A peer-reviewed publication of the California Pharmacists Association

# California Pharmacist

VOL. LXII, NO. 3
SUMMER 2015

## Community Pharmacy or Mail Order?

## Role of a Pharmacy Technician in Tobacco Cessation

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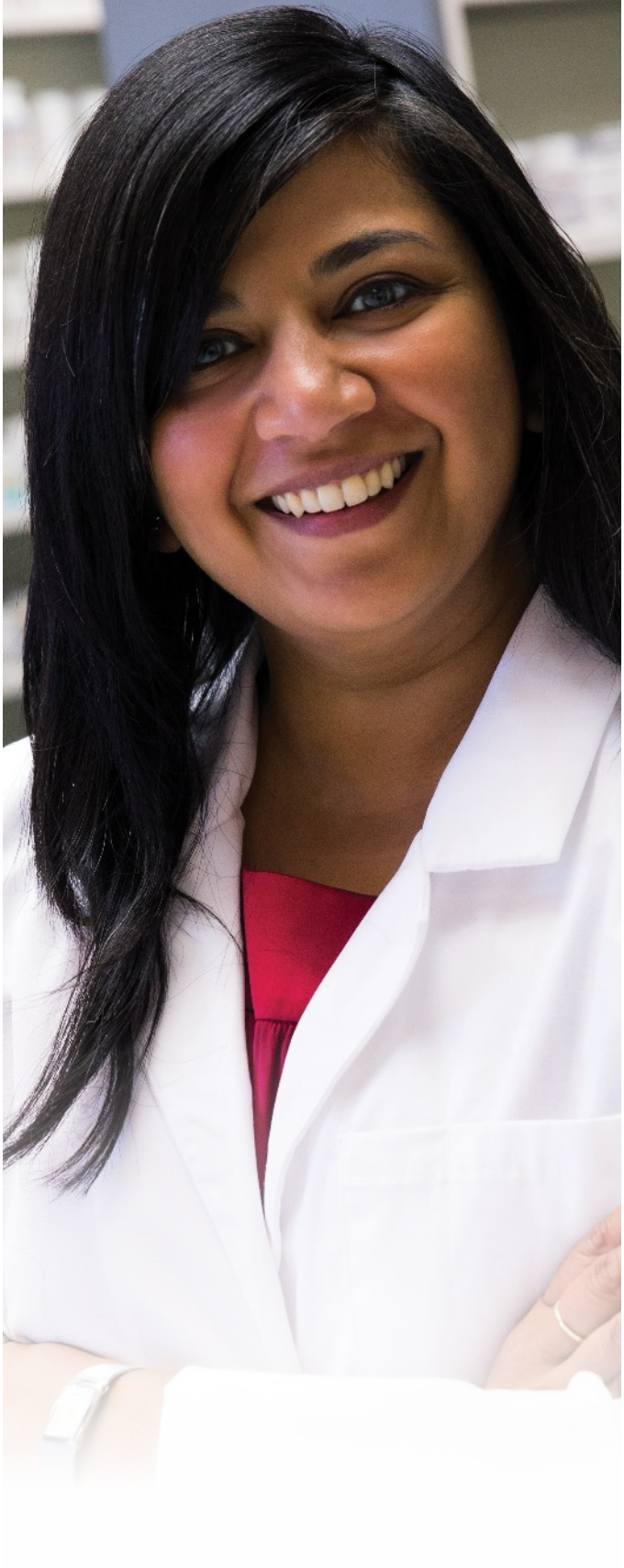

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# California Pharmacist Journal

SUMMER 2015

*California Pharmacist* (SSN 0739-0483) is published quarterly on or about February 1, May 1, August 1 and November 1 by the California Pharmacists Association, 4030 Lennane Drive, Sacramento, CA 95834. *California Pharmacist* is distributed as a regular membership service, paid for through allocation of membership dues. Subscription rate is $80 per year domestic; single copies are $20. The international rate is $100 per year; $30 per copy. Periodicals postage paid at Sacramento, California and at additional mailing offices. Postmaster: send address changes to *California Pharmacist,* 4030 Lennane Drive, Sacramento, CA 95834. Publisher assumes no responsibility for unsolicited material. Manuscripts, artwork, and photographs must be accompanied by stamped, self-addressed envelopes, if return is desired. Letters to the editor are encouraged; publisher reserves the right to edit and publish, in whole or in part, all letters received. Byline articles express the opinions of the authors and do not necessarily reflect the view or policies of the California Pharmacists Association. Nothing in this publication may be reproduced in any manner, either in whole or in part, without specific written permission of the publisher.

*California Pharmacist,* the official publication of the California Pharmacists Association, is a professional journal devoted to informing pharmacists and enabling them to better serve the health and welfare of their patients.

**2015**
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http://www.cpha.com
ISSN# 0739-0483

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### CONTINUING EDUCATION

# Moving the Ball Down the Field?

I have used this column in the past to describe the many exciting aspects of the California Pharmacists Association (CPhA) sponsored legislation, Senate Bill 493. That legislation granted provider status to California pharmacists and expanded the clinical care services that pharmacists can perform in this state.

Advocates for SB 493 knew then, and continue to believe, that when pharmacists are engaged in the clinical care of patients, good things result. Those results include better access to care, higher quality of care, and a reduction to health care costs. In health policy circles we call this the "Triple Aim," which is in reference to the federal efforts under the Affordable Care Act to expand health care in America.

Since the signing of SB 493 in October 2013 many consumer groups, pharmacists, and others have asked what has occurred since that time. Understandably after most legislation is signed into law it is necessary to promulgate relevant regulations by the state agency that will be charged with overseeing and implementing the measure. These regulations should clarify administrative processes or add detailed information that was silent in the law.

In the case of SB 493, the state agency charged with implementing the measure was the California Board of Pharmacy (BOP). The BOP began hearings under a special SB 493 Sub-committee of the full Board immediately after the measure was enacted. That Sub-committee held numerous hearings in 2014. CPhA, as well as many of the schools/colleges of pharmacy and other stakeholders, showed up every time to provide expert testimony, public comment, and recommendations to the Sub-committee. This process occupied the better part of 2014. The Sub-committee then submitted information to the full BOP with recommendations. The full BOP held several hearings through early 2015, yet failed to take definitive action on many of the recommendations from the Sub-committee.

The full BOP then re-assigned the SB 493 work to yet another committee, the Licensing Committee. This Committee had only one member that came from the previous SB 493 Sub-committee, which meant that most of the new members had little history of the discussions and testimony that occurred the entire prior year.

In mid-2015, the full BOP met and drafted a set of regulations for the implementation for SB 493 that had little of the input or recommendations of public stakeholders. Unfortunately these draft regulations went far beyond the administrative process or clarifying details that are the basis of regulation. Instead, the BOP created regulations that added significant and detrimental burdens to the process of implementing SB 493 that had little to do with providing safeguards to the public, which is the charge of the Board. Instead, the draft regulations simply added hurdles for pharmacists to begin practicing in the manner in which the legislature intended.

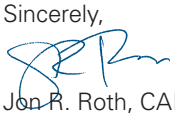
CPhA and many other stakeholders are frustrated by the pace and nature of the regulatory process. The BOP has taken two years since the signing of the legislation to get to the point of issuing draft regulations. And now that the draft regulations are promulgated, we couldn't be more disappointed with the result.

Members of the profession united and advocated with one voice when SB 493 was moving through the legislative process. This unification ensured that the legislature understood the important benefits that patients would receive as pharmacists expanded their scope of practice as health care providers. The rest of the nation has followed California's lead with provider status and expanded scope of practice. There are even companion Congressional legislative measures (S 314 and HR 592) that would expand pharmacist's roles in the Medicare program. For California to now fall behind because of the Board of Pharmacy is frustrating and embarrassing. But most importantly it is costing patients the health care they deserve and the health delivery system time and expense; neither of which we can afford.

We encourage all pharmacists to once again unite and let your voice be heard. Contact the President of the BOP, Dr. Amy Gutierrez, and let her know that the regulatory process has taken too long and the draft regulations are unnecessarily burdensome and simply place artificial barriers to community pharmacists caring for their patients.

To review the draft regulations, please go to the BOP website: http://www.pharmacy.ca.gov/laws_regs/regulations.shtml

Sincerely,



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# Aren't We All Pharmacy Students?

My day job is in academic pharmacy - I am a faculty member at UC San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences. As you most likely know, many schools of pharmacy in California recently started a new school year. It's always a very exciting time to see new students joining the profession. We start teaching our students practical skills during the first week of classes. I gave lectures and led workshops on communication skills and documentation, which are fundamental skills for practicing pharmacists. We use these skills every day. It can be a bit tricky to teach on these topics, particularly communication - after all, we all know how to talk to someone, right? However, those who have been practice a while recognize the importance of good patient-pharmacist communication and know that it's not always easy.

We also delivered the immunization course to our first year students to get them ready for flu season. As soon as their intern licenses arrive, our first year students are involved in immunization outreaches. Those of you who are immunization certified may remember how intimidating the course seems at first, with the material on the various vaccines, the schedules, and the technique training. Like a lot of things, sticking a needle in someone's arm seems scary at first, but most students and pharmacists find that the anticipation is worse than the activity itself. The immunization course provides a safe environment where you can learn about vaccines and practice good technique.

In some ways, all of us have occasions where we feel like a brand new pharmacy student. Perhaps we're faced with a new software system in the pharmacy or a new class of medications. The underlying anxiety comes from the fact that we want to do our best, for our patients and ourselves. Pharmacy students have the benefit of a structured program to try out new knowledge and skills, but pharmacists have to find other resources. I think this is one of the most valuable benefits of membership in CPhA. Pharmacy organizations, like CPhA, provide that safe place for us to continue learning, practicing new skills, and becoming ever better pharmacists.

# Community Pharmacy OR Mail Order:

## Whom Do Our Seniors Prefer for Their Rx Medications?

By Riddhi Zalavadia, 2015 PharmD Candidate; Yuna Bae, PharmD; and Anandi V. Law, B. Pharm, PhD, FAPhA

"Have your 90 day supply of medications shipped to your home at no extra cost. It's safe, convenient and easy." It is not uncommon to get these kinds of letters, e-mails, and phone calls from your insurance companies explaining the benefits of switching from a retail to mail order pharmacy. Some health plans have been so bold as to suggest mail order as the only option for obtaining maintanence medications.

This trend has been the result of an increase in the cost of prescription drugs over the past quarter century; from $40.3B in 1990 to $329B in 2013 to $374B in 2014. This increase has been attributed to many factors such as the development of new drugs, increase in marketing, and expansion of drug coverage by public and private payers.[1,8] This rising cost of prescription drugs has become a significant issue for the payers, resulting in cost containment becoming one of their top priorities. In addition to cost control efforts such as copayments, formularies, tiered pricing, etc. instituted by the health plans, Pharmacy Benefit Management (PBM) companies have found mail order pharmacy service as a key strategy to control costs.[2,3] PBMs have been promoting mail order pharmacy service as a "win-win" situation for all: offering cost containment for PBMs/health plans while providing multiple benefits for patients: of convenience (with medications being delivered to the patient's doorstep) and cost savings (allowing a 90 day supply of medication). Considering the cost effectiveness of high volume mail-order pharmacies that benefit from economies of scale and low overhead cost (no expensive retail real estate), PBMs continue to encourage patients towards using mail-order pharmacies for obtaining their chronic medications.[3] Some examples of incentives to use mail-order include: offering low copayments for mail order drugs while charging higher deductibles for retail purchases and limiting the number of times a prescription may be refilled at a retail pharmacy.[3]

## The Debate

As expected, response to these strategies has been less than favorable from community pharmacists. They argue that elderly patients who are on multiple chronic medications benefit from going to the store and having the pharmacist oversee their medication use. Community pharmacists quote studies showing that a personal interaction with the pharmacist enables greater trust in the patient-pharmacist relationship and increases the overall quality of service.[4] "My pharmacist who knows me, has a relationship with me, and knows my family"—can reinforce the importance of taking medications correctly and on a timely basis leading to better health outcomes.[11] Studies conducted on community based medication therapy management programs have concluded that face-to-face counseling by a pharmacist is two to three times more effective at increasing patient adherence.[12,13]

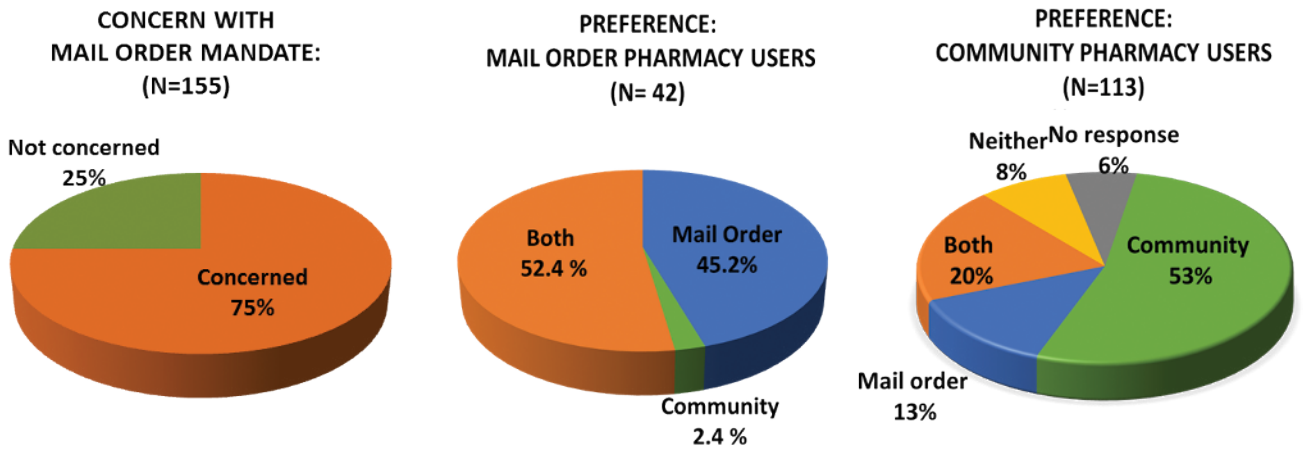
PBMs equate mail order to the delivery service that community pharmacies provide as a service to their customers. To complicate the state of impasse, about 19% of health plans have now made mail order service mandatory for chronic medications.[6] This mandate was met with much controversy. A bill was proposed in California (AB2418) in April 2014 that would require health plans to allow their enrollees/patients to opt out of mandatory mail order programs.[7] It was intended to support patients' access to medications and hence to drive improved medication adherence, better health outcomes, and improved quality of life for the patients. However, this bill was opposed by the health plans and proponents of mail order pharmacy who quoted the literature on the demonstrated cost effectiveness of mail order, and the bill was subsequently rejected.[2,7]

