharmacists to learn and network with one another. Members traveled from all over the State to attend outstanding keynote presentations and continuing education programs; participate in the House of Delegates; and to network and enjoy fellowship with colleagues at the special programs and receptions. Another big draw for attendees was the Outlook Exhibit Hall, which gathered more than 100 vendors from all over the country to share the latest products and services for the pharmacy profession and to connect with their customers.

**CPhA Awards**

One of the highlights of Outlook is the Annual Awards ceremony that illuminates the outstanding accomplishments of CPhA’s members. Each year, CPhA members nominate colleagues who have made significant contributions to the profession of pharmacy and have helped to advance the practice in a meaningful or innovative manner. This year’s winners include:

- Pharmacist of the Year – John Cronin, PharmD, JD
- Bowl of Hygeia – Pete Vanderveen, PhD
- Innovative Pharmacist of the Year – Karl Hess, PharmD, FCPhA
- New Practitioner of the Year – Ken Thai, PharmD
- Student Pharmacist of the Year – Hilary Campbell, 2011 PharmD Candidate, UCSF School of Pharmacy
- Technician of the Year – Shawn Deck

Photos of all winners accepting their awards during the Awards Ceremony may be seen on the following page. In addition to the member-nominated CPhA awards mentioned above, a few CPhA members were recognized for their achievements and lifelong service including: Karl Hess – CPhA Fellow; George Pennebaker – CPhA Life Member; Chris Woo – CPhA #1 Club and Lisa Kroon, PharmD and Caroline Lindsay, UCSF Student Pharmacist – Academy of Pharmacy Educators 2011 Best Practice Award.

If you are interested in nominating a colleague for next year’s Outlook awards, please visit the “Awards” page of the CPhA website, located under the “Membership” tab, to learn more about the criteria for each award and to download a submission form.

**House of Delegates**

The annual House of Delegates session included a review of existing policies as well as an array of new policies for consideration. Thanks to the efforts of the CPhA Policy Committees, the business of updating and amending the five-year-old policies was relatively smooth and their recommendations generated consensus amongst the delegates. It was the items of new business that produced the greatest amount of discussion. For more details on final policy decisions, see the House of Delegates final report in this issue of the Journal.

CPhA extends a heartfelt thanks to its conference sponsors, exhibitors, speakers, and volunteers who participated in making Outlook 2011 a tremendous success. A special note of thanks is due to our academic partners at all eight of California’s schools of pharmacy. It is because of the faculty leaders, deans and the Academy of Student Pharmacists that we are able to draw hundreds of students to Outlook, where they learn about the policy-setting process and the importance of belonging to the profession. They are our future, and not only is their participation energizing, but it is integral to furthering the profession.

Please join us next year for Outlook 2012 in Sacramento, February 2-5.
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Pete Vanderveen, PhD – Bowl of Hygeia Award

Ken Thai, PharmD – New Practitioner of the Year
Shawn Deck – Technician of the Year
Karl Hess, PharmD, FCPHA – Innovative Pharmacist of the Year

Hilary Campbell, 2011 PharmD Candidate, UCSF – Student Pharmacist of the Year

Karl Hess, PharmD, FCPHA – Innovative Pharmacist of the Year

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Community Pharmacy Needs Your Help!

CPhA has joined with other health care providers to fight a legal battle that has now made its way to the United States Supreme Court. **WE NEED YOUR FINANCIAL SUPPORT IN THIS LEGAL EFFORT.**

Since 2008, CPhA has supported multiple legal battles to protect pharmacy reimbursement under Medi-Cal. Those efforts currently involve two of the cases before the Supreme Court as well as others in federal and state court. For example, the lawsuit filed last year that challenged the rollback of AWP and resulted in an injunction to block implementation of new upper billing limits and MAIC pricing will require more legal action regardless of how the Supreme Court rules.

We are working with a committed and experienced team of lawyers in all these efforts. As you are aware, this sort of legal action comes with considerable cost. **We need to generate enough funds not only for the Supreme Court cases, but also to fight the battles that will follow. We are asking every pharmacist and pharmacy in California to contribute.** If you wish, your contribution may be spread out over monthly installments if a credit card is provided.

Please contact CPhA PDFC at 916-779-4511, email to vvo@cpha.com or online at www.cpha.com.

Send your contribution to: Pharmacy Defense Fund of California, 4030 Lennane Drive Sacramento, CA 95834

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Or call Veronica Van Orman at CPhA to make your donation 916-779-1400 x311 vvo@cpha.com
The annual House of Delegates sessions convened during the Outlook Annual Meeting over the weekend of February 10-13, 2011 in Palm Springs.

The goal of the proceedings was to review the CPhA policy recommendations drafted by the CPhA Policy Committees and to develop new policies that would reflect the needs of the pharmacy profession and the health care marketplace today. This aspect of the Association’s business provides members with an opportunity to have their voices heard in a dynamic forum, but more importantly, to participate in the process of developing the foundation for CPhA’s legislative representation at the Capitol and with regulatory agencies in California.

There were approximately 300 delegates who represented their affiliated CPhA local associations, practice academies and schools of pharmacy. Thanks to the efforts of the CPhA Policy Committees, the business of updating and amending the five-year-old policies was relatively smooth. It was the items of new business that produced the greatest amount of discussion on the floor.

At issue were important issues related to health care reform, designation of pharmacists as health care providers, expansion of pharmacist CPT codes, pharmacy intern hours, consistency in labeling over-the-counter medications and, finally, criminal prosecution of medical errors. Following the opening session, delegates were eager to carry the debate back to their groups and to develop their final language proposals for discussion on the floor of the House at the closing session. The end result was 12 policies that were simply retained and renumbered; 13 policies that were amended and adopted; six items of new business that were adopted; and one policy that was repealed. Please turn the page to see the policy items in detail and visit the House of Delegates page of the CPhA website to refer to the updated CPhA policy manual.

If you or a colleague would like to participate as a delegate in next year’s House of Delegates proceedings, please contact Veronica Van Orman by email at vvo@cpha.com.
Retained & Renumbered Policies

2011-01 Corporate Officer Liability
2011-02 Pain Assessment
2011-03 Due Process Against Licensees
2011-04 Collaborative Medication Therapy Management
2011-05 Patient Choice of Pharmacies in Health Facilities
2011-06 Retention of California State Board of Pharmacy
2011-07 Dietary Supplements – Labeling and Quality
2011-08 Professional Corporations
2011-09 Recruitment of Underrepresented Minorities
2011-10 Universal Health Care
2011-11 Work Schedules/Shifts for Pharmacists
2011-12 General Standards – Scope of Services

Amended & Adopted Policies

2011-13 FDA Oversight of all Herbal, Alternative, Botanical Products and Dietary Supplements
The California Pharmacists Association supports extending the authority of the FDA to include dietary supplements, herbal, botanical or alternative medicine products that purport to affect the health, structure or function of a human being.

2011-14 Infection Control – Blood-Borne Pathogens/HIV
The California Pharmacists Association supports following CDC guidelines for infection control including universal precautions to prevent the spread of blood-borne pathogens and disease. In addition, the California Pharmacists Association supports that pharmacy personnel receive on-going training for infection control policy and procedures.

The California Pharmacists Association supports that pharmacy personnel infected by a blood-borne pathogen should be provided confidential consultation and reasonable accommodation. Arbitrary and/or discriminatory work-related restrictions and punitive or retaliatory procedures are not appropriate.

The California Pharmacists Association supports voluntary, confidential HIV testing and opposes mandatory HIV testing of pharmacy personnel.

2011-15 Point of Sale – Electronic Claims Systems
The California Pharmacists Association supports uniform standards for electronic claims systems for products and professional services.

2011-16 Employee/Employer Relations – Professional Practice Decisions
The California Pharmacists Association supports the establishment of mechanisms to assure that employee pharmacists in all practice settings have an opportunity to participate in the development and formulation of policies and procedures affecting their professional practices. The California Pharmacists Association also supports the development and implementation of guidelines for pharmacists and pharmacy-employer relations.

2011-17 Complementary and Alternative Therapies
The California Pharmacists Association supports the education of pharmacists and student pharmacists regarding complementary and alternative therapies.

2011-18 Manufacturers’ Drug Product Labeling – Expiration Date, NDC Number and Lot Number
The California Pharmacists Association supports the standardization of drug product labeling by manufacturers such that the lot number, National Drug Code number, NDC or UPC barcode, and expiration date are clearly visible. Further, the expiration date and lot number should not be cut or embossed into the surface of the label. The California Pharmacists Association encourages the manufacturer to include product image and imprint information on the container.

2011-19 Rights of Conscience
The California Pharmacists Association supports the use of procedures to ensure timely patient access to legally prescribed therapy and/or pharmaceutical care without compromising the pharmacist’s right to conscientious refusal.

To this end, the California Pharmacists Association supports:

1. The right of any pharmacist to object on ethical, moral or religious grounds to the performance of any act, or omission of any act, in the normal course of providing professional services to a patient.
2. Prior notification by the pharmacist to their employer where conscientious objection may arise so that a system is developed to ensure that patients have timely access to legally prescribed therapy and/or pharmaceutical care.
3. Pharmacists’ membership and participation on institutional committees, such as bio-ethics committees, charged with developing policies and making ethical decisions.

2011-20 Prescription Distribution and Patient Care
The California Pharmacists Association supports essential safeguards to public health and safety. Any pharmacy service system must furnish at minimum, the following:

1. Immediate access to pharmacist consultation for all patients or their representatives. The best time for consultation to occur is when the patient (or representative) is receiving the medication, product, device and/or services.
2. Full compliance with ethical responsibilities and Federal and State laws and regulations.
3. Timely and accurate medication or device distribution based on a prescription order initiated by a person legally allowed to prescribe who also has a personal professional relationship with the patient.
4. Patient care activities including, but not limited to, reducing medication errors and misuse, developing adherence strategies, evaluating and modifying medication therapy, and interacting with other health care providers.

2011-21 OTC Compounding
The California Pharmacists Association supports that compounding by pharmacists of over-the-counter products for an individual patient without a prescription falls within the scope of practice. CPhA encourages the State Board of Pharmacy to form a committee of stakeholders to determine regulations that would protect public safety and access.

2011-22 Controlled Substance Utilization Review and Evaluation System
The California Pharmacists Association supports:

- All pharmacists having access to the real time Drug Utilization Review (DUR) via the Controlled Substance Utilization Review and Evaluation systems (CURES).
- Utilization of the CURES program by both the prescriber and the pharmacist to initiate a Patient Activity Report, when appropriate.
- Collaboration between prescribers and pharmacists to analyze and evaluate Patient Activity Report data in order to ensure safety and efficacy.

2011-23 Medication Therapy Management
The California Pharmacists Association supports:

A. Medication Therapy Management (MTM) Programs furnished by a pharmacist that are designed to assure that medications are appropriately used to optimize therapeutic outcomes.

B. Pharmacist access to necessary privileged health information via electronic data exchange for patient assessment.

2011-24 FDA Policy/Unapproved Drugs
The California Pharmacists Association supports the Food and Drug Administration's policy which requires an approved New Drug Application before a drug can be marketed.

2011-25 Manufacturer Pricing Policies
The California Pharmacists Association supports the development of drug product pricing and marketing policies that reduce the burden of research & development costs on the American public.

2011-26 Criminal Prosecution of Medical Errors
The California Pharmacists Association supports programs that are designed to prevent or eliminate medical errors. In addition, the California Pharmacists Association supports the position that medical errors should not be subject to criminal prosecution, absent clear evidence of intent to harm.

2011-27 Consistency In Labeling For Over-the-Counter and Prescription Products
The California Pharmacists Association supports manufacturers and distributors of over-the-counter and prescription products to include the company and location (City, State, or Country) where the product is manufactured and packaged on the label.

2011-28 Pharmacist Practitioner Designation
The California Pharmacists Association supports the establishment of a “Pharmacist Practitioner” designation with all of the responsibilities and duties of one who is allowed to render Primary Care.

2011-29 Pharmacist Provider Recognition
The California Pharmacists Association supports the recognition of pharmacists as providers by public and private payors. Further, CPhA supports the expansion of pharmacist CPT codes to enable appropriate compensation for pharmacists’ clinical services.

2011-30 California Health Benefit Exchange
The California Pharmacists Association supports inclusion of compensated MTM services, provided by pharmacists, in the mandated health benefit package offered under the California Health Benefit Exchange.

2011-31 Pharmacy Intern Positions
The California Pharmacists Association supports all pharmacists and pharmacies providing as many intern opportunities as possible, both paid and volunteer, at their place of practice so that student pharmacists can complete intern hours in a timely fashion.

Repealed Policies
Medication Therapy Management (2005-14)

Rejected Item
Removal of Pseudoephedrine from the Marketplace
What follows are brief summaries of major pharmacy news items reported over the past quarter that have had a significant impact on the profession of pharmacy and the health care industry as a whole. These news items are intended to provide readers with a quick recap of the issues.

To follow these stories and keep on top of all developing pharmacy news each week, members can sign up to receive the CPhA CEO Message by contacting Cindy Westphal in the Membership Services department at: cindyw@cpha.com.

Medicaid and Medi-Cal

In January, Governor Brown proposed a budget that would require “sacrifices” on everyone’s part in an effort to get California’s spending under control. In mid-February, the Senate Budget Committee took its first steps to cut state spending, by increasing Medi-Cal costs for beneficiaries and reducing the program’s reimbursement rates. Other states were also feeling budgetary pressures as they developed their own plans to contain Medicaid costs. Oregon implemented a new Medicaid reimbursement benchmark, going from Average Whole Price (AWP) to Actual Average Acquisition Cost (AAAC), while Tennessee became the sixth state to require Medicaid patients, who need long-term care, to enroll in managed care plans. These practices were cause for concern by NACDS and NCPA who sent a joint letter to all the governors in the U.S. expressing concern that the “significantly reduced reimbursement rates could have a major impact on the willingness of pharmacy providers to continue their participation in the Medicaid program, thereby threatening access to fragile patient populations.” Given the Medi-Cal lawsuits levied against the State by CPhA and several other health care organizations, and the proposed solutions from the Governor appears to add more stress to an already broken system.

Further evidence of the broken system was seen a few weeks later in March when a Sacramento federal judge ordered the State not to go forward with a planned freeze of Medi-Cal reimbursements to hospitals for inpatient care. Adding pressure to the mounting difficulties with the Medicaid/Medi-Cal program, the top Republicans dealing with health care policy in the U.S. Congress released a report in early March that estimated the cost of the health care reform law’s Medicaid expansion at $118 billion - almost twice the Congressional Budget Office’s estimate.

Medicare reimbursement practices for the federal Medicare program also came under fire in February when a study revealed that beneficiaries in California, who make up about 20% of the Medicare population, had been readmitted to hospitals within 30 days of being discharged. This practice is prone to penalty for hospitals in the U.S. as health reform provisions aim to penalize hospitals for high readmission rates. In addition, seven California counties and other plaintiffs filed a first amendment complaint in a $3.2 billion lawsuit alleging that Medicare uses outdated reimbursement formulas that underpay physicians in 200 counties across the U.S. Access to care for Medicare patients would be a significant problem under these reimbursement models.

FDA News

In January, The FDA warned of extortionists posing as FDA agents who were targeting customers of online and over-the-phone pharmacies and demanding some individuals pay cash fines or face law enforcement action, according to an FDA statement released last Friday.

In March, the FDA took action against companies that manufacture, distribute, or market certain unapproved prescription oral cough, cold, and allergy products. The affected products cannot be legally marketed in the United States. As reported in the FDA news release 03.02.11.
Health Care Reform

Late in January, the U.S. House of Representatives voted to approve legislation to repeal the health care reform law. All Republicans and three Democrats voted in favor of the repeal, however it was expected to face a greater challenge in the Democratic-led Senate. If repealed, millions of Americans would face losing health care coverage.

In spite of this development, the U.S. Department of Health and Human Services announced new grants for states to develop their own health insurance exchanges under federal health reform law. The grants would require these exchanges to include coverage options for individuals and small businesses by January 2014 - a key provision of the Affordable Care Act. Following the HHS announcement, the California Healthcare Foundation produced a report with side-by-side comparisons of how California’s health benefit exchange would compare with federal provisions. As the first state to establish an exchange, many were looking to California to take the lead in executing the federal plan covering nearly five million uninsured patients.

One sign of good things to come was the fact that nearly four million people with Medicare who reached the program’s Part D coverage gap in 2010 had received a one-time, tax-free $250 rebate check through provisions of the Affordable Care Act. Meanwhile health care reform suffered another blow when a U.S. District Court Judge ruled that the federal health reform law’s individual mandate was unconstitutional and agreed with plaintiffs in a multistate lawsuit against the overhaul that the mandate exceeded Congress’ power to regulate interstate commerce. This created further division among states about what to do next. Some states said the ruling meant that the law was no longer relevant and would not implement it unless an appellate court reversed the decision, while other states began moving forward as planned. A few weeks later, their uncertainty was answered when the same federal Judge who originally declared Obama’s health care overhaul unconstitutional, ruled that states must continue implementing it while the case made its way through the courts. As of this printing, the nation’s focus has shifted away from the implementation and regulatory details of health care reform towards more pressing budgetary concerns.

State Medicaid and Managed Care

Desperate to rein in rising Medicaid costs, last year Tennessee became the sixth state to require its frailest and costliest patients - the elderly and disabled who need long-term care - to enroll in managed care plans, prompting other states to consider similar plans. In March, the top Republicans dealing with health care policy in the U.S. House and Senate released a report that estimates the cost of the health care reform law’s Medicaid expansion at $118 billion - almost twice the Congressional Budget Office’s estimate. In March, Republican governors went to Washington, during the National Governors Association meeting, with a loud and clear message on Medicaid: it’s time for more flexibility in how federal dollars in the state-administered entitlement program are spent.

Added to these budgetary concerns is the fact that nearly five million uninsured California residents could gain access to health insurance in 2014, when Medicaid eligibility is expanded and the state’s health benefit exchange is launched as called for in the federal health care reform law. In a report published by the UCLA Center for Health Policy Research, 3.1 million of California’s seven million uninsured residents will qualify for Medi-Cal, the state’s Medicaid program. Many of the newly insured will include low-income adults who do not qualify for Medi-Cal now because it only applies to families.

California News

CPhA Academy of Hospital Pharmacists Changes Name

The CPhA Board of Trustees approved a name change for the Academy of Hospital Pharmacists. The name was changed to the Academy of Health-System Pharmacists to better reflect the practice setting of these members and to better represent the larger base of CPhA members in this Academy.

