

FINAL PROGRAM



2ND ANNUAL

FMCP
Research Symposium

**CONTEMPORARY APPLICATIONS
FOR SPECIALTY PHARMACY RESEARCH
MEETING PROCEEDINGS**

TUESDAY | OCTOBER 2, 2012 | CINCINNATI, OH





2ND ANNUAL

FMCP Research Symposium



Foundation for Managed Care Pharmacy

100 North Pitt Street, Suite 400

Alexandria, VA 22314

800.827.2627

www.fmcenet.org

These proceedings were written by S.M. Health Communications LLC
www.smhealthcom.com

Special thanks to StrategiCare, LLC (310-379-3996)
for their help in producing this program.



TABLE OF CONTENTS

Symposium Sponsors	4	Updating the AMCP Format for Specialty Pharmaceuticals, Companion Diagnostics, and Comparative-Effectiveness Research <i>Peter Penna, PharmD</i>	15
Introduction	5	Transforming Research Into Action: Specialty Pharmacy Research Showcase <i>Atheer Kaddis, PharmD</i>	17
Bringing About Healthcare Transformation Through Evidence-Based Research: Challenges Introduced by Specialty Pharmaceuticals <i>Maggie Gunter, PhD</i>	6	Comprehensive Specialty Pharmacy Management: A Payer’s Perspective <i>Suzanne Tschida, PharmD, BCPS</i>	19
Industry Utilization of Real-World Evidence <i>Brian Sweet, BSPHarm, MBA</i>	9	Panel Discussion 2—Using Real-World Evidence to Optimize Effectiveness of Specialty Pharmaceuticals <i>Moderated by Welton O’Neal, Jr., PharmD</i>	21
Maximizing Payer/Pharma Research Partnerships Utilizing <i>Mark J. Cziraky, BSPHarm, PharmD</i>	10	Closing Comments <i>Diana Brixner, RPh, PhD</i>	23
Panel Discussion 1—Capitalizing on Collaborative Research: Partnerships to Transform Care in Complex Diseases <i>Moderated by Diana Brixner, RPh, PhD</i>	12		



2ND ANNUAL
FMCP
Research Symposium

SYMPOSIUM SPONSORS

FMCP would like to thank the following organizations for their support of the Research Symposium:

PLATINUM SPONSOR



GOLD SPONSOR



Daiichi-Sankyo

SILVER SPONSOR



BRONZE SPONSORS



GILEAD

Advancing Therapeutics.
Improving Lives.



Xcenda[®]

AmerisourceBergen Consulting Services



INTRODUCTION

The second annual Foundation for Managed Care Pharmacy (FMCP) Research Symposium was held October 2, 2012, in Cincinnati. The theme of this meeting, “Contemporary Applications for Specialty Pharmacy Research,” raises a few key questions. First, why is the issue of specialty pharmacy so important that it should merit a symposium? Second, what exactly is specialty pharmacy?

That is, what differentiates it from traditional pharmacy?

Edith A. Rosato, RPh, IOM, stated, “The estimates are that within four years, 40% to 45% of all pharmaceutical sales will be for specialty drugs. The specialty drug trend is projected to increase from 17% in 2012 to 22% in 2014.”¹ This means that managed care pharmacists are increasingly challenged today to manage their pharmacy budgets, while ensuring appropriate access to specialty medications.

A complete consensus on the definition of specialty pharmacy products does not necessarily exist. Is it based on relatively high expense? On the chemical structure of the agent or how it is manufactured? Or perhaps on how it is distributed? Ms. Rosato, CEO of the Academy of Managed Care Pharmacy (AMCP), noted, “Although we can’t always agree on the definition of specialty pharmacy [medications], we can agree that they are complex and high touch—they need special handling and storage. Probably, the most important consideration of specialty pharmaceuticals is that it is all about patient care management and the impact these drugs can have on the health of patients if taken appropriately.”

The program’s moderator, Diana Brixner, RPh, PhD, Professor and Chair, Department of Pharmacotherapy, and Executive Director of the Outcomes Research Center, University of Utah College of Pharmacy commented that the market drivers predicting significant growth of specialty products and the increasing percentage of pharmacy budgets they will represent,

naturally stimulates the need to discuss research opportunities within this rapidly growing area. “Research is needed to build the evidence based on the clinical efficacy, safety, and real-world effectiveness of these agents. This can be done prelaunch by incorporating clinical trial endpoints of value to payers and by developing cost-effectiveness models that can predict

clinical and economic outcomes versus standard therapies,” said Dr. Brixner. Once these specialty drugs are available, real-world studies can be conducted to collect evidence of outcomes across health care system patient populations to compare and contrast with the outcomes of clinical trials. Cost models can be validated to determine whether predicted and actual clinical and economic benefits are realized. The demand for this type of information is increasingly greatly for traditional pharmacy medications. The increasing utilization of specialty pharmaceuticals and their associated expense will drive even greater demand for

appropriate research to inform decision making.

This symposium comprised five general sessions and two panel discussions, spanning the challenges of specialty pharmaceuticals to case studies in specialty pharmacy research.

The FMCP Research Symposium and these proceedings were made possible through grants from Amgen, Daiichi-Sankyo, Teva Pharmaceuticals, Gilead, and Xcenda. Their support helps FMCP, the research arm of AMCP, fulfill its mission to advance the knowledge and insights on major issues associated with the practice of pharmacy in managed care settings.

The objectives of this educational program are:

- To highlight the innovative research initiatives undertaken by AMCP members in specialty pharmaceuticals, particularly with regard to clinical and outcomes management for specialty pharmaceuticals
- To understand the potential value of integrated data from multipayer claims databases, state health insurance exchanges, and payers as the basis for making evidence-based decisions
- To understand how the AMCP Format for Formulary Submissions has been updated to address evaluation of specialty pharmaceuticals
- To identify what research questions can be answered today with available resources and what gaps must be filled in order to effectively evaluate and manage specialty pharmaceuticals

1. 2011 Drug Trend Report. Express Scripts, April 2012, St. Louis, MO.



BRINGING ABOUT HEALTHCARE TRANSFORMATION THROUGH EVIDENCE-BASED RESEARCH: CHALLENGES INTRODUCED BY SPECIALTY PHARMACEUTICALS

Maggie Gunter, PhD

**President and Executive Director, LCF Research, New Mexico Health Information Collaborative Albuquerque;
Member of the Governing Board, HMO Research Network**

This is an exciting time in healthcare, presenting exciting opportunities but also critical challenges. Many organizations are presently planning their strategic response to these challenges and opportunities, particularly those posed by evidence-based research and specialty pharmaceuticals.

CONDUCTING RESEARCH IN AN INTEGRATED HEALTHCARE ENVIRONMENT

LCF Research, formerly known as the Lovelace Clinic Foundation, has been performing research and using data from an integrated healthcare delivery system since 1991. The mission of LCF Research is to improve quality, control costs, and expand access to healthcare by conducting applied research in healthcare delivery and public health, providing continuing professional education, and advancing meaningful use of health information technology. LCF Research promotes innovation, focuses on population-based health research, and designs and evaluates real-world health interventions (i.e., translational research).

LCF Research is a member of the HMO Research Network, a consortium of research arms of 19 integrated health systems, each of which maintains a data warehouse of claims data and data from electronic health records (EHRs) in a standard format to facilitate multi-site research.

Furthermore, LCF Research developed and operates New Mexico's health information exchange (HIE) network, which serves as another source of data for healthcare research.