## Did Anyone Ask the Patient?

Noticeable in this discussion is a lack of input from the end user. Only one previous study conducted by Rupp examined the patient's perspective by assessing the attitude of Medicare eligible Americans towards mail order pharmacy service.[5] This study concluded that seniors were very sensible and knowledgeable about the sources of their prescription medications as well as its advantages and limitations. It also showed that many seniors believed that having a personal relationship with the local pharmacist was an important part of leading a healthy lifestyle and this need could not be met by the mail order pharmacy service. However, the literature remains silent on patient preference for mail order and community pharmacy, and their overall trust and satisfaction with mail order. Trust has been shown to be a top driver for brand advocacy in pharmacy.[9] Furthermore, satisfied patients are more likely to adhere to prescribed treatment plans and maintain an ongoing relationship with their healthcare provider hence leading to better health outcomes.[10] Hence, we extended Rupp's study by measuring 1) patient perception of benefits, challenges, and 2) their trust, satisfaction, and preference for mail order and community pharmacy services.

Our target sample was elderly prescription users since they are high utilizers of chronic prescription medications and, therefore, more likely to have had experience with using mail order pharmacies The sample was drawn from local senior centers in Southern California as neutral ground to obtain input from prescription users (as opposed to in a community pharmacy). Participants were included in the IRB-approved study if they were able to speak, read and write English, had experience of taking at least one prescription medication and were willing to take the survey. Participants were excluded if they had difficulty with vision, hearing or cognition that impaired their ability to participate in the study. Willing patrons at senior centers were asked to sign an informed consent and complete the survey.

**Figure 1: Preference for community/mail order and Concern about a possible mail order mandate**



Rupp's survey measured patient perspective on factors such as cost effectiveness, medication safety, timeliness of delivery, etc. to determine benefits and challenges of mail order pharmacy. We extended Rupp's survey (with permission) to include patient's trust, satisfaction and preference for mail order or community pharmacy services. All questions were examined on a four-point Likert scale ranging from "strongly agree"(4) to "strongly disagree"(1). The survey also included descriptive information such as gender, age, residential ZIP code, highest level of education, annual household income, prescription medication usage, drive time to nearest community pharmacy and type of pharmacy setting used for filling most/any prescriptions. Additional questions asked if their insurance plan had a mail order pharmacy option and if there was an incentive or mandate to use the mail order pharmacy.

Comparisons were made between respondents who used community pharmacy ONLY versus those who used mail order for chronic medications (and possibly community pharmacy for acute care medications).

## What We Found (Figure 1)

We received completed surveys from 155 participants from 4 senior centers, of which 113 were community pharmacy users and 42 mail order users. There were no statistically significant differences between the two groups on any demographic characteristics other than use of a mail order option.

1. Each group seemed to appreciate the benefits of their current pharmacy services and preferred using the current pharmacy service (community or mail order).
2. The majority of both groups reported being offered financial incentives by insurance plans to use a mail order option (79% and 68% in community and mail order groups, respectively) and were not mandated to use a mail order option for their maintenance medications (88% and 85% in community and mail order groups, respectively). Thus, mail order mandates were reported in about 15% of the plans, according to our sample; this is similar to national averages.
3. Community pharmacy users were more concerned with the challenges of mail order pharmacy and indicated less trust and satisfaction for the same as compared to mail order pharmacy users.
4. More mail order users (52%) reported NO preference between community and mail order service; compared to community pharmacy users (20%).
5. Mail order pharmacy users were also more willing to use either pharmacy service compared to community pharmacy users.
6. Perceived benefits and challenges were correlated with trust and satisfaction for each group.
7. More than half the sample (60%) was concerned regarding a lack of personal interaction with a pharmacist who knew them and their medications; in mail order service.
8. A majority (75%) of the respondents expressed concern if mail order pharmacy was mandated for obtaining maintenance medications.

## Limitations

Our study used a convenience sampling method to recruit participants, which may have caused sampling bias in our results. Our survey could have been strengthened by use of a free response item that would allow participants to expand on their views.

## Conclusion

Overall, more community pharmacy users seemed less willing to adopt mail order pharmacy service. Both groups seemed to appreciate freedom to choose their pharmacy service and were concerned if a mail order mandate were applied.

## Implications / Impact in California

As cost of prescription drugs continues to increase (example, hepatitis C drugs Sovaldi and Harvoni costing about $84,000 for one course of treatment, and several anticancer therapies costing $42 billion annually14), payment for these medications remains a continuous challenge. Given its cost effectiveness and claim as a method of controlling costs, mail order may not

be an unpalatable option. However, on the other hand, with the increase in utilization of medications and medication regimen complexity, one-on-one medication therapy management (MTM) becomes even more vital to our patients. A middle of the road solution could be to continue dispensing medications by community and mail order while redirecting the community pharmacist role to be more clinical and patient focused as is now possible with SB493 and the national push for provider status.

## About the Authors


Riddhi Zalavadia, BPharm, PharmD is a graduate from Western University of Health Sciences College of Pharmacy and was an AE student in Health Systems Research with Dr. Law when she wrote this manuscript. She was central to the development and data collection of this project. Dr. Zalavadia has no bias to report.

Yuna Bae, PharmD is a Health Outcomes Fellow at Western University of Health Sciences College of Pharmacy, under the mentorship of Dr. Law. She was central to the data analysis of this project. Dr. Bae has no bias to report.

Anandi V. Law, BPharm, PhD, FAPhA, is a Professor and Chairperson of the Department of Pharmacy Practice and Administration at Western University of Health Sciences College of Pharmacy, where she has been since 1999. Dr. Law is an established researcher in the field of Patient Reported Outcomes and pharmacist patient interaction. Dr. Law has no bias to report.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IAPP Institute for Advanced Pharmacy Practice

NEW

# 2015 CERTIFICATE PROGRAMS

Hosted by: California Pharmacists Association

## Anticoagulation Certificate Program

### November 21, 2015
**Sacramento, CA**

### December 12, 2015
**Pomona, CA**

The Anticoagulation certificate program provides pharmacists with the basic knowledge and skills necessary to care for patients taking anticoagulation therapies. With expanded use of anticoagulant agents, the number of patients receiving these drugs has increased dramatically. Safe and effective anticoagulation must include a number of key components to avoid complications. These include careful patient assessment, an understanding of the clotting cascade and mechanisms of action of anticoagulant therapies, a detailed focus on factors which influence therapy and knowledge of current guidelines.

This certificate training program's 22 hours of continuing education (14 hours of home study and 8 hours of live training) is a comprehensive program.

*This is an AzPA Certificate Training Program hosted by the California Pharmacists Association.*

AzPA Arizona Pharmacy Association

## Community Pharmacy-Based Point-of-Care Testing

### December 13, 2015
**Fullerton, CA**

The Community Pharmacy-Based Point-of-Care Testing certificate program provides community pharmacists and members of academia, industry and government with the skills necessary to develop and implement a collaborative testing program for influenza, Group A streptococcus, HIV and hepatitis C. There is a recognized need for community pharmacists to collaboratively improve patient access to care through the use of point-of-care tests.

This certificate training program's 20 hours of continuing education (12 hours of home study and 8 hours of live training) will cover information on the targeted disease state, the physical assessment of a patient presenting to a community pharmacist, point-of-care tests and how to establish a point-of-care testing service.

*This is an NACDS Certificate Training Program hosted by the California Pharmacists Association.*

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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### IMPORTANT SAFETY INFORMATION

EVZIO is contraindicated in patients known to be hypersensitive to naloxone hydrochloride or to any of the ingredients in EVZIO.

The following warnings and precautions should be taken when administering EVZIO:

- Due to the duration of action, keep the patient under continued surveillance and repeated doses of naloxone should be administered, as necessary, while awaiting emergency medical assistance.
- Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.
- Reversal of respiratory depression by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete.
- Use in patients who are opioid dependent may precipitate acute abstinence syndrome.
- Patients with pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects should be monitored in an appropriate healthcare setting.
- In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated.

The following adverse reactions have been identified during use of naloxone hydrochloride in the postoperative setting: hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. Excessive doses of naloxone hydrochloride in postoperative patients have resulted in significant reversal of analgesia and have caused agitation.

Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated signs and symptoms of opioid withdrawal including: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and tachycardia. In the neonate, opioid withdrawal signs and symptoms also included: convulsions, excessive crying, and hyperactive reflexes.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

**Please see brief summary of full Prescribing Information on next page.**

**References**
1. EVZIO Prescribing Information. kaléo. 2014
2. Data on file. kaléo. 2014

kaléo

**BRIEF SUMMARY OF PRESCRIBING INFORMATION (see full Prescribing Information for complete product information)**

**EVZIO® (naloxone hydrochloride injection) Auto-Injector for intramuscular or subcutaneous use**
**Initial U.S. Approval: 1971**

## INDICATIONS AND USAGE

EVZIO is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. EVZIO is intended for immediate administration as emergency therapy in settings where opioids may be present. EVZIO is not a substitute for emergency medical care.

### Important Administration Instructions

- EVZIO is for intramuscular and subcutaneous use only.
- Because treatment of suspected opioid overdose must be performed by someone other than the patient, instruct the prescription recipient to inform those around them about the presence of EVZIO and the *Instructions for Use*.
- Seek emergency medical care immediately after use. Since the duration of action of most opioids exceeds that of naloxone hydrochloride, and the suspected opioid overdose may occur outside of supervised medical settings, seek immediate emergency medical assistance, keep the patient under continued surveillance, and administer repeated doses of EVZIO as necessary. Always seek emergency medical assistance in the event of a suspected, potentially life-threatening opioid emergency after administration of the first dose of EVZIO.
- Additional doses of EVZIO may be required until emergency medical assistance becomes available.
- Do not attempt to reuse EVZIO. Each EVZIO contains a single dose of naloxone.
- Visually inspect EVZIO through the viewing window for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear and the glass container is undamaged.

The *Instructions for Use* should be read by the patient or caregiver at the time they receive a prescription for EVZIO. Provide the following instructions to the patient or caregiver:

- EVZIO must be administered according to the printed instructions on the device label or the electronic voice instructions (EVZIO contains a speaker that provides voice instructions to guide the user through each step of the injection). **If the EVZIO electronic voice instruction system does not operate properly, EVZIO will still deliver the intended dose of naloxone hydrochloride when used according to the printed instructions on its label.**
- Once the red safety guard is removed, EVZIO must be used immediately or disposed of properly. Do not attempt to replace the red safety guard once it is removed.

Upon actuation, EVZIO automatically inserts the needle intramuscularly or subcutaneously, delivers 0.4 mg naloxone hydrochloride injection, and retracts the needle fully into its housing. Post-injection, the black base locks in place, a red indicator appears in the viewing window, and electronic visual and audible instructions signal that EVZIO has delivered the intended dose of naloxone hydrochloride and instructs the user to seek emergency medical attention.

### Dosing Information

Administer the initial dose of EVZIO to adult or pediatric patients intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary, and seek emergency medical assistance. Administer EVZIO as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death. The requirement for repeat doses of EVZIO depends upon the amount, type, and route of administration of the opioid being antagonized.
If the desired response is not obtained after 2 or 3 minutes, another dose of EVZIO may be administered. If there is still no response and additional doses are available, additional doses of EVZIO may be administered every 2 to 3 minutes until emergency medical assistance arrives. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

Reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete or require higher doses of naloxone.

Dosing in Adults and Pediatric Patients over Age One
Instruct patients or their caregivers to administer EVZIO according to the *Instructions for Use*, intramuscularly or subcutaneously.

Dosing in Pediatric Patients under Age One
In pediatric patients under the age of one, the caregiver should pinch the thigh muscle while administering EVZIO.

## CONTRAINDICATIONS

EVZIO is contraindicated in patients known to be hypersensitive to naloxone hydrochloride or to any of the other ingredients.

## WARNINGS AND PRECAUTIONS

### Duration of Effect

The duration of action of most opioids is likely to exceed that of EVZIO resulting in a return of respiratory and/or central nervous system depression after an initial improvement in symptoms. Therefore, it is necessary to seek immediate emergency medical assistance after delivering the first dose of EVZIO, keep the patient under continued surveillance, and repeat doses of EVZIO as necessary. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

### Limited Efficacy with Partial Agonists or Mixed Agonist/Antagonists

Reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete. Large doses of naloxone hydrochloride are required to antagonize buprenorphine because the latter has a long duration of action due to its slow rate of binding and subsequent slow dissociation from the opioid receptor. Buprenorphine antagonism is characterized by a gradual onset of the reversal effects and a decreased duration of action of the normally prolonged respiratory depression.

