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Communication in the 21st Century

C-O-M-U-N-I-C-A-T-I-O-N = easier to spell than it is to perform successfully. Communication is a skill that most people take for granted, yet is something that is routinely cited as one of the most important aspects in human relationships – whether that be pharmacist to patient; parent to child; or spouse to spouse. Effective communication can foster the roots of our most enjoyable relationships, and when done poorly, vice versa. There are countless communication theories and styles available to describe the array of ways in which humans transmit information amongst each other. Simply Googling “communication” brings up more four-quadrant models than you can shake a stick at, which proves my first point – communication is hard to perform successfully.

Today, we live in a world of abbreviations, where the written form of communication can easily dominate our personal, social, and business lives. Sometimes that written word is in sophisticated and comprehensive prose (such as the outstanding manuscripts in this edition of California Pharmacist); and other times it is redacted down to 140-character tweets, profile updates, or simple emoticons. Each of these has the ability to communicate emotion, technical knowledge, and calls to action. However, they can also lead to misinterpretation, insinuation, and dangerous assumptions being void of inflection and intent.

Additionally, the spoken word has become equally truncated and subject to a host of mid-sentence interjections such as ‘like’, ‘seriously’, and ‘whatever’. Youth today verbalize their communication skills in a very different fashion than previous generations, leaving those of us from that prior generation to sometimes wonder what precisely this young individual in front of us is attempting to communicate.

For the health professions and associated educational institutions, these transformations in communication present unique challenges: How do we ‘meet our students where they are at’ in regards to communication style and preference, but at the same time ensure they have the ability to affectively and comprehensively communicate important messages to a broad array of patients that will come to their practices for care? How do we embrace the shifts in communication style and modalities while ensuring we are meeting patients’ needs and interprofessional dependencies?

As if those considerations are not difficult enough, on top of these complexities is the fact that patient populations are becoming more outwardly diverse and pharmacists need to understand, adopt, and adapt appropriate communication styles based on the patient’s personal, social, and identifying characteristics. As a pharmacist, how do you provide culturally competent care to an ever-increasing socioeconomic and demographically diverse patient base, not to mention those patients who seek your counseling who may have nontraditional lifestyle needs such as transgender patients? The intersection of this complex web of shifts in communication are only the tip of the iceberg in terms of how pharmacists relate, are educated, learn, and ultimately interact with their patients.

This edition of California Pharmacist will begin to unpack these interesting and complex situations with manuscripts that explore effective communication tools and tactics for the practicing pharmacist. Enjoy!

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Are We There Yet?

The profession of pharmacy has made some great strides over the past 15 months. The legislative agenda has been robust, provider status within California has been achieved, the scope of practice has been expanded and H.R. 4190 has the potential to further support our role as a health care provider. Are we there yet? In the last issue, I wrote about the need for pharmacists to engage in our new roles and put into their practice these changes. I am optimistic that the profession will embrace the changes. During this time of change, I would encourage everyone to remember how practice has arrived, where it is today and heading tomorrow, through the good, hard work by good people.

Implementing practice change takes a village. Learning to apply new skills to years of experience takes time and involves learning from each other. By working together, helping each other, and focusing on the goal of improving the care of patients, we can change practice. On occasion, I hear some say, “we don’t have time for ___” or “how can I add this to what I am already doing?” One solution to finding time or extending the “reach” is utilizing our student pharmacists. Student pharmacists have tremendous energy and gain needed experience when they are engaged in practice, doing things a pharmacist does and not standing by watching. You can’t learn to ride a bike reading the book or watching someone else do it. You can’t learn how to manage patients or practice pharmacy by reading or watching either. Students need to practice pharmacy, engaging them in our practice is a win-win. I encourage all pharmacists to consider taking on students, our professional future, to assist us in the implementation of practice change. Students can perform all the functions of a pharmacist under supervision, if we let them. We all learned how to practice from preceptors and mentors at some point in our career.

I would like to voice public appreciation to those pharmacists who serve as role models and preceptors. Preceptors and mentors play pivotal roles in shaping practice and will shape the future of our profession. Are we there yet? Probably not, but we are all on the journey.
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Patient-pharmacist communication is an essential part of clinical practice. The ability to communicate well enhances patients’ health regimes and improves medication adherence outcomes. Formal training programs have been created to enhance and measure specific communication skills. Many of these efforts, however, focus on pre-health professional education and post-graduate programming, and therefore remain isolated in academic settings. Thus, the communication skills of the busy pharmacist remain poorly developed and the need for established pharmacists to become better communicators often times remains unmet. Effective communication is especially important at this juncture in time, as protocols for SB 493 are implemented in California and similar movements to change pharmacist practice models gain momentum nationwide. Along with this historic evolution in practice models, pharmacists must prepare to advance into the role of provider to care for patients and work with other healthcare professionals with a full spectrum of healthcare skill sets including advanced communication skills.

Many health care practitioners concede that the manner in which they communicate information to a patient is proportional to the information being communicated. Furthermore, they acknowledge that patients, who understand their instructions, are more likely to recognize health problems, understand their treatment options, modify their behavior accordingly, and follow their medication and treatment schedules. The importance of effective communication can be seen, for example, during the typical 5- or 10-minute patient-pharmacist encounter when the pharmacist makes nuanced choices regarding the words, questions, silences, tones, and facial expressions he or she chooses. These choices either enhance or take away from the overall level of excellence of the pharmacist’s delivery of care and patients health outcomes. Indeed, research has shown that effective patient-pharmacist communication can improve a patient’s health as quantifiably as many drugs—perhaps providing a partial explanation for the prevailing placebo effect seen in clinical trials.\(^1\)

Many healthcare professionals obtained their “soft” communication at experiential educational sites as students, and many others learned their skills on the job. Today, the communication and interpersonal skills of the health care professional are no longer viewed as absolute personal styles that emerge during experiential education or in practice but, instead, as a set of measurable and modifiable behaviors that can evolve, in fact they must evolve to keep pace with the vibrant changes that occur with the patient and overall healthcare environment.

Today, based on emerging literature on the importance of effective communication, pharmacy students are given instruction on techniques for listening, explaining, questioning, counseling, and motivating, all central to delivering sound patient care. Recognizing the importance of this skill 100% of the accredited pharmacy schools in the U.S. now teach communications skills as part of their curriculum.\(^2\) Practitioners can elect to take one of the courses and

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By Cyndi Porter Fraser, MBA, MS
workshops many professional organizations offer at annual conferences or attend employer provided training. The web is an excellent source to find many other offerings geared towards sharpening