Integrated systems have long been interesting environments to conduct healthcare research: They were among the first health organizations to have EHRs, with access to both medical and pharmacy information. Additionally, the organizations'

incentives are aligned to implement improvements in care practices and test innovations.

THE GROWING ROLE OF DATA AND RESEARCH IN HEALTH TRANSFORMATION

Overall, changes in the environment today will stimulate more translational research, comparative-effectiveness research (CER), and population health research to help advance healthcare outcomes.

The creation of accountable care organizations and the increased use of capitation and bundled payments have changed the focus of reimbursement and payments from one of volume to that of quality, efficiency, and outcomes. This is evidenced by Medicare's Shared Savings Program and by its refusal to pay providers for "never events," like surgery performed on the wrong anatomical site or wrong patient, the development of stage 3 or 4 pressure ulcers while in the hospital, or nosocomial infections following surgery or associated with catheterization, to name just a few.

The Centers for Medicare & Medicaid Services has also promoted the growth of data availability through its "Meaningful Use" payment incentives for health information technology utilization. They encourage better data usage to improve care and control costs.

The healthcare system needs to incorporate more translational research to help speed proven interventions into clinical practice. It is often said that it may take up to 17 years for an innovation in practice to be adopted across the healthcare system. The National Institutes of Health is funding clinical translational science centers to quicken the pace of translational research and hopefully shorten the gap from innovation to practice change.

The adoption of EHR and HIE networks to generate and connect electronic data can greatly improve patient care but is also a boon for managed care research. The amount of data becoming available today and in the near future can fuel CER,

This article was summarized by S.M. Health Communications from a podium presentation and approved by the speaker.



which will identify treatments and clinical approaches that are most effective.

Other health data sources can contribute significantly to today's data-intensive healthcare environment. Not only is the number of EHRs growing but the data incorporated into them will expand as well. Consider the availability of human genomic data, as the price for a personal genomic analysis continues to sink below \$1,000. Secondary data sources, including drug surveillance, homeland security and global epidemiology, and public health databases are expected to contribute to the mass of information available for healthcare research, posing incredible opportunities, especially when collated through regional HIEs. Patient registry information can also be integrated and evaluated as a data source; however, these registries lack some clinical data elements and cost information. Complex ethical, political, technical, and economic challenges remain, and questions must be answered as to who owns the data, who has the right to access and manage them, and the ethical question of patient consent and rights versus the benefits data access can bring to health care.

EXISTING "BIG DATA" EXAMPLES

Notably, state-mandated "all-payer" claims databases allow comparisons of payments for interventions across payers. These all-payer claims databases offer population-based data on all insured persons, and comprehensive data across age groups and disease states. However, they lack data elements needed for specific types of research: They generally do not include laboratory data, information about patients' vital signs, nor any medical data that might otherwise be found on an EHR. Since they capture only information on the insured, claims data on people without insurance are missing. Other issues include the time lag between utilization of the service and payment for it and the recording of these transactions into the database.

A federal data repository, Medicare's SEER Registry Linked Database has long provided a wealth of information to health services researchers. It is a database of fee-for-service claims linked to SEER Tumor Registry data. Although it covers cancer only and contains only information on Medicare beneficiaries, its data include many key fields, such as diagnoses, interventions, lab tests, medications, and cancer stage at diagnosis.

The HMO Research Network, as mentioned earlier, incorporates multiple integrated healthcare systems with standardized EHR and claims databases. It is a virtual data warehouse, maintained in a standard format across all individual member sites to expedite multisite research. The HMO

Research Network has also participated in numerous external collaborations with university health sciences centers, the U.S. Department of Veterans Affairs, and other payers, the HMORN includes a number of funded disease specific research networks, such as the Center for Research and Education on Therapeutics, the Mental Health Research Network and the Cancer Research Network.

Although HIE network repositories hold great promise for researchers because they would encompass true population-based data for research, public reporting, and policy development (including detailed clinical data, much of it from EHRs), they are not ready in most states (except Delaware) for research use today. Generally, privacy and data ownership concerns still need to be resolved.

USING HMO RESEARCH NETWORK DATA TO EVALUATE SPECIALTY DRUGS

In several instances, specialty pharmaceuticals have offered significant new therapies for many diseases, but their costs are considerably higher (especially biologic agents) than conventional small-molecule agents. Therefore, cost effectiveness can be an issue, though in some cases, only one agent exists to treat a rare condition or patients may only be able to turn to one drug if others are ineffective. In many cases, specialty pharmaceuticals have allowed patients to return to productive life.

As a result of unrestrained pricing and questions about appropriate use, health plan coverage of specialty products continues to be an issue. Yet the highly personalized discussions that take place if one has, for instance cancer, helps frame the ethical and rationing debate (i.e., "if it were my mother, I'd want her to get the drug," but from a societal point of view, this argument may not be supported). There is a real need to educate the public about the complexity of these issues to help inform the discussion.

The HMO Research Network has engaged in several studies to determine safety, patterns of use (e.g., dose escalation and concomitant treatments), and validation of commercial electronic data use in evaluating specialty drugs (See Sidebar for examples).

Funding for HMO Research Network projects comes from many sources, with federal money accounting for 55% of projects, followed by pharmaceutical industry (14%) and HMO Research Network member organizations (12%). The remaining 19% is obtained from foundations, state grants, and other miscellaneous resources.



2ND ANNUAL
FMCP
Research Symposium

SAMPLES OF STUDIES BY THE HMO RESEARCH NETWORK INVOLVING SPECIALTY PHARMACEUTICALS

Patterns of Infliximab Use Among Crohn's Disease Patients in a Community Setting

Objective: A cohort study to examine predictors of infliximab initiation and discontinuation among community-based Crohn's disease patients.

Notable Methods: Data obtained through linkage of computerized clinical information.

Results: Rapid increase of infliximab observed since 2001 but 3 years after initiation, only one-fifth of patients continue administration.

Conclusions: Age and comorbidity factors were associated with initiation of therapy but not sex or race/ethnicity. Utilization has steadily increased. Further research is needed to determine reasons for therapy discontinuation.

Source: Pressman AR, Huffless S, Velayos F, et al: Patterns of infliximab use among Crohn's Disease patients in a community setting. *Inflamm Bowel Dis.* 2008;14:1265-1272.

Comparative Safety of Infliximab and Etanercept on the Risk of Serious Infections

Objective: To determine whether certain characteristics predicted which patients were at higher risk for administration-related infections.

Notable Methods: Study population was members of Kaiser Permanente Northern California with rheumatoid arthritis.

Conclusions: Increased risk of infections for infliximab versus etanercept was not modified by sex, race/ethnicity, body mass index, or smoking status. Increased risk for infliximab-related infections may be limited to patients younger than 65 years.

Source: Toh S, Li L, Harrold LR: Comparative safety of infliximab and etanercept on the risk of serious infections: Does the association vary by patient characteristics? *Pharmacoepidemiol Drug Saf.* 2012;21:524-534.

RESEARCH CHALLENGES FOR SPECIALTY DRUGS

For most specialty drugs used to treat chronic disease or diseases that affect the working-age population, calculating return on investment can be a difficult, long-term project. If one considers patients with rheumatoid arthritis or Crohn's disease, utilization of these high-cost drugs may require many years of productivity benefits to enable demonstration of true cost effectiveness.

However, employment measures are difficult to obtain and to calculate. Absenteeism, presenteeism, productivity, and quality of life are critical measures but not inexacting. In addition, access to employer data is not easily obtained and corporations are often reluctant to share this information.