### Precipitation of Severe Opioid Withdrawal

The use of EVZIO in patients who are opioid dependent may precipitate an acute abstinence syndrome characterized by the following signs and symptoms: body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may include the following signs and symptoms: convulsions, excessive crying, and hyperactive reflexes.
Abrupt postoperative reversal of opioid depression after using naloxone hydrochloride may result in nausea, vomiting, sweating, tremulousness, tachycardia, hypotension, hypertension, seizures, ventricular tachycardia and fibrillation, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. These events have occurred in patients most of whom had pre-existing cardiovascular disorders or received other drugs which may have similar adverse cardiovascular effects. Although a direct cause and effect relationship has not been established, after use of naloxone hydrochloride, patients with pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects should be monitored for hypotension, ventricular tachycardia or fibrillation, and pulmonary edema in an appropriate healthcare setting. It has been suggested that the pathogenesis of pulmonary edema associated with the use of naloxone hydrochloride is similar to neurogenic pulmonary edema, ie, a centrally mediated massive catecholamine response leading to a dramatic shift of blood volume into the pulmonary vascular bed resulting in increased hydrostatic pressures.

## ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in the labeling:

- Duration of Effect
- Precipitation of Severe Opioid Withdrawal

The following adverse reactions have been identified during postapproval use of naloxone hydrochloride in the postoperative setting. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. Excessive doses of naloxone hydrochloride in postoperative patients have resulted in significant reversal of analgesia and have caused agitation.
Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated an acute withdrawal syndrome. Signs and symptoms have included: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and tachycardia. In the neonate, opioid withdrawal signs and symptoms also included: convulsions, excessive crying, and hyperactive reflexes.

## USE IN SPECIFIC POPULATIONS

### Pregnancy

Pregnancy Category B
*Risk Summary*
There are no adequate and well-controlled studies with EVZIO in pregnant women. Animal studies were conducted with naloxone hydrochloride given during organogenesis in mice and rats at doses 4-times and 8-times, respectively, the dose of a 50 kg human given 10 mg/day. These studies demonstrated no embryotoxic or teratogenic effects due to naloxone hydrochloride. Because animal reproduction studies are not always predictive of human response, EVZIO should be used during pregnancy only if clearly needed.
*Clinical Considerations*
Naloxone hydrochloride crosses the placenta, and may precipitate withdrawal in the fetus as well as in the opioid-dependent mother. The fetus should be evaluated for signs of distress after EVZIO is used. Careful monitoring is needed until the fetus and mother are stabilized.
*Data*
Animal Data
Naloxone hydrochloride was administered during organogenesis to mice and rats at doses 4-times and 8-times, respectively, the dose of 10 mg/day given to a 50 kg human (when based on body surface area or mg/m2). These studies demonstrated no embryotoxic or teratogenic effects due to naloxone hydrochloride.

### Nursing Mothers

It is not known whether naloxone hydrochloride is present in human milk. Because many drugs are present in human milk, exercise caution when EVZIO is administered to a nursing woman.

### Pediatric Use

The safety and effectiveness of EVZIO (for intramuscular and subcutaneous use) have been established in pediatric patients for known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Use of naloxone hydrochloride in pediatric patients is supported by evidence from adequate and well-controlled studies of naloxone hydrochloride in adults with additional data from 15 clinical studies (controlled and uncontrolled) in which neonates and pediatric patients received parenteral naloxone in doses ranging from 0.005 mg/kg to 0.01 mg/kg. Safety and effectiveness are also supported by use of other naloxone hydrochloride products in the postmarketing setting as well as data available in the medical literature and clinical practice guidelines.

Absorption of naloxone hydrochloride following subcutaneous or intramuscular administration in pediatric patients may be erratic or delayed. Even when the opiate-intoxicated pediatric patient responds dramatically to naloxone hydrochloride injection, he/she must be carefully monitored for at least 24 hours as a relapse may occur as naloxone is metabolized. In opioid-dependent pediatric patients, (including neonates), administration of naloxone may result in an abrupt and complete reversal of opioid effects, precipitating an acute opioid withdrawal syndrome. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening and should be treated according to protocols developed by neonatology experts.

In neonates and pediatric patients less than 1 year of age, careful observation of the administration site for evidence of residual needle parts and/or signs of infection is warranted.

### Geriatric Use

Geriatric patients have a greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Therefore, the systemic exposure of naloxone can be higher in these patients. Clinical studies of naloxone hydrochloride did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

## NONCLINICAL TOXICOLOGY

### Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis
Long-term animal studies to evaluate the carcinogenic potential of naloxone have not been completed.

Mutagenesis
Naloxone was weakly positive in the Ames mutagenicity and in the in vitro human lymphocyte chromosome aberration test, but was negative in the in vitro Chinese hamster V79 cell HGPRT mutagenicity assay and in the in vivo rat bone marrow chromosome aberration study.

Impairment of Fertility
Reproduction studies conducted in mice and rats at doses 4-times and 8-times, respectively, the dose of a 50 kg human given 10 mg/day (when based on surface area or mg/m2), demonstrated no adverse effect of naloxone hydrochloride on fertility.

## PATIENT COUNSELING INFORMATION

Advise the patient and family members or caregivers to read the FDA-approved patient labeling (*Instructions for Use*).
Instruct patients and their family members or caregivers to:

- Become familiar with the following information contained in the carton as soon as they receive EVZIO:
  - EVZIO *Instructions for Use*
  - Trainer for EVZIO *Instructions for Use*
  - Trainer for EVZIO
- Practice using the Trainer before EVZIO is needed.
  - Each EVZIO (which is purple and yellow) can only be used one time; however, the Trainer (which is black and white) can be re-used for training purposes and its red safety guard can be removed and replaced.
  - Both EVZIO and the Trainer for EVZIO incorporate the electronic voice instruction system.
- Make sure EVZIO is present whenever persons may be intentionally or accidentally exposed to an opioid to treat serious opioid overdose (ie, opioid emergencies).

Instruct patients and their family members or caregivers how to recognize the signs and symptoms of an opioid overdose requiring the use of EVZIO such as the following:

- Extreme sleepiness – inability to awaken a patient verbally or upon a firm sternal rub.
- Breathing problems – this can range from slow or shallow breathing to no breathing in a patient who cannot be awakened.
- Other signs and symptoms that may accompany sleepiness and breathing problems include the following:
  - Extremely small pupils (the black circle in the center of the colored part of the eye) sometimes called "pinpoint pupils."
  - Slow heartbeat and/or low blood pressure.

Instruct them that when in doubt, if a patient is unresponsive, and an opioid overdose is suspected, administer EVZIO as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death. Instruct them to seek emergency medical assistance after administering the first dose of EVZIO.
Duration of Effect
Instruct patients and their family members or caregivers that since the duration of action of most opioids may exceed that of naloxone, seek immediate emergency medical assistance, keep the patient under continued surveillance, and administer repeated doses of EVZIO as necessary.
Limited Efficacy for/with Partial Agonists or Mixed Agonist/Antagonists
Instruct patients and their family members or caregivers that the reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete.
Precipitation of Severe Opioid Withdrawal
Instruct patients and their family members or caregivers that the use of EVZIO in patients who are opioid dependent may precipitate an acute abstinence syndrome characterized by the following signs and symptoms: body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated, and may include the following signs and symptoms: convulsions, excessive crying, and hyperactive reflexes.
Administration Instructions
Instruct patients and their family members or caregivers about the following important information:

- EVZIO is user actuated and may be administered through clothing (eg, pants, jeans) if necessary.
- Inject EVZIO while pressing into the anterolateral aspect of the thigh. In pediatric patients less than 1 year of age, pinch the thigh muscle while administering EVZIO.
- Upon actuation, EVZIO automatically inserts the needle intramuscularly or subcutaneously, delivers the naloxone, and retracts the needle fully into its housing. The needle is not visible before, during, or after injection.
- Each EVZIO can only be used one time.
- If the electronic voice instruction system of EVZIO does not work properly, EVZIO will still deliver the intended dose of naloxone hydrochloride when used according to the printed instructions on its label.
- The electronic voice instructions are independent of activating EVZIO and are not required to wait for the voice instructions to be completed prior to moving to the next step in the injection process.
- Post-injection, the black base locks in place, a red indicator appears in the viewing window and electronic visual and audible instructions signal that EVZIO has delivered the intended dose of naloxone hydrochloride.
- EVZIO's red safety guard should not be replaced under any circumstances. However, the Trainer is designed for re-use and its red safety guard can be removed and replaced.
- It is recommended that patients and caregivers become familiar with the training device provided and read the *Instructions for Use*; however, untrained caregivers or family members should still attempt to use EVZIO during a suspected opioid overdose while awaiting definitive emergency medical care.
- Periodically visually inspect the naloxone solution through the viewing window. If the solution is discolored, cloudy, or contains solid particles, replace it with a new EVZIO.
- Replace EVZIO before its expiration date.

Manufactured for: kaleo, Inc.
Richmond, VA 23219

* For California Only: This product uses batteries containing Perchlorate Material – special handling may apply.
See www.dtsc.ca.gov/hazardouswaste/perchlorate

# The Role of a Clinical Pharmacy Technician in a Tobacco Cessation Program

By Crystal Zhou, PharmD; Stacey C. Nguyen, PharmD; Khanh L. Nguyen, PharmD; Mark G. Myers, PhD; and Timothy C. Chen, PharmD

## Introduction

Traditionally, a pharmacy technician's role was limited to medication preparation and excluded direct patient care.[1-2] Along with the constantly changing role of a pharmacist, the role of a pharmacy technician has evolved over the years. Within a healthcare system, pharmacy technicians' roles have expanded to include billing, patient assistance, procurement, 340B program management, informatics, and pharmacy automation support.[3] At other medical institutions, pharmacy technicians may also provide medication reconciliation services to obtain a complete medication list.[4] In a sense, the technician is a data collector, gathering all the pertinent patient information so that the pharmacist can use the information to make clinical decisions. Most technicians that practice under this advanced capability are Certified Technicians.[5] Advanced Certified Pharmacy Technicians (CPhT), under the supervision of a licensed pharmacist, may potentially reduce a pharmacist's workload by up to 50 hours per month, thus allowing more opportunities for pharmacists to perform clinical interventions.[6] With the intention to allow pharmacists more time to manage patients and perform more efficiently, a Tobacco Cessation Pharmacy Technician (TCPT) was introduced to the Veterans Affairs San Diego Healthcare System's (VASDHS) Pharmacist Managed Telephone Tobacco Cessation Clinic (PMTTCC) in 2010.[7-8]

## Developing Standards for the TCPT

### Certification

In order to ensure baseline competency, pharmacy technicians are required to pass the Pharmacy Technician Certification Exam (PTCE).[5] The PTCE focuses on key domains of functioning that apply to the TCPT, such as personal, interpersonal, and professional knowledge; skills, medication safety, technology and informatics, regulatory issues, and quality assurance.[9]

The technician must also complete 20 hours of continuing education every two years in order to maintain licensure.[5]

### Clinical Training

The main component of training focuses on ensuring that the TCPT is able to gather core data, provide brief interventions as outlined by the clinical practice guidelines, and triage special populations (e.g., mental health patients, women, HIV patients).[10] Didactic training consists of a two-hour modified version of Rx for Change: Clinician-Assisted Tobacco Cessation (http://rxforchange.ucsf.edu)[10-14] and focuses on military veterans.[10-15] Although some information may extend beyond the scope of the technician, it is important to introduce the technician to a broad range of situations and potential issues that may arise. Clinical training varies from three to six months in duration and consists of training with the tobacco cessation pharmacist provider in the Pharmacist Managed Telephone Tobacco Cessation Clinic (PMTTCC) at the VA San Diego Healthcare System (VASDHS).[7-8] TCPTs are deemed trained by pharmacist providers upon demonstration of their competency in providing brief and effective counseling strategies and upon

familiarization with the functions of the PMTTCC.[7-8]

**Clinical Duties of the TCPT**

The TCPT is trained to conduct follow-up calls and collect data (e.g., slips/relapses, use of tobacco cessation medications, adverse reactions) from veterans treated for tobacco cessation. Pharmacists are responsible for all initial calls and follow-up calls for patients with slips/relapses who may need further behavioral treatment or assessments. TCPTs also provide general behavioral interventions in a manner similar to counselors at the California Smokers Helpline.[16-17] In Shu-Hong Zhu et al.'s study, tobacco cessation counselors employed by the helpline had no more than a master's degree, and all received 60 hours of training. These counselors were able to significantly prolong smokers' abstinence rates by providing telephone counseling.[16] At the VA, TCPTs do not perform any assessments nor provide a plan, and do not offer medical advice similar to helpline counselors. TCPTs simply collect data and offer brief interventions under the supervision of a tobacco cessation pharmacist provider (Table 1). Follow-up calls are adapted for technicians and modeled after the Pharmacist Managed Telephone Tobacco Cessation toolkit and provider manuals developed by Veterans Affairs.[18-21] This model allows more time for the pharmacist to work on prioritizing clinical management of patients, provide more intensive integration of behavioral and pharmacologic interventions (e.g., coping strategies, tapering of nicotine replacement, and stress management), and individualize his or her call to focus on patient specific needs (e.g., slips/relapses, adverse reactions, and change in therapy).