California Pharmacist Named Remington Honor Medal Winner

In early January, APhA announced that Paul Loholm, PharmD, FCPHA would be the 2011 recipient of the Remington Honor Medal, making him the fourth pharmacist from California to earn the honor since 2002, and one of eight California award recipients overall.

San Francisco Bans Tobacco Products in Pharmacies - CPhA Member Leads Efforts

In January, CPhA member and consumer advocate Fred Mayer played a key role in getting San Francisco to pass an ordinance banning tobacco sales in all pharmacies. The issue was well-covered in the S.F. area press and in Drug Topics.

CPhA Member Moves MTM Services Forward

Roger Klotz and Micah Hata, two full-time faculty members at Western University of Health Sciences College of Pharmacy, partnered with an independent pharmacy to provide direct patient care services. Their services include anticoagulation and medication therapy management (MTM). In addition, they have been entered into the Anthem Blue Cross computer system as providers to be reimbursed for direct patient care services and clinical laboratory testing, thereby advancing the practice of pharmacy in California.

UCSF Pharmacist Appears on Dr. Oz to Discuss ‘The Dangers of OTC Drugs’

In early February, UCSF Pharmacist Dr. Nancy Nkansah, was featured on Dr. Oz in a four segment piece about the dangerous misuse of non-prescription products. Dr. Oz counted down the top five most misused over-the-counter medications and Nancy helped provide consumers with important tips about the safe use of these products.
Health Care Reform
No Solution to Rising Medical Premiums

While the future of health care reform continues to be sorted out by Congress and the courts, members will have to make important decisions about health insurance for themselves and their employees, especially when it comes to managing premium costs.

No matter which path health care reform follows, it seems likely that annual increases in health insurance premiums will be part of everyone’s immediate future.

So what can you do until then?

• If you are not enrolled in a qualified High Deductible Health Plan which enables you to open a Health Savings Account, consider the significant savings this option provides. With individual only coverage you are eligible to contribute up to $3,050 to your account, or $6,150 with family coverage, on a tax deductible basis*.

Members between the ages of 55 and 64 are eligible to add an additional $1,000 per year ($4,050 and $7,150 totals respectively) to their accounts. Many members utilize the savings from premiums to fund their accounts. Funds may be accessed immediately, and without penalty, for health-related expenses.

• Investigate RAF Sales - Health plans offer incentives through discounts off their risk adjustment factors (RAFs) for you to change health plans. Instead of your medical rates increasing this year, we might be able to help you offset some of that increase.

• Mercer Select HRKnowHow - If you play a role in your medical group’s health care and benefit plan decisions, stay current on the challenging issues. Access is included at no charge for all members who purchase group (2-50 members and employees) health insurance through Marsh. It includes:

  • News and analysis of important group benefit issues and the latest information on health care reform.
  • Compliance Link - tool to assist with health care and group benefit plan administration and samples of notices and forms.

We serve members who want assistance in evaluating the medical insurance choices before them. We can assist you with the information you need to make the critical choices on the road ahead. Call Marsh at 888-926-CPhA for more information or a quote.

* Marsh and the Association do not provide tax, investment or legal advice. Please consult with your professional advisors for guidance on these issues.

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*Marsh and the Association do not provide tax, investment or legal advice. Please consult with your professional advisors for guidance on these issues.
While incremental changes are made along the way, you’ll still need to continue to make important decisions about health insurance for you and your employees, especially when it comes to managing premium costs.

So what can you do until then?

- **Enroll in a qualified High Deductible Health Plan** and open a Health Savings Account. This provides significant premium savings that can fund your HSA account. With individual only coverage you are eligible to contribute up to $3,050 to your account, or $6,150 with family coverage, on a tax deductible* basis (members age 55 – 64 are eligible to contribute another $1,000).

- **Investigate RAF Sales** Health plans offer incentives through discounts off their risk adjustment factors (RAFs) for you to change health plans. Instead of your medical rates increasing this year, we might be able to help you offset some of that increase.

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  * **Includes:**
    - News and analysis of important benefit issues
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* Marsh and the Association do not provide tax, investment or legal advice. Please consult with your professional advisors for guidance on these issues.

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Understanding HOPE in Today's World

by Anandi V. Law, B Pharm, PhD, Guest Editor

In a world where patient care and business viability collide, the field of Health Outcomes (and Pharmacoeconomics within it) could help us to make better decisions and to answer questions such as those listed in the sidebar.

The disciplines of Health Outcomes (HO) and Pharmacoeconomics (PE) are relatively new in the health care arena, having evolved along with the era of managed care. In effect, the origin of the word “Pharmacoeconomics” can be traced back four decades when it was coined by researchers within pharmacy.1

The introductory CE article in this themed issue on HO and PE provides a brief overview of the area and outlines common PE techniques. These techniques help in assessing and evaluating the entire gamut of health care issues. Of course, the final answers to the questions rest with the decision makers. Therein lies the limitation in scope of these techniques, in that they are only tools, albeit powerful ones.

Health outcomes evaluations find applicability globally; many countries with government-funded health care (the EU, Australia, Canada)2 routinely use PE techniques for prioritizing areas of need and for allocating resources. Closer to home, any national-level discussion on health care policy or reform includes assessments and evaluations of cost, access and quality.

One such national policy was Medicare Part D, purported to stabilize spending for enrollees. MTM, as a program through pharmacies, has yet to gain momentum. Various studies have shown that pharmacists shy away from documentation and billing issues. The article “Documenting and Describing the Value of Medication Therapy Management Services (MTMS) and Outcomes in Community Pharmacy: Methods and Case Study” presents a quick and easy method of documentation at the pharmacy level that may be extremely useful to all community practitioners.

With advances in pharmacotherapy and new innovative technologies, the conversation takes on a new turn: we would like to provide the latest and best therapy but who will pay for it? Some of these issues are addressed in the article “Biologics: What Solutions Do We Have for Their High Costs?”

It would have been simple (and predictable) to restrict this theme issue to evaluating the impact of pharmacists on outcomes in various inpatient and ambulatory care/community clinical services. However, my attempt has been to investigate a range of issues within HO and PE, involving product, program and policy, to challenge some of our thinking, pique interest and raise more questions. I hope that the readers will enjoy the flavor of these articles.

About the Author

Anandi V. Law, B.Pharm., PhD., is an Associate Professor and Chair of the Department of Pharmacy Practice and Administration at Western University of Health Sciences, Pomona, CA. Her primary area of research is studying the impact of pharmacist services on patient outcomes, and developing tools to better measure health outcomes. She teaches courses in pharmacy practice management and health outcomes at the University, and is actively involved in professional associations such as CPhA, APhA and ISPOR.

References


1. Should our pharmacy begin this new smoking cessation program? What is the ROI on that osteoporosis screening program? Will patients be satisfied with the new brown bag service and will traffic into the pharmacy increase? [Community/ambulatory care pharmacy]
2. Which drug should receive formulary approval? What would be the clinical and budgetary impact of the drug? [Institutions or Health Plans]
3. Which therapeutic area would give the best returns for limited research dollars? [Pharmaceutical company]
4. To which disease areas should research dollars be allocated? [Federal funding agency]
5. Which program will lead to better overall value and health outcomes? [Countries with socialized medicine]
Learning Objectives:
After reading the following article, the pharmacist will be able to:
1. Define health outcomes, pharmacoeconomics and list different types of outcomes that are measured in pharmacoeconomic analyses.
2. Compare and contrast four cost-consequence analyses that are commonly used in pharmacoeconomics.
3. Discuss applications of health outcomes and pharmacoeconomic in today’s “real world” pharmacy practice environment.

Most practitioners may have heard of the terms Pharmacoeconomics and Health Outcomes in the context of health care. This brief article will present the genesis of these terms in health care as well as re-orient the reader to their definitions, techniques and applications in pharmacy practice.

Background of the Outcomes Movement
Given the trend of increasing health care expenditures in the U.S. that became noticeably challenging around the late 1960s, there was an increased volume of studies (such as the RAND HIE – Health Insurance Experiment) conducted to understand user behavior in health care and the cause of these increasing costs. Various strategies to contain these costs were proposed in the decade that followed; many of these were initiated within the realm of economics which deals with decisions under limited resources. Further, there was not much evidence that the increased costs were correlated with improved health outcomes for patients. Managed care delivery systems arose in the 1980s as one such major attempt to address issues of cost, access and quality of health care. In parallel, an “outcomes movement” began in health care that has been called the “third revolution in medical care” or the “era of assessment and accountability” introducing terms such as “value” and “quality” to health care. “Value” refers to the ratio of inputs to outputs (or the efficiency), and “quality” or effectiveness refers to the degree to which health care products and services are successfully delivered and used. In effect, the outcomes movement gained momentum to address the 3As – Access, Accountability and Affordability, which continue to be concerns in the current environment of health care reform.

Health Outcomes
An outcome is defined as a “result, consequence or aftermath.” Donabedian, in his classic Structure-Process-Outcomes framework for measuring health care quality, defined health care outcomes as the “effects of care on the health status of patients and populations.” Health outcomes can be viewed within the all-inclusive ECHO (acronym for economic, clinical and humanistic outcomes) model; that provides a clear guideline in categorizing and measuring outcomes.
Economic outcomes are measured using various types of costs – direct (in the line of medical care), indirect (costs related to lost productivity resulting from health care problems), and intangible (associated with pain and suffering). Clinical outcomes are well known to all pharmacy practitioners, and include intermediate endpoints (e.g., level of blood pressure control or other physiologic monitoring parameters) and final endpoints (such as cure rates, cardiovascular events, and death). Humanistic, better known as patient reported outcomes (PROs) provide the patients’ perspective and are becoming increasingly prominent in health care. PROs include intermediate endpoints such as patient knowledge, medication adherence, willingness to pay and final endpoints such as quality of life, patient satisfaction and treatment satisfaction.

**Why Are All Three Outcomes Important?**

Consideration of only one of these three perspectives provides an incomplete picture of value or quality of health care. Clinicians are trained to measure and act on clinical endpoints which are objective and easily measureable. However, we cannot ignore the economic and humanistic components of quality health care which are equally important but difficult to measure and quantify.

For example, without PROs, we cannot examine the value of an intervention or service to the end-user, who ultimately benefits from health care delivery. In the context of practice, even if it was established that a certain medication therapy management (MTM) clinic was saving money and patients were improving based on laboratory values; the clinic would not be completely effective unless patients were satisfied and motivated to return to the clinic periodically to maintain these outcomes.

**Pharmacoeconomics**

An assessment of value and quality involve assessing the cost-consequence balance of health care products/services. Pharmacoeconomics, which evolved in the 1970s as a sub discipline of health outcomes, is the field that deals with the description and analysis of these costs and consequences. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) defines Pharmacoeconomics (PE) as “the scientific discipline that evaluates the clinical, economic and humanistic aspects of pharmaceutical products, services, and programs, as well as other health care interventions to provide health care decision makers, providers and patients with valuable information for optimal outcomes and the allocation of health care resources.” Pharmacoeconomics incorporates various disciplines such as health economics, epidemiology, decision sciences and health services research. PE analyses provide tools for better decision-making in a health care environment that is increasingly value-conscious.

There are four different types of cost-consequence analyses in PE based on how consequences are valued (figure 1), and additionally cost-of-illness analysis, all of which are explained below. In all these analyses, costs may be enumerated using resource utilization units (e.g., hours of physician service, medications per patient) but they are always valued in monetary terms. It is worthwhile mentioning that the “perspective” used in these analyses is critical and has an impact on the results. For example: Costs from a patient’s perspective would only include transportation costs, copayment, etc., whereas a health plan perspective would include direct costs for reimbursing physicians and other providers for delivery of care.

Cost-of-Illness studies (COI): COI identifies and estimates the overall burden of an illness in terms of the different types of costs or resources necessary to screen, diagnose, prevent and treat a condition, within a defined population. Examples of health conditions evaluated by cost-of-illness studies include: diabetes, cancer, depression, arthritis, stroke. Information from COI is helpful to federal health agencies in prioritizing focus areas for allocating funds for primary prevention and research. It is also used by managed care organizations to estimate the economic burden of patients who have the disease and by pharmaceutical research companies to determine the role and pricing of an investigational agent in reducing economic burdens to society.

Cost-Minimization Analysis (CMA): CMA is a cost-consequence analysis that is used to compare two or more drugs (or interventions) if the outcomes of these comparators are equivalent in efficacy or effectiveness; in which case CMA provides comparison purely on the basis of costs. Equivalency of clinical outcomes is essential for a CMA and cannot be assumed unless proven with evidence from head-to-head trials. CMA is generally applied to compare costs of: brand versus generic drugs, chemically identical drugs with different routes of administration, or utilization of the same drug in different settings.

Cost-Benefit Analysis (CBA): CBA is an economic analysis that assesses whether the consequences of a product, procedure or program outweigh the costs; where both costs and consequences are valued in mon-
Figure 2: Comparisons between a new versus existing drug therapy

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Cost-Effectiveness Analysis (CEA): CEA is the most commonly used cost-consequence analyses in PE, given its wide applicability in evaluation of products, programs and policies. Hence the term is often misunderstood and sometimes loosely used as a catch-all phrase for PE. CEA is used when outcomes between comparators are not equivalent or cannot be valued in monetary terms. CEA computes cost in monetary terms and outcomes in natural units; i.e., cure rates, drop in blood pressure per mm Hg, etc. The alternative agent or intervention with the lower average cost-effectiveness ratio (ACER) is favored over its comparator. When comparing alternatives, it is important that the outcomes be measured in the same natural unit. In other words, CEA cannot compare a drug that lowers blood pressure to a drug that prevents MI. CEA is most commonly used to compare new FDA approved drug to its older well-established comparator; the possibilities are provided in the grid in Figure 2. In most cases, the newer drug is both more expensive and more efficacious than the older one (quadrant I). Hence, the appropriate analysis is to examine what is the added cost to the system in adopting the newer drug over the older one, measured using the ICER (incremental cost-effectiveness ratio) which calculates the ratio of the differences in costs to differences in consequences. Thus, an ICER of $7,500 in comparing New Drug to Old Drug (Quadrant I in Figure 2) indicates that it costs the system $7,500 for an additional MI prevented with New Drug. So how does one know if $7,500 is a reasonable value to include the New Drug? That is up to the decision makers and their willingness-to-pay for any scenario, since PE only provides analysis to help decisions.

Cost-Utility Analysis (CUA): CUA is a PE analysis which incorporates “utility” or patient preferences for the health condition as the consequence. A commonly used metric for utility is Quality Adjusted Life Years (QALY) that is a single numeric that incorporates both the quantity (Y) and quality of life (Q) weighted from the patient’s perspective. There are many techniques to obtain Q weights and the reader is referred to detailed explanations on the concept. Generally speaking, a Cost/QALY gain of less than $50,000 is considered acceptable in adopting the therapy (refs). A CUA is considered an offshoot of a CEA but is expensive to conduct, so it is typically used when the disease state is considered to affect quality of life more than other clinical outcomes (such as chronic pain, rheumatoid arthritis, and psoriasis).

Additional Tools in PE

Sensitivity Analysis: Since there may be many parameters that impact costs and consequences of interventions, sensitivity analysis is used to vary these parameters and examine the resultant impact on the ACER and ICER. When the results do not vary by a large margin, they are categorized as robust to the analysis.

Decision Analysis: When there are multiple possibilities or outcomes that occur with therapies and decisions have to be made under uncertainty, decision tree modeling is used to help chart out the possible options, probabilities of occurrence and cost of each occurrence to provide better tools for decision making.

For a complete review of sensitivity and decision analysis, the reader is directed to the references.

Applications of Health Outcomes and Pharmacoeconomics

Community Pharmacy Practice

Health outcomes and PE could be useful in community practice in various ways: 1. To help decide in allocating resources between two competing programs – an example is a CBA to decide between spending on promotion of influenza vaccinations versus coupon discounts for prescription; or between starting a diabetes class and a smoking cessation program. 2. To help measure the effectiveness of pharmacist interventions, such as in a diabetes management program or MTM – an example is the Asheville Project which used the ECHO model and documented an improvement in clinical and patient reported outcomes, along with resource savings and a decrease in patient absenteeism. Patient satisfaction is also a common measure that has been used to document the impact of pharmacist service on patients.

Inpatient Pharmacy Practice

The study of health outcomes and PE is also beneficial in supporting the value of pharmacists in an inpatient setting. Services provided by the pharmacists (e.g. medication reconciliation, therapeutic recommendations on medical teams) can be justified by reviewing the desirable outcomes achieved by patients. For example, inpatient pharmacist counseling on discharge medications reduced the rate of hospital readmission and improved rates of medication adherence. Clinical pharmacy services have also been associated with cost savings in the hospital setting.

Knowledge of health outcomes and PE is also important for the inpatient pharmacist to make evidence-based decisions in drug therapy recommendations. This evidence allows pharmacists to provide effective health care by reducing costs and complications associated with prolonged unnecessary therapy or by recommending a more cost-effective therapeutic alternative.

Managed Care

The aim of managed care organizations (MCOs) is to maintain high-quality care while allocating resources efficiently. MCOs are increasingly utilizing health outcomes and PE data to assess the total cost of providing quality care. Strategies by MCO to allocate resource cost-effectively are not limited to drug expenditures, but instead on assessing health outcomes (which ultimately affect downstream medical costs). Pharmacists who participate on Pharmacy and Therapeutics
(P&T) Committees are tasked with evaluating the evidence and making decisions based upon the outcomes of interest for a given disease state and the costs associated with the condition. Ultimately, a P&T Committee can promote the use of the cost-effective alternative through the use of tiered formulas and prior authorization procedures. MCOs also have the means to conduct their own outcomes analyses using patient claims data. The establishment of computerized electronic records provides MCOs with a large database to investigate trends and identify areas to focus their cost-effective strategies. Analyses generated from their own set of members may provide the most applicable evidence to influence future decisions.

Industry
Pharmaceutical industry uses PE analyses at various stages; COI is used in determining allocation of research dollars in a particular therapeutic area; and COI and CEA may be used in determining pricing for an FDA approved drug. CEA or CUA is sometimes incorporated into clinical trials and in Phase IV studies to justify the value of a new drug over existing therapies. With the growing emphasis on comparative effectiveness research, pharmaceutical companies may de-emphasize the investment in “me too” drugs, with a shift in focus to therapies which have potentially greater value. In order for newly developed drugs to gain market share on conditions that already have existing gold standard therapy, pharmaceutical companies must be able to show that the new drug provides greater value than the competing products. Therefore, pharmaceutical company-sponsored research must go beyond simply showing efficacy, safety, and quality. With the availability of existing gold standard therapy, head-to-head trials are preferred to demonstrate the comparative effectiveness of two therapy options. Cost-of-illness analyses are also utilized by pharmaceutical industry to determine the potential role of their investigational agent; the pharmaceutical industry may be able to sway health care decision makers to increase the usage of their products to decrease downstream costs of the disease.