The recognition of the need for research, such as CER, may be encouraging a new willingness on the part of the federal government and private entities to share data to enhance both research and practice.

CONCLUSION

What must be addressed to promote evidence-based research that can transform healthcare? Although some inroads have been made, including all-payer databases, EHR-based data, and linked data sources, several issues need to be resolved. Access to cost data continues to be critical. Routine availability of data on race, ethnicity, and language is not yet on hand to allow for comparing care, outcome, nor adherence by group, and therefore cannot adequately address disparities. The ability to link comprehensive health-risk assessment data to utilization information could improve predictive modeling and targeting patients for case management. Furthermore, true population-based datasets, such as that promised by HIEs, have yet to materialize but offer significant promise in the next 5-10 years. Better access to employer-based productivity measures will help more accurately determine the value of care provided.

Key to this effort is the need to better understand how to integrate or link these datasets to improve the quality of the data used for managed care research.



INDUSTRY UTILIZATION OF REAL-WORLD EVIDENCE

Brian Sweet, BSPHarm, MBA
Executive Director, Healthcare Alliances
AstraZeneca Pharmaceuticals

The pharmaceutical industry spends a great of time discerning and developing a “value proposition” for its products. This requires having better data and evidence to support that the medication is safe, effective, and cost effective.

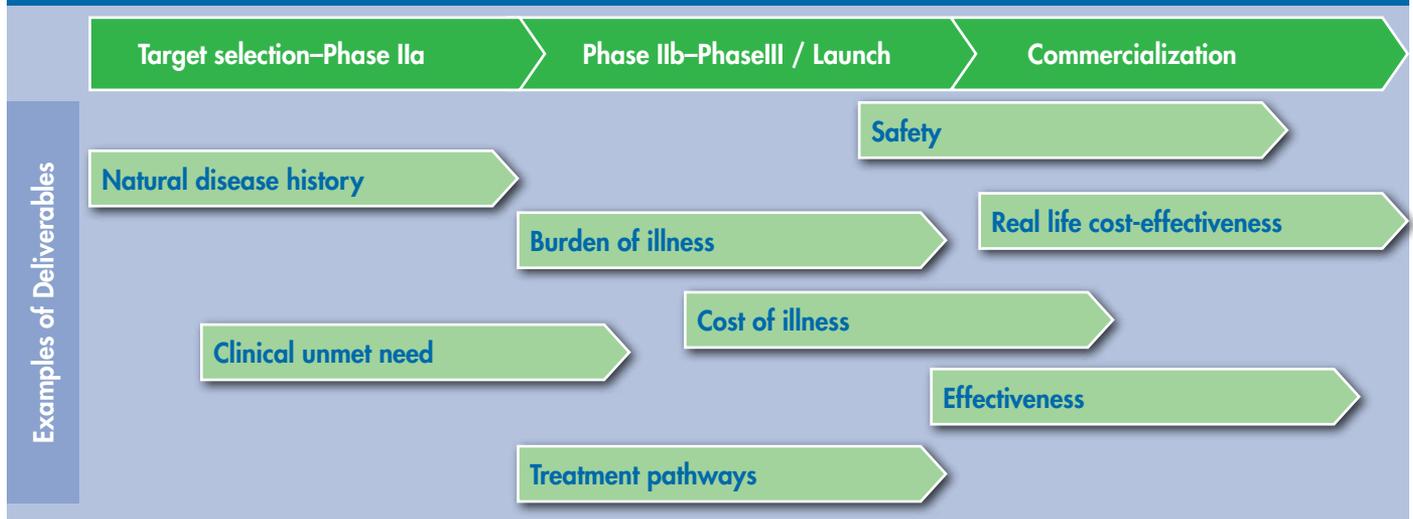
AstraZeneca took the initiative in 2010 to focus its efforts on obtaining and using payer real-world evidence (RWE), understanding that RWE is a vital component in demonstrating the value of its medicines in improving health outcomes in cost-effective ways. This new RWE capability at AstraZeneca was intended to create three separate core functions to improve the value proposition of the company’s products: (1) obtain the data in various payer environments (like payer claims databases) and use those data to generate the evidence that matters (i.e., not necessarily a surrogate endpoint, but an endpoint that matters to the payers, providers, and patients); (2) create the skill center to be able to do the analytics on the data that we collected to understand true health outcome information; and (3) use those insights in the marketplace to better demonstrate the value proposition of these products.

This emphasis on RWE has begun to change the way AstraZeneca discovers, develops, and commercializes its medications. The firm has created a different and centralized function around this concept, and has partners and collaborators around the globe that share its vision of getting the evidence that matters to payers.

Efforts are ongoing to include RWE in business development as well as at every stage of the product lifecycle. The organization evaluates RWE as it applies to investment decisions—whether to license or acquire a new agent from another entity, such as a drug discovery company, to evaluate where value can be provided to the healthcare system.

Real-world evidence is also being used at each stage of product development and during its lifecycle to meet the needs of payers by evaluating cost of illness, unmet medical need, burden of illness, treatment pathways (Figure). Payers need RWE because it demonstrates how a medicine may affect patients, healthcare systems, and costs in real-world settings. It also helps guide

Figure: RWE will deliver across the product lifecycle to meet player needs



This article was summarized by S.M. Health Communications from a podium presentation and approved by the speaker.



2ND ANNUAL FMCP Research Symposium

forecasts on return on investment (ROI) for both the company and the health system.

EXAMPLES OF HOW RWE CAN BE USED

In several areas of comparative effectiveness, AstraZeneca has used RWE to evaluate products in early-, middle, and late-stage commercial lifecycles. In one example, the organization studied the effectiveness of a mid-stage medication head to head with another drug on hospital length of stay and total cost of care.

Real-world evidence can also be used to study how diseases are treated in practice. Using retrospective claims analysis, researchers studied patient outcomes for those treated according to recommended guidelines compared with “real-world” treatment patterns. This analysis revealed supporting evidence showing that providers do not always follow the FDA-approved labels nor the accepted guidelines.

As mentioned earlier, RWE can help inform investment decisions, by identifying the extent of an unmet need. In one case, RWE was used to establish the incidence, prevalence, and usual course of treatment for patients with a particular disorder to better evaluate a business development opportunity for drug treatment. This RWE helped determine whether the company would see an ROI with an investigational compound.

EVOLUTION OF INFORMATION NEEDS

Payers’ informational needs are evolving with a shift toward medical cost offsets, cost effectiveness, and comparative-effective research-related outcomes. They are seeking more than data on safety, efficacy, and tolerability—payers are asking for data demonstrating clear reductions in morbidity and mortality, so they can better understand the value of medical interventions. This is also reflected in the payers’ informational needs involving specialty pharmaceuticals and the efforts by the Academy to change the *Format for Formulary Submissions* to address specialty products.

This means that the industry’s previous focus on safety, efficacy, and tolerability has to change to meet the demands of payers and patients. AstraZeneca is striving to meet these evolving needs, and seeks the opportunity to partner with payers to attain a better understanding of value in today’s marketplace. The organization is patient-centric in its philosophy, and cares about outcomes and costs of care. AstraZeneca believes that RWE can provide crucial information not necessarily available from randomized, controlled trials.

The organization is seeking to partner with patients, providers, and plans to obtain evidence that matters and that will result in value to the healthcare marketplace.