**Table 1: Key components of a follow-up call performed by a TCPT**

| |
|---|
| • Ask about current tobacco status: "Were you able to quit on your quit date?"<br><br>If the patient has not quit, investigate what happened. Focus on positives of reducing the number of cigarettes; determine if patient will continue to trial quit attempt. |
| • Ask if patient has experienced any withdrawal symptoms: "Have you experienced any withdrawal symptoms?"<br><br>◦ TCPT should be able to provide brief recommendations for specific withdrawals such as hunger and how to cope with/relieve the withdrawal symptoms<br>◦ Cravings due to behavioral cues can last for years, so TCPT is expected to discuss the DEADS (Delay, Escape, Avoid, Distract, Substitute) coping strategies with patients at each follow-up (Note: TCPT will also provide specific examples in each of these steps.)<br>◦ Delay – sometimes the urge will pass; wait five-10 minutes<br>◦ Escape – another technique for dealing with an urge is to remove yourself from the situation or event that led to the urge<br>◦ Avoid – avoid any potential triggers<br>◦ Distract – thinking about something else or just doing something that is not associated with tobacco<br>◦ Substitute – give examples to substitute for the tobacco, such as sugar-free candy, sugar-free gum, a straw |
| • Ask about slips and relapses and investigate what happened. |
| • Ask about current medication use, how much the patient is using, any side effects the patient has experienced, and whether or not the medication is effective for the patient. |
| • Reaffirm health benefits if patient is successful. |

## Conclusions

By triaging patients and gathering information, integration of TCPTs into the PMTTCC has allowed pharmacists to focus more on making interventions. This model has been an important component of the PMTTCC since 2010, and given the potential for expansion of pharmacists' scopes of practice in the near future, clinical technicians can take on a greater role in managing patient outcomes, whether it be in the PMTTCC or other inpatient or outpatient pharmacy settings.

*The opinions expressed in this article are those of the authors and do not necessarily represent those of the Veterans Health Administration (VHA).*

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# Driving Under the Influence:
## Counseling on the Effects of Prescription Drugs on Driving Performance


By Linda Hill, MD, MPH

**Abstract:** Motor vehicle crashes are a major cause of morbidity and mortality in the United States. Medical conditions and medications have the potential to increase crash risk. While medications can affect drivers of any age, older adults are more likely to be taking prescription medications. Pharmacists have an important role in educating patients on medication side effects that could affect driving. This report reviews the major prescription medications that affect driving and provides guidance on counseling.

Motor vehicles crashes are a leading cause of death in the US, with 33,561 fatalities in 2012. Prescribed medications, over-the-counter (OTC) medications, and abused drugs, including alcohol, have the potential to interfere with the ability to drive safely,[1,2] with the risk increasing with the number of medications.[3] Pharmacists have a responsibility to patients and the public to minimize this risk through their dispensing and counseling practices. In a 2003 professional standard statement, the International Pharmaceutical Federation provided guidance to pharmacists and reiterated that pharmaceutical organizations should provide clear guidelines on the side effects of medications with regard to driving and the operation of machinery.[4]

The potential for impaired driving due to medication can occur at any age, though older adults are more likely to be taking prescribed medication, including multiple pharmaceuticals, and could experience drug interactions. A study by the AAA Foundation for Traffic Safety found that over 90% of older drivers take prescription medications, and over two-thirds of those taking any medication take multiple medications.[5] In an earlier study, AAA found that only half of these drivers (52%; 58% of women vs. 46% of men) on prescription medication talked to a health care provider about the possible effect of these drugs on their ability to drive.6 In addition, increased age, low education, and widowhood are associated with less awareness, experience, and health professional warnings.[7] However, studies have found that medical profession-

**Objectives:**

- Understand the effect prescription drugs can have on driving performance
- Demonstrate the importance of including the effects on driving as part of a consultation
- Understand the key classes of prescription drugs which can impair driving skills

als are generally unaware of medicines' effects on driving and are reluctant to discuss them with patients.

The classes of prescription drugs and their potential side effects are outlined in Table 1. The main side effects that impair driving skills include drowsiness, confusion, hypotension and possible associated syncope, hypoglycemia, and poor muscle tone or incoordination. Less common are problems such as double vision, nausea, blurred vision, and memory impairment. Specific drug effects on driving are reviewed here.

## Anticonvulsants

Seizure disorders, when uncontrolled, can interfere with driving,[8-13] though the risk may have been overestimated.[14] Anticonvulsants may cause drowsiness, confusion, ataxia, nausea, and double vision. The response to the medication varies by individual and may not always be linearly correlated with dosage. Checking patients' blood drug levels are helpful with some drugs, such as phenytoin, where high blood levels are correlated with ataxia.

## Antidepressants

Antidepressants are the second most frequently prescribed medications, according to the Institute for Health Care Informatics.[15] There is evidence that the crash rate in individuals with depression is three times higher than unaffected individuals. However, the treatments for depression may be associated with side effects that interfere with driving as well. Even one psychotropic prescription drug increased the crash risk more than twofold for drivers over 45 years old, with dramatic increases to eightfold for more than two CNS-affecting drugs. The tricyclic antidepressants have higher rates of hypotension and drowsiness, one of the reasons they are prescribed at night to help with depression-associated insomnia. They have been associated with a more than twofold crash risk in the elderly.[16,17]

## Anxiolytics

Benzodiazepines can cause drowsiness, confusion, and amnesia, and may interfere with muscle tone and coordination. Ten mg of Valium has been found to be equivalent to a blood alcohol concentration (BAC) of 0.10%. Benzodiazepines were shown to increase crash risk 60% in one study,[18] and another case control study found an odds ratio of 5:2 with benzodiazepines in drivers 65 and older.[16] Some studies have shown an effect for intermediate and long-acting benzodiazepines, but not short-acting ones.[19]

## Antipsychotics

Both antipsychotics and psychosis can affect judgment, with the drugs causing nausea and drowsiness. Psychosis can impair driving due to lapses in judgment, impulsivity, and inattention. In one study, persons with schizophrenia were examined before discharge. Only 32% of these persons passed reaction testing prior to discharge. Persons on atypical antipsychotics and clozapine performed better than those on older antipsychotics.[20]

## Stimulants

This class of drugs is used to treat a variety of conditions, including hyperactivity. In a small study of attention deficit hyperactivity disorder (ADHD) subjects, they self-reported higher rates of crashes and citations, performed worse than non-ADHD subjects on the simulator, but they improved when taking Ritalin.[21] Another study found increased crash rates in ADHD patients, with medications reducing the crash risk.

## Somniacs

Medications for sleep also have the potential to interfere with driving. Zopiclone (the stereoisomer eszopiclone (Lunesta)) is marketed in the US and was found to impair driving manyfold over zaleplon.[22] Another study found residual effects at eight-12 hours with zopiclone, but not with zolpidem or midazolam.[23] In a 2011 survey of drivers over 65, 22-27% of men took sleep medications, as did 33-35% of women. The use of pain medications was reported by 50-58% of men and 59-71% of women. However, the vast majority of respondents reported taking multiple medications, leading to the potential for drug potentiation and interaction.[5]

## Antihistamines

This class of drugs also impairs driving performance. This has been demonstrated in multiple studies, with one finding diphenhydramine more impairing than alcohol.[24] Only third-generation antihistamines, fexofenadine and levocetirizine, did not impair performance.[25]

## Hypoglycemics

With the increasing rates of diabetes, hypoglycemics are currently the sixth most commonly prescribed class of drugs. Type 1 diabetics are at highest risk of driving impairment due to hypoglycemia.[26,27] Hypoglycemia can impair cognitive and motor skills, and diabetics should be cautioned to check their sugar before driving, as well as periodically on long trips.[28] While hypoglycemia is especially a risk during medication adjustments, it can occur at any time with changes in food intake, activity, or acute illnesses. Diabetic drugs have many interactions with other medication that can potentiate their hypoglycemic effects. In addition, diabetic patients are at risk of eye diseases, including retinopathy, cataracts, and glaucoma, with the potential to affect vision and driving safety.

## Chemotherapy

Chemotherapeutics can also impair driving skills due to side effects that include nausea, confusion, drowsiness, poor muscle tone, and dehydration, with associated hypotension and syncope. The frailness alone associated with cancer and chemotherapy (and other treatments) alone reduces driving skill and increases crash risk. Individuals under acute care for cancer should be advised to find alternative transportation when the chemotherapy is associated with these common side effects.

## Narcotic analgesics

Prescription narcotics, especially but not exclusively in the acute setting, are associated with impaired judgment, confusion, drowsiness, and nausea,

**Table 1: Side Effects of Prescription Medications with the Potential to Impair Driving**

| | Drowsiness | Confusion, poor judgment | Syncope, hypotension | Hypoglycemia | Poor muscle tone, incoordination | Other side effects | Offending agents | Recommended alternatives |
|---|---|---|---|---|---|---|---|---|
| Anticonvulsants | X | X | | | X | Double vision, neuropathy, nausea, ataxia | class effect | |
| Antidepressants | X | | X | | | | tricyclics, trazodone, mirtazapine, MAOIs | SSRIs, SNRIs, buproprion |
| Antiemetics | X | X | X | | X | Blurred vision | promethazine, metoclopramide, prochlorperazine, chlorpromazine | ondansetron |
| Antihistamines | X | | | | | Blurred vision, hyperkinesia | diphenhydramine, chlorpheniramine, hydroxyzine, dimenhydrinate, meclizine | loratadine, cetirizine, fexofenadine |
| Anticholinergics | X | X | | | | | atropine/diphenoxylate, benztropine, oxybutynin, trihexyphenidyl, dicyclomine, belladonna alkaloids | |
| Antihypertensive | | | X | | | | b blockers, calcium channel blockers, clonidine | ACEIs, ARBs, thiazide |
| Antiparkinsonians | X | X | X | | X | Dizziness, nausea, headache | trihexyphenidyl, benztropine, selegiline, rasagiline, ropinirole, pramipexole, rotigotine | entacapone, tolcapone, amantadine |
| Antipsychotics | X | X | X | | X | Tremors, nausea | class effect | |
| Anxiolytics | X | X | | | X | Memory impairment | benzodiazepines, buspirone | |
| Chemotherapy | x | x | | | x | Nausea, weakness | class effect | |
| Muscle relaxants | X | X | | | X | Dizziness, nausea | class effect | |
| Narcotic analgesics | X | X | | | X | Nausea | class effect | |
| Stimulants | | X | | | | Emotional labiality, tremors | amphetamine, methylphenidate | |
| Antidiabetics | | | | X | | Nausea | insulin, sulfonylurea, glinides (repaglinide, nateglinide), exenatide, liraglutide | metformin, gliptins (sitagliptin, saxagliptin, linagliptin), TZDs (pioglitazone, rosiglitazone) |
| α1 antagonist | | | X | | | | prazosin, terazosin, doxazosin | tamsulosin, silodosin |
| PDE-5 inhibitors | | | X | | | | class effect | |
| Marijuana | X | X | | | X | | marijuana, dronabinol | |

all with the potential to impair driving safety. Individuals with these side effects are at risk of being charged with driving under the influence if stopped by law enforcement, even if they have prescriptions for these drugs. Driving should be stopped when narcotics are first prescribed, and only resumed once the level of impairment is felt to be low enough not to interfere with safe driving. A large epidemiologic analysis found the crash rate in people taking narcotic analgesics increased by 1.7-2.4.[29] A recent analysis of fatal crashes found an association between opiates and crashes in middle-aged but not older adults.[30]

## Alcohol

The effect of alcohol on driving safety is profound, due to both the

level of impairment and the high prevalence of use. Alcohol is estimated to be implicated in 60% of traffic fatalities, a greater influence than any other substance. Alcohol further impairs driving in persons taking many pharmaceuticals.[18] While it is beyond the scope of practice of most pharmacists to counsel on isolated alcohol use, discussion of the accentuating effects of alcohol is appropriate.

**Reporting and Support Systems**

California is one of nine states requiring physician-mandated reporting to the Department of Health Services (DHS) for lapses of consciousness[31] associated with an underlying condition. Lapses include loss of consciousness, dementia, seizures, or other conditions, including medication side effects that cause a reduction in alertness. Pharmacists are not mandated reporters; however, any healthcare professional or citizen can report concerns to the DMV.[32] DMV websites provide forms online for reporting.

Pharmacists can help patients manage their medications and drug interactions by guiding them to online databases or paper systems, such as AAA's Roadwise program, Consumer Reports' My Medication Tracker app, ConsumerMedSafety.org, and SafeMedication.com.

## Conclusions

Pharmacists should discuss possible drug interactions and side effects with all patients on one or more prescription medications. A counseling checklist is provided in Figure 1. Patients should be educated about the medications they are taking and whether these medications, in conjunction with their condition and OTC medications, can impair driving ability.

Resources for further information on the topic of medication, medical conditions, and driving include:

- Roadwise Rx: http://www.roadwiserx.com/, sponsored by AAA.
- The National Highway Traffic Safety Administration Report DOT HS 809 725, 2004.
- Medical Conditions and Driving: A Review of the Scientific Literature: DOT HS 809 690, 2005.
- www.treds.ucsd.edu
- Understanding Older Drivers: An Examination of Medical Conditions, Behaviors, Medication Use and Travel Behavior, AAA Foundation for Traffic Safety
- https://www.aaafoundation.org/sites/default/files/Medication%20and%20Travel%20Behaviors%20--%20FINAL%20FTS%20FORMAT%20copy.pdf
- Consumer Reports: http://consumerist.com/2009/09/10/keep-track-of-your-prescriptions-with-this-free-app/

## About the Author

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## Acknowledgments

The author would like to acknowledge the contributions of Thu Truong and Tiep Ly, PharmD candidates in the Skaggs School of Pharmacy and Pharmaceutical Sciences at the University of California, San Diego, and Anne-Marie Engler and Francis Fu of the University of California, San Diego.