Conclusions
The field of health outcomes has evolved in response to escalating costs in the health care system and a need to measure the value (cost/quality) of health care delivery. The ECHO model typifies outcomes that can be measured in all health care settings and provides the ideal process for further comprehensive studies and decision-making. Pharmacoconomics is a subspecialty within health outcomes that deals with the cost-consequence analysis of pharmaceutical products, procedures and pharmacy programs. Among the four types of pharmacoeconomic analysis techniques that help provide the tools for decision-makers, in community pharmacy, institutional, managed care and industry settings, CEA and CUA are the most commonly used by decision-makers.

About the Authors
Anandi V. Law, B.Pharm., PhD., is an Associate Professor and Chair of the Department of Pharmacy Practice and Administration at Western University of Health Sciences, Pomona, CA. Her primary area of research is studying the impact of pharmacist services on patient outcomes, and developing tools to better measure health outcomes. She teaches courses in pharmacy practice management and health outcomes at the University, and is actively involved in professional associations such as CPhA, APhA and ISPOR. She has no conflicts of interest or bias to report.

Dr. Phung teaches evidence-based clinical practice and practices pharmacy in family medicine/primary care. Her research expertise lies in conducting systematic reviews and meta-analyses (including Bayesian mixed-treatment comparison), with emphasis in the treatment of diabetes and other aspects of the metabolic syndrome. Dr. Phung has no relevant conflicts of interest or bias to report.

Dr. Prashant Sakharkar is currently Outcome Research Fellow at College of Pharmacy, Western University of Health Sciences. Born and raised in India, he obtained his Bachelor’s and Masters in Pharmacy at Nagpur University, relocated to the Bahamas to work in hospital pharmacy after spending 6 years in academia. Most recently, he completed both his PharmD & MPH from University of Florida.

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12. Stroke PORT Study 1994. Duke University Medical Center, Durham, NC.
How Do Health Outcomes and Pharmacoeconomics Impact “Real World” Pharmacy Practice? (cont.)

1. Willingness to pay and medication adherence are examples of what type of pharmacoeconomic outcomes?
   a. Economic outcomes  c. Humanistic outcomes
   b. Clinical outcomes  d. Clinical endpoints
2. Costs associated with pain and suffering are examples of:
   a. Direct costs  c. Intangible costs
   b. Indirect costs  d. Hospital costs
3. Pharmaceutical industry’s ability to sway health care decision makers to increase usage of their products is often based on:
   a. Cost effectiveness analysis  c. Cost benefit analysis
   b. Cost minimization analysis  d. Cost of illness analysis
4. Incremental Cost Effectiveness Ratio (ICER) is a measure used to calculate:
   a. The cost of obtaining a specific therapeutic outcome
   b. The cost per quality adjusted life year gained
   c. Cost and benefit of new strategy regardless of other alternative
   d. Ratio of the differences in costs to differences in consequences between two interventions
5. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) defines ‘Pharmacoeconomics’ as:
   a. Scientific discipline that evaluates the clinical, economic and humanistic aspects of pharmaceutical products, services and programs
   b. A discipline that provides valuable information to health care decision makers, providers and patients for optimal outcomes
6. Comparing costs of brand versus generic drugs, different routes of administration of the same drug, or use of the same drug in different settings are examples of:
   a. Cost effectiveness analyses  c. Cost benefit analyses
   b. Cost minimization analyses  d. Cost utility analyses
7. Quality Adjusted Life Year (QALY) is a commonly used metric under:
   a. Cost minimization analysis  c. Cost of illness analysis
   b. Cost benefit analysis  d. Cost utility analysis
8. Cost Effectiveness Analysis (CEA) is used when outcomes between comparators are equivalent or can be valued in monetary terms.
   a. True  b. False
9. Incremental Cost Effectiveness Ratio (ICER) measures the cost of obtaining a specific therapeutic outcome.
   a. True  b. False
10. Cost Effectiveness Analysis (CEA) can be used to compare a drug that lowers blood pressure to a drug that prevents MI.
    a. True  b. False
11. Patient satisfaction has been used to measure impact of pharmacist services on patients.
    a. True  b. False

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**Comments/future topics welcome.**

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Date: April 15, 2011  
CAPE Program #: 016-2011

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Choosing the

Lowest Cost Medicare Part D Stand-Alone Prescription Drug Plan: How Can Beneficiaries Decide?

by Mark P. Walberg, PharmD, PhD, Nicholas D. Baker, MPH, PharmD, James A. Uchizono, PharmD, PhD, Rajul Patel, PharmD, PhD

Abstract

Since the inception of Medicare Part D, certain plan benefit parameters, e.g. annual deductible and monthly premiums, have received a great deal of public attention, despite the lack of evidence supporting their relationship to beneficiary out-of-pocket costs. For most, an accurate comparison of the total estimated cost of each drug plan can only be calculated by using the Medicare website.

This study will examine parameter trends of stand-alone prescription drug plans in California for each year between 2007 and 2009 to determine if premiums and/or deductible amounts are indicators of total out-of-pocket costs by comparing the lowest, median, and highest ranked estimated annual cost drug plans. Pharmacy claims records for 50 patients were randomly selected from a database of Medicare-eligible beneficiaries. Patient medication profiles were entered onto the Medicare website to determine the lowest, median, and high-
est cost plans for each patient in California in 2007, 2008 and 2009. For all three years the annual costs were significantly different between lowest, median, and highest cost levels. Annual premiums were not significantly different between each cost level in all three years compared. In two out of three years, significantly more high cost plans did not charge a deductible compared to the lowest cost plans. These results indicate that beneficiaries using premium and deductible information alone may result in sub-optimal plan selection and increased out-of-pocket costs. Additionally, it is imperative that Medicare beneficiaries annually reexamine drug plan offerings so as to minimize their out-of-pocket costs.

**Introduction**

Since the inception of Medicare Part D in January of 2006, a few different plan benefit parameters have received a great deal of public attention, despite the lack of evidence supporting their relationship to beneficiary out-of-pocket costs. Cline and Gupta showed that the annual deductible and monthly premium were the two most relied upon plan parameters by seniors when discerning between various insurance plans.1 However, to date there is no empirical evidence to support this belief in regards to the Part D benefit.

Attention to annual changes in the Part D benefit by the media and general pharmacy community, similarly, has focused on increasing premiums and other individual plan attributes.2,3 Some have speculated that this plan parameter bias has caused Part D beneficiaries to enroll in a stand-alone prescription drug plan (PDP) that does not best suit their prescription drug insurance needs.1

The potential for beneficiaries to enroll in a less than ideal Part D PDP is further complicated when considering the vast number of PDPs offered in each Part D region (e.g., California). Table 1 shows that each year since the inception of Part D, Medicare beneficiaries have had between 47 and 56 PDPs from which to choose. The data in Table 1 does not account for Medicare Advantage plans that were available, and vary on a county by county basis, which may further obscure beneficiary plan selection. As such, the large number of Part D plan offerings creates a labyrinth of information that is difficult for most Medicare beneficiaries to effectively navigate.8

While plans with a wide range of premiums have been offered in California each year, the average PDP premium has steadily increased since 2007 (Table 1). Prescription drug plan enrollment decisions have been made even more complex as a result of the number of plans waiving the deductible and/or offering gap coverage each year. In both 2006 and 2007, at least one PDP in California offered coverage of both brand and generic formulary medications during the gap. In contrast, PDPs offering gap coverage in 2008 and 2009 only covered certain generic medications. Additionally, since PDPs can alter their cost-sharing structure (e.g., monthly premium, deductible amount, and gap coverage) on an annual basis, some beneficiaries who chose to remain in the same PDP in subsequent years may lose the incentive benefits that initially promoted enrollment into that specific PDP. Most importantly, there has yet to be any empirical evidence as to whether or not the lowest cost plan for a beneficiary is a PDP offering a low monthly premium and/or a $0 deductible.

While it is possible for beneficiaries to estimate the total out-of-pocket cost associated with each PDP offered in their region based on their specific medication profile, only 6% of beneficiaries surveyed in 2006 did so using the Plan Finder Tool available on the Medicare website (www.medicare.gov).9 This tool systematically evaluates PDP choices and enables beneficiaries to objectively compare the estimated annual cost (EAC) of all available PDP offerings. Beneficiaries who fail to use the PlanFinder Tool or call Medicare (1-800-MEDICARE) may not be enrolled in the lowest cost PDP.

The anticipated rise in the number Medicare-eligible beneficiaries over the next two decades coupled with the escalation in drug costs and drug utilization will place increasing financial stress on the Part D benefit.20 As such, it is purported that the expected rise in Part D costs will be addressed through cost-shifting behavior, which will reallocate an increasing proportion of the financial responsibility from private drug plans to plan beneficiaries.20 Therefore, it will become increasingly important for Medicare beneficiaries to understand their prescription drug plan options in order to minimize their out-of-pocket expenditures. Moreover, the factors that beneficiaries consider during this evaluation must serve as reliable estimators of total out-of-pocket costs.

Considering the overwhelming number of PDPs annually offered throughout this country and the variation in plan parameters of each PDP, this study will narrow the focus to PDPs in California, the PDP region with the most Medicare beneficiaries. Using a randomly sampled cohort of Medicare-eli-

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**Table 1. Characteristics of stand-alone prescription drug plans (PDPs) offered in California from 2006 to 2009**

<table>
<thead>
<tr>
<th>Year</th>
<th># PDP</th>
<th>CA Average Premium</th>
<th>Lowest Premium</th>
<th>Highest Premium</th>
<th>#PDPs with a $0 Deductible</th>
<th>#PDP with Gap Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>47</td>
<td>$31.95</td>
<td>$5.41</td>
<td>$66.08</td>
<td>28</td>
<td>7</td>
</tr>
<tr>
<td>2007</td>
<td>55</td>
<td>$31.72</td>
<td>$9.70</td>
<td>$80.90</td>
<td>33</td>
<td>14</td>
</tr>
<tr>
<td>2008</td>
<td>56</td>
<td>$37.65</td>
<td>$14.30</td>
<td>$102.70</td>
<td>33</td>
<td>15</td>
</tr>
<tr>
<td>2009</td>
<td>51</td>
<td>$46.86</td>
<td>$18.30</td>
<td>$129.30</td>
<td>29</td>
<td>12</td>
</tr>
</tbody>
</table>

---
Prescription drug plan enrollment decisions have been made even more complex as a result of the number of plans waiving the deductible and/or offering gap coverage each year.

gible patients, this study will examine trends in various PDP parameters in California from 2007 to 2009 to determine if premium or deductible amounts are consistent indicators of patient out-of-pocket costs.

Methods
A database of approximately 18,000 Medicare-eligible patients was provided by the data analytics company, MedInitiatives®. This database consisted of pharmacy claims data provided by the pharmacy benefits management company Catalyst Rx®. All protected health information and unique patient identifiers were stripped from the database prior to provision. A sample of 50 patients was randomly selected from the provided database. Pharmacy claims records for each study patient were obtained from this database during the six-month period from January 1 to June 30, 2007 in order to determine each patient’s medication profile. Prescription medications taken on a regular basis, defined as having at least an 84-day supply filled during the six month interval, were included in the patient’s medication profile. Patients without any medications meeting this criterion over the six month time frame of interest were excluded from further analyses and replaced by a new randomly selected patient.

A patient medication profile (e.g., medication name, strength, dosage form, and frequency of use) was created and saved on the Medicare website for each of the 50 sample patients. The medication profile represents the monthly medications that would be taken on a regular basis at the time of Part D PDP evaluation. The Medicare PlanFinder Tool was used to determine the lowest, median, and highest EAC plan for the same 50 patient medication profiles in California in 2007, 2008 and 2009. Data for 2007 and 2008 was collected during the 2008 open enrollment period (November 15th to December 31st, 2007) and data for 2009 was collected in the first quarter of 2009. For each plan, the following parameters were retrieved and recorded for each patient medication profile: EAC, total monthly drug cost, monthly premium, and annual deductible. The EAC includes all costs paid by the beneficiary during the

Table 2. Comparisons of lowest, median, and highest estimated annual cost (EAC) stand-alone prescription drug plans (PDPs) from 2007 to 2009 (CPI-adjusted values) for the sample cohort

<table>
<thead>
<tr>
<th>YEAR</th>
<th>PDP Rank</th>
<th>Mean EACa</th>
<th>Mean Annual Premiumb</th>
<th>Mean SOCc</th>
<th>$0 Deductible (%PDP)d</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>Lowest</td>
<td>$1,450</td>
<td>$438</td>
<td>50</td>
<td>66%</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>$2,065</td>
<td>$397</td>
<td>76</td>
<td>64%</td>
</tr>
<tr>
<td></td>
<td>Highest</td>
<td>$3,447</td>
<td>$587</td>
<td>163</td>
<td>72%</td>
</tr>
<tr>
<td>2008</td>
<td>Lowest</td>
<td>$1,702</td>
<td>$239</td>
<td>57</td>
<td>28%</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>$2,267</td>
<td>$418</td>
<td>92</td>
<td>62%</td>
</tr>
<tr>
<td></td>
<td>Highest</td>
<td>$3,729</td>
<td>$731</td>
<td>185</td>
<td>68%</td>
</tr>
<tr>
<td>2009</td>
<td>Lowest</td>
<td>$1,720</td>
<td>$530</td>
<td>62</td>
<td>30%</td>
</tr>
<tr>
<td></td>
<td>Median</td>
<td>$2,530</td>
<td>$502</td>
<td>100</td>
<td>52%</td>
</tr>
<tr>
<td></td>
<td>Highest</td>
<td>$4,086</td>
<td>$1,095</td>
<td>218</td>
<td>70%</td>
</tr>
</tbody>
</table>

* P < 0.05 between all groups  
* P < 0.05 Highest compared to Lowest and Median  
* SOC: share of cost; P < 0.05 between Lowest and Highest  
* No significant differences between groups  
* P < 0.05 Lowest compared to Median and Highest
year including monthly premiums, co-pays in each Part D coverage level, and out-of-pocket costs for Medicare-excluded or non-formulary medications. Total monthly drug costs and monthly premiums recorded from the PlanFinder Tool were multiplied by 12 to obtain annual drug costs and annual premium amounts, respectively. Plan deductibles were grouped into either having a deductible (full or partial deductible) or not (e.g., a $0 deductible) due to the few number of plans offering a partial deductible.

Cost parameters (EAC, total drug cost, and premium) from 2007 and 2008 were adjusted using the medical care commodities Consumer Price Index (CPI) to account for the average change in prescription drug prices prior to comparison with 2009 values. Consumer Price Index was calculated at the regional level (e.g., West) from December 2006 to November 2008 in order to reflect drug price changes occurring between the 2007 and 2009 open enrollment periods.11

In order to determine the percent out-of-pocket savings afforded by enrolling into a specific PDP, the patient's share of cost (SOC) was calculated as follows:

\[
SOC = \frac{EAC}{\text{annual drug cost}}
\]

Within each year, the CPI-adjusted EAC, annual premium, and SOC for the lowest, median, highest EAC PDPs were compared to one another for all 50 sample patients via the repeated measures analysis of variance test. Statistically significant findings were further analyzed using Tukey's post-hoc test. The CPI-adjusted EAC, annual premium, and SOC of the lowest EAC PDP between years (2007-2009) were likewise compared to one another. The number of lowest, median, and highest EAC plans not charging a deductible was compared within each year for all sample patients. Additionally, the number of lowest cost PDPs not charging a deductible was compared between years for all sample patients. Both of these comparisons were tested using the Cochran's Q test. Significant findings were further analyzed using the post-hoc Critical Difference test.

All statistics were performed in Microsoft Excel 2007 and verified using StataCorp 2007. Stata Statistical Software: Release 10. College Station, TX: StataCorp LP. Alpha was set a priori at 0.05 for all performed statistical analyses.

Results

Comparisons between the lowest, median, and highest cost plans within each year for the sample cohort are shown in Table 2. A significant difference in EAC between each of the three plans was observed for each examined year. Annual premiums were significantly different from each other for all three PDPs in 2008 and 2009, with only the highest EAC PDP premium differing significantly from the lowest and median EAC PDPs in 2007. In all three years, SOC showed a significant difference between the lowest and highest EAC PDPs, with the SOC of the highest EAC PDP averaging over 160% in each year. The number of PDPs at each level with a $0 deductible varied considerably between years with no significant difference seen in 2007. The lowest ranked PDPs had significantly fewer PDPs with $0 deductibles than the median and highest PDPs in 2008, and the lowest ranked PDPs had significantly fewer PDPs with $0 deductibles than the highest ranked PDPs in 2009.

Between-year comparisons of the lowest EAC PDPs showed that the 2007 EAC was significantly less than the 2008 or 2009 EAC value. Overall, the annual premium of the lowest EAC PDPs significantly decreased in 2009 compared to 2007. The annual premium of the lowest EAC PDP significantly decreased by approximately $200 between 2007 and 2008, and significantly increased by almost $100 between 2008 and 2009. The results showed a statistically significant increase in SOC of the lowest EAC PDP between 2007 and 2009. Also, significantly fewer lowest EAC PDPs offered a $0 deductible in 2008 and 2009 compared to 2007.
Some beneficiaries may be basing plan enrollment decisions on non-cost related prescription drug plan parameters such as customer service ratings, plan loyalty, or plan reputation.

Discussion

This study indicates that, when accounting for inflation, beneficiaries enrolled in the lowest cost PDP in California may not have paid more in 2009 compared to 2008. As seen in Table 2, and assuming beneficiaries are annually reevaluating PDP offerings, it is possible that Part D PDP costs for the lowest EAC PDPs peaked between 2008 and 2009 in California.

The smaller percent of PDPs with the lowest EAC having a $0 deductible (as compared to median and highest) in both 2008 and 2009 or the lack of variation between differentially ranked PDPs in offering $0 deductibles (as in 2007) show plan deductible to be a poor plan parameter to use in identifying the lowest cost PDP. Data presented in Table 2 shows evidence contrary to the notion that PDPs without a deductible would be less expensive since the highest EAC PDP was more likely to offer a $0 deductible than the lowest EAC PDP in both 2008 and 2009. Additionally, the variability in annual premium of the lowest EAC PDP between 2007 and 2009 suggests that PDP premium is also a poor surrogate when trying to predict EAC, and therefore should not serve as the sole criterion used when selecting a PDP. Benficiary reliance on either a plan’s annual deductible or monthly premium may lead to sub-optimal plan selection and avoidable out-of-pocket costs.