MAXIMIZING PAYER/PHARMA RESEARCH PARTNERSHIPS UTILIZING REAL-WORLD EVIDENCE

Mark J. Cziraky, PharmD
Vice President, Industry Sponsored Research
HealthCore Inc.

The landscape of the U.S. healthcare system is shifting, and the payer has emerged in the decision-making process right in the middle of the field. Payers are setting the bar higher than ever before for coverage decision making. The studies that were needed to obtain FDA approval, which were once all that were needed to be placed on formulary, are often insufficient today as the sole basis for payer approval.

A long-time challenge for healthcare researchers has been the disparate sources of data needed to obtain a comprehensive view

of the factors that may affect patient outcomes. These include clinical chart or medical record data, laboratory results, pharmacy claims, patient-reported outcomes, and other sources. HealthCore has collaborations not only with AstraZeneca but other pharmaceutical other biotechnology companies. HealthCore’s partners seek to analyze the organization’s research environment, which may include databases derived from WellPoint-owned health plans and other Blue Cross Blue Shield plans in several states. The database includes integrated medical and pharmacy data on 28 million members (the database, as of April 2012, comprised medical data only on an additional 16 million members). This results in an excellent, linked environment for healthcare research.

This article was summarized by S.M. Health Communications from a podium presentation and approved by the speaker.



REAL-WORLD EVIDENCE (RWE) IN SPECIALTY PHARMACY RESEARCH

Although there is limited information available on specialty pharmacy using RWE, some examples do exist. In multiple sclerosis (MS), for instance, a longitudinal (4 yr), sequential survey of patients with MS was conducted to gather patient-reported outcomes. The researchers linked the survey information from a patient registry to a claims database to evaluate the effect of natalizumab treatment (and adherence) on resource utilization. As MS is a progressive disease, findings of stable disease or fewer flares would indicate positive outcomes. Results of the analysis indicated that the majority of patients either had stable disease or improved while receiving natalizumab treatment. The researchers found that patients who adhered to treatment with the drug experienced reduced inpatient and emergency room visits as well as decreased MS-related relapse compared with nonadherent patients. The study has been presented in numerous abstracts and two articles in the peer-reviewed literature.^{1,2}

A second example of RWE in specialty pharmacy research involved pneumonia, to determine the rehospitalization rate of patients with pneumonia using vancomycin versus linezolid. The researchers sought to determine whether the declining use of linezolid was having an effect on hospitalization rates. Patients were identified through a database of pneumonia-related hospitalizations between 2007 and 2009. In this collaboration with researchers from the University of Maryland, HealthCore investigators demonstrated that in patients with pneumonia who were rehospitalized for any reason or for a pneumonia-related cause, those initially treated with linezolid generally had lower rates of readmission. This may have implications for plans and insurers, because linezolid is in many cases on a nonpreferred tier (and requires prior authorization).

The third example involved specialty drugs used to treat rheumatoid arthritis (RA). The tumor necrosis factor (TNF) blockers are relatively costly products and have been associated with dosage escalation over time, which can magnify the cost implications of these agents. As the various TNF blockers differ in dose, frequency of dosing, and route of administration, a better understanding of the dose used in practice and the dosage patterns observed over time would provide additional valuable information that could be used during the review of the medication class. Using HealthCore's Integrated Research Database (HIRD), the analysis confirmed that dose escalation was indeed occurring, with etanercept associated with the lowest incremental increase in dose over 1-year of follow-up (all patients had to be diagnosed with RA for at least 6 mo before the index date [their first claim]).

Infliximab was associated with the greatest dose escalation. Real-world evidence was thus used in this example to confirm the previous research findings in this specific population.

OPEN ARCHITECTURE KEY TO COLLABORATIVE EFFORTS

Collaborations among several organizations can only occur in an environment that encourages a variety of perspectives and expertise to the focused discussion. For this reason, HealthCore, with its parent organization WellPoint, has embraced the concept of "open architecture" in their collaborations with external partners. Open architecture is not truly a structure, as its name implies, but rather a framework for the collaboration itself, which emphasizes transparency and open disclosure in collaborative projects that are evidence focused and seek to provide information that is valuable to the larger healthcare community. The overall intent is to be able to publish the results of these collaborations to the general healthcare audience. This is generally targeted to studying a critical disease or cost of care issue that can meet the collaborators' shared goals. Open architecture collaborations seek to provide information that would support better coverage decision making. This may relate to disease burden, current treatment patterns, cost trends, or the relationship between interventions and outcomes.

These collaborations can be focused on a specific research project or a method of information sharing, all with the goal of enabling manufacturers to better understand the value their new products may have, based on the payer's perspective, earlier in the development process.

CONCLUSION

Involving multiple organizations needs to stand the test of time; similarly, studies involving RWE take time. Obtaining the necessary linked databases and collecting the data over extended periods will better reveal patterns of care or resource utilization.

Open architecture or other collaborative arrangements seem to be a valuable tool towards jointly investigating, using linked databases, important issues involving care outcomes, cost, and value.

1. Kamat SA, Rajagopalan K, Stephenson JJ, et al: Impact of natalizumab on patient-reported outcomes in a clinical practice setting: A cross-sectional survey. *Patient*. 2009; 2:105-112.

2. Tan H, Cai Q, Agarwal S, et al: Impact of adherence to disease-modifying therapies on clinical and economic outcomes among patients with multiple sclerosis. *Adv Therapy*. 2011;28:51-61.



PANEL DISCUSSION 1

CAPITALIZING ON COLLABORATIVE RESEARCH: PARTNERSHIPS TO TRANSFORM CARE IN COMPLEX DISEASES

GROWING A COLLABORATION

Dr. Brixner, the Symposium Chair, related her experience when working for Novartis some years ago. She met Maggie Gunter, PhD, who led Lovelace Clinic Foundation, a close non-profit research affiliate of Lovelace Health System, and they began to build a working relationship while managing projects relating to epilepsy. “It took time to build the relationship and then the collaboration between the two organizations,” Dr. Brixner emphasized.

Dr. Gunter added, “The emphasis of the collaboration was really on what would work for patients and providers. Lovelace had not only outcomes data but also collected patient-reported data and provider surveys. Our project was a well-rounded disease management initiative.” She commented that the collaboration worked so well because “Novartis avoided a product-driven focus.”

IMPROVING THE VALUE OF THE RANDOMIZED CONTROLLED TRIAL

This is an exciting time for real-world evidence and comparative-effectiveness research, said David L. Clark, RPh, MBA, President and founder of VisumRx, Seattle. “With the introduction of health information exchanges and new linked databases, the volume of data we’ll obtain is unprecedented.” However, is there a way to increase the validity of randomized controlled trials for the practice setting? “What advice would you give to improve the validity of these studies?” Mr. Clark asked.

The best place to start is by understanding the appropriate methods to use in gathering the data. “One of the dangers today,” explained Mark J. Cziraky, BSPHarm, PharmD, “is the lag of methods behind the availability of data.” Dr. Cziraky, Co-founder and Vice President, Industry Sponsored Research, HealthCore, Wilmington, Delaware, said, “We have to be able to ask the right questions based on the data we’re analyzing.”

Brian Sweet, BSPHarm, MBA, Executive Director, Healthcare

This article is a summary of a panel discussion moderated by **Diana Brixner, RPh, PhD**, Professor and Chair, Department of Pharmacotherapy and Executive Director, Outcomes Research Center, University of Utah College of Pharmacy, Salt Lake City

Alliances, AstraZeneca, Wilmington, Delaware, added that an “informed data environment” is essential—that is, knowing whether a prior authorization is in place for the agent being studied if the study is investigating the utilization of the product.