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**Figure 1. Counseling Checklist**

| | Yes | No | Provide driving counseling as follows: | | | |
|---|---|---|---|---|---|---|
| | | | **Provide health educationaboutside effectsbothverbally and in writing.** | **Advise against driving until side effects are known and manageable, especially when starting medications.** | **Counsel diabetics to check their sugar before driving and during long trips.** | **Report lapses of consciousness or other driving concerns to the DepartmentofMotor Vehicles** |
| The patient is on a medication with side effects that impair driving. | | | X | X | | |
| The patient is on two drugs that may interact to impair driving. | | | X | X | | |
| The patient is on medication where alcohol may potentiate the side effects. | | | "Avoid alcohol" | | | |
| The patient is over 65 years old. | | | X | X | | |
| The patient reports a recent seizure or lapse of consciousness. | | | | | | X |
| The patient has diabetes. | | | | | X | |


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# CONTINUING EDUCATION QUIZ

## Driving Under the Influence: Counseling on the Effects of Prescription Drugs on Driving Performance

1. **Motor Vehicle accidents are the leading cause of death in the United States.**
   a. True
   b. False:

2. **Pharmacists:**
   a. Are responsible to educate the public on the effect on driving of only prescription drugs
   b. Can provide clear guidelines on effects of medications in regards to operation of machinery
   c. Have no impact on the minimizing the risk of persons driving under the influence through consultation
   d. All the Above

3. **Potential for impaired driving due to medication only occurs with older adults since they take more medication.**
   a. True
   b. False:

4. **Antidepressants:**
   a. Can increase crash risk twofold.
   b. Are the most frequently prescribed drug which increases crash risks
   c. Evidence that crash rate is higher in individuals with depression than unaffected individuals
   d. a and c
   e. All of the above

5. **The response to anticonvulsant medication varies by individual and may not always be linearly correlated with dosage.**
   a. True
   b. False:

6. **AAA found that:**
   a. Only about half of the drivers on medications talked to a health profession about the effects of their medication on their ability to drive
   b. Increased age, low education and widowhood was associated with less awareness of the effect of medication on the ability to drive
   c. Medical professionals are generally unaware of medicine's effects on driving and reluctant to discuss them with their patients.
   d. All of the Above
   e.

7. **Benzodiazepines:**
   a. Interfere with muscle tone and relax the driver to help with coordination
   b. 5 mg of Valium is equivalent to a blood alcohol level of 0.10%
   c. Can increase crash risk 60%
   d. Increase crash risk only in those 65 years and older

8. **Hypoglucemics:**
   a. Type 1 diabetics are at highest risk of driving impairment due to hyperglycemia
   b. Hypoglycemia can impair cognitive and motor skills
   c. Diabetic drugs seldom interact with other drugs, so there is no worry about additive effects
   d. Eye diseases associated with diabetes does not affect driving safety
   e. All of the above

9. **Alcohol:**
   a. Is the number one substance implicated in traffic fatalities
   b. Alcohol further impairs driving in persons taking prescription medication
   c. Pharmacist should include in their consultation the accentuating effects of alcohol
   d. All of the above

10. **Pharmacist should educate patients about the impact of their medication on their ability to drive.**
    a. True
    b. False:

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*Source: http://www.cbs.state.or.us/external/dir/wc_cost/map.html

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# Integrated Practice Unit (IPU) Model

## at Western Diabetes Institute

By Christal Pham, PharmD, RPh; and Andrew S. Pumerantz, DO, FACP

Diabetes mellitus (DM) is a chronic, complex, and lifestyle-driven condition that is typically associated with multimorbidity and, if poorly controlled, can eventually lead to debilitating and costly complications. For people living with DM and multimorbidity, primary care providers (PCP) lack the resource capacity to evaluate and solely manage the complexity of care across the continuum. Indeed, it is not uncommon for such patients to see a dozen providers from disparate disciplines who are rarely co-located and whose patient health records are not interconnected. More complex multimorbidity also typically requires more extensive pharmacotherapeutic regimens. As a result, care delivery is often fragmented, lacks integration and coordination, and predisposes the patient to potential harm. Patient engagement and accessibility to their personal and comprehensive health data are vital to improving outcomes and lowering costs. In contrast to acute conditions, DM and associated chronic multimorbidity requires a reframing of health and disease and a fundamental redefining of care delivery that focuses on team-based, cross-disciplinary models.

Western Diabetes Institute (WDI) was founded in 2009 as an integrated practice unit (IPU) organized around people living with DM and multimorbidity. Today, WDI encompasses several important sub-units (Care Coordination; Heart and Vascular; Eye Care; Fitness and Function; Kidney Health; Periodontal Health; Diabetes Education and Nutrition; Endocrine and Metabolic Health; Clinical Pharmacy; and Research) that are housed within the Patient Care Center at Western University of Health Sciences (WesternU) in Pomona, CA. At the core lies the "collaborative therapeutic alliance" (or "CoreCTA") comprised of the patient, a clinical pharmacist, and a community health worker/promotora de salud (care coordinator). The care coordinators/promotoras work alongside the pharmacist to bridge communication between patient and the healthcare team. The care coordinators are highly skilled lay members/leaders in the community who are known to be effective in community-based lifestyle intervention and system navigation, especially in Hispanic communities, through mutual understanding, respect, empathy, and trust that aid in supporting patients in health education and preventive efforts.

### Description of the practice model

Launched in January 2013, the WDI IPU is a patient-centric, cross-disciplinary care delivery model that begins with an initial, same-day, comprehensive evaluation (see Appendix 1) to establish a precise, composite diagnosis of the complexity and severity of each patient's condition. During that day, which typically starts at 8:00 AM, patients see a clinical endocrinologist; dental hygienist; optometrist; registered dietitian nutritionist/certified diabetes educator (RDN/CDE); and physical therapist. The evaluation includes a dilated retinal scan; foot and functionality assessments; panoramic dental x-rays and periodontal probing; echocardiography to screen for structural heart disease; a depression screen; and medication review with education, training, and resource assistance provided by the clinical pharmacist. At noon, along with a lunch provided by corporate partner Cardenas Markets, the RDN/CDE provides an introductory diabetes self-management education session. At the end of the day, the patient, the care coordinator/promotora, and the clinical pharmacist review at-a-glance the patient's composite health condition that is visual-

**Appendix 1**

## WDI "One-Stop" Cross-Disciplinary Evaluation

| Time | Patient 1 | Patient 2 | Patient 3 |
|---|---|---|---|
| 8-9 AM | Registration<br>Meet Coordinator<br>Vitals/BMI/Blood Glucose<br>Medication Review with Pharmacist<br>Perception Surveys | Registration<br>Meet Coordinator<br>Vitals/BMI/Blood Glucose<br>Medication Review with Pharmacist<br>Perception Surveys | Registration<br>Meet Coordinator<br>Vitals/BMI/Blood Glucose<br>Medication Review with Pharmacist<br>Perception Surveys |
| 9-10 | Periodontal | Eye | Endocrine |
| 10-11 | Eye | Endocrine | Periodontal |
| 11-12 | Endocrine | Periodontal | Eye |
| 12-1 | Group Lunch with RDN/CDE | Group Lunch with RDN/CDE | Group Lunch with RDN/CDE |
| 1-2 | PT/foot + ABI | Pharmacy Education | EKG/ ECHO |
| 2-3 | EKG/ ECHO | PT/foot + ABI | Pharmacy Education |
| 3-4 | Pharmacy Education | EKG/ ECHO | PT/foot + ABI |
| 4-5 | Coordinator Wrap Up | Coordinator Wrap Up | Coordinator Wrap Up |

ized and communicated through the aid of a "balanced scorecard", referred to as the Diabetes Cross-Disciplinary Index (DXDI©)(See Appendix 2). The DXDI scorecard enhances patient understanding and engagement while facilitating communication through a common language that is shared among all members of the provider team. On the following Friday morning, the entire WDI IPU team formulates a precise and personalized care plan that is stratified and triaged based on urgency for intervention and is aligned with the patient's own goals. The care coordinator/promotora works closely with the clinical pharmacist to help identify the existence of any implementation challenges pertaining to a patient's health literacy as well as psychosocial and socioeconomic issues.

The CoreCTA is an extension of the entire care team that increases patient-provider communication across the healthcare ecosystem and throughout the full, longitudinal care cycle. To leverage cross-disciplinary and cross-ecosystem communication with real-time health record accessibility for all types of actionable data by all parties involved in the patient's care the CoreCTA uses ClickMedix (a global leader in HIPAA-compliant mobile health technology) as its IT platform. ClickMedix has enabled referring

**Apprendix 2.**

# Diabetes Cross-Disciplinary Index (DXDI)



Western University Western Diabetes Institute

| | A1C | | $LDL_c$ | | | | | | | BMI | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | <7.0% (<53 mmol/mol) | No Structural Heart Disease | < 100 mg/dL or <70 with CVD | SBP < 130 mmHg and DBP < 80 mmHg | No Nephropathy | No Retinopathy | No Dental Infection | No Neuropathy No PAD | Independent | 18.5-24.9 | No Depression PHQ-9 Score 0 |
| 2 | 7.0-7.9 (53-63) | Asymptomatic Structural Heart Disease | 100-130 | SBP 130-139 and DBP < 90 | Albuminuria UACR 30-299 mg/g | Mild Non-Proliferative | Mild Gingival Inflammation | Neuropathy | Modified Independent | 25-29.9 | Minimal Depression PHQ-9 Score 1-4 |
| 3 | 8.0-8.9 (64-74) | Symptomatic Structural Heart Disease | 131-160 | SBP 140-149 and DBP < 90 | Albuminuria UACR 300-999 or eGFR 30-60 | Moderate Non-Proliferative | Moderate Gingival Inflammation | PAD +/- Neuropathy | Minimal Assist 75% | 30-34.9 | Mild Depression PHQ-9 Score 5-9 |
| 4 | 9.0-9.9 (75-85) | Symptomatic Heart Failure | 161-190 | SBP <150 and DBP 90-99 | Albuminuria UACR 1000-2999 or eGFR 15-29 | Severe Non-Proliferative or Inactive Proliferative | Severe Gingival Inflammation | Active or Previous Ulcer | Moderate Assist 50% | 35-39.9 | Moderate Depression PHQ-9 Score 10-14 |
| 5 | ≥ 10.0 (≥86) | Refractory Heart Failure | >191 | SBP ≥ 150 or DBP ≥ 100 | Albuminuria UACR ≥3000 or eGFR ≤15 | Active Proliferative | Acute Dental Infection | Previous Amputation | Dependent High safety Risk | ≥40 or <18.5 | Severe Depression PHQ-9 Score ≥15 |

PCPs and other healthcare providers to securely receive the initial comprehensive reports and triaged, team-based care plans using smartphones, tablets, or computers. By connecting every stakeholder and the patient across the full care cycle, all contextual data and trends can be aggregated to form the basis of a robust and cross-disciplinary disease registry. In turn, this connectivity affords the opportunity for analysis and ongoing learning about living with, and caring for, complex health conditions in the 'real-world'.

## Resource requirements (staffing, equipment, capital)

The IPU team consists of a clinical endocrinologist; clinical pharmacist; community health worker/promotora de salud; medical assistant; RDN/CDE; physical therapist; optometrist; dental hygienist; cardiac sonographer; and registry coordinator. Embedded within the larger team are a nephrologist, cardiologist, and podiatrist.

Dedicated equipment includes point-of-care testing devices for glycated hemoglobin (A1C) and urine albumin-creatinine ratio (UACR); glucometer; periodontal probe, mirror, air-water syringe, and saliva ejector, and panoramic digital x-rays, electrocardiographic and echocardiographic machines, and retinal scanner.

## Description of successes both anecdotal and measurable

This innovative connectivity model promotes the effectiveness of an integrated, team-based care plan and improves patient safety as well as the value of health care that is delivered. It has allowed patients to better understand and visualize the complexity of their DM and multimorbidity while mitigating the health literacy barrier. It has empowered patients to ask questions, identify personal barriers, and express their goals regarding healthy eating, being physically active, monitoring blood glucose, taking medications, identifying healthy coping strategies, increasing their problem-solving skills, and reducing risk. Patients are active participants in their care and have expressed their enthusiasm regarding their progress.

WDI's research registry, which is approved by the Institutional Review Board of Western University of Health Sciences, tracks the longitudinal health and care outcomes of the IPU cohort. A seminal query was recently performed on data collected on the first 273 patients who were evaluated and managed in the IPU from January 2013 through December 2014. Data on cohort demographics, improvement in glycemic control at 3-month follow-up, and results of follow-up standardized diabetes knowledge testing are displayed in Appendix 3.

## Business Case and limitations of the model or restrictions that limit its portability

Limitations to scaling up our model lie within the existing care paradigm

**Appendix 3. Demographic and Results Data**

| Patient Demographics (n=273) | | | |
|---|---|---|---|
| Gender (%) | | | |
| Female | 158 (58) | | |
| Male | 115 (42) | | |
| Mean age in years | 54 years | | |
| Preferred Language (%) | 179 (66) Spanish | | |
| Type 2 diabetes (%) | 256 (94) | | |
| Mean HgA1C reduction | | | |
| | HgA1C % reduction | | P-value |
| At 3 months follow up (n=127) | 0.6% | | <0.05 |
| At 3 months follow up subgroup analysis (n=46, baseline HgA1C greater than 9%) | 1.7% | | <0.05 |
| DM 15 question knowledge test scores | | | |
| | Pre-test | Post-test | P-value |
| Number of correct answers (%) | 10 (67) | 12 (82) | <0.05 |
| *Frequency (%) is based on the total number of participants and varies depending on missing data to a specific item | | | |

and reimbursement mechanisms. Though doctor visits are the basis for the fee-for-service model, most "care" for people with DM and multimorbidity is delivered outside both hospitals and doctors' offices 365 days of the year. To improve the value of health care for lifestyle-driven chronic conditions, new paradigms of care delivery are needed and, to be sustainable, must be supported by new business models.