Based on the comparisons between the lowest, median, and highest EAC PDPs between 2007 and 2009, EAC remains the most consistent indicator of benficiary out-of-pocket costs. In the three years that were examined (Table 2), EAC was the only plan parameter that consistently showed significant differences between the lowest, median, and highest EAC PDPs. The calculated parameter SOC also depicts interesting changes between the lowest EAC PDPs of each year and between differentially ranked PDPs within each year. As seen in Table 2, SOC indicates that benficiaries, even if enrolled in the lowest cost PDP each year, may be paying a higher percentage of total drug costs between 2007 and 2009. While not surprising, this trend does beg the question as to whether or not the PDPs offered through Part D are maintaining the same cost-sharing benefit structure from year to year.

Essentially, a SOC equal to 100% would indicate that the patient’s out-of-pocket costs if enrolled in that specific PDP would be equivalent to not having prescription drug insurance and paying cash prices for all of their prescription medications. A value less than 100% would indicate that the patient would be paying less than the full cash price for their prescription medications, while a value greater than 100% indicates that the PDP EAC exceeds the cash prices of the beneficiary’s prescription medications. The latter situation may arise if a beneficiary with inexpensive medications enrolls in a PDP with a large monthly premium and/or co-pays relative to the actual price of the medications. For example, if a patient only has one generic medication with a retail cost of $5 per month and enrolls in a plan with a $100 monthly premium and $0 deductible and copays for this medication, the SOC would be 2000% ($1200 annual premium divided by annual drug cost of $60). While this example is extreme, patient perspectives of anticipated coverage needs may influence enrollment into plans offering $0 deductibles and higher cost premiums leading to higher drug expenditures.

The discrepancy in cost-sharing is further emphasized when considering the significant increase in SOC between the lowest and highest ranked PDPs in each year. Clearly, beneficiaries choosing PDPs that are not the lowest EAC PDP will pay a larger percent of their drug costs. Surprisingly, beneficiaries may pay one and one-half to two times more for their medications under the highest EAC PDP than they would if they were without prescription drug insurance and paid cash for all of their prescription medications. For instance, a beneficiary enrolled in the highest EAC PDP in 2009, would pay on average 118% more out-of-pocket than they would if they were without prescription drug insurance altogether and paid cash for their prescription medications. Furthermore, beneficiaries enrolled in the median EAC PDP in 2009 would have roughly equivalent out-of-pocket costs if they were without prescription drug coverage and paid cash prices for their prescription medications. The gradual increase in SOC may serve as the harbinger that enrolling in the lowest EAC PDP may become even more important in subsequent years if a beneficiary hopes to minimize out-of-pocket costs.

Based on present findings coupled with previous research, the necessity for annual reexamination of PDP offerings remains essential to minimize Medicare beneficiary out-of-pocket costs.12,13 Study findings reveal that beneficiaries desiring to minimize out-of-pocket prescription drug costs must base PDP enrollment decisions on EAC over specific plan parameters such as monthly premiums or annual deductibles. However, some beneficiaries may be basing plan enrollment decisions on non-cost related PDP parameters such as customer service ratings, plan loyalty, or plan reputation. Considering that fewer than 10% of Part D beneficiaries were enrolled in the lowest EAC PDP in the first year of the Part D benefit, non-cost parameters may play an important role when enrollment decisions are made.14 Beneficiaries having difficulty affording their prescription drug costs, or those simply desiring lower out-of-pocket costs, must annually evaluate PDP offerings based on EAC.

In light of the fact that pharmacists are the most accessible health care professional and likely have the most experience in dealing with the Part D benefit, it is vital for pharmacists to educate beneficiaries about the importance of annual reexamination of PDP offerings. If provided by trained pharmacists, Medicare Part D plan assistance may result in significant reductions in beneficiary out-of-pocket spending, and perhaps serve as the foundation for future discussions pertaining to reimbursement for provision of such cognitive services.
Acknowledgements

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References


www.cpha.com
Abstract

In order to demonstrate the value of an MTMS program, data need to be collated across patients, and over time, to provide a detailed description of the MTMS patient population, specific MTM actions performed, and the outcomes of the MTMS. The objective of this paper is to outline methods that can be used to describe an MTMS program and its outcomes, including a case example.

At a minimum, pharmacists should be able to describe the age, gender, and disease states of the MTMS population. Other useful descriptors include the number of medications per patient, the medication adherence level (self-reported and/or revealed via medication refill history), and indications of problematic treatment regimens. The actions taken by a pharmacist will depend on the scope of MTMS practice and the existence of any collaborative practice agreement with physicians. Regardless of the scope of
MTMS activities, describing the actions taken by pharmacists providing MTMS requires documentation in the patient record in an easily retrievable format.

Three types of outcomes of an MTMS program can be assessed: (1) clinical, (2) economic and (3) humanistic. The effect of an MTMS program on each of these outcomes is important to describe and document. A case study is presented with discussion of the implications of the MTMS program results.

Introduction

Medication Therapy Management Services (MTMS) are patient specific interventions aimed to improve response to medications and avoid potential drug-related complications. The provision of MTMS has been mandated for high risk Medicare Part D enrollees (e.g. with multiple chronic conditions, multiple medications and high drug costs) and has begun to expand to commercially insured populations as well. However, the types of medication therapy problems identified will vary based on the demographics and needs of the patient population, the expertise of the pharmacists, and available resources. At a minimum, pharmacists should be able to describe the age, gender, and disease states of the MTMS population. Other useful descriptors include the number of medications per patient, the medication adherence level (self-reported and/or revealed via medication refill history), and indications of problematic treatment regimens. A simple adherence tool that a patient can complete very quickly is an eight-item Morisky Medication Adherence Scale (MMAS). This scale yields a score that indicates the patient has a low, medium or high level of adherence with their medication regimen. For example, in diabetes patients the level of adherence has been shown to correlate with clinical outcomes such as degree of glycemic control as evidence by hemoglobin A1c (HbA1c). The Pharmacy Quality Alliance (PQA) has endorsed a set of measures that can be assessed via prescription records. The set includes measures indicative of adherence for common chronic therapies (proportion of days covered and gaps in therapy), as well as measures of sub-optimal or high-risk treatment regimens.

Description of the MTMS Patient Population

An MTMS program will usually target certain groups of patients with chronic conditions who have complicated medication regimens. The specific type of patients targeted will vary based on the demographics and needs of the patient population, the expertise of the pharmacists, and available resources. At a minimum, pharmacists should be able to describe the age, gender, and disease states of the MTMS population. Other useful descriptors include the number of medications per patient, the medication adherence level (self-reported and/or revealed via medication refill history), and indications of problematic treatment regimens. A simple adherence tool that a patient can complete very quickly is an eight-item Morisky Medication Adherence Scale (MMAS). This scale yields a score that indicates the patient has a low, medium or high level of adherence with their medication regimen. For example, in diabetes patients the level of adherence has been shown to correlate with clinical outcomes such as degree of glycemic control as evidence by hemoglobin A1c (HbA1c). The Pharmacy Quality Alliance (PQA) has endorsed a set of measures that can be assessed via prescription records. The set includes measures indicative of adherence for common chronic therapies (proportion of days covered and gaps in therapy), as well as measures of sub-optimal or high-risk treatment regimens.

Describing MTMS Patient Population

1. Age, gender, race/ethnicity, disease(s)
2. Number of medications per patient
3. Adherence (self reported and/or medication refill history)
4. Overdosing and suboptimal treatment
5. Use of high-risk medications

Describing MTMS Actions

1. Number of patients with a drug therapy problem identified
2. Type of drug therapy problems identified
   a. Unnecessary drug therapy
   b. Need for additional therapy
   c. Drug dose too low
   d. Non-adherence to therapy
   e. Adverse drug reaction
3. Number of patients with a medication change recommended/changed
4. Type of change recommended/changed
   a. Added medication
   b. Increased dose
   c. Decreased dose
   d. Changed medication
   e. Discontinued medication
5. Laboratory tests reviewed, performed, recommended, ordered
6. MTMS billing codes- time with patient and preparation and follow-up time
   a. New Patient
      Initial 15 mins. (99605)
      Additional 15 mins. (99607)
   b. Established Patient
      Initial 15 mins. (99606)
      Additional 15 mins. (99607)
   c. Phone Visit
      5-10 mins. (98966)
      11-20 mins. (98967)
      21-30 mins. (98968)

Using SOAP notes (Subjective findings, Objective findings, Assessment and creating a clinical care Plan) is a common method for documenting patient care services. However, this is only the first step in describing the value of an MTMS program. To demonstrate the value of an MTMS program, data need to be collated across patients, and over time, to provide a detailed description of the MTMS patient population, specific MTM actions performed, and the outcomes of the MTMS.

The objective of this paper is to outline methods that can be used to describe a MTMS program and its outcomes, including a case example.
Describing Outcomes of MTMS

1. Clinical
   a. Patient at target goal? (patient reported or pharmacist assessed, e.g. BP, BMI)
   b. Patient change since last visit (if ongoing) (Worsened, No change, Improved)

2. Economic
   a. Cost impact of medication recommendations/changes
      i. Savings (e.g. generic, therapeutic substitution or formulary optimization)
      ii. Addition (e.g. add-on drug therapy)
   b. Resources likely avoided due to MTMS (e.g. MD visit)
   c. Impact on patient work or activity due to MTMS (e.g. able to return to work, able to work more hours)
   d. Revenue generated via MTMS billing and reimbursement.
   e. Return on MTMS Investment (ROI)

3. Humanistic
   a. Patient satisfaction (e.g. with MTMS, pharmacy overall)
   b. Patient Quality of Life

For example, although a pharmacist may have identified that a patient experienced a drug therapy problem (e.g. need for additional therapy), the notation in the notes may not be explicit and only implied in the assessment and plan. To illustrate, the pharmacist may have recorded a dosage adjustment of a medication along with patient education provided but these actions may not be readily retrievable in a medical record or clearly specified. Rather than relying on a retrospective interpretation at a later date, reporting specific details at the time of the encounter is crucial. While, providing appropriate and accurate MTMS is important for patient care, documenting the actions and outcomes is essential to provide evidence that the service was performed. Using the SOAP note format, as described above, will help keep the note content organized and easy to access when future chart note evaluation is necessary. A set checklist of potential clinical interventions allows the pharmacist to quickly and efficiently document MTMS activities. These interventions are then easily identifiable and quantified for future documentation or justification of services. Check boxes indicating that the pharmacist identified a drug therapy problem(s) (yes or no), the type of problem identified, and the action(s) recommended or taken to resolve the problem allow for easy summary over many patients. Actions taken may not always just involve medications. Assessment of laboratory testing results (or ordering and reviewing under a collaborative practice agreement) is an action requiring pharmacist time and expertise to make informed MTMS decisions and should be documented. A final step is to document the level of MTMS billing appropriate for the patient encounter. This is important even if reimbursement for MTMS does not occur because it serves to describe and provide a value for the encounter in current billing terms (refer to documenting the economic outcomes of MTMS section below).

Describing the Outcomes of an MTMS Program

Similar to documenting MTMS actions, describing outcomes of a specific program will depend on the program scope and patient population. However, regardless of the disease state(s) managed, there are three types of outcomes that can be assessed: (1) clinical, (2) economic and (3) humanistic. The effect of an MTMS program on each of these outcomes is important to describe and document. Clinical outcomes describe the effect of MTMS on a specific disease state, while economic and humanistic outcomes capture associated resource utilization and the patient’s perception of the clinical outcomes achieved and the MTMS program, respectively. Again, accurate and consistent documentation of these specific outcomes in the patient record in an easily retrievable format facilitates future reporting.

Most community pharmacists do not have access to the patient’s medical record kept at the patient’s medical provider(s)’ office(s). Thus clinical outcomes are usually limited to those that can be observed by the pharmacist or self-reported by the patient. Physical assessments (e.g. Blood Pressure (BP) and point of care testing (e.g. HbA1c, cholesterol panel) provide specific, objective values (e.g. BP 140/90 mmHg, HbA1c 10.0%, LDL 124 mg/dL, TG 280 mg/dL, HDL 35 mg/dL) that should be recorded in the patient’s record. The addition of a simple check box indicating if the value meets a goal (per evidenced based guidelines or patient or facility specific targets) allows for quantifying the number of patients achieving goals before or after the MTMS program. Another useful assessment may be whether or not the patient’s condition has worsened, improved or has not changed since the last MTMS visit with the pharmacist.

Economic outcomes are usually not specifically recorded in the patient record and thus require other data sources or the pharmacist’s estimate. Economic outcomes can represent fiscal savings that occur, revenue generated, or costs incurred due to MTMS. The economic impact of medication recommendations (or changes) may reduce costs (e.g. use of generic drugs, therapeutic substitution or formulary use optimization) or produce additional costs (e.g. add-on drug therapy) that are usually easily quantified using pharmacy cost data. However, there may be non-medication costs that are either avoided (e.g. an MD or ER visit is avoided due to a drug therapy problem being identified and resolved by the pharmacist) or added (laboratory testing to monitor a new medication) that are not as easily determined nor valued in monetary terms. Having the pharmacist estimate the type of resource that may have been avoided due to an MTMS intervention is an acceptable method of estimating saved resources in a practice setting. A monetary dollar value for that resource (e.g. from a government source such as Centers for Medicare and Medicaid Services; http://www.cms.gov/ FeeScheduleGenInfo) can then be applied to express the savings in terms of a dollar value. The impact of MTMS on the patient may also result in fewer work days or hours lost due to the patient’s improved clinical status. Estimating this economic impact is most useful for disease states that are clearly causing lost work time that can easily be self-reported by the patient; for example migraine headaches. However, while there are validated questionnaires to assess changes in work productivity, such as the Work Productivity and Activity Impairment (WPAI) questionnaire, the results should always be viewed as estimates. Finally the medical cost savings generated from MTMS can be estimated and balanced against the economic outcomes of MTMS section below.
investment in pharmacist time and other resources used to provide MTMS to express a monetary return on investment (ROI). However, it is important to recognize there may be non-monetary benefits of providing MTMS in a community pharmacy, such as improved patient satisfaction and enhancement of patient quality of life. These benefits would be classified as humanistic outcomes and must be reported directly by the patient. As with work productivity, there are validated questionnaires to assess both patient satisfaction and quality of life. The Pharmaceutical Care Satisfaction Questionnaire (PSQ) assesses general satisfaction with pharmacy services.7 A general quality of life questionnaire that can be used with patients with any disease state is the Short Form-36 (SF-36).10 The results can be compared between before and after MTMS, between patients with different diseases, and to published norms for the general population. Although not patient outcomes, the effect of providing MTMS on the overall image of the pharmacy, increase in traffic volume for OTC or ancillary purchases and pharmacist job satisfaction may also be important to consider. The case study below provides an example MTMS assessment and report.

Case Study: Medication Therapy Management Services (MTMS) and Outcomes: Satterhall Technologies

Springdale Pharmacy has a contract with Satterhall Technologies to provide MTMS to patients with type 1 and type 2 diabetes (employees or their dependents). Satterhall is a local company with 5,000 employees and approximately 12,000 covered lives. To qualify for the program, a patient must have a diagnosis of diabetes, be taking at least one anti-diabetic medication, and have a HbA1c of > 9%. The pharmacists (two, both residency trained, one also as certified diabetes educator) at Springdale Pharmacy have offered the MTMS program for the past six months and have collected the types of data they believed were most feasible to collect within their MTM workflow and that would be most useful in demonstrating the value of their MTMS program. Data were compiled from multiple sources [e.g. prescription entry system (medications), patient questionnaires and self-report (e.g. adherence, satisfaction, OTC medications, HbA1c, blood glucose)] into an Excel spreadsheet. Descriptive statistics (means, standard deviations, and proportions) were used to summarize the data. They have completed interim data analysis to evaluate their program effectiveness thus far and their summary report is presented below. Note: all data presented are hypothetical but are based on unpublished data from the operation and outcomes achieved in actual pharmacist provided MTMS clinics between May 2010 – October 2010.

Description of Springdale Pharmacy MTMS program

The MTMS program consists of an initial one hour face-to-face meeting with the pharmacist followed by a follow-up visit in three months, with phone calls as needed. The focus of the initial visit includes assessment of diabetes-related medications (although all medications are reviewed including over the counter), adherence, most recent HbA1c (patients instructed to obtain from their physician and bring to initial visit), patterns of recent blood glucose monitoring, blood pressure, weight, height, and other diabetes-related conditions. Patient education regarding diet, exercise and self-monitoring blood glucose is also included as needed.

Summary of Results

The patients in the MTMS program are generally older and overweight, with HbA1C’s ranging from 9 to 13.8 (Table 1).

<table>
<thead>
<tr>
<th>Table 1: MTMS Population (based on initial visit) (n=120)</th>
<th>Mean (SD) range unless otherwise noted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male % (n)</td>
<td>51.7% (62)</td>
</tr>
<tr>
<td>Age</td>
<td>65.7 (10.8) 40 – 88</td>
</tr>
<tr>
<td>Number of Medications % (n)</td>
<td></td>
</tr>
<tr>
<td>4 or less</td>
<td>25.0% (30)</td>
</tr>
<tr>
<td>5 to 9</td>
<td>54.2% (65)</td>
</tr>
<tr>
<td>10 or greater</td>
<td>20.8% (25)</td>
</tr>
<tr>
<td>Range</td>
<td>2 - 21</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>11.1 (1.6) 9 – 13.8</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>33.5 (6.9) 22.5-50.6</td>
</tr>
<tr>
<td>BP: systolic (mmHg)</td>
<td>138 (18) 105 - 175</td>
</tr>
<tr>
<td>BP: diastolic (mmHg)</td>
<td>78 (13) 45 - 102</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2: MTMS Actions at Initial Visit (n=120)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with a drug therapy problem identified % (n)</td>
<td>42.5% (51)</td>
<td></td>
</tr>
<tr>
<td>Type of drug therapy problem % (n) of patients with problem</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unnecessary drug therapy</td>
<td>33.3% (17)</td>
<td></td>
</tr>
<tr>
<td>Need for additional therapy</td>
<td>27.5% (14)</td>
<td></td>
</tr>
<tr>
<td>Drug dose too low</td>
<td>17.6% (9)</td>
<td></td>
</tr>
<tr>
<td>Non-adherence to therapy</td>
<td>15.7% (8)</td>
<td></td>
</tr>
<tr>
<td>Adverse drug reaction</td>
<td>5.9% (3)</td>
<td></td>
</tr>
<tr>
<td>Patients with a medication change recommended % (n)</td>
<td>34.2% (41)</td>
<td></td>
</tr>
<tr>
<td>Type of change recommended % (n) of patients with change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Added Medication</td>
<td>43.9% (18)</td>
<td></td>
</tr>
<tr>
<td>Increased Dose</td>
<td>36.6% (15)</td>
<td></td>
</tr>
<tr>
<td>Decreased Dose</td>
<td>12.2% (5)</td>
<td></td>
</tr>
<tr>
<td>Changed Medication</td>
<td>7.3% (3)</td>
<td></td>
</tr>
</tbody>
</table>

A single patient may have more than one drug therapy problem.
The results of the MTMS program for the initial 75 patients with at least one 3 month follow-up visit are encouraging with 45% reporting a 1.1-2% improvement in HbA1c and 75% reporting they were very or extremely satisfied with the MTMS program.