Dr. Gunter suggested that we need “pragmatic clinical trials,” which would apply the rigor and accuracy of randomized controlled trials to real-world evidence.

INVOLVING MORE ORGANIZATIONS IN COLLABORATIVE RELATIONSHIPS

Large health plans and those participating in the HMO Research Network, for example, have the ability to perform pragmatic clinical trials (or at least participate in them). Smaller health plans, however, have fewer resources and less opportunity to participate. One Research Symposium attendee pointed out that the need exists to find better ways to involve these smaller plans and perhaps align them with potential partners. It is possible that the Academy can play a role to meet this need—or perhaps to develop relationships with other associations, such as the International Society for Pharmacoeconomics and Outcomes Research, (ISPOR) to raise the capability of these smaller managed care plans to participate.

Hardly any of the health plan representatives attending the conference indicated that they had the capability of producing clinical and claims data for research purposes. Dr. Brixner commented, “It may be that the smaller plans do not have the information technology or research personnel capacity to do this.”

USING RESEARCH RESULTS FOR PRACTICAL DECISION MAKING

Some plans participate in health services research on medications, but the interval between completion of the study and the time it takes to publish the results can be up to a year or more. Managed care pharmacy directors often need to make business decisions about new technologies before these data are available. Dr. Gunter agreed, “When we surveyed members of the HMO Research Network, we found that the plan executives wanted the results of the research faster than we could give it to them. The time needed to obtain funding for specific research



questions was often too long to meet their real-world needs.”

Mr. Sweet elaborated, “We need better evidence when new drugs enter the market, not only when they’ve been out for a year.” He continued, explaining that “the pharmaceutical industry is concerned because the value proposition of some products is not fully available at launch, but only later on, with experience and real-world evidence.”

Part of the answer, according to Dr. Cziraky, “is to ask the studies to answer better questions. We need better collaboration in these research designs to yield more value after their completion.”

FILLING IN THE DATA GAPS

In the case where no medical data exists (only claims data), can an open-architecture collaboration still work? In collaborations, Mr. Sweet pointed out, “you may be dealing with two very different network styles. We all want to be in an integrated approach, but it takes money and time to get there. Consider the challenges of trying to capture data from a PPO environment—it is even more complex—too many data points are missing.” He stated, “If you can connect up these data points, you can get a more 360-degree view of the patient.”

Dr. Cziraky said, “We can answer some of the more resource-intensive questions today, by capturing data that are in the electronic health record (EHR), for example.”

ARE THERE LESSONS FOR US FROM OVERSEAS EFFORTS?

Changes are occurring with regard to coverage decision making in Germany and in the United Kingdom. The panel considered whether those countries provide a model that can be applied for coverage decision making in the United States.

Mr. Sweet commented that it’s usually more challenging to access the necessary data in other countries. In the United Kingdom, for example, “the best way to get the data is to have the research conducted through academic institutions.” However, he pointed out that even in the United States, “many health plans say they have EHR data, but the quality and comprehensiveness of those data varies. You have to be careful when evaluating data and how well informed they are. Many organizations are still building their EHR.”

In the United States, smaller providers are having difficulty coming up with the resources to collect all of these data, said Dr. Gunter. “The federal government is providing technical assistance to them, through the funding of HIT Regional Extension Centers, to help them adopt EHRs and qualify for incentives (i.e., the ‘meaningful use’ provisions) from the Centers for Medicare & Medicaid Services. It will take a few years,” she stated, “but it will make a big difference in the quality of data available.”

One encouraging point was also raised, in that accountable care organizations, when these comprise disparate entities, may have the ability to form “virtual” integrated systems, and therefore be able to link their data sources into a high-quality source for research.

UPDATING THE AMCP FORMAT FOR SPECIALTY PHARMACEUTICALS, COMPANION DIAGNOSTICS, AND COMPARATIVE-EFFECTIVENESS RESEARCH

Peter Penna, PharmD
Co-Founder and Partner
Formulary Resources, LLC
Mercer Island, WA
and
Chair, AMCP Format Executive Committee

The Academy of Managed Care Pharmacy (AMCP) first released its *Format for Formulary Submissions* in 2000.¹ It has since become widely accepted as the standard for manufacturers

This article was summarized by S.M. Health Communications from a podium presentation and approved by the speaker.

seeking to provide health plans and insurers with information about their pharmaceutical products that would be of value in formulary decision making.

In the past decade, specialty pharmaceuticals have been increasingly prescribed and this trend is forecast to continue.² Many of the new agents in the pipeline are specialty products.³



2ND ANNUAL FMCP Research Symposium

To optimize the use of some of these products, companion diagnostic tests are being developed and evaluated along with the investigational pharmaceutical. These tests may search for specific biomarkers, including gene mutations or biochemical levels, which may inform the prescriber whether the agent would be appropriate to use in a particular patient. Furthermore, higher costs associated with these specialty pharmaceuticals have raised scrutiny of their value in patient care, and this has prompted greater demand for comparative-effectiveness research (CER) to support their use.

The landscape of formulary decision making and technology assessment is being transformed by these trends. As a result, Academy members and leadership held wide-ranging discussions about whether to consider revisions to the *Format*, which would lead to improved evaluations of pharmaceuticals.

ADAPTING THE *FORMAT* TO A CHANGING ENVIRONMENT

The process for making changes to the *Format* is run through AMCP's *Format* Executive Committee. After studying and evaluating the need for an update to the *Format*, the committee will draft recommendations for change which are then sent to the AMCP Board of Directors for ratification. The last revision (version 3.0) was released in October 2009.

In 2011, the *Format* Executive Committee, in discussions with the Board, determined that a full revision of the *Format* would not be necessary, but that several changes would be appropriate to assure that the *Format* was providing proper guidance for pharmaceutical companies, health plans and other interested stakeholders. This would be accomplished via addenda in three areas: (1) specialty pharmaceuticals, (2) companion diagnostics, and (3) CER. One subcommittee of the *Format* Executive Committee was established to evaluate each topic (i.e., three committees in total) and recommend any changes that would provide improved guidance for these issues. Each subcommittee was further divided into a writing team and a review team. Several external experts were added to each subcommittee.

There was an initial call for public comment and input for each topic. Following this input, each subcommittee created a draft of the assigned addendum, which was then released for public comment. Final versions have now been approved by the full *Format* Executive Committee [*Editor's Note*: The AMCP Board approved the addendum at its December 2012 meeting].

SPECIALTY PHARMACEUTICALS

Although the issue of specialty pharmaceuticals is generally covered by version 3.0 of the *Format*, it was determined that

improvements would be appropriate. Included would be a standardized definition of the term "specialty pharmaceutical." The definition used for the addendum focuses on the complexity of drug use and methods of drug delivery (administration process as well as issues of supplying the patient), rather than cost. Other areas to be covered would be:

- Evidentiary requirements
- Listing of National Drug Code as well as Healthcare Common Procedure coding and current procedural terminology codes
- Special dosing instructions, administration requirements, and delivery devices not included in the prescribing information
- Full disclosure of access issues (e.g., limited specialty pharmacy distribution)
- Comparator issues for unique drugs and rare conditions
- Discussion of the ancillary disease/care management concerns

COMPANION DIAGNOSTICS

The issues surrounding companion diagnostics are more complex. Pharmaceutical and companion diagnostic test (CDT) manufacturers need guidance concerning the clinical and economic evidence required by managed care decision makers and other interested parties. The goal of companion diagnostic testing is to help identify those patients who may benefit (or may not benefit) from a drug, and who may be at increased risk (or decreased risk) for adverse events from using a drug. Companion diagnostic testing will also be useful in managing the course of therapy, by measuring response to therapy. Although companion diagnostic testing can be useful for traditional drugs, it may be especially useful for specialty pharmaceuticals.