Our model shifts essential tasks from traditional health care providers to historically underutilized resources such as community pharmacists and lay community health workers. Furthermore, by re-envisioning the value of local pharmacies and connecting them to each patient's health care ecosystem through mobile health technology, the locus of chronic care delivery shifts from medical office buildings to neighborhoods and communities where patients live.

Disrupting care delivery requires regulatory change. The passage of SB 493 granting pharmacists "provider status" in California, the reintroduction of the pharmacist provider status bill in Congress, and emerging healthcare delivery reimbursement through the Affordable Care Act (ACA) will help to clear a pathway for the scaling up of WDI-like integrated care delivery models within community pharmacies. Indeed, current reimbursement models challenge the financial sustainability of delivering truly patient-centered, community-oriented, and high-value longitudinal care.

Currently, we are collaboratively piloting with regional third-party payers, including managed Medi-Cal plans, to implement the IPU program

for their poorly-controlled diabetic patients by blending traditional fee-for-service with bundled payments and yearlong, subscription fees based on outcomes. These pilots are ongoing and results will be forthcoming.

## Any legal, or regulatory issues, or restrictions on the model

Although SB 493 has expanded the scope of practice for licensed pharmacists within California, the need for increased coordination and collaboration between all providers across a patient's health care ecosystem is essential. There is a need for more collaborative practice agreements within community settings in order to optimize the CoreCTA and pharmacists' patient care services. Currently, reimbursement is still the limiting factor due to federally unrecognized provider status for non-physician specialists such as clinical pharmacists.

## Future plans and direction

By leveraging mobile technology to connect all of the stakeholders across the health care ecosystem for people with chronic conditions, the goal of the model is to shift the locus of longitudinal, lifestyle-based health care away from hospitals and medical office buildings and into more accessible, community pharmacies. Pharmacists may find themselves with the opportunity to shift tasks within their community-based stores by creating new on-site jobs for care coordinators/promotoras and RDN/CDE who in turn will help engage and motivate patients to take more accountability for their health and lifestyle. In so doing, community pharmacists could reinvent their industry by becoming an indispensable 'medication therapy management specialist provider' who is embedded within a virtual and ad hoc team that delivers increased patient access to high-value care with aligned goals,

shared knowledge and wisdom, and real-time, personalized, and actionable plans.

## About the Authors

Dr. Christal Pham (CP) received her Doctorate of Pharmacy (PharmD) and completed her residency in community pharmacy practice from Western University of Health Sciences, College of Pharmacy. During her residency, she worked with Hendrick's Pharmacy and WesternU Pharmacy to implement and manage patient care services, such as travel medicine, medication therapy management, pain management, and anticoagulation and antithrombotic medication management. Her area of expertise is collaborative-practice based ambulatory care services.

Dr. Andrew S. Pumerantz (ASP) founded and leads the interprofessional Western Diabetes Institute (WDI) at Western University of Health Sciences (WesternU) in Pomona, CA, where he is also Professor of Internal Medicine (Infectious Disease), and Assistant Provost for Strategic Initiatives. In 2007, Dr. Pumerantz transitioned from partnership in a clinical infectious disease practice on Long Island's North Shore to become Chief of Infectious Disease at WesternU's College of Osteopathic Medicine of the Pacific (COMP). Between 2008 and 2012, he served as WesternU COMP's Chair of Internal Medicine. In 2009, focused on improving the value of team-based care delivery to people living with type 2 diabetes and multimorbidity, Dr. Pumerantz launched WDI as a startup within an academic health center. In 2011, he developed the Diabetes Cross-Disciplinary Index (DXDI©) as a balanced health scorecard to better visualize a person's composite health status and to communicate actionable data between all the stakeholders scattered across that person's health care ecosystem. Since January 2013, DXDI has been an integral tool within WDI's care delivery model. In 2015, WDI and NHS Scotland forged an international collaboration whereby all Scots with diabetes, and their provider teams, will have access to their health data displayed via a modified version of DXDI on the award-winning Scottish Care Information-Diabetes Collaboration (SCI-DC) platform. Dr. Pumerantz has spoken nationally and internationally on disruptive innovations in health care delivery and is a project consultant to groups in India, the Middle East, and Latin America seeking to develop WDI-style institutes. He is also Medical Advisor to global connected mHealth social enterprise, ClickMedix. Dr. Pumerantz holds an AB from Occidental College and a DO from Philadelphia College of Osteopathic Medicine. He trained in internal medicine and was Chief Resident at Beth Israel Medical Center in New York. Dr. Pumerantz completed infectious diseases fellowship at Yale School of Medicine. He maintains American Board of Internal Medicine certification in internal medicine and infectious disease, and is a Fellow of the American College of Physicians.

*Conflict of Interest: ASP is medical advisor to ClickMedix and the inventor of DXDI. CP has no conflict of interest to disclose.*

***Evidence-Based Medicine: Putting Research Evidence into Practice*** *-- This type of article utilizes an evidence-based practice framework to create a concise, practical, high-quality critical appraisal of published medical literature. The goal of this type of article is to assist health care professionals with improving their provision of evidence-based patient care.*

# Paradigm-HF: A Paradigm Shift In Heart Failure Management?

*Citation: McMurray JJ, Packer M, Desai AS, Gong J, Lefkowitz MP, Rizkala AR, Rouleau JL, Shi VC, Solomon SD, Swedberg K, Zile MR. Angiotensin-neprilysin inhibition versus enalapril in heart failure. N Engl J Med 2014;371:993-1004. PMID 25176015*

**By Kristine Widboom, PharmD; Noelle de Leon, PharmD**

PARADIGM-HF randomized 8,339 patients with NYHA Class II-IV heart failure with reduced ejection fraction who were on a stable dose of a β-blocker and angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) to either a combination of valsartan and sacubitril (a neprilysin inhibitor) 200 mg (equivalent to 160 mg valsartan) twice daily or enalapril 10 mg twice daily. Patients were excluded from randomization if they had hypotension, renal impairment, hyperkalemia, or a history of angioedema or unacceptable adverse effects with an ACEi or ARB. At the last assessment in the study, mean daily doses in the valsartan-sacubitril and enalapril groups were 375±71 mg and 18.9±3.4 mg, respectively. The primary outcome was a composite cardiovascular death or hospitalization for heart failure with a mean follow-up of 27 months.

## I. Trial Validity

| | |
|---|---|
| **START OF TRIAL** | |
| Randomization/ Concealment | • Patients were randomized in a double-blind fashion following a run-in period, in which patients received single-blinded treatment with enalapril 10 mg twice daily for 2 weeks followed by valsartan-sacubitril 100 mg twice daily (titrated up to 200 mg twice daily) for an additional 4-6 weeks. Patients with no unacceptable side effects of the target doses of the study medications were randomly assigned 1:1 with the use of a computerized randomization system involving concealed study-group assignments to double-blinded treatment with either enalapril 10 mg twice daily or valsartan-sacubitril 200 mg twice daily.<br>• Computerized randomization effectively concealed group assignments and ensured the randomization process was unbiased. daily or valsartan-sacubitril 200 mg twice daily. |
| Baseline Characteristics (valsartan-sacubitril vs enalapril) | • There were no clinically significant differences between the study groups (refer to Table 1 in reference 1). On average, patients were over 60 years old, male, Caucasian, overweight, and residing in Europe. Most patients had Class II (70%) or III (24%) heart failure with left ventricular ejection fraction ≤40% and were on a stable dose β-blocker (93%) and an ACEi and/or ARB (100%) on study entry. ACEi and ARB doses had to be equivalent to at least enalapril 10 mg per day for entry into the study. Only about half of patients were on 50% or better of the target dose of β-blocker. Mean vital signs included systolic blood pressure 120/70 and heart rate 70 beats per minute. At randomization, only 15% of patients had an implantable cardioverter-defibrillator and 7% had cardiac resynchronization therapy.<br>• The 1:1 randomization process led to comparable groups that had no clinically important differences that could affect the study outcome. |
| **DURING TRIAL** | |
| Blinding | • Treatment with enalapril and valsartan-sacubitril during the run-in period was singled-blinded. Patients, investigators, assessors, and data analysts were blinded to the identity of treatment from the time of randomization until the conclusion of the study.<br>• Double-blinding during the randomization period led to decreases in behaviors which could bias results. |

| | |
|---|---|
| Equal Treatment | • Efforts were made to keep doses of heart failure and other cardiovascular medications the same throughout the study. However, if a patient's condition warranted a change in medication or dosing this was allowed at the discretion of the study investigator. Patients were instructed to notify study site staff of any changes in concomitant medications (new medications or changes in dosing of existing medications).<br>• Concomitant use of open-label ACEi or ARB therapy was prohibited while the patient was receiving the study medication. If patients discontinued the study medication they were allowed to use open-label ACEi or ARB therapy, which introduced the possibility of contamination. Diuretic doses could be adjusted throughout the length of the study. Between the two groups (valsartan-sacubitril vs enalapril), there were statistically significant differences in mineralocorticoid antagonist (54.2% vs 57%, p=0.01) and digoxin (29.2% vs 31.2%, p=0.04) use at baseline. The increased use of mineralocorticoid antagonists and digoxin in the enalapril group may bias this group to a reduction in hospitalizations for heart failure. In addition, patients may have received other interventions, such as a low-sodium diet or exercise, which may have contributed to a decrease in cardiovascular death or heart failure hospitalization. It is unknown if any patients received an implantable cardioverter-defibrillator or cardiac resynchronization therapy during the study, but this could contribute to a reduction in cardiovascular death.<br>• The investigators made efforts to avoid co-intervention and contamination bias with the use of double-blinding, stipulations regarding medication therapies, and encouraging patient reporting of changes in concomitant medications and significant non-drug therapies (including physical therapy and blood transfusions) |
| **END OF TRIAL** | |
| Completeness of Outcome Data | • Out of the 8,399 patients randomized, 20 patients (0.24%) did not have a final outcome result. Of the patients without final vital status, nine (0.21%) were in the enalapril group and eleven (0.26%) were in the valsartan-sacubitril group. Between the two treatment groups there was no considerable difference in the proportion of patients without final vital status.<br>• Considering the magnitudes of absolute risk reduction for the outcomes in this study, it is unlikely that the small number of patients with incomplete data at the end of the study was large enough to skew the study results. |
| Method of Outcome Analysis | • An intention-to-treat analysis was not used. The authors employed a modified intention-to-treat analysis in which patients with missing data and those affected by non-adherence to study protocols were excluded from the final data analysis. Initially, 8,442 patients were enrolled and randomized in the study. However, 43 (0.51%) of these patients were excluded from data analysis- six patients were excluded because of invalid randomization and 37 patients were excluded because their sites were closed as a result of Good Clinical Practice violations. Twenty patients (0.24%), nine (0.21%) in the enalapril group and 11 (0.26%) in the valsartan-sacubitril group, who did not have final outcome data were also excluded from the analysis.<br>• The number of patients excluded from data analysis was not significantly different between groups. Considering the magnitudes of absolute risk reduction for the outcomes in this study, it is unlikely that the number of patients excluded from data analysis was large enough to bias the study results. |

## II. Trial Results

| Efficacy Outcome | Valsartan-Sacubitril 200 mg twice daily N=4187 | Enalapril 10 mg twice daily N=4212 | HR and 95% confidence interval | Relative Risk Reduction (RRR) | Absolute Risk Reduction (ARR) | Number Needed to Treat (NNT) | p-value |
|---|---|---|---|---|---|---|---|
| Cardiovascular death or hospitalization for heart failure | 914 (21.8%) | 1117 (26.5%) | 0.80 (0.73-0.87) | 17.7% | 4.7% | 21 | <0.001 |
| Cardiovascular death | 558 (13.3%) | 693 (16.5%) | 0.80 (0.71-0.89) | 19.0% | 3.1% | 32 | <0.001 |
| Hospitalization for heart failure | 537 (12.8%) | 658 (15.6%) | 0.79 (0.71-0.89) | 17.9% | 2.8% | 36 | <0.001 |
| All-cause mortality | 711 (17%) | 835 (19.8%) | 0.84 (0.76-0.93) | 14.3% | 2.8% | 36 | <0.001 |

The composite outcome of cardiovascular death or hospitalization for heart failure is not driven significantly by either individual component. Outcomes for the individual components of cardiovascular death and hospitalization for heart failure are similar in their direction and magnitude of effect, and are each statistically significant. The treatment effect for valsartan-sacubitril is appreciable. The number of patients that would need to be treated with valsartan-sacubitril to prevent a death or hospitalization from heart failure is small compared to the magnitude of treatment effect.

| Adverse Event | Valsartan-Sacubitril 200 mg twice daily N=4187 | Enalapril 10 mg twice daily N=4212 | Absolute Risk Increase (ARI) | Number Needed to Harm (NNH) | p-value |
|---|---|---|---|---|---|
| Symptomatic Hypotension | 588 (14.0) | 388 (9.2%) | 4.8% | 21 | <0.001 |
| Elevated Serum Creatinine ≥2.5 mg/dl | 139 (3.3%) | 188 (4.5%) | 1.1%A | 87A | 0.007 |
| Cough | 474 (11.3%) | 601 (14.3%) | 3.0%A | 34A | <0.001 |

[A]Reported ARI and NNH are for enalapril

Angioedema occurred in 19 patients (0.45%) of patients in the valsartan-sacubitril group and 10 patients in the enalapril group (p=0.13). Therapy was permanently discontinued because of hypotension in 36 patients (0.9%) in the valsartan-sacubitril group and 29 patients (0.7%) in the enalapril group (p=0.38). Renal impairment led to therapy discontinuation in 29 patients (0.7%) in the valsartan-sacubitril group and 59 patients (1.4%) in the enalapril group (p=0.002).