Table 3: MTMS Encounter Billing Summary (May 2010 – October 2010)

<table>
<thead>
<tr>
<th>MTMS billing codes</th>
<th>Initial Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
</tr>
<tr>
<td>New Patient</td>
<td></td>
</tr>
<tr>
<td>Initial 15 mins. (99605)</td>
<td>120</td>
</tr>
<tr>
<td>Additional 15 mins. (99607)</td>
<td>285</td>
</tr>
<tr>
<td>Established Patient (3 month visit)</td>
<td></td>
</tr>
<tr>
<td>Initial 15 mins. (99606)</td>
<td>75</td>
</tr>
<tr>
<td>Additional 15 mins. (99607)</td>
<td>85</td>
</tr>
<tr>
<td>Phone Visit (after initial visit)</td>
<td></td>
</tr>
<tr>
<td>5-10 mins (98966)</td>
<td>20</td>
</tr>
<tr>
<td>11-20 mins (98967)</td>
<td>13</td>
</tr>
<tr>
<td>21-30 mins (98968)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>598</td>
</tr>
</tbody>
</table>

(Contracted rates: Face to Face visits ($45/15 minutes), Phone visits ($30/10 minutes)

Figure 1: Self-reported Adherence (at initial visit) n=120

Figure 2: Outcomes – Patients with HbA1c Change (3 months vs. initial visit) n=75

Figure 3: Patient Satisfaction with MTMS at 3 Months n=72

The majority (75%) of patients are on five or more medications. The pharmacists have identified at least one drug therapy problem for almost half (42.5%) of the patients with “unnecessary drug therapy” and “need for additional therapy” being the most common (Table 2). Approximately two-thirds of patients report low to medium adherence levels with their medications (Figure 1). The results of the MTMS program for the initial 75 patients with at least one three month follow-up visit are encouraging with 58% reporting a 1.0-3.0% improvement in HbA1c and 75% reporting they were very or extremely satisfied with the MTMS program (Figures 2 and 3). Medical cost savings due to improved HbA1c levels were estimated at approximately $36,000; a return of $2.20 per every $1 invested.

Having these data allowed Springdale Pharmacy to clearly, and succinctly, communicate the value of its MTMS program to Satterhall Technologies in terms of clinical outcomes achieved and medical costs saved. In addition, data regarding the time spent with each patient (from the MTMS Encounter Billing Summary and tracking of pharmacist preparation and follow-up time) allowed Springdale Pharmacy to more accurately plan for pharmacist staffing that may be needed for future MTMS clients.

Number of Patients Receiving MTMS: 120 patients initial visit, 75 patients with at least one 3 month follow-up visit

Conclusion
Developing and providing an MTMS program in a community pharmacy requires significant time, resources and effort. However, without adequate documentation the value of the program may be very difficult to describe to patients or payers. Once a documentation system is developed it is then relatively simple to record data for each patient and then summarize using simple spreadsheet software. Consistently using a documentation and data collection system is essential to collect data across patients and time, to allow for detailed description of the MTM actions performed and ultimately the outcomes achieved.

About the Authors
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In Health Shift, More Patients Get Pharmacist’s Appointment. nytimes.com/2010/08/14/health/14pharmacist.html

Table 4: Estimated Return on MTMS Investment (ROI)

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical Cost Saving</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>per HbA1c decline</td>
<td>4</td>
<td>$0</td>
</tr>
<tr>
<td>0-0.9%</td>
<td>27</td>
<td>$0</td>
</tr>
<tr>
<td>1% or greater</td>
<td>44</td>
<td>$35,948</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>75</td>
<td>$35,948</td>
</tr>
<tr>
<td><strong>Investment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist Time: MTMS Provision</td>
<td>147 hours (8805 minutes)</td>
<td>$10,584</td>
</tr>
<tr>
<td>Pharmacist Time: MTMS Preparation and Follow-up</td>
<td>33 hours (1950 minutes)</td>
<td>$2,376</td>
</tr>
<tr>
<td>MTM Patients Education Supplies</td>
<td>300 brochures</td>
<td>$300</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td>$12,960</td>
</tr>
<tr>
<td><strong>NET (Medical Cost Savings -Investment)</strong></td>
<td></td>
<td>$22,988</td>
</tr>
<tr>
<td>Return on Investment (ROI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Cost Savings/Investment</td>
<td>$2.9 per $ invested</td>
<td></td>
</tr>
</tbody>
</table>

References
1. In Health Shift, More Patients Get Pharmacist’s Appointment. nytimes.com/2010/08/14/health/14pharmacist.html


www.cpha.com
Abstract

Innovative pharmacologic therapies (e.g., biologics) have provided novel, disease modifying agents to treat diseases such as rheumatoid arthritis and psoriasis. However, the high costs of these innovations have burdened an already burgeoning health care system that is threatened by an inability to afford such benefits.

Potential strategies for addressing these issues include the use of payment-for-performance methods, co-insurance, and the facilitation of regulatory processes for biosimilar approvals; however, their effectiveness and application remain untested. Biosimilar or follow-on-biologics may offer some relief to the rising cost of biologics, but implementation and an uncertain competitive market provide challenges to the generic biologics manufacturers.
economics application to decision making is encouraged, but the elimination of quality-adjusted life years as a metric of cost-effectiveness will limit its use in decision making. Unless a consensus can be reached on how to efficiently apply pharmacoeconomics into reimbursement strategies or decision making, health care plans will continue to experience increased costs associated with biologics.

Introduction

Biotechnology drugs (i.e., biologics) are pharmaceuticals that are derived or generated from living organisms (e.g., bacteria, fungus, animals, and humans).1 They are large complex molecules made via recombinant deoxyribonucleic acid technology that are designed to repair, stimulate, or enhance the immune response with great specificity. Monoclonal antibodies, for example, can mark cancer cells and make them more visible to the immune system. They can also block growth-factor receptors and inhibit the growth of new cancer cells. Other biologics include interferons that allow communication between cells to trigger the immune system to regulate inflammatory and immune responses. The advent of biologics has provided novel therapies for chronic conditions such as multiple sclerosis, psoriasis, rheumatoid arthritis, and inflammatory bowel diseases that are difficult to control and treat with conventional agents. For example, the use of biologics (e.g., tumor-necrosis factors inhibitors and selective T-cell co-stimulation modulators) for rheumatoid arthritis have provided effective disease control and symptom improvement that have not been seen with conventional disease-modifying antirheumatic drugs.2 Moreover, biologics also improve patient’s quality-of-life and provide relief for debilitating diseases.3,4 The benefits of biologics are compelling reasons for making these medications available to patients.

However, the prices of these agents, and hence, their benefits, are costly and add additional burden to an already burgeoning health care system. Due to the safety profiles of biologic agents coming to market, many have U.S. Food and Drug Administration (FDA) required Risk Evaluation and Mitigation Strategies (REMS). Several REMS include programs that require additional health care resources that, although not measured, may add to the overall cost to the health care system. The average annual price of biologics per patient can range from $514 (for short-course low-molecular weight heparin) to $494,000 (for imiglucerase used in Gaucher’s disease) (Table 1).6 In 2008, 16% of the U.S. pharmaceutical spending was on biologics (over $45 billion) which is estimated to increase rapidly in the future.7 From a pharmaceutical company’s perspective, the cost of bringing a new biologic into the market is approximately $1.2 billion (U.S. dollars).2 Pharmaceutical companies that invest heavily in this area are likely interested in not only serving society, but also in advancing technology while capitalizing on the economic profit for this advancement. Despite an expensive drug approval process, the windfall profits that come with biologics have allowed many pharmaceutical companies to recoup that up-front investment within a single year based on U.S. sales alone.8 However, the question should not focus on whether innovation should be rewarded; rather, the focus should be on how much should such innovation be rewarded? Secondly, at what point do some medications become so expensive that they cease being beneficial for society on the whole? The importance of balancing new innovation with cost-effectiveness is critical in how these agents affect society’s ability to afford these high cost biologics.

Balancing spending with increased benefits is a challenging problem. Currently, there are three regulatory hurdles that pharmaceutical companies must achieve for medicine approval by the FDA which include efficacy, safety, and quality. Most industrialized countries (e.g., most of Europe, Australia, Canada, New Zealand, and South Korea) have already begun to address the issue by requiring pharmaceutical companies to provide cost-effectiveness analyses before regulatory approval is granted, otherwise known as the “fourth hurdle.”9,10 However, the U.S. FDA does not require demonstration of cost-effectiveness in order to receive regulatory approval. This, among many other factors, is a prime example as to why U.S. health care expenditures far outpace the rest of the world. According to data from the Organization for Economic Cooperation and Development (OECD) in 2007, the U.S. ranked first among 35 OECD countries in health care spending per capita ($7,285), percent of GDP spent on health care (15.7%), and pharmaceutical spending per capita ($876).11 Conversely, the U.S. ranked 28 out of 35 OECD countries who reported life expectancy at birth (a common measure of mortality). Based on this data, one may conclude that the U.S. investment in health care has been spent irrationally and unwisely with little benefit or return in positive health outcomes.12 Strategies to defray health care costs are needed in order to invest our resources more cost-effectively. As more of these agents receive FDA approvals their inevitable use in clinical practice will test the health care system’s ability to pay for them.

Potential Strategies to Address the Rising Costs of Biologics

These problems highlight the importance and urgency to develop strategies to contain the cost of health care while balancing achievable health outcomes. Several strategies have been presented to address the high costs of these agents. Payment-by-results is a strategy that is dependent on the performance of the drug therapy.14 This strategy is analogous to a warranty that guarantees the performance of a product. In reference to medicine, pharmaceutical companies can provide warranties on their medication’s performance. The health care plan that purchases the medication will be reimbursed for the full amount of medication used if the patient does not achieve a predefined outcome. These outcomes must be agreed upon by the pharmaceutical company and health care plan and the performance measure must be “predictable, reliable, and difficult to manipulate.”15 This novel approach offers security for the health care plan by guaranteeing a medication’s performance, and it also allows providers to have more freedom to offer medications to patients who will likely respond to therapy. While payment-by-results may provide a novel solution to
### Table 1. List of biologics with their indications, dose, and costs (not all inclusive)

<table>
<thead>
<tr>
<th>Medication, generic (Brand)</th>
<th>FDA Approved indication(s)</th>
<th>Available doses</th>
<th>Annual cost*</th>
</tr>
</thead>
<tbody>
<tr>
<td>abatacept (Orencia)</td>
<td>Rheumatoid arthritis</td>
<td>250mg/15mL</td>
<td>$32,789</td>
</tr>
<tr>
<td>adalimumab (Humira)</td>
<td>Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis</td>
<td>40mg/0.8mL x 2 pens</td>
<td>$24,939</td>
</tr>
<tr>
<td>aldesleukin (Proleukin)</td>
<td>Metastatic melanoma, metastatic renal cell carcinoma</td>
<td>22 million IU/1.2 mL</td>
<td>$34,955</td>
</tr>
<tr>
<td>alemtuzumab (Campath)</td>
<td>B-cell chronic lymphocytic leukemia</td>
<td>30mg/mL</td>
<td>$6,354</td>
</tr>
<tr>
<td>anakinra (Kineret)</td>
<td>Rheumatoid arthritis</td>
<td>100mg/0.67mL</td>
<td>$24,893</td>
</tr>
<tr>
<td>darbepoetin alfa (Aranesp)</td>
<td>Anemia due to chemotherapy (weekly dosing)</td>
<td>200mcg/mL</td>
<td>$1,287</td>
</tr>
<tr>
<td>bevacizumab (Avastin)</td>
<td>Metastatic breast cancer, metastatic renal cell carcinoma</td>
<td>100mg/4mL</td>
<td>$5,480</td>
</tr>
<tr>
<td>certolizumab (Gimzia)</td>
<td>Rheumatoid arthritis</td>
<td>200mg</td>
<td>$2,791</td>
</tr>
<tr>
<td>cetuximab (Erbitux)</td>
<td>Head and neck cancer</td>
<td>2mg/mL</td>
<td>$1,980</td>
</tr>
<tr>
<td>dalteparin (Fragmin)</td>
<td>Deep vein thrombosis (DVT) prophylaxis</td>
<td>5000 IU/mL</td>
<td>$514</td>
</tr>
<tr>
<td>dalteparin (Fragmin)</td>
<td>Acute coronary syndrome (ACS), associated with unstable angina or non-Q-wave myocardial infarction - Myocardial ischemia</td>
<td>10,000IU/mL</td>
<td>$9,611</td>
</tr>
<tr>
<td>dalteparin (Fragmin)</td>
<td>Venous thromboembolism (VTE) due to cancer</td>
<td>12,500 IU/0.5mL</td>
<td>$15,411</td>
</tr>
<tr>
<td>denosumab (Prolia)</td>
<td>Postmenopausal osteoporosis</td>
<td>60mg/1mL</td>
<td>$1,980</td>
</tr>
<tr>
<td>enoxaparin (Lovenox)</td>
<td>Inpatient/outpatient treatment of acute DVT with or without pulmonary embolism</td>
<td>80mg/0.8mL</td>
<td>$2,457</td>
</tr>
<tr>
<td>enoxaparin (Lovenox)</td>
<td>Inpatient treatment of acute DVT with or without pulmonary embolism</td>
<td>120mg/0.8mL</td>
<td>$1,843</td>
</tr>
<tr>
<td>epoetin alfa (Epogen)</td>
<td>Anemia due to chemotherapy (once weekly dosing)</td>
<td>40,000 units</td>
<td>$727</td>
</tr>
<tr>
<td>erlotinib (Tarceva)</td>
<td>Non-small cell lung cancer</td>
<td>150mg</td>
<td>$1,148</td>
</tr>
<tr>
<td>etanercept (Enbrel)</td>
<td>Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis (moderate to severe)</td>
<td>50mg/mL</td>
<td>$26,660</td>
</tr>
<tr>
<td>filgrastim (Neupogen)</td>
<td>AIDS-induced neutropenia, febrile neutropenia, chronic neutropenic disorder (severe)</td>
<td>480mcg/0.8mL</td>
<td>$961</td>
</tr>
<tr>
<td>glatiramer (Copaxone)</td>
<td>Relapsing remitting multiple sclerosis</td>
<td>20mg</td>
<td>$40,657</td>
</tr>
<tr>
<td>golimumab (Simponi)</td>
<td>Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis</td>
<td>50mg/0.5mL</td>
<td>$27,011</td>
</tr>
<tr>
<td>imiglucerase (Cerezyme)</td>
<td>Gaucher's disease</td>
<td>200 U/vial</td>
<td>$494,832</td>
</tr>
<tr>
<td>infliximab (Remicade)</td>
<td>Rheumatoid arthritis</td>
<td>100mg/20mL</td>
<td>$41,051</td>
</tr>
<tr>
<td>interferon alfa-2b (Intron A)</td>
<td>Malignant melanoma</td>
<td>5 million IU/0.2mL</td>
<td>$63,078</td>
</tr>
<tr>
<td>interferon alfa-2b (Intron A)</td>
<td>Chronic hepatitis B</td>
<td>5 million IU/0.2mL</td>
<td>$36,795</td>
</tr>
</tbody>
</table>
the problem of increased biologic costs, it also comes with some challenges. Frequency of measurement, disease progression, how the criteria are interpreted, and lack of incentive for pharmaceutical manufacturers are potential barriers for its adoption. To this point, the practice has not been widely adopted and its application is dependent on contracting agreements between health plans and pharmaceutical companies. Regardless, some institutions may benefit from this strategy if the above problems can be resolved.

Co-insurance or the fourth tier co-payment system is a strategy that requires patients to pay for a part of the cost of their medications. Co-payments were developed to make patients cost-conscious, as well as contribute to the total cost of their health care. Despite paying co-payments for generic and brand prescriptions, some patients are still cost-ignorant when it comes to therapies like biologics. The proposed co-insurance system requires patients to pay a certain percentage of the total drug cost. For example, if a monthly prescription for adalimumab (Humira®) costs the health care plan $2,000 per month, the patient may be required to pay 20% or $400 per month. This would not only increase the co-payment, but requires the patient to significantly contribute financially to their therapy by paying approximately 20 to 33% of the total drug cost. While this strategy would achieve the goal of increased cost-awareness and help eliminate some of the cost burden shouldered by the health care plan, it does nothing to assist patients out-of-pocket costs. In fact, it would mean that patients would need to spend more in order to achieve a benefit, which will vary from individual to individual based on their willingness-to-pay.

Traditional co-payment systems based on formulary tiers are another tool used by Pharmacy Benefits Management (PBM) to control costs. Just as a health plan may prefer one statin agent over another due to contracted pricing, certain biologics can be similarly preferred. The circumstance where costs may escalate exponentially occurs when a novel drug is approved for a clinical area with limited therapeutic options. With no other competition to force prices down, the drug price for the novel agent can be substantially high. For example, sipuleucel T (Provenge®), the first approved cancer vaccine to treat prostate cancer, is estimated to cost approximately $93,000 per patient. This is due in large part to a lack of similar competitors.

Another strategy includes introducing a quick and reliable regulatory pathway that permits generic biologics to enter the market, similar to the Drug Price Competition and Patent Term Restoration Act of 1984 (otherwise known as the Waxman-Hatch Act). The availability of generic biologics may provide cheaper alternatives to costly brand biologics. However, the length of patent protection for the brand and the lack of clear definition of a generic biologic create barriers for potential

*Drug prices were based on the AWP costs from the Drug Red Book. Medications without AWP were estimated based on the market value of their comparators. Annual cost does not reflect induction therapy. For biologics that required weight-based dosing, an 80 kg patient was assumed. Body surface area was calculated using the DuBois & DuBois formula: 0.20247 x height (m)^0.725 x weight (kg)^0.425 where height was assumed to be 68 inches.
When a biologic is approved, payers are often faced with the difficult task of determining how to efficiently spend health care dollars on these agents.

generic drug manufacturers that want to enter the market. As more than half of the top 20 biologics have either lost or will lose patent protection by 2012, approving and defining generic biologics are pressing issues that affect pharmaceutical companies (generic and brand), health care payers, and patients.\textsuperscript{15} The Waxman-Hatch Act provided a regulatory pathway for small molecule generic drugs to be approved. A major limitation of the Waxman-Hatch Act has been its oversight to include biologics which originated from the lack of a clear definition for generic biologics. On March 15, 2010, the U.S. House of Representatives passed the Biologics Price Competition and Innovation Act of 2009 (HR 3590; Title VII, Subtitle A, Sec 7002, “Approval pathway for biosimilar biological products”), a legislation that calls for a 12-year market exclusivity on biologic agents after their approval.\textsuperscript{16} It is also the first regulatory pathway for small molecule generics to be developed and adopted by the U.S. government.