In terms of formulary decision-making, managed care executives will want to see how companion diagnostics affect the safety, efficacy, effectiveness, and overall value of the drug in question. To do this, communications between CDT manufacturers and managed care executives will have to occur; generally, this has not taken place in the past.

Complicating the area of companion diagnostics coverage evaluation is the fact that regulatory approval for these tests is very different than that for pharmaceuticals. Depending on where the CDT was developed, either the FDA or CMS may be the agency that grants approval, and in either case, the approval process is much less stringent than that used for pharmaceuticals.

A further complication is that the implementation of dossier requests for CDTs using the *Format* may be complicated by the variety of potential relationships between a pharmaceutical



manufacturer and the CDT manufacturer or provider. The following are possible CDT development scenarios:

1. The CDT is co-developed with drug, and FDA-approved together with drug
2. The CDT is developed independently of drug, typically after drug approval, but the FDA may require its use in the labeling of the specialty drug
3. The CDT is developed independently and targeted for a class of medications, and is not required per the approved labeling for a drug.

COMPARATIVE-EFFECTIVENESS RESEARCH

Many types of CER data are already addressed in version 3.0 of the *Format*, including head-to-head data and health economic or cost-effectiveness evidence. These are mentioned in three separate areas of the existing *Format*. The addendum to the *Format* will include more information on CER, such

as definitions (taken from the Institute of Medicine) and a detailed explanation of the various types of CER. Although the additional guidance provided in the CER addendum will be helpful, it is not intended to provide a comprehensive review of the complexities of CER nor its methods in this revision to the *Format*.

1. History of AMCP. Academy of Managed Care Pharmacy (www.amcp.org/AboutUs.aspx?id=2538). Accessed October 26, 2012.
2. Specialty: Fastest growing health care cost line item. 2011 Insights: Changing Rules, Changing Roles. CVS Caremark 2011. (www.amcp.org/WorkArea/DownloadAsset.aspx?id=10384). Accessed October 26, 2012.
3. Medicines in development: Biotechnology. PhRMA 2011 (www.phrma.org/sites/default/files/1776/biotech2011.pdf). Accessed October 27, 2012.

TRANSFORMING RESEARCH INTO ACTION: SPECIALTY PHARMACY RESEARCH SHOWCASE

Atheer Kaddis, PharmD
Senior Vice President, Managed Markets/Clinical Services Diplomat Specialty Pharmacy

Some of the most costly disease categories as they relate to specialty pharmacy include oncology, multiple sclerosis, hepatitis C, and rheumatoid arthritis. In total, \$100 billion was spent in 2010 on specialty pharmaceuticals.¹ The annual trend in specialty pharmacy expenditures has been between 15% and 25% in the past 5 years—a trend that is expected to continue in the future.^{1,2} In contrast, health plans have experienced flat annual trends for traditional pharmaceuticals over the same period.

Factors driving this growth include new specialty pharmaceutical introductions and approvals by the U.S. Food and Drug Administration, more than 50% of the agents in the pharmaceutical pipeline are specialty pharmaceuticals,¹ and the significant off-label use for specific categories of specialty medications. It is estimated that specialty pharmaceuticals will represent the top selling drugs by revenue by 2014.³ The specialty pharmacy market is maturing, and although there is heavy

competition in some categories (e.g., chronic myeloid lymphoma and rheumatoid arthritis) for others, few alternatives are available.

A higher proportion of specialty drug expenditures is under the medical benefit today, but health plans and insurers have been moving coverage toward the pharmacy benefit or through specialty pharmacy dispensing, in an effort to better manage their costs. Other steps being taken to manage the category consist of basic drug cost management, formulary access management, utilization management, and drug therapy management at the patient level (Figure). Each of these efforts involve some degree of management costs, with high-touch patient care management being the most resource intensive and obtaining better discounts being the least cost intensive.

CASE STUDIES IN SPECIALTY PHARMACY RESEARCH

Partial-Fill Program for Oral Oncolytics. In addition to improving upon several aspects of patient care programs for individuals with cancer, in 2011, Diplomat Pharmacy focused a partial-fill program on eight highly prescribed oral oncolytics, all of which have high discontinuation rates (related to poor

This article was summarized by S.M. Health Communications from a podium presentation and approved by the speaker.



2ND ANNUAL FMCP Research Symposium

response, tolerability, and poor adherence). When complete fills are permitted, the discontinuation rates may result in considerable drug waste, and based on the costs of these agents, this represented a significant cost-saving opportunity.

For Tarceva® (erlotinib), Sutent® (sunitinib), Nexavar® (sorafenib), Gleevec (imatinib), Afinitor® (everolimus), Sprycel® (dasatinib), Targretin® (bexarotene), and Votrient® (pazopanib), patients initiating therapy were given 14 or 15-day supplies for the initial two fills. According to Diplomat's data, 52% of patients discontinued therapy after one or two partial fills (with up to 15% discontinued after the first partial fill). Diplomat Pharmacy believes that implementing a partial fill program for these oncolytics could result in potential savings of 25% of the total drug spend on these eight agents. Based on the potential of this program, the company has now expanded it to limit partial fills to 15 oral oncolytic agents and two non-oncolytic agents. Some of Diplomat's health plan clients are actually considering partial fills on all oral oncolytics.

Depression Screening in Patients With Hepatitis C or Multiple Sclerosis. One aspect of the organization's patient care program is to screen for the presence of depression in those with several chronic diseases, such as hepatitis C and multiple sclerosis.

Of nearly 1,200 patients with hepatitis C screened using the Patient Health Questionnaire (both the PHQ 2 and PHQ 9) over 1 year, two patients were found to have suicidal ideation. Of

2,930 patients with multiple sclerosis screened over the same period, 42 were revealed to have suicidal ideation (average depression scores, 9.3 and 10.6, respectively). In these cases of major depression, Diplomat coordinates with case management personnel to help address the problem.

Dose Escalation in Rheumatoid Arthritis. The occurrence of dose escalation in the long-term use of tumor necrosis factor (TNF) inhibitors is important, as costs of these expensive specialty drugs can rise significantly with the utilization of greater doses. The American College of Rheumatology recommends the use of disease-modifying antirheumatic drugs (DMARDs) in patients taking TNF inhibitors to provide better outcomes and potentially reduce the incidence of dose escalation.⁴

In January 2011, Diplomat added a question to its quality-of-life survey regarding DMARD use in those patients with rheumatoid arthritis. Patients who respond that they are not taking a DMARD with their TNF inhibitor therapy have their report pulled, and the prescriber is notified and given information about the American College of Rheumatology's recommendation. In 55% of the cases in which patients were not taking DMARDs with TNF inhibitors, it was simply not prescribed by the physician. For the remainder, they had either tried taking a DMARD (typically methotrexate) and could not tolerate the therapy or declined to take DMARD therapy.

Figure: Tools for managing rising specialty pharmacy expenditures

What Are We Doing About It?