## III. Trial Applicability

| | |
|---|---|
| Patient Applicability | • Patients with symptomatic hypotension, systolic blood pressure less than 100 mm Hg at screening or 95 mm Hg at randomization, estimated glomerular filtration rate (GFR) below 30 ml/min/1.73 mm2 at screening or randomization or a decrease in eGFR of more than 25% (amended to 35%) between screening and randomization, serum potassium greater than 5.2 mmol/L at screening or 5.4 mmol/L at randomization, or a history of angioedema or unacceptable side effects while on ACEi or ARB therapy were excluded from the study. The majority of patients in PARADIGM-HF had mild to moderate heart failure with reduced ejection fraction. Only patients who were able to tolerate full dose enalapril 10 mg twice daily were randomized to treatment. Therefore, it is unknown how patients in poor health would tolerate valsartan-sacubitril therapy. |
| Patient Applicability (cont.). | • Notably, only 5% of patients in PARADIGM-HF were African American and therefore the effects of valsartan-sacubitril therapy in this patient population remain to be seen.<br>• The use of device therapy was low, with only 15% of patients having an implantable cardioverter-defibrillator and 7% with cardiac resynchronization therapy. Given the positive effects of device therapy on morbidity and mortality, the benefits of valsartan-sacubitril therapy may be overestimated in this study.<br>• Patients with preserved ejection fraction were excluded from PARADIGM-HF and therefore the treatment effects in this population are unknown. However, valsartan-sacubitril therapy is currently being studied in patients with preserved ejection fraction in a Phase III clinical trial.<br>• Based on the population studied, the results of this study are generalizable to patients with mild to moderate heart failure with reduced ejection fraction who tolerate enalapril 10 mg twice daily at baseline. Questions remain regarding the applicability of this study's results to patients who have severe heart failure, renal dysfunction, are African American, or have heart failure with preserved ejection fraction. |
| Intervention Applicability | • Enalapril 10 mg twice daily was used in both the CONSENSUS and SOLVD trials. The mean daily dose of 18.9 mg enalapril in PARADIGM-HF was comparable to the CONSENSUS (16.6 mg) and SOLVD (18.4 mg) trials. Val-HeFT studied the effects of valsartan 160 mg twice daily. A 200 mg dose of valsartan-sacubitril contains 160 mg of valsartan. The PARADIGM-HF study dose of valsartan-sacubitril 200 mg twice daily is therefore equivalent to valsartan 160 mg twice daily.<br>• It is expected that brand name valsartan-sacubitril therapy will be very expensive compared to current generic medications used for heart failure management. The twice daily dosing of valsartan-sacubitril is comparable to current ACE inhibitor and ARB regimens.<br>• Overall, the comparator arms in this study were well-matched and are valid based on historical trials. The outcomes of this study are likely to persuade insurance companies to include valsartan-sacubitril in their formulary, but it is unknown at this time what cost this brand name medication will pose to patients. |

| | |
|---|---|
| Patient-Important Outcomes Measured | • The primary outcome of a composite of cardiovascular death and hospitalization due to heart failure is highly clinically important. The secondary outcomes were time to death from any cause, change from baseline to 8 months in the Kansas City Cardiomyopathy Questionnaire (KCCQ) clinical summary score, time to new onset atrial fibrillation, and time to decline in renal function. The KCCQ clinicaly summary score, which assesses quality of life, is likely to be of great importance to patients.<br>• Adverse events were pre-specified and documented with each occurrence after randomization. If the study drugs were permanently discontinued, a reason why was documented and the resulted were summarized. Safety data was appropriately assessed and analysed.<br>• The primary, secondary, and safety outcomes evaluated in this study are clinically relevant and were appropriately evaluated. |
| Balance of Benefits vs. Harms | • Valsartan-sacubitril is associated with significant reductions in death from cardiovascular and all causes, as well as hospitalizations for heart failure. These effects were more substantial with valsartan-sacubitril than enalapril in this study. If 1,000 patients were treated with valsartan-sacubitril, 31 deaths from a cardiovascular cause and 28 hospitalizations for heart failure or deaths due to any cause would be avoided, but 48 patients would develop symptomatic hypotension. The number of patients that would need to be treated with valsartan-sacubitril to prevent a death or hospitalization from heart failure is small in comparison to the magnitude of the treatment effect.<br>• At the last assessment in the study, mean daily doses in the valsartan-sacubitril and enalapril groups were 375±71 mg and 18.9±3.4 mg, respectively. These mean doses of valsartan-sacubitril and enalapril were just short of the target study doses of 400 mg and 20 mg, respectively. Doses of study medication were reduced if the patient experienced adverse effects. The incidence of symptomatic hypotension was higher with valsartan-sacubitril (14%) than with enalapril (9.2%) ($p < 0.001$). Serum creatinine elevation ≥2.5 was less frequent with valsartan-sacubitril (3.3%) than with enalapril (4.5%) ($p=0.007$). In fact, serum creatinine elevation ≥2.5 was associated with increased rates of permanent drug discontinuation in the enalapril group ($p=0.002$). Overall, study drug was discontinued in 746 patients (17.8%) receiving valsartan-sacubitril and 833 patients (19.8%) receiving enalapril ($p=0.02$). Of note, potential bias in adverse event data was introduced with the exclusion of 591 patients (5.6%) in the enalapril run-in phase and 547 patients (5.8%) in the valsartan-sacubitril run-in phase. Namely, the incidence of adverse effects and associated drug discontinuation rate due to adverse effects were likely underestimated. |
| Balance of Benefits vs. Harms (cont.) | • Previous studies of a neprilysin inhibitor in combination with an ACEi had unacceptable occurrence rates of angioedema. For this reason, during the run-in period in this study there was a 36 hour washout period built in for when patients were transitioning from enalapril to valsartan-sacubitril. Angioedema occurred in 19 patients (0.5%) with valsartan-sacubitril and 10 patients (0.2%) with enalapril ($p=0.13$).<br>• Enalapril and valsartan are generic medications that carry a low cost burden compared to the high expected cost of the brand name valsartan-sacubitril combination. Unfortunately, the valsartan-sacubitril combination is a drug fusion product and individual sacubitril will not be marketed, at least initially.<br>• The median study follow-up of 27 months was too short to establish long term safety and efficacy outcomes.<br>• The substantial benefits of reductions in cardiovascular and all-cause mortality and hospitalizations for heart failure outweigh the risks of adverse effects and cost of valsartan-sacubitril therapy. |

## Health Care Provider Summary

Valsartan-sacubitril, a novel combination of an ARB and a neprilysin inhibitor, reduced death from cardiovascular causes and hospitalizations for heart failure in patients with Class II-III heart failure with reduced ejection fraction in this well-designed large, multicenter, randomized 1:1 double-blinded, active-controlled trial. The magnitude of treatment effect with valsartan-sacubitril 200 mg twice daily was significantly greater (ARR 4.7%, $p < 0.001$) than with the current goal standard of therapy enalapril 10 mg twice daily. The robust findings of this study support the use of valsartan-sacubitril over ACEi or ARBs in the treatment of congestive heart failure with reduced ejection fraction. The applicability of this study to patients who are not able to tolerate enalapril 10 mg twice daily or who have severe heart failure, renal dysfunction, are African American, or have heart failure with preserved ejection fraction is unknown.

## Patient Summary

Valsartan-sacubitril is a new medication that reduces death and hospitalizations compared to a current standard therapy, enalapril, in patients with mild to moderate heart failure with weakened heart function. Patients that were studied were given high doses of medications that may not be tolerated by all patients, especially those with severe heart failure. Similar to current treatments for heart failure this medication is taken twice daily, but unfortunately it will initially be more expensive than current therapies because it will be a brand name rather than a generic medication.

## About the Authors

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Cynthia Jackevicius, PharmD, a Professor of Pharmacy Practice at Western University of Health Sciences, is the Evidence-Based Practice Section Editor. Dr. Jackevicius teaches evidence-based practice skills to health care professionals. She advocates for the adoption of an evidence-based practice, incorporating the best available evidence, patients' values and preferences, and clinicians' expertise into clinical decision-making.

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# California Health Sciences University

**By Vigil Beth Rapiz, CPhA Board of Directors Representative**

## Legislative Day

The legislative days at CHSU was a success. We met our goal of at least 25 participants by having more than 30 attend. Speakers who were scheduled to attend, Assemblyman Perez and Assemblyman Videk, were unable to attend. So representatives were sent to speak on their behalf. The main objective of the night was to better equip pharmacists, pharmacist technicians and others involved in pharmacy about laws effecting them.

Laws which were discussed included Ab 627 which would make MTM as a Medi-Cal benefit, SB 672 which would protect from discovering the records and proceedings of peer review bodies for numerous health-care professionals, and finally SB 277 which would mandate that all children get vaccinated; which also got rid of personal and religious exemption. Speakers included Clifford Yong, Brain Warren, Megan Maddox, and the key-note speaker Ryan Gates who is CEO and president of Frontline Pharmacy Consulting.

## CPhA Membership Drive

On Wednesday, August 19, the first event for our membership drive kicked off at Buffalo Wild Wings at 5:30pm. There were about a dozen P1 students, two P2 students, and four pharmacists went to the event. New P1 students were able to ask P2 students and pharmacists about the school and ask pharmacy-related questions.

On Thursday, August 20, there were three P1s and 1 P2 at Denny's for dinner at 5:30pm. Even though it was a small turnout, the P1s were able to ask more questions and relate to the P1 students.

On Friday, August 21, the VP of Membership, Cecilia, presented CPhA to the P1 class at CHSU. Following the presentation, Beth, Anabell, and Cecilia set up the CPhA booth at the information fair. The booth consisted of two questions for the P1s to answer on a post-it note. This included how they would help the community and how they help themselves. These questions would help gauge what type of events these future members would like. The students were very engaging and asked great questions. They seemed very excited about this club and asked about volunteering opportunities along with future events. Many were concerned with mandatory events, but we assured them that each meeting and event is voluntary. CHSU is also paying for their membership. At the end of the fair, there were 58 sign-ups out of a possible 60.

Yoga night took place at the CHSU campus on August 24. The tables were all moved aside in one of the classrooms and approximately 10 members showed up to follow a 45-minute instructional yoga video. It was a great workout and also very relaxing. The members enjoyed it so much that they requested more yoga nights.

Bowling took place at AMF Lanes in Clovis on August 25. More P1 students showed up to this event since it was more universal. Everyone had a great time bowling and getting to know each other more since we barely see each other on campus. The P1 students were very kind in thanking us for putting on these events since they knew that we had no organizations or events when we started out school last year.

The fundraiser at Sweet Tomatoes closed out the Membership Drive. A small group of P1 students came to eat a healthy, predominantly vegetarian, buffet style dinner. There were multiple flyers to leave with the cashier for the other students who showed up. There was a good showing of students and some new faces. Overall, the membership drive was a success and they all show interest in attending our first meeting and getting more involved.

# University of Southern California

**By Irene Chen, CPhA Board of Directors Representative**

First year students at the USC School of Pharmacy attend a professional organization fair to learn about the various opportunities available at USC.

## Professional Events

USC's American Pharmacy Student Alliance (APSA) hosted their annual retreat for their Executive and General Boards on July 17-19, 2015 in Anaheim, CA. With over 40 student pharmacists in attendance, the weekend was designed to review and build on the organization's mission and vision statements. The goal for the weekend was to ensure that all new board members were familiar with the structure of our student organization and able to promote opportunities to current and new members. Professionalism and expectations as an organization were also discussed and collaboration between different organizations and health professions were encouraged. Moreover, there was a focus on individual project directors' goals for this upcoming year. This was a highly productive weekend for USC's APSA, with great feedback from board members.

On Tuesday, August 18, 2015, the USC School of Pharmacy hosted a student organization fair in order to inform the new first year student pharmacists of the opportunities available to them at USC. APSA promoted the state, national, and international pharmacy organizations (APhA, ASHP, CSHP, and IPSF). It was exciting to meet the first year student pharmacists who were extremely eager to get involved and we look forward to engaging their participation throughout their next four years as student pharmacists.

USC School of Pharmacy highly encourages students to get involved in California Pharmacists Association. The three local associations that are closely related to the school are San Gabriel Valley Pharmacists Association (SGVPhA), Pharmacists Professional Society of the San Fernando Valley (PPSSFV), and Orange County Pharmacists Association (OCPhA). Each month, there will be meetings or events hosted by these organizations. For SGVPhA, meeting is held usually on the third Monday of the month, which was on August 17. For OCPhA, meeting is held usually on the first Thursday of the month, which was on August 6. These two local associations usually have their meetings in a pharmacy school or a hospital. For PPSSFV, meeting is held usually on the first Wednesday of the month, which was on July 1 and August 5. During the meeting, the board members went over treasurer's report and trustee's report, and discussed future events. This was a great opportunity for students to invite pharmacists to events and to promote the school. Board members also promoted upcoming events to pharmacists and students. There were professional events such as CE courses for pharmacists and social events such as bowling for everyone. Through attending local associations meetings and events, students can network with their local pharmacists and know the current pharmacy issues.

## Community Outreach

During the summer of 2015, the Directors of Women's Health held two health fairs that provided services to primarily the underserved Hispanic communities in the Los Angeles area. These health fairs provided mainly osteoporosis screenings and education to members of the Hispanic communities. The first health fair provided screening, counseling, and education to approximately 30 participants, and the second health fair, held in conjunction with Proyecto Pastoral's 18th Annual Women's Conference, reached over 50 participants.