Unlike small molecule generics, the precise definition of a generic biologic is difficult to determine. Even since the first biologic was created (e.g., insulin), the debate on what is considered a generic biologic is still unclear.\textsuperscript{14} Biosimilars or follow-on biologics (FOB) have been used interchangeably to describe potential generic biologics that may make biologics more affordable to both patients and health care plans while balancing profits for generic and brand drug manufacturers. Unlike small molecule generics which are identical molecular compounds of the brand product, biologics are often derived from living organisms and are large complex molecules that cannot be identically reproduced. Furthermore, the manufacturing of biologics involves a complex process that cannot be replicated by another company and will ultimately lead to small discrepancies.

**Demonstrating a Value of Biologics Through Pharmacoeconomics and Health Outcomes**

When a biologic is approved, payers are often faced with the difficult task of determining how to efficiently spend health care dollars on these agents.\textsuperscript{16} One way to efficiently allocate health care dollars with limited resources is to determine the value of a product compared to alternatives through health technology assessment (HTA). HTA evaluates the safety, efficacy, cost-effectiveness, and ethical implications of new technology, which includes drugs, medical devices, procedures, and programs.\textsuperscript{17,18} HTA is often used interchangeably with pharmacoeconomics, and the goal of these disciplines is to simply determine the value of new products as they compare to existing or competing products. Unlike other countries where a centralized federal organization evaluates new products that come to the market, the use of HTA in the U.S. has been restricted to the private sector, leading to fragmentation, overlap, and haphazard diffusion of new technology along with wasted resources.\textsuperscript{17}

The recent Patient Protection and Affordable Care Act created a Patient-Centered Outcomes Research Institute to conduct comparative effectiveness research to develop and disseminate evidence based information about the effectiveness of treatments relative to other options.\textsuperscript{19} Although this is a first step towards HTA in the United States, the act prohibits the use of quality-adjusted life years (QALY) as a metric of health effects, and thus, hinders the efficient allocation of resources across different disease states, an issue which cannot be fully addressed in this article.\textsuperscript{20} Currently, there are few pharmacoeconomic studies on biologics in the literature, and those that exist are not definitive. As a consequence, payers and providers are required to make utilization and coverage decisions for biologics with little or no information about their actual value.\textsuperscript{19} Collective efforts efforts to assess the value of biologics are scarce, and one of the major obstacles to widespread use of economic evaluations for biologics is the low variability of their efficacy results.\textsuperscript{16} Thus, with the limited resources

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
<th>Equivalency criteria</th>
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<tbody>
<tr>
<td>1</td>
<td>The physical and chemical characteristics of enoxaparin</td>
<td>Equivalence of heparin source material and mode of depolymerization</td>
</tr>
<tr>
<td>2</td>
<td>The nature of the heparin material and the chemical process used to break up heparin chains into smaller pieces</td>
<td>Equivalence of physiochemical properties</td>
</tr>
<tr>
<td>3</td>
<td>The nature and arrangement of components that constitute enoxaparin</td>
<td>Equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species</td>
</tr>
<tr>
<td>4</td>
<td>Certain laboratory measurements of the product’s anticoagulant activity</td>
<td>Equivalence in biological and biochemical assays</td>
</tr>
<tr>
<td>5</td>
<td>Certain aspects of the drug’s effect in humans</td>
<td>Equivalence of in vivo pharmacodynamic profile</td>
</tr>
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</table>
and high costs of biologics, more economic evaluations and HTA will need to be conducted in the future.

Current and Future Work

On June 23, 2010, the FDA approved the first generic enoxaparin, an anticoagulant biologic used for prevention of deep vein thrombosis.21-23 According to the Waxman-Hatch Act, in order to be considered a generic, the manufacture needs to demonstrate that the generic drug is bioequivalent to the brand drug (in this case, Lovenox®).24 Based on these guidelines from 2003, Sanofi-Aventis, the manufacturer of Lovenox®, submitted a citizen's petition to the FDA to halt approval of all abbreviated new drug applications (ANDA) for generic versions of enoxaparin in 2003 until regulatory guidelines for the approval of generic biologics were developed. Enoxaparin is a complex mixture of oligosaccharides that is cleaved from heparin which makes it impossible to determine the exact chemical structure and size.23 Therefore, the FDA developed five criteria for determining the active ingredient equivalency taking into account the complex chemical structure of enoxaparin. These five criteria are outlined in Table 2.20 A detailed description of the FDA's decision is posted on their website.23 Unlike the European Medicines Agency (EMA) which requires clinical studies for a generic to demonstrate equivalence to the brand, the FDA does not require clinical studies if bioequivalence is established through pharmacokinetic and pharmacodynamic parameters.25 This latter regulatory process permits the quick introduction of less costly generics into the market thereby reducing the economic burden on the health care system.

During the writing of this article, the FDA announced a 2-day public hearing in November 2-3, 2010 to discuss issues and challenges to implementing the Biologics Price and Competition Act of 2009.26 In particular, the agency will discuss its plans for implementing the abbreviated regulatory pathway for generic biologics approval. Clearly, there will need to be some transparency and agreement on how generic biologics are approved and to balance access to affordable care with innovation and profits. The approval of generic enoxaparin has established some precedence on how the FDA will handle these ANDAs, but further guidelines will need to be presented in order to direct the future of generic biologics approval.

Conclusion

Ultimately, the health care system will need to provide biologic therapies to patients. Cost containment strategies such as payment-by-results, generic production, and co-insurance offer some possible solutions for reducing expenditure, but their outcomes are yet to be determined. Although
generic biologics have some preliminary regulatory pathway for approval, generic equivalents of newer biologics will not be available until 12 years post-approval due to the patent protection of the Biologics Price and Competition Act of 2009. In addition, it remains to be seen how difficult or timely the production process will be for biosimilar manufacturers. Immediate answers to the high cost of biologics will depend largely on the abilities of individual health care plans (or facilities) to negotiate the best prices with pharmaceutical companies; however, reimbursements through Medicare and increases in health care expenses (through increased deductibles) will continue to burden taxpayers and patients. HTA may be a solution to balance the cost of biologics with health outcomes, but its application has been impaired by the prohibition of QALY use in decision making. There is a great need to evaluate biologics in a cost-effective manner; however, there is no consensus in the U.S. on how to implement this idea. Unless we develop a consensus for regulating costs or FDA approval to achieve the “fourth hurdle,” we will continue to pay high prices for innovative therapy in health care—potentially until we are financially depleted.

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Unless we develop a consensus for regulating costs or FDA approval to achieve the “fourth hurdle,” we will continue to pay high prices for innovative therapy in health care.

References


Although heart disease continues to be the leading cause of death in the United States, mortality rates have declined over the last forty years, largely due to the use of medical and surgical treatments.1 Secondary preventative medical therapies that have been shown to reduce the rates of cardiovascular death and myocardial infarction include the use of dual antiplatelet therapy, namely aspirin and clopidogrel.2 The combined use of aspirin and clopidogrel is recommended following an acute coronary syndrome (ACS) event and percutaneous coronary intervention (PCI), which include angioplasty and stenting.2,3 However, recent reports suggest potential drawbacks with the use of clopidogrel, including potential drug interactions with proton pump inhibitors and genetic variations in the population that may decrease patient response to therapy. Prasugrel is a new antiplatelet agent approved by the Food and Drug Administration in 2009 to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndromes who are to be managed by PCI.5

Comparison of the pharmacology between prasugrel and clopidogrel5,6

Similar to clopidogrel, prasugrel is a thienopyridine antiplatelet agent whose active metabolite binds irreversibly to the adenosine diphosphate (ADP) receptor on platelets to inhibit platelet activation and aggregation. Both prasugrel and clopidogrel are prodrugs that require hepatic metabolism by cytochrome (CYP) P450 in order to be activated. Unlike clopidogrel that is largely metabolized into inactive metabolites and involves CYP450 enzymes in both steps of its activation, prasugrel only undergoes metabolism through CYP450 enzymes once.
Pharmacokinetics and pharmacodynamics of prasugrel compared with clopidogrel 5-10

<table>
<thead>
<tr>
<th></th>
<th>Prasugrel</th>
<th>Clopidogrel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absorption</td>
<td>≥ 79% bioavailable, unaffected by food</td>
<td>At least 50% bioavailable; unaffected by food</td>
</tr>
<tr>
<td>Metabolism</td>
<td>Converted to active metabolite in one step primarily by CYP 3A4 and 2B6, and to a lesser degree 2C9 and 2C19</td>
<td>Converted to active metabolite in two steps primarily by CYP2C19, 3A4, 2B6, 1A2</td>
</tr>
<tr>
<td>Half-life</td>
<td>Active metabolite = 7 hours (range 2-15 hours)</td>
<td>Active metabolite = 0.5 hours Parent compound = 6 hours</td>
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<tr>
<td>Time to peak inhibition of platelet aggregation</td>
<td>1 to 1.5 hours following a 60 mg loading dose</td>
<td>6 hours following a 300 mg loading dose</td>
</tr>
<tr>
<td>Mean % of steady state platelet inhibition</td>
<td>~ 60% after 5 days of 10 mg maintenance dose</td>
<td>~ 50% after 6 days of 75 mg maintenance dose</td>
</tr>
<tr>
<td>Time to steady state platelet aggregation</td>
<td>2 to 4 days following 10 mg maintenance dose</td>
<td>~ 6 days following 75 mg maintenance dose</td>
</tr>
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</table>

Clinical evidence for prasugrel TRITON-TIMI 38 11,12

<table>
<thead>
<tr>
<th>Study design</th>
<th>Randomized, double-blind, double-dummy, parallel-group phase 3 clinical trial to compare prasugrel with clopidogrel in patients with ACS with scheduled PCI</th>
</tr>
</thead>
</table>
| Study population | Inclusion criteria: patients with ACS with scheduled PCI  
- UA or NSTEMI patients: ischemic symptoms occurring within 72 hours and TIMI risk score of 3 or greater  
- STEMI patients: symptom onset within 12 hours if primary PCI was planned or within 12 hours to 14 days after medical management  
Exclusion criteria: patients at increased risk of bleeding, including a history of hemorrhagic stroke or ischemic stroke within 3 months, thrombocytopenia, anemia, NYHA functional class IV congestive heart failure, and use of thienopyridine within 5 days of PCI |
| Intervention | Prasugrel (n = 6813) – LD 60 mg PO x 1, MD 10 mg PO daily vs clopidogrel (n = 6795) – LD 300 mg PO x 1, MD 75 mg PO daily  
- STEMI (within 12 hours) or patients whose coronary anatomy was previously known: LD within 24 hours before PCI, MD given daily after PCI  
- UA, NSTEMI, or STEMI (12 hours – 14 days) patients: LD was given any time after diagnostic catheterization and within 1 hour after PCI. The coronary anatomy had to be known prior to giving the study drug in order to ensure that it was amenable to PCI. MD given daily after PCI |
| Endpoints | Primary efficacy: composite of death from CV causes, nonfatal MI or stroke  
Primary safety: major bleeding that results in a drop in hemoglobin of 5 gm/dL or greater, intracranial hemorrhage, or death |
| Main findings | Efficacy:  
- Prasugrel had a lower rate of the primary efficacy endpoint (9.9%) compared with clopidogrel (12.1%) (HR 0.81, 95% CI: 0.73-0.90, p < 0.001)  
  - ARR = 2.2%, RRR = 18%  
  - For every 45 patients treated with prasugrel instead of clopidogrel, 1 patient will avoid cardiac death, MI or stroke over ~14 months  
- The outcome was driven by a significantly lower rate of nonfatal MI in the prasugrel group (p < 0.001). The rates of CV death and nonfatal stroke were not different  
- The rate of stent thrombosis was significantly lower with prasugrel (1.1%) compared with clopidogrel (2.4%) (p < 0.001)  
Safety:  
- Non-CABG (99% of patients): experienced significantly greater major bleeding with prasugrel (2.4%) compared with clopidogrel (1.8%) (HR 1.32, 95% CI: 1.03-1.68, p = 0.03)  
- CABG (1% of patients): experienced 4 times greater bleeding with prasugrel (13.4%) compared with clopidogrel (3.2%) (HR 4.73 95% CI: 1.90-11.82, p < 0.001)  
Sub-group analysis:  
- Patients with diabetes and those with STEMI taking prasugrel had significantly lower rates of CV death, MI or stroke versus clopidogrel, with no significant increase in major bleeding in non-CABG patients  
Post-hoc analysis identified 3 subgroups with less clinical efficacy and greater risk of bleeding:  
- Patients with a previous stroke or transient ischemic attack experienced higher rates of death, MI, stroke or major bleeding when taking prasugrel compared with clopidogrel  
- Patients 75 years or older and those weighing less than 60 kg did not experience a reduction in death, MI or stroke from prasugrel |

CV = cardiovascular, ACS = acute coronary syndrome, PCI = percutaneous coronary intervention, MI = myocardial infarction, UA = unstable angina, NSTEMI = non-ST elevation MI, STEMI = ST-elevation MI, LD = loading dose, MD = maintenance dose, CABG = coronary artery bypass graft, NYHA = New York Heart Association, ARR = absolute risk reduction, RRR = relative risk reduction, NNT = number needed to treat, HR = hazard ratio
Dosage and dosage forms

- Initial one-time loading dose of 60 mg PO followed by 10 mg daily
- For patients weighing < 60 kg, a maintenance dose of 5 mg PO daily has been suggested by the manufacturer; however, the efficacy and safety of this dose has not been prospectively studied in TRITON-TIMI 38, which is currently the only major clinical trial for prasugrel.
- As with clopidogrel in dual antiplatelet therapy, prasugrel should be taken with aspirin (75 mg to 325 mg daily).
- Prasugrel 5 mg or 10 mg tablets: $190.00 (30 tablets).

Contraindications

- Active pathological bleeding
- Prior transient ischemic attack (TIA) or stroke
- Hypersensitivity to prasugrel

Precautions

- Black Boxed Warning for significant, and sometimes fatal, bleeding:
  - Prasugrel is not recommended for use in patients 75 years or older.
  - It must be used with caution in patients who weigh less than 60 kg, have a propensity to bleed (such as recent trauma or active peptic ulcer disease), and use concomitant medications such as warfarin and chronic NSAIDs.
- Prasugrel should be discontinued, if possible, 7 days prior to CABG due to an increased risk of major bleeding, as seen in TRITON-TIMI 38. This recommendation differs from clopidogrel, which should be discontinued at least 5 to 7 days prior to CABG.
- Interruption or discontinuation: as with clopidogrel, prasugrel should be discontinued for active bleeding, elective surgery, stroke, or TIA. In patients who are managed with PCI and stent placement, premature discontinuation increases the risk of stent thrombosis, MI or death. Lapses in therapy should be avoided.

Drug interactions

- Warfarin: concurrent use increases the risk of bleeding.
- Chronic use of NSAIDs: concurrent use may increase the risk of bleeding.

Adverse effects

- Major life-threatening bleeding (1.3%), epistaxis (6%), GI hemorrhage (1.5%), hemoptysis, subcutaneous hematoma, retroperitoneal and retinal hemorrhage
- Dizziness (4%), headache (5%)
- Hypertension (7.5%), hypotension (4%), bradycardia (3%), atrial fibrillation (3%)
- Nausea (4.6%), diarrhea (2%)
- Severe thrombocytopenia (0.06%), anemia (2.2%), angioedema (0.06%), malignancies (colon, lung) (1.6%)

Patient counseling

- Do not discontinue prasugrel without first discussing it with your physician.
- Take prasugrel with aspirin when prescribed together.
- May bruise and bleed more easily, and bleeding will take longer than usual to stop.
- Report unanticipated, prolonged, or excessive bleeding or blood in stool or urine.
- Thrombotic thrombocytopenic purpura is a rare but serious condition reported with prasugrel, so seek immediate medical attention if you experience the following symptoms that cannot be explained otherwise: fever, weakness, extreme skin paleness, purple skin patches, yellowing of the skin or eyes, or neurological changes.

Place in therapy: Current national recommendations from the American College of Cardiology/American Heart Association

- Undergoing primary PCI (PCI during acute STEMI): prasugrel 60 mg should be given promptly (Class I, level B evidence).
- Undergoing secondary PCI (i.e., patients with recurrent ischemia post-MI): if the patient did not receive fibrinolytic therapy and the coronary anatomy is known, prasugrel 60 mg should be given promptly and no later than 1 hour after PCI (Class I, level C evidence).
- Duration of therapy: at least 12 months for patients receiving a bare metal or drug eluting stent (DES) (Class I, level B evidence). Continuation of prasugrel beyond 15 months may be considered in patients undergoing DES placement (Class IIb, level B evidence).
- Guidelines do not endorse the use of prasugrel over clopidogrel, and vice versa.

Place in therapy: Current national recommendations from the American College of Cardiology/American Heart Association

- STEMI patients
- Undergoing primary PCI (PCI during acute STEMI): prasugrel 60 mg should be given promptly (Class I, level B evidence).
- Undergoing secondary PCI (i.e., patients with recurrent ischemia post-MI): if the patient did not receive fibrinolytic therapy and the coronary anatomy is known, prasugrel 60 mg should be given promptly and no later than 1 hour after PCI (Class I, level C evidence).
- Duration of therapy: at least 12 months for patients receiving a bare metal or drug eluting stent (DES) (Class I, level B evidence). Continuation of prasugrel beyond 15 months may be considered in patients undergoing DES placement (Class IIb, level B evidence).
- Guidelines do not endorse the use of prasugrel over clopidogrel, and vice versa.

Place in therapy: Current national recommendations from the American College of Cardiology/American Heart Association

- UA/NSTEMI patients
- No specific recommendations at this time.