Drug Therapy Management \$\$\$
(High touch patient care management)

Channel Therapy Management \$\$\$
(Medical to Pharmacy)

Utilization Management \$\$
(PA/Step therapy)

Formulary Management \$\$
(Preferred Drugs)

Drug Cost Management \$
(Discount Improvement)



CONCLUSIONS

Specialty pharmacies have typically relied on data obtained from their own patient and provider interventions. The previously mentioned interventions were the result of this type of internal data analysis. Much more can be accomplished through collaboration and data sharing.

Specialty pharmacies are capable of doing excellent quality research, based on their innovative programs. As specialty pharmaceuticals continue their trend toward dominance of the drug industry, more research focusing on specialty medications should be conducted and become available. Specialty pharmacies should share the results of their work through publications, and be encouraged to focus on research in this area.

1. *2011 Insights. Changing Rules Changing Roles.* CVS Caremark 2012, www.caremark.com.
2. *Complex Challenges, New Solutions: 2010 Drug Trend Report.* Express Scripts, St. Louis, MO, 2011.
3. Bartholow M: Top 200 prescription drugs of 2009. *Pharmacy Times* May 11, 2010 (<http://www.pharmacytimes.com/publications/issue/2010/May2010/RxFocusTopDrugs-0510>). Accessed October 20, 2012.
4. Saag KG, Teng GG, Patkar NM, et al: American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* 2008;59:762-784.

COMPREHENSIVE SPECIALTY PHARMACY MANAGEMENT: A PAYER'S PERSPECTIVE

Suzanne Tschida, PharmD, BCPS
Vice President, Specialty Benefit & Strategy
OptumRx

The goal of UnitedHealthcare's Specialty Pharmacy Program (SPP), which is managed by its business unit OptumRx, is to improve the healthcare outcomes of members taking specialty medications. These are defined as biotechnology or other drugs that are relatively high cost (avg, \$1,300/mo) that can be used to treat rare, chronic, or life-threatening conditions, but that also may be subject to additional monitoring, lab tests, or clinical interventions.

UnitedHealthcare's SPP offers the following:

- Clinical expertise in pharmacology and disease states
- Comprehensive member education
- Interventional adherence programs
- Pharmacist practice interventions to help members manage medication and disease state issues
- Clinical management programs that meet specific requirements for members
- Competitive financial performance and operational excellence
- Outcomes reporting
- Accreditation by URAC (formerly known as the Utilization Review Accreditation Commission) for Specialty Pharmacy

This article was summarized by S.M. Health Communications from a podium presentation and approved by the speaker.

This program seeks to guide patients to the right providers and provide the appropriate level of support to gain excellent results, in terms of adherence and health outcomes, as well as lower total healthcare costs.

STUDYING THE OUTCOMES OF SPECIALTY PHARMACY SERVICES

In order to compare the effectiveness of services received at UnitedHealthcare's designated specialty pharmacy network with services provided at retail pharmacies, UnitedHealthcare conducted retrospective claims analyses on 2 years of data for patients with cancer or organ transplants, and 4 years of data for patients with multiple sclerosis (MS) or rheumatoid arthritis (RA). For these studies, members were categorized as being in the specialty pharmacy cohort if they filled at least 80% of the specialty medication prescriptions through the specialty pharmacy. Those assigned to the retail pharmacy cohort filled at least 80% of their specialty pharmacy prescriptions in the retail drug store. All patients were matched by age and sex, comorbidities, geographic region, and by medical and pharmacy costs. The primary outcomes of the studies were costs (total, outpatient, medical, and pharmacy costs). The secondary outcomes were clinical resource utilization; visits to the hospital



2ND ANNUAL FMCP Research Symposium

outpatient department, inpatient admissions, and emergency room visits; and specialty disease-specific total medical and pharmacy costs.

Oral Oncology. For claims for oral oncology medications that were deemed specialty pharmacy items for oncology patients, total costs in year 1 were significantly higher when received in the retail pharmacy setting compared with the specialty pharmacy setting (\$97,196 vs. \$84,105, respectively; $P = .02$) but in year 2, this difference was narrowed (\$90,021 vs. \$83,598, respectively; $P = .32$). Medical costs followed a similar pattern in this patient cohort, with a \$15,000 difference in year 1 (\$61,137 vs. \$45,696, respectively; $P = .007$), compared with an \$11,500 difference in year 2 (\$52,243 vs. \$40,837, respectively; $P = .03$).

Adherence to oral oncology specialty medications was higher in the specialty pharmacy group, with the greatest difference appearing in year 2 (69% medication possession ratio vs. 53%, respectively; $P < .0001$). Pharmacy costs were higher in the specialty pharmacy group, though this was likely driven by the greater adherence. Medical costs were 25% lower in year 1 and 22% lower in year 2 in the specialty pharmacy group, which were driven by somewhat lower outpatient, inpatient, and office visits.

Of note, we also analyzed the claims of only those new to therapy. This subgroup analysis demonstrated greater savings but owing to the small sample sizes, there was no statistical difference.

Organ Transplant. For all transplantations, costs associated with obtaining medications and services through the retail pharmacy were approximately \$31,000 compared with roughly \$25,000 in the specialty pharmacy arm ($P = .05$) in year 1. The difference was about \$5,000 based on year 2 data, but this was no longer statistically significant ($P = .09$). Pharmacy costs in the specialty pharmacy group were found to be higher than in the retail pharmacy group, but not statistically so.

Multiple Sclerosis. Over the 4 years of retrospective claims analysis data for multiple sclerosis, medical costs in the specialty pharmacy group were found to trend lower, and prescription

costs were significantly lower in year 2 and 3 only. Patients in the specialty pharmacy group were associated with some lower total costs (\$948 saved per member utilizing specialty medications per year compared with the retail pharmacy group), which again may be attributable to competitive contracted medication reimbursement rates within the specialty pharmacy network. One possible reason for the lack of notable differences in medical cost outcomes is that multiple sclerosis is a slowly progressive disease; longer duration studies may be needed to demonstrate cost savings.

Rheumatoid Arthritis. For rheumatoid arthritis, use of specialty pharmacy resulted in lower overall costs (\$792 per member using specialty pharmaceuticals per year) but not significantly lower medical costs (although a lower trend was evident). Interestingly, there was no significant difference in terms of medication possession ratios between the groups for the majority of the 4-year claims evaluation.

This overall savings may be the result of savings derived from competitive contracted medication reimbursement rates within the UnitedHealthcare network. Again, the nature of rheumatoid arthritis may require longer-duration longitudinal studies.

CONCLUSION

Although these claims data analyses have many study limitations (e.g., retrospective studies, no quality-of-life data, no productivity data, no consideration of utilization management tools), there is a trend toward improved adherence with lower total costs in specialty pharmacy programs that focus on patient education and specialty clinical oversight. Some of this savings is the result of competitive medication reimbursement rates associated with the specialty pharmacy program.

Specialty pharmacists appear to help coordinate pharmaceutical care and reduce medical resource utilization among members with cancer, organ transplantation, multiple sclerosis, and rheumatoid arthritis. Investment in these programs can improve medication adherence and reduce overall resource utilization.



PANEL DISCUSSION 2

USING REAL-WORLD EVIDENCE TO OPTIMIZE EFFECTIVENESS OF SPECIALTY PHARMACEUTICALS

THE PSYCHOLOGY OF PARTIAL FILLS

When considering partial fill programs (particularly for life-threatening disorders), it is important to evaluate the “emotional and psychologic effect this can have on a patient,” said one of the attendees. What the pharmacist or doctor tells the patient can be very important: “Do you tell them that you’re only giving them a partial fill because these agents have serious side effects, or because you don’t think the medication will work for them?”