This past summer, IPSF aided USC School of Pharmacy faculty Dr. Wincor in a summer exchange program. He hosted several groups of pharmacy students from different countries at USC School of Pharmacy. APSA members had the opportunity to converse with them about the similarities and differences between pharmacy in the United States and in their respective country as well as the curriculum to becoming a licensed pharmacist in our respective countries. APSA also sent one our students from USC School of Pharmacy to Japan to study pharmacy there. Lastly, students participated in some American culture immersion events by taking our international visitors to events such as baseball games and the Hollywood Bowl.

USC School of Pharmacy students show international students around the Health Sciences Campus.

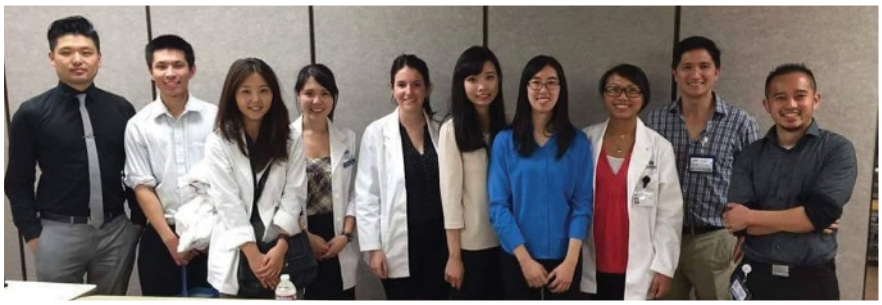

American Pharmacy Student Alliance Executive and General Board, Anaheim, CA

# Touro University

**Supannee Sandra Lertpaichaiyon, CPhA Board of Directors Representative**

## Summertime Involvement

Partnering with Berkeley Suitcase Clinic, the Diabetes Committee helped increase awareness and educate on proper use of glucometer, healthy diets, and lifestyle choices to help in the management of diabetes to the underserved. Our focus was not only on testing their blood sugar, but also included educating the patients on what diabetes is and what options are available to help manage it. Patients learned proper blood glucose testing procedures, guided on how to react during hypoglycemic event, and walked away knowing which foods will help for better management of diabetes. The event was very much a success!



Our student pharmacists and preceptors helped make this event a success! Mike Kwong, John Wang, Catherine Cho, Ashley Jung, Jamie Russell, Khin Htwe, Helen Chiu, Binh Thai; Preceptors: Dr. Sai Ly, Dr. Chris Ching

## New Year, New Board!

Congratulations to the new APhA/CPhA board for the Touro University chapter 2015-2016 school year! We are all excited to work together as a team to accomplish great goals for our Touro chapter this year!

## Increasing Student Membership

School just began and one of our chapter's top priorities is to increase membership amongst our fellow student pharmacists. We have done many events to highlight the benefits of joining such a great organization, like CPhA. In the fun and friendly atmosphere of a local Vallejo restaurant, we hosted an informal social gathering where students were able to meet and chat with the chapter board and advisors. Many students gained interest in becoming members, even in the first week of school! We also had an APhA/CPhA Committee Information session that described the wide variety of committees our chapter has to offer this year and beyond. This event was very successful, as we received numerous participation interests for each committee! We recently promoted our APhA/CPhA chapter on Club Day. With our active board members, awesome poster, and some candy, we recruited MANY students, both P1s and P2s. Our chapter is very excited to work with our fellow student pharmacists in furthering the pharmacy profession!

## Upcoming Events

We have many upcoming interactive campus events for our members. "Lexicomp Lunch" will allow our members to learn how to navigate around Lexicomp, which will be very useful for rotations! "Pizza and Policy" is a lunchtime event where students will help create new policy proposals to further the pharmacy profession. We hope this will also increase the students' awareness about the importance of legislative advocacy for the pharmacy profession.

We are excited to participate in UOP's ASP Land Park Intercollegiate Health Fair on September 13 to educate locals about certain healthcare topics. Hopefully, we can partner with more schools in the future. We also can't wait to see everyone at Rx Boot Camp on October 3!

Jenny Nguyen, Kyle Smith, and Monica Rhee

Club Day excitement! Jenny Nguyen, Kyle Smith, Sandra Lertpaichaiyon, Kalvin Lam, Katherine Tran

(Top) Jenny Nguyen, Kyle Smith, Sandra Lertpaichaiyon; (Bottom) Laura Hoang, Katherine Tran, Monica Rhee, Tamana Ahmadi

# Keck Graduate Institute

### By Rajan Vaidya, CPhA Board of Directors Representative

This summer was filled with exciting activities at the Keck Graduate Institute (KGI) located in Claremont, CA. The newly elected KGI CPha-ASP Board held multiple summer meetings to prepare for the upcoming academic year. In addition, KGI School of Pharmacy hosted its first CPhA Regional Legislative Day on June 27th with over 50 participants in attendance.

The academic year is already proving to be an exciting time here at KGI. Now with two PharmD classes on campus, the KGI CPhA-ASP chapter is preparing for its fair share of community outreach. The chapter is working toward hosting its first flu clinic and health fair, performing educational outreach, building stronger bonds with local CPhA chapters, and engaging student pharmacists into being active participants early in their pharmacy careers.

Pictured (left to right): Armando Cortes (KGI SoP Student), Carolyn Woodside (KGI SoP Student), Senator Connie Leyva (District - Chino), Dr. Samit Shah (KGI Chair of Biopharmaceutical Sciences), and Sagar Bhakta (KGI SoP student)

# Loma Linda University

### By Grace Shinn, CPhA Board of Directors Representative

Although the start of Fall Quarter is still a couple of weeks away, Loma Linda's student CPhA members remain as active as ever. With the spirit of outreach, mission, and advocacy of the pharmacy profession, students have volunteered at a local Children's Diabetes camp, participated in mission trips to Romania & Brazil, interned at pharmacies abroad, and much more.

As the summer draws to a close, the student chapter board at Loma Linda is also working hard to prepare for the coming academic year. Our new board this year includes members from various academic years:

- **President-Elect:** David Downham, PY2
- **Secretary:** Sharon GeeHae Jung, PY2
- **Treasurer:** Michelle Do, PY3
- **Publicist/Historian:** Jason Kiroyan, PY2
- **Grass Roots Advocate/Delegates:** James Dexter, PY2 & Sarah SoHyun Kim, PY2
- **Outreach Coordinators:** Melissa Yong, PY3 & Joseph Tiongson, PY2
- **Fundraising Coordinators:** Crystal Lestari, PY3 & Eshban Lee, PY2
- **IEPA Representative:** Amanda Avey
- **OCPhA Representative:** Mia Choi
- **SGVPhA Representative:** Ben Cheung

Medical Staff including Loma Linda Pharmacy students at Camp Conrad Chinook (a local Type I Diabetes Summer Camp)

The board is excited to be planning major school events for this coming year at the Annual Leadership Retreat held by Loma Linda School of Pharmacy. This retreat is an awesome opportunity to not only plan and prepare for the year, but to also bond and reconnect as a board. Our board is thrilled to welcome the new class of 2019 to Loma Linda University and to the pharmacy profession and can't wait to see what this year holds!

# University of the Pacific

**By Connie Lin, CPhA Board of Directors Representative**

Our now 3rd year girls having a blast with the photobooth

## Spring Picnic

University of the Pacific (UOP) celebrated the end of Spring Midterms with its annual Spring Picnic sponsored by Walgreens on June 18th. More than 400 students stepped outside from their morning lectures to see the front lawn covered in tables with giveaways, raffles, food, bounce houses, jousting, and bungee-run setups hosted by ASP. This was a great opportunity to de-stress and have some fun in the sun.

## Legislative Affairs

The next day, a group of passionate students sat down and discussed legislation with the Office of Assembly member Susan Eggman. This included the discussion of SB 672 regarding the legal protection of pharmacists in hospital settings or pharmacists peer review bodies. Just this past August, the bill passed unanimously within the Assembly and is headed to the Governor.

## Senior Ball

On June 26th, UOP held its Annual Pharmacy Ball where second year pharmacy students celebrated the end of their didactic years and the exciting start of APPE rotations. This event was made possible through the Senior Board's successful auction in which professors and students offered items, food, lessons, or even full day events in return for donations for the annual ball. This event really brought everyone together for one final hurrah before sending the second year students off.

## NCCCP Research Symposium

Students involved in research presented projects they worked on all year long during the Northern California College of Clinical Pharmacy's Research Symposium on July 9th. More than 20 posters were proudly presented to the student body and faculty. Topics ranged from genetic research on Parkinson's disease to our Medicare Team's research on pharmacy practice. Not only did the students researching learn a lot from their experience but those who attended also had the opportunity to learn about advancements in all fields of pharmacy.

## Welcoming the New Academic Year

At the end of August, UOP welcomed its new class of ambitious first year pharmacy students. The first years kicked off their first week with the Mentor BBQ graciously sponsored by Rite Aid. First year pharmacy students paired up with second years to talk about anything and everything pharmacy related. Second years offered tips for success, ways to relax, and ultimately helped first year students' transition more smoothly into the start of their pharmacy career.

## Events to Look Forward To

Fall semester will be filled with many health fairs including the Land Park Intercollegiate Health Fair which will include organizations from UOP, Touro University, and California Northstate University. October is American Pharmacists Month and it is already packed with events to bring awareness to all that pharmacists can do for patients. The month will end with the First Annual Legislative Week originally created by our very own CPhA-ASP Board of Directors Chair, April Nguyen. Students will get a first look at new bills and will be taught the importance of advocating for the profession of pharmacy.

From the left: Winnie Ho (1st year), Gloria Choi (2nd year, Mentor), Jennifer Wyatt (1st year)

Marc Peralta with Walgreens representatives who made Spring Picnic possible

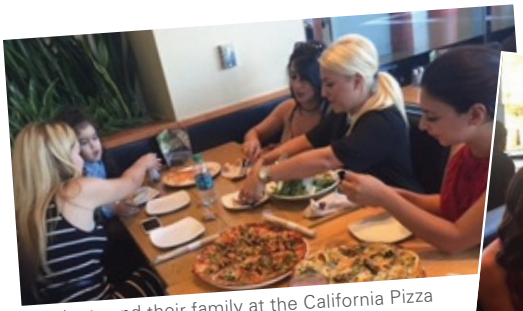
# West Coast University

**By Narine Arakelyan, CPhA Board of Directors Representative**

As a long summer break came to and end for West Coast University SOP students, the CPhA chapter executive members decided to organize a productive event that would bring P1 class and P2 class together for a "Meet and Greet" social event to celebrate the beginning of the academic year and at the same time raise funds for our CPhA chapter for future events and gatherings. The purpose of this event was to promote and introduce CPhA organization to the new comers of WCU SOP while enjoying friendly dinner on a sunny day at the California Pizza Kitchen in Glendale, CA that took place on Sunday, August 30th. Participants presented flyers at the register when ordering food; consequently, California Pizza Kitchen was generous enough to donated 20% of the total revenue that day to CPhA WCU chapter.

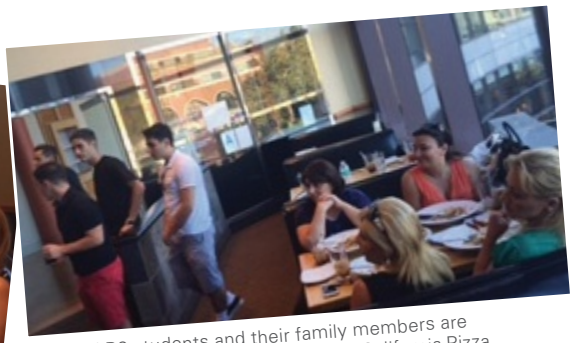
CPhA members who attended West Coast Exchange and Expo event in Spring of 2015 were eager to share their amazing experience with the P1 class, which in turn got the new class quite interested and excited for the upcoming West Coast Exchange in San Francisco in May of 2016. Students brought their family and friends as well, to enjoy good food and get to know each other. The event lasted for the whole day, which allowed others to join throughout the day. Professors of Pharmaceutical Department at WCU also had a chance to join that day in support of their students and CPhA chapter. After having some good laughs and spending some quality time, students rushed to their homes to study for the upcoming quizzes.

WCU CPhA executive members are planning on the future events some time during the fall semester, where students will be promoting health through an organized health fair that will be giving free flu shots to people living in underserved areas of Los Angeles. The members of CPhA chapter are currently looking for sponsors to organize this mutualistic event.



Students and their family at the California Pizza Kitchen fundraiser event for CPhA.

CPhA members having fun at the California Pizza Kitchen fundraiser event for CPhA in Glendale, CA. From left to right: Jeanne Villaluz, Mona Badawy, Nawal Alteliani, Anna Babakhanyan, Nemat Shafizadeh, Parmis Ashoftehtehrani, Aikoui Ohanyan. August 30th, 2015



P1 and P2 students and their family members are waiting in line to place an order at the California Pizza Kitchen in Glendale, CA.

# University of California San Francisco

**By Kari Ehm, CPhA Board of Directors Representative**

Over the summer, our board has been focused on planning for the coming fall quarter. We have many amazing events in store for our members including Networking Workshops, Wine and Cheese night, resume and CV clinics, Legislative Week fun, Know Your Pharmacist Month promoting, and many others. I'm getting tired just thinking of all the planning in store for our board, but being the incredibly hard workers they are, I know we are geared up to accomplish so much this quarter. Watch out for our upcoming events, and let us know if you'd like to join the fun.

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