Summary

Prasugrel shows greater reduction in the rates of cardiac death, MI or stroke compared with clopidogrel, but is associated with a greater risk for bleeding. Patients with diabetes and patients presenting with STEMI have shown benefit when taking prasugrel by reducing the rates of cardiac death, MI or stroke without increasing the risk of bleeding compared with clopidogrel. Prasugrel should not be taken by patients with a history of stroke or TIA due to an increased risk of bleeding, CV death, MI or stroke and should be used in caution in patients older than 75 years and those weighing less than 60 kg.

There is currently no evidence to support the use of prasugrel as an alternative in patients who have genetically been shown to be poor responders to clopidogrel. And although prasugrel has not demonstrated a significant interaction with drugs that elevate gastric pH, there is currently no data to suggest its use as an alternative to clopidogrel in patients that require proton pump inhibitor therapy. The choice between prasugrel and clopidogrel in ACS patients who undergo PCI should balance the risk of bleeding with the clinical benefits.

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- Cynthia Jackevicius, BScPhm, PharmD, MSc, BCPS, AQ Cardiology is an Associate Professor of Pharmacy Practice and Administration at Western University of Health Sciences, College of Pharmacy. Dr. Jackevicius’ interests are in...
cardiovascular diseases (particularly acute cardiac care, acute coronary syndromes, heart failure, and secondary prevention), evidence-based medicine and pharmaceutical care. Dr. Jackevicius has no biases to report.

References:
Assessment of California Pharmacists’ and Student Pharmacists’ Knowledge and Attitudes Regarding Medical Marijuana as a Factor for Determining the Need for Continuing Education

by 2011 PharmD Candidates Lindsay Holte, Jonathan Hutchinson and Allison Mruk; James Lightwood, PhD; Eleanor M Vogt, RPh, PhD

Abstract

The appropriate use of medical marijuana is a concern for health professionals and they should be prepared to address the concerns or questions patients may have surrounding its usage. However, no study has yet assessed California pharmacists’ and student pharmacists’ knowledge and attitudes regarding medical marijuana.

Our online survey created through SurveyMonkey was sent to 5,154 California Pharmacist Association (CPhA) members via email and the overall response rate was 14.6% (n=753). When presented with medical marijuana knowledge questions, approximately 30% of participants were uncertain about side effects, 49% were uncertain about drug-drug interactions, 49.8% were uncertain about the law, and 25.7% were uncertain about indications. Furthermore, approximately 90% of participants see a need for continuing education (CE) and nearly 87% would participate in a medical marijuana CE course. California pharmacists and student pharmacists’ responses demonstrate the need and desire to participate in CE courses on medical marijuana focusing on indications, side effects, drug-drug interactions, laws and regulations.

Background

California is one of fourteen states that currently allow patients to use medical marijuana. In addition to the estimated 50,000 medical marijuana program participants in California, the National Institute of Drug Abuse estimates that 6.55% of Californians...
have used marijuana at least once in the past month. Marijuana does have medicinal benefits, but can potentially cause serious adverse effects if not used properly. Appropriate use of medical marijuana is a concern for health professionals, and health professionals should be prepared to address any concerns or questions patients have regarding this product. However, no study has yet assessed California pharmacists’ and student pharmacists’ knowledge and attitudes regarding medical marijuana. Our survey assesses the knowledge and attitudes of California pharmacists and student pharmacists with the purpose to evaluate the need for continuing education (CE).

In 1996, California Proposition 215, also known as The Compassionate Use Act, allowed for the medicinal use of marijuana without legal repercussion from the State of California. However, this conflicts with its illegal, federal status under the Controlled Substances Act of 1970. The federal government classifies marijuana as a Schedule I substance meaning it has no currently accepted medical purpose or use. With the passage of Senate Bill 420 in 2004, the California Medical Marijuana Program (MMP) Act was established and further defined medical marijuana indications. These indications include: AIDS, anorexia, arthritis, cachexia, cancer, chronic pain, glaucoma, migraine, persistent muscle spasms, seizures, and severe nausea. In addition, “any other chronic or persistent medical symptom that either 1) substantially limits the ability of the person to conduct one or more major life activities as defined in the Americans with Disabilities Act; or 2) if not alleviated, may cause serious harm to the patient safety or physical or mental health.”

Under California’s MMP, patients and their caregivers are able to voluntarily obtain a Medical Marijuana Identification Card allowing access to California medical marijuana dispensaries under the recommendation of their physician. Physicians provide only a recommendation, not a prescription, for the use of medical marijuana. Medical marijuana at dispensaries is not a standardized product and is not regulated by the FDA. Thus, California pharmacies are not legally allowed to dispense medical marijuana. Pharmacists are not legally able to inform patients where to obtain medical marijuana or inform patients of the dose, frequency, or duration of its clinical use. However, pharmacists can provide patient counseling on medical marijuana’s side effects, drug-drug interactions, laws and regulations surrounding its usage.

The use of medical marijuana is not without risks to the patient such as cardiac, respiratory, CNS, and psychiatric adverse effects. Listed in Table 1.

Since medical marijuana can interact with prescription and over-the-counter medications, pharmacists should be aware of their patient’s medical marijuana use. The following list of drug-drug interactions is not all inclusive. The evidence supporting these interactions is limited and retrieved primarily from case reports. These potential interactions include opioids, alcohol, benzodiazepines, muscle relaxants, protease inhibitors, selective serotonin reuptake inhibitors, anticholinergics, sympathomimetics, alpha agonists, barbiturates, sildenafil, theophylline, tricyclic antidepressants, and neuroleptic antipsychotics.

### Purpose/study objective

Our study assessed California pharmacists’ and student pharmacists’ knowledge, attitudes, and behaviors regarding medical marijuana. We surveyed participants regarding the extent of their knowledge about medical marijuana’s indications, drug interactions, side effects, laws and regulations. In addition, we assessed participants’ behaviors surrounding counseling and obtaining patient information regarding medical marijuana use. The study survey was distributed electronically through SurveyMonkey™ in conjunction with California Pharmacists Association (CPhA). The study determines if CE on medical marijuana is warranted and desired by California pharmacists and student pharmacists.

We set out to test several general hypotheses, a) California pharmacists and student pharmacists would like the opportunity to complete CE on medical marijuana; b) California pharmacists and student pharmacists do not have sufficient medical marijuana knowledge and attitudes.
knowledge regarding its indications, side effects, and drug interactions; c) California pharmacists and student pharmacists do not have adequate background of California medical marijuana laws.

Methods
Our 15 question online survey was sent to 5,154 CPhA members via email from a CPhA representative. The email provided a URL link to the electronic survey hosted through SurveyMonkey™. Participants provided consent prior to initiating the online survey. Inclusion criteria for participants required the participant be 18 years or older and have current licensure as pharmacists or pharmacy interns in California. Participants were given the option to decline the survey or stop at any time. Upon completion, participants were provided with a URL to a medical marijuana fact sheet compiled from peer reviewed sources.

SurveyMonkey™ compiled survey responses and all potentially identifying data such as demographic information regarding years, practice setting and county of practice was not correlated to that respondent’s completed survey. Our survey was approved by the University of California, San Francisco Committee on Human Research. The survey was open 25 days from September 15th, 2010 through October 10th, 2010.

Descriptive and comparative statistical analyses were completed with Microsoft Excel 2007 and SAS® 9.2.

Results
The overall response rate of our survey was 14.6% (n=753). Demographics were divided into practice setting and years practiced. Of those that participated, 67.5% reported practicing in community/outpatient settings, which included community/retail, compounding, hospital/clinic outpatient, and home infusion. Furthermore, 17% reported practicing in the inpatient setting, which include hospital inpatient and long term care/hospice. Finally, 15.5% reported practicing in the academic or other setting.

Regarding years of practice, the majority of participants were interns (38.6%) followed by those with greater than 25 years of practice (28.8%). The remaining participants reported as practicing less than or equal to 5 years (17%), 6 to 25 years (8.7%), and 6 to 15 years (6.9%).

Approximately 34% of participants report being asked by their patients about medical marijuana. Of those that responded to this question, 58.6% of licensed pharmacists and intern pharmacists asked their patients about marijuana use either medicinally or recreationally.

The practice settings where patients asked about medical marijuana are identified in Table 2.

Discussion/Conclusion
In the California November 2010 election, the Regulate, Control and Tax Cannabis Act was brought to ballot. Although, Californians did not vote to legalize marijuana, the proposition emphasized the implications of marijuana use on public health and safety. Health practitioners need to be aware and knowledgeable...
Health practitioners need to be aware and knowledgeable about the use of marijuana and its potential impact on patient health, especially pharmacists, who are an accessible source of health information for their patients and the general public.

Table 2. Practice Settings Where Patients are Asking about Medical Marijuana

<table>
<thead>
<tr>
<th>Pharmacy Setting</th>
<th>Yes (%)</th>
<th>No (%)</th>
<th>Total Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community/ Retail</td>
<td>131 (38.5)</td>
<td>209 (61.5)</td>
<td>340</td>
</tr>
<tr>
<td>Compounding</td>
<td>10 (37.0)</td>
<td>17 (63.0)</td>
<td>27</td>
</tr>
<tr>
<td>Hospital/ Clinic Outpatient</td>
<td>20 (37.0)</td>
<td>34 (63.0)</td>
<td>54</td>
</tr>
<tr>
<td>Hospital Inpatient</td>
<td>23 (26.1)</td>
<td>65 (73.9)</td>
<td>88</td>
</tr>
<tr>
<td>Academia</td>
<td>11 (45.8)</td>
<td>13 (54.2)</td>
<td>24</td>
</tr>
<tr>
<td>Long-term Care/ Hospice</td>
<td>3 (15.0)</td>
<td>17 (85.0)</td>
<td>20</td>
</tr>
<tr>
<td>Home Infusion</td>
<td>3 (42.9)</td>
<td>4 (57.1)</td>
<td>7</td>
</tr>
<tr>
<td>Other</td>
<td>21 (28.4)</td>
<td>53 (71.6)</td>
<td>74</td>
</tr>
<tr>
<td>Overall</td>
<td>222 (34.1)</td>
<td>412 (65.9)</td>
<td>634</td>
</tr>
</tbody>
</table>

about the use of marijuana and its potential impact on patient health, especially pharmacists, who are an accessible source of health information for their patients and the general public. Our survey examines California pharmacists and student pharmacists’ knowledge of medical marijuana and their need and interest to participate in CE on medical marijuana. Our survey indicates that regardless of years practiced, participants could benefit from further education regarding medical marijuana. Participants overwhelmingly responded that California pharmacists and student pharmacists are not effectively trained on medical marijuana. Furthermore, approximately 90% of participants see a need for CE and nearly 87% would participate in a medical marijuana CE course.

One limitation is that our survey was sent only to CPhA members and may not accurately represent statewide demographics of pharmacists and student pharmacists. Additionally, we are making the assumption that California pharmacists and student pharmacists would respond similarly to CPhA members. In order to protect privacy, we did not collect participants’ IP addresses which allowed for the unlikely, but possible, multiple survey attempts per participant.

In conclusion, California pharmacists and student pharmacists have indicated in our study a need and an interest to participate in a CE on medical marijuana focusing on indications, side effects, and drug-drug interactions. In order for pharmacists to legally practice within California law and to protect their professional licenses, CE work should also contain a law and regulation component. Additional CE activities should be offered through professional organizations targeting pharmacists working in community and/or retail settings. Lastly, due to the lack of clinical knowledge and familiarity of the laws and regulations surrounding medical marijuana reported by pharmacy interns, we recommend that medical marijuana topics be incorporated in California pharmacy schools curricula.

About the Authors:

Lindsay Holts, Jonathan Hutchinson, and Allison Mrsk are 2011 PharmD Candidates at the University of California, San Francisco School of Pharmacy. Dr. Lightwood and Dr. Vogt are faculty members in the Department of Clinical Pharmacy at the University of California, San Francisco School of Pharmacy. The authors have no biases to report.

References

Introduction

The Arbiter 6 Halts trial was conducted to evaluate the efficacy of two statin combination therapies. The study compared niacin+statin versus ezetimibe+statin in order to evaluate which statin combination was more effective at slowing progression of atherosclerosis. The primary end point/outcome measure was carotid intima-media thickness (IMT), which researchers used as a surrogate marker.

Based on the results of a 14-month prospective, randomized, parallel-group, open-label study, authors concluded that using a combination of statin+niacin was a superior therapy compared to using ezetimibe+statin. The purpose of this evidence-based evaluation of ARBITER 6 HALTS is to determine if this new combination drug therapy is a viable and efficacious option for those patients who are not well controlled by statins alone.
<table>
<thead>
<tr>
<th>Element</th>
<th>Criteria</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Study Design Assessment       | **Is the design appropriate to the research question? Is the research question useful?**  
- For *efficacy*, use of experimental study design (meaning study subjects and others were not allowed choice in determining interventions)  
- **Clinically significant area** for study (morbidity, mortality, symptom relief, & functioning & health-related quality of life) & reasonable definitions for clinical outcome such as response, treatment success or failure  
- If *composite endpoints* used, reasonable combination used – & used for safety if used for efficacy | **THREAT:** The ARBITER 6 HALTS trial was designed as an open-label randomized study designed to assess adjunct pharmacological treatment to reduce the risk of cardiovascular events in patients with coronary heart disease or risk equivalent.  
**THREAT:** The study used carotid intima-media thickness as a surrogate marker for atherosclerosis progression, but there could potentially be other outcomes, such as heart attack, stroke, & other various cardiovascular events, that could more accurately assess the progression of atherosclerosis. |
| Internal Validity Assessment  | **Can bias, confounding or chance explain the study results?**  
- Ensure prespecified & **appropriate** 1) research questions, 2) populations to analyze, 3) outcomes, 4) group assignment methods, 5) study conduct methods, 6) analysis methods, & 7) level for statistical significance | **THREAT:** The open-label study design allows both researchers & participants to be aware of who was getting the different drug combinations which could have influenced results.  
**THREAT:** Of the 363 participants initially randomized, only 208 participants were analyzed at the 14 month premature termination of the trial. As a result, conclusions & study findings were based on only these participants. |
| Selection Bias                | **Groups are appropriate** for study, of appropriate size, **concurrent** & **similar** in **prognostic variables**  
- Methods for generating the group assignment sequence are truly random, sequencing avoids potential for anyone affecting assignment to a study arm & randomization remains intact  
- Concealment of allocation strategies are employed to prevent anyone affecting assignment to a study arm | **THREAT:** A small sample size was used & thus may not be reflective of the general patient population who may potentially receive this therapy.  
**THREAT:** The study was conducted at two centers – Walter Reed Army Medical Center & the Washington Adventist Hospital. Computer-generated sequence of random numbers was used to allocate treatment groups.  
**THREAT:** Concealment of allocation strategies was not detailed by the study authors. |
| Performance Bias              | **Double-blinding** methods employed (i.e., subject & all working with the subject or subject’s data) & achieved  
- Reasonable *intervention* & reasonable *comparator* used (e.g., placebo)  
- No bias or difference, except for what is under study, between groups during course of study (e.g., intervention design & execution, co-interventions, concomitant medication use, adherence, inappropriate exposure or migration, cross-over threats, protocol deviations, measurement methods, study duration, etc.) | **THREAT:** This trial was not double-blinded, but instead an open label study (only endpoint evaluators & the sole ultrasonographer were blinded). Therefore, all others involved in the study were fully aware of which treatment arm to which patients were assigned.  
**THREAT:** Though both groups received an active medication, biases could have affected behavior based on perception of potential drug efficacy.  
**THREAT:** Because the two treatment arms received active drug, either niacin+statin or ezetimibe+statin, the study lacked a comparator group of either just statin therapy &/or placebo, which would have better determined true cardiovascular risk reduction. |
### Attrition Bias
- **Zero or minimal missing data points** or loss from randomization (e.g., approximately 5% with differential loss, or approximately 10% without differential loss) unless good ITT analysis (see ITT below).

**THREAT:** 9% of patients taking ezetimibe and 15% of patients taking niacin discontinued the medication mostly due to adverse drug effects. The drop out rate of the niacin group is almost double that of the ezetimibe group; thus, the niacin group is missing more data points for analysis, possibly misrepresenting positive or negative outcomes.

**THREAT:** The loss of data, due to the drop out rate, threatens the internal validity of the study.

### Assessment Bias
- Assessors are **blinded**
- Low likelihood of findings due to chance, false positive and false negative outcomes (judgment call on statistical significance, including confidence intervals)
- Non-significant findings are reported, but the confidence intervals include clinically meaningful differences
- Intention-to-Treat Analysis (ITT) performed (all people are analyzed as randomized + reasonable method for imputing missing values which puts the intervention through a challenging trial or reasonable sensitivity analysis)
- Use of **modeling** only with use of reasonable assumptions

**THREAT:** This study was conducted using single-variable correlation coefficients which failed to take into account other variables other than carotid intima-media thickness. In addition the study performed post hoc analyses. Both these are quite sensitive to bias due to confounding.

The primary investigators were not blinded; however, both assessors of the study and a single observer (the single ultrasonographer) were blinded.

**THREAT:** Because the study was prematurely terminated, there is an increased likelihood for chance effects especially in a small study as well as an exaggerated/overestimated assessment of the potential benefit of niacin.

**THREAT:** Not all randomized patients were accounted for in the analysis. Therefore this is not an ITT analysis. Only 208 (about two-thirds of the starting patient population) completed the study and were accounted for in final analyses.

### Usefulness Assessment
- Clinically significant area + sufficient benefit size = meaningful clinical benefit (consider efficacy vs effectiveness)

**THREAT:** The trial failed to substantiate that statin adjunct therapy using niacin or ezetimibe was more effective than simply maintaining statin monotherapy and increasing the dosage/strength of the statin, and due to multiple threats to trial validity such as the primary outcome being a surrogate marker. In order to further strengthen study claims on the superiority of the statin + niacin adjunct therapy, additional trials evaluating clinical outcomes, such as MI or stroke, are necessary.

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ARBITER 6 HALTS = Arterial Biology for the Investigation of the Treatment Effects of Reducing Cholesterol - 6 - HDL and LDL Treatment Strategies in Atherosclerosis
Author's Results and Conclusion:
The final changes in LDL were -17.6±20.1 mg/dL and -10.0±24.5 mg/dL in the ezetimibe and the niacin groups respectively. The final changes in HDL levels were -2.8±5.7 mg/dL and 7.5±9.2 mg/dL in the ezetimibe and the niacin groups respectively. Primary outcome measurement evaluated the change in carotid intima-media thickness. Compared to ezetimibe, which had a -0.0007±0.0035 (p = 0.84) change in mean thickness, niacin had a -0.0181±0.0050 mm (p=0.001) change in mean thickness. More patients in the niacin+statin study arm withdrew from the study than those on ezetimibe+statin, mainly due to adverse drug effects. The authors concluded that the niacin+statin combination was superior to ezetimibe+statin due to the greater decrease in carotid media-intima thickness.

Reviewer's Conclusions:
The ARBITER 6 HALTS trial presents many claims in support of statin+niacin as a superior drug combination therapy to statin+ezetimibe combination therapy stating improved outcomes for patients with cardiovascular risk. Due to a number of threats to study validity, initializing statin+niacin therapy in the clinical setting has not been determined to be superior and thus, should not yet be considered standard of practice. Major downsides of this trial include the open-label design, early termination of the study, loss of data points including differential loss and the lack of ITT analysis. While the open-label study design assures participants that they are receiving actual pharmacologic therapy, it creates a performance bias because each individual in fact knows what they are really getting which may influence study outcomes. The lack of ITT analysis weakens study claims that would be rather promising. Because the study size was rather small (363 participants), as each participant drops out, whether it is from adverse events or lack of compliance, there is a larger percentage of the total outcome placed on each patient, making it increasingly more possible for outcomes to be distorted by bias, rather than to be explained by treatment effects.

Additionally, both investigator and participant bias are potentially confounding factors. Although the reproducibility of carotid IMT is among the highest ever achieved in a clinical trial, a small number of participants completed the trial over a short time period (208 participants enrolled for a total of 14 months in a trial that was terminated early). This is certainly not enough to convince most that a statin+niacin combination is more effective for treating a disease state.

The recruited patient population is another study design that threatens external validity. Men and women with HDL levels less than 50 and 55 mg/dL, respectively, do not accurately represent the average patient population that would require a statin combination therapy. Patients with HDL levels this high are less likely to experience a cardiovascular event and may not require the drug therapy used in the trial. We should consider whether the drug therapies in question would have positive outcomes for individuals who have much lower HDL levels. Therefore, due to the number of threats to internal and external validity, asserting that using a statin+niacin drug combination is more efficacious and superior to a statin+ezetimibe combination cannot be corroborated.

Although the ARBITER 6 HALTS trial suggests a beneficial statin+niacin combo therapy, further research and trials are needed to fully evaluate the long-term potential and risk in using such statin combinations in treating cardiovascular disease.

Overall Grade: U = Uncertain in validity and usefulness

About the Authors
Melody Chien is a 2012 PharmD Candidate at the UXC School of Pharmacy. Justin Yee is a 2012 PharmD Candidate at the UXC School of Pharmacy.
Craig Stern, PharmD, MBA is president of ProPharma Pharmaceutical Consultants, Inc. and Chair of the CPhA Editorial Review Committee. Dr. Stern has no bias to disclose.
Guest Editors Dr. Michael E. Stuart and Sheri A. Strie of Delfini Group are experts at systematic literature reviews. The chart template is adapted from “Delfini Group, L.L.C. Short Critical Appraisal Checklist: U

References
Chart adapted from Delfini Group, L.L.C. Short Critical Appraisal Checklist

Delfini Evidence Grading Scale

Grade A Evidence: Useful
The evidence is strong and appears sufficient to use in making health care decisions – it is both valid and useful (e.g., meets standards for clinical significance, sufficient magnitude of effect size, physician and patient acceptability, etc.).

Grade B Evidence: Probably Useful
The evidence appears potentially strong is probably sufficient to use in making health care decisions. Some threats to validity were identified.

Grade B-U Evidence: Possible to Uncertain Usefulness
The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B and the uncertainty is not great enough to fully warrant a Grade U.

Study quality is such that it appears likely that the evidence is sufficient to use in making health care decisions; however, there are some study issues that raise continued uncertainty. Health care decision-makers should be fully informed of the evidence quality.

Grade U Evidence: Uncertain Usefulness
There is sufficient uncertainty that caution is urged regarding its use in making health care decisions.

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In January of 2011, the California Korean American Pharmacists Association (CKAPhA) officially partnered with CPhA, which added approximately 50 new members to CPhA. The union strengthens the profession of pharmacy in California overall and provides CKAPhA with “voice power” that it did not have before.

In this article, CPhA shares a conversation between Immediate Past President, Eric Gupta (EG), and Past President of CKAPhA, Martin Kim (MK), in which they discuss the evolution of the partnership between the two organizations and the inherent value in the collaboration.

Currently CKAPhA is made up of approximately 1,200 members and 150 pharmacies. By next year, they anticipate a greater level of growth. The majority of CKAPhA members are first-generation owners who speak English as a second language. However, the number of second-generation students who are graduating and becoming practitioners is growing at a rapid pace. Their involvement will help CKAPhA gain greater visibility in their respective communities and in CPhA. Like the Indian Pharmacists Association (IPA) before them, CPhA welcomes CKAPhA with open arms, knowing that they will not only bring a unique perspective to the table, but also a fresh approach to problem-solving and working together.

Q Can you give us some background on how the partnership with the California Korean American Pharmacists Association began?

EG Shortly after I was elected as President-Elect in 2008, I was approached by a very good friend of mine named James Pai, who is a member of CKAPhA and whose father, Kiho Pai, was the CKAPhA Chairman of the Board. James offered to be of help in any way he could and invited me to meet the members of his Association. I attended their Christmas banquet, met all the members, and I presented the idea of forming a partnership between CKAPhA and CPhA similar to the partnership that we have with the IPA. Over the course of the next year, we maintained open communication with Martin Kim, while the CPhA Board of Trustees came to an agreement on a group membership structure that they could offer to potential partnering entities such as CKAPhA. That process took one year to come to fruition. Meanwhile, CPhA began to include CKAPhA in our communications and involve them in our legislative and legal efforts.

Q What are your perspectives about the two organizations coming together and why is this partnership important?

MK I had expressed an interest to join CPhA 15 years prior to these discussions with Eric Gupta, during which time CKAPhA worked slowly to develop relationships with
CPhA. As time went by, I saw a growing need for representation in the pharmacy schools where the population of ethnic students was growing exponentially. In addition, I noticed that smaller ethnic groups didn't have much leverage in the political arena or in the area of pharmacy regulations. I felt we needed a more influential way to present our opinions and concerns. In order to be heard, CKAPhA needed to be part of a larger organization with a greater sphere of influence.

One of the main objectives for joining forces with CPhA at this time is to be represented at the table on legislative bills that have a great impact to our profession. As members of CPhA, CKAPhA can paint a clear picture of our needs for CPhA's lobbyists so that they clearly understand our challenges, and can work towards a solution that will have a lasting impact. As a single entity, CKAPhA is a small organization. In partnership with CPhA, we gain strength and influence.

Being a part of the California Pharmacists Legislative Day event last year was a very good experience. I was able to visit with my elected officials and represent the needs of the pharmacy profession, while using specific examples from my own pharmacy to demonstrate how legislation and regulations are impacting my practice. I was one of hundreds of pharmacists who were there doing the same thing, which gave me a sense of power.

**Q** How do you expect the partnership to impact the members of CKAPhA?

**M** We have a great record of getting involved with CPhA. When CPhA put out a call to support its legal efforts to fight back against the 10% Medi-Cal budget cuts, 90% of our members contributed to the Pharmacy Defense Fund of California (PDFC). We are very proud of how CKAPhA members responded. Going forward, I anticipate that we will continue to respond at similarly high levels and will reach out to other pharmacists in our community to get involved as well.

**Q** What are the top two issues for your members today?

**M** Our main issues are the Medi-Cal budget cuts and the advancement of medication therapy management (MTM) services in the pharmacy. We have been closely tied to CPhA throughout the legal battle to fight back against the State, and were part of the California Pharmacy Alliance that was formed in 2009. The “voice power” that we have established is very important to us.

I would love to send a message to elected officials about how wrong the reimbursement formulas are. Out of 100 prescriptions in my pharmacy, the insurance companies have underpaid in 90% of cases. The reasons given are related to maximum allowable ingredient costs (MAIC), citing a difference between the pharmacy’s costs, and their estimate of what the pharmacy’s costs should be. Yet, there is no transparency coming from the insurance companies. I’d like to know what their actual MAIC costs are based on, but they do not give out that information when they underpay the claim. The Legislature is calling for transparency from pharmacies, but insurance companies are not transparent with us. That’s another issue that we can all work on together as a profession.

**E** This is a great example of how the members of CKAPhA can get involved in the policy-setting process of CPhA and to help set state-wide policy that CPhA’s Board of Trustees and lobbyists can then follow through on. The House of Delegates is the best forum for calling attention to the most pressing issues affecting the profession. In some cases, the HOD will refer an item of business to the Board of Trustees, who can then form special committees to vet the issue in greater detail and then provide recommendations to the Board for further action. By joining forces and enacting policy at the House of Delegates level, CKAPhA will be able to have a voice in these matters and CPhA will be better positioned to develop strategies to fight on behalf of pharmacists’ needs for both the short and the long-term.

**Q** How can CPhA support CKAPhA going forward?

We need legislative representation to stop harmful practices to our patients and pharmacy operations. In addition, we are very focused on enhanced patient care models through MTM services such as diabetes education centers (Kim is currently managing a pilot project in his pharmacy) and immunization services. We also want to work on durable medical equipment (DME) accreditation. Finally, CKAPhA would like CPhA to continue to provide up-front information to stay on top of the issue with tools such as easily digestible talking points that members can share with their home legislators. We are glad to come along and do our part and plan to work on increasing voter registration with our members and our community so CKAPhA can speak more powerfully.

**Q** Why is this partnership with CKAPhA important to CPhA and do you anticipate CPhA forming more similar partnerships in the near future?

The greatest benefit of bringing all pharmacy organizations together is that our voices can be more effectively heard. Does CPhA want to form more partnerships like this? Absolutely. The more we bring together various groups under one banner, the more powerfully we will be able to advance our cause, and the bottom line is that we will be better positioned to focus on patient care and advance issues that will help to improve outcomes while lowering costs.

**Closing Thoughts**

CPhA looks forward to working with CKAPhA, along with all the various pharmacy entities in California, to build on the “one profession, one voice” motto in such a way as to develop the most powerful voice for pharmacy possible. Group membership between organizations is one small step on the road to achieving that goal. In the words of Martin Kim, “It’s not too late to do anything, but not too early either.” If your organization is interested in forming a greater alliance with CPhA and ensuring that your members have a seat at the table on important issues that affect your practice in California, contact Jon Roth, CEO of CPhA for more information at jroth@cpha.com.

www.cpha.com

CPhA, CKAPhA and McKesson executives meet at Outlook to discuss the benefits of group membership. Front row left to right: Ed Escalante, Kenny Scott, Frank Lee, Ryan Kim Back row left to right: Jay Lee, Eric Gupta, Sean Inglis, Jon Roth, Martin Kim, Edgar Cardona
Thomas J. Long School of Pharmacy at University of the Pacific

By Elizabeth Chang, 2012, CPhA Board of Trustees, Pacific ASP Representative

On Tuesday January 25th, Jon Roth, CEO of CPhA, visited the Pacific pharmacy campus to speak about his vision for CPhA and how this vision ties into the CPhA policy process. Mr. Roth, who was welcomed by about 70 pharmacy students and pharmacists, was accompanied by CPhA Staff Veronica Van Orman and Erin Moeller. Mr. Roth spoke to students and pharmacists alike about how he plans to promote the pharmacy profession at the state capital. Mr. Roth also instructed students on what they could do now to advocate for the pharmacy profession. “I could tell from Mr. Roth’s presentation that he had a plan on how to make the pharmacy voice heard to legislators,” says Jan Zhang, ’13. “He genuinely cares about my future as a California pharmacist.”

Mr. Roth’s presentation was followed by Dr. Nancy DeGuire, the CPhA immediate past Speaker-of-the-House and Assistant Dean of External Relations at the Thomas J. Long School of Pharmacy and Health Sciences. Dr. DeGuire described the background of the House of Delegates, and the new policies pending adoption in the 2011 House of Delegates. These policies, if approved, would affect the pharmacy profession for years to come.

Professionalism, elegance, and leadership were themes of Pacific’s inaugural Leadership Dinner sponsored by Target and hosted by ASP. This Etiquette Dinner, which took place on the night of February 25th, matched second-year Pacific pharmacy students with pharmacists in their prospective specialized field of pharmacy. The five-course meal was accompanied by dining etiquette lessons explaining the proper formalities typical of company dinners. Throughout the evening, Target representatives Dr. Amir Khan ’98 and Onna Poeter presented interview tips and suggested conduct that would impress recruiters. The event was a huge success and served about 100 students and pharmacists, who thoroughly enjoyed a nice evening of networking, leadership, and professionalism.

On February 26th, Pacific hosted its second annual Black History Month Health Fair in order to both serve the Stockton African American community and promote February as Black History Month. At this health fair, Pacific pharmacy students provided blood pressure and blood glucose screenings, as well as immunization vaccines, for the public. Pacific students also offered visitors health information, such as smoking cessation and breast cancer awareness information. It was a great way to promote the pharmacy profession and help an underserved community in Stockton.

In the near future, ASP’s Legislative Committee will be hosting its annual Legislative Dinner on April 25th. Pacific will have the pleasure of welcoming guest speakers Dr. Eric Gupta, CPhA immediate past President, and Dr. Jason Bandy, CSHP Legislative advocate, as they inspire students to advocate for the pharmacy profession through legislation.

This event will serve to inform students on the importance of student participation in pharmacy legislation and the necessity of dialoguing with legislators about pharmacy related issues.
Standing Board Meetings:

**Week 1:**

**FIRST TUESDAY OF THE MONTH:**
Ventura County Pharmaceutical Association
Walgreens Infusion Center - 4867 Colt St., Ventura, CA 91320
7:00 – 9:00 pm
Contact John Sandstrom, President (415) 519-9010
johnsandstrom@me.com

**FIRST WEDNESDAY OF THE MONTH:**
Pharmacists’ Professional Society of the San Fernando Valley
Lulu’s Restaurant - 16900 Roscoe Blvd., Van Nuys, CA 91406
7:00 pm Dinner, Meeting 7:30 pm
Contact: Aileen DeRevere, President (818) 676-4129
aderevere2003@yahoo.com

Sacramento Valley Pharmacists Association
CPhA Headquarters – 4030 Lennane Dr., Sacramento, CA 95834
6:30 – 9:00 pm
Contact: Sonya Frausto, President (916) 631-8108 x204
sfrausto@calpharm.org

Southeast Los Angeles Pharmacists Association
Location TBD
7:30 – 9:30 pm
Contact: Kalsang Dorji, President (714) 310-8664
kalsang.dorji@gmail.com

**FIRST THURSDAY OF THE MONTH:**
Marin County Pharmaceutical Association
Eduardo’s Restaurant - 4200 Redwood Hwy, San Rafael, CA 7:00 am - 8:30 am
Contact: Aglaia Panos, President (510) 907-0717
aglaia.panos@yahoo.com

Orange County Pharmacists Association
Garden Grove Medical Bldg, Plaza Rm, 12555 Garden Grove Blvd, Garden Grove, CA 92843
7:30 – 9:30 pm
Contact: Caroline Atwood (949) 252-6854
caroline.atwood@prescriptionsolutions.com

San Mateo County Pharmacists Association
Poplar Creek Grill (at the golf course) - 1700 Coyote Point Drive, San Mateo, CA 94401
7:00 - 9:00 pm
Contact: Co-Presidents: Drew Donovan (650) 697-0166 or Mark Reynolds (650) 522-4566 smcpharm@yahoo.com

**SECOND TUESDAY OF THE MONTH:**
Alameda County Pharmacists Association
Location TBD
6:30-9:00 pm
Contact: Donna Thai, President (415) 519-9010
donna.tai@gmail.com

Fresno-Madera County Pharmacists Association
Rx relief- Pridestaff Building - 7535 N. Palm Ave #101, Fresno, CA 93711
6:30-8:30 pm
Contact: Brett Borba, President (559) 303-3915
Brett.Borba@va.gov

**SECOND THURSDAY OF THE MONTH:**
Santa Barbara Pharmaceutical Association
Location TBD
7:00 – 9:00 pm
Contact: Colleen Carter, President (805)893-2116
crcarter1@verizon.net

**Week 2:**

**SECOND MONDAY OF THE MONTH:**
Pharmacists’ Society of San Francisco
UCSF, Room S159 - Medical Sciences Building - 513 Parnassus Ave, S.F., CA 94143
8:00 -10:00 pm
Contact: Philip Koerpel, President (415) 290-7499
pkoerpel@pacbell.net

**SECOND TUESDAY OF THE MONTH:**
Alameda County Pharmacists Association
Location TBD
6:30-9:00 pm
Contact: Donna Thai, President (415) 519-9010
donna.tai@gmail.com

Fresno-Madera County Pharmacists Association
Rx relief- Pridestaff Building - 7535 N. Palm Ave #101, Fresno, CA 93711
6:30-8:30 pm
Contact: Brett Borba, President (559) 303-3915
Brett.Borba@va.gov

**SECOND THURSDAY OF THE MONTH:**
San Joaquin Pharmacists Association
Thomas J. Long School of Pharmacy & Health Sciences at Pacific
3601 Pacific Avenue, Stockton, CA 95211, Room TBD
6:30 – 8:30 pm
Contact: Nam Nguyen, President, (209) 609-7181
nblue17@yahoo.com

**Week 3:**

**THIRD TUESDAY OF THE MONTH:**
San Diego County Pharmacists Association
San Diego VA Medical Center- Basement Rm. B145 - Pharmacy Conf. Rm.
3350 La Jolla Village Drive, San Diego, CA 92161
6:00 - 8:00 pm
Contact: Kodhayar Farahmand, President (phone)
farahmand.k@gmail.com

**FOURTH TUESDAY OF THE MONTH:**
Contra Costa Pharmaceutical Association
Walnut Creek Kaiser Conference Room
1425 South Main Street, Walnut Creek, CA 94596
Contact: Alan Wong, President (925) 254-1211
awong@comcast.net

**FOURTH THURSDAY OF THE MONTH:**
San Joaquin Pharmacists Association
Thomas J. Long School of Pharmacy & Health Sciences at Pacific
3601 Pacific Avenue, Stockton, CA 95211, Room TBD
6:30 – 8:30 pm
Contact: Nam Nguyen, President, (209) 609-7181
nblue17@yahoo.com

San Gabriel Valley Pharmaceutical Association
(meet every other month: May, July)
Huntington Memorial Hospital Cafeteria in Pasadena - 100 West California Boulevard, Pasadena, CA 91105
7:30 – 9:00 pm
Contact: Ken Thai, President, (626) 674-6718
pharmacy@sgvpha.com

www.cpha.com
**Pharmacy Lawyer**

37 years experience in pharmacy law
Former Deputy Attorney General
Representing Pharmacy Board
Statewide representation of pharmacists

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