Atheer Kaddis, PharmD, of Diplomat Specialty Pharmacy added that there is a reason we may not believe that the oncology drug will work for them. He explained, “The therapies are being started too late in disease course for them to have a useful effect. Maybe the real question should be why we’re not more aggressive in having end-of-life care discussions with these patients with advanced metastatic disease.”

PATIENT COST-SHARING SUBSIDIES AND ADHERENCE

Much has been published regarding the relationship between rising patient cost sharing and copayments and declining adherence. However, manufacturer subsidy coupons can reduce the patient’s out-of-pocket burden and may therefore have a positive effect on adherence.

Suzanne J. Tschida, PharmD, BCPS, Vice President, Client Clinical Programs and Outcomes of OptumRx, acknowledged that patient cost burden associated with specialty drugs is a worrisome issue for both members and payers. “We would welcome broader discussions regarding copay cards with the manufacturers and other payers. It has us very concerned,” commented Dr. Tschida. Copay coupons circumvent formulary placement as a pharmacy management tool. She added, “Currently, 78% of our members with rheumatoid arthritis

are using manufacturer coupons/copay cards for their tier-3 rheumatoid arthritis medication. Next year, we plan to no longer accept manufacturers’ copay coupons for a limited number of specialty tier 3 agents that have lower tier specialty medication options. This would not apply to copay coupons from charitable organizations.” The best way to avoid this problem would be to have managed care organizations educate physicians and members to steer them to available tier-2 medications.

From the perspective of specialty pharmacy providers, “there is nothing more important to us than copay support for our patients,” stated Dr. Kaddis. Ordinarily, patients may have to pay \$100 to \$200 each month that they take the specialty pharmaceutical therapy. “Without these copay assistance programs, our adherence rates would be much, much lower, which would result in higher costs overall.” Dr. Kaddis noted, “We received \$17 million in patient cost-share assistance just from charitable organizations (which may be indirectly funded by pharmaceutical companies). Without it, we would see much more discontinuation of therapy from these patients.”

The panelists discussed how the cost of specialty pharmaceuticals continues to rise, and how, at some point, increasing adherence will lead to greater pharmacy costs that may not be offset by lower medical costs in a short period of follow-up, such as 6 to 12 months of utilization. Dr. Tschida agreed with this point and noted that given the high cost of specialty medications, it is pivotal to insure that many management strategies are deployed including adherence, utilization, and clinical management programs along with tiering, leveraging rebates and contracting, and optimal benefit design for specialty medications including those in the rheumatoid arthritis, HIV/AIDS, and multiple sclerosis disease states that are more slowly progressive and whose treatment therapies are for chronic use. In these disease states, longer follow-up periods will be necessary to show the implications of specialty programs on outcomes.

PATIENT RESPONSIBILITY

The increasing costs of care have reached a point where patients will have to be held accountable for adhering to the medical

A summary of a panel discussion moderated by **Welton O’Neal, Jr., PharmD**, Vice President of Pharmacy Affairs, AMCP, and Executive Director, FMCP. Panelists included: Atheer Kaddis, PharmD, Diplomat Specialty Pharmacy; Douglas Burgoyne, PharmD, President, VRx Pharmacy Services, LLC; and Peter Penna, PharmD, Chair, AMCP Format Executive Committee.



2ND ANNUAL FMCP Research Symposium

regimens prescribed by their doctors. In this context, it seems that patient report cards (completed by physicians) may be a future consideration.

Douglas Burgoyne, PharmD, President, VRx Pharmacy Services, LLC, and 2012 President of AMCP, believes that accountable care organizations and shared savings models may help drive this. Peter Penna, PharmD, Principal of Formulary Resources LLC, agreed, saying, “We’re entering a phase where patients will have to take more responsibility for their own care.”

DATA COLLECTION ON FACEBOOK?

The moderator, Welton O’Neal, Jr., PharmD, asked the panel to consider whether social media will be an emerging source of data that can be of benefit to specialty pharmacy. This is still in its infancy, said Dr. Penna, “but one of the principal concerns is the quality of data that you’re collecting.”

Dr. Burgoyne confirmed that “data collection from sites like Facebook is fairly commonplace for market research outside of the medical field; but specialty pharmacy or managed care in general has not really used this as a data source.”

CLOSING COMMENTS

Diana Brixner, RPh, PhD

**Professor and Chair, Department of Pharmacotherapy and Executive Director, Outcomes Research Center
University of Utah College of Pharmacy
Salt Lake City**

In this symposium, we presented a great deal of information, and had excellent dialogue around research in the specialty pharmacy arena. It is apparent that true value exists in sharing our research with others in the Academy of Managed Care Pharmacy.

There may be an opportunity to spur communication of managed care research in this area, by perhaps offering more research presentations at the annual meeting of the Academy, similar to those presented at other major clinical society conventions. Furthermore, the FMCP Research Symposium may serve as a venue for posting the results of such research (i.e.,

poster presentations) in combination with the AMCP scheduled meetings.

In any case, the rapidly expanding world of specialty pharmacy offers unique opportunities to delve into questions of value, adherence, and management. The higher costs associated with these agents, the increased patient out-of-pocket costs required by health plans and insurers, and the questions of resource limitations make it imperative that the managed care research establishment focus on these issues to improve patient care and the efficiency of the healthcare system.



Improving Patient Care

At Gilead, we are working to discover, develop and commercialize innovative therapeutics in areas of unmet medical need. Through our portfolio of marketed products and our pipeline of investigational compounds, we strive to set new standards that can ultimately change the way diseases are treated with the goal of improving patient care around the world.



For more information, please visit www.gilead.com.

© 2012 Gilead Sciences, Inc.

A hand holding a stethoscope over a military uniform with an American flag patch.

We Make Quality Healthcare Accessible Around the World

Teva Pharmaceuticals continues to be a proud partner with Federal Health Care—providing health care solutions where they matter most.

For innovation and expertise in the fields of respiratory, neurology, women's health, oncology, pain care, biologics, and specialty products, look to Teva Pharmaceuticals.

www.tevapharm-na.com

proving value. maximizing access.®



GIVE PAYERS A PIECE OF YOUR MIND.

SHARE CLINICAL AND ECONOMIC INSIGHTS FOR
EVIDENCE-BASED VALUE.

Xcenda's integrated team of clinicians, HEOR, and creative professionals understands what Payers need to know. We ask – and answer – the questions others don't. Connect with the experts who are redefining what it means to be a Managed Markets agency.



Contact:

Matt Sarnes, PharmD
Vice President, Payer Agency Services

Matt.sarnes@xcenda.com

610.489.6311

Xcenda.com

[Start a conversation today.](#)

Passion for Innovation.
Compassion for Patients.™



Daiichi Sankyo is a global pharmaceutical company with its corporate origin in Japan. We provide innovative products and services in more than 50 countries around the world. With more than 100 years of scientific expertise, our company draws upon a rich legacy of innovation and medical advancements.

Building on our experience in hypertension, antiplatelet and anticoagulation therapies, we are excited to be expanding into other important areas such as oncology, where significant unmet medical needs remain. Today, with our growing presence in developing and emerging markets, we are pleased to serve the needs of patients throughout the world.



Discover more at
WWW.DSI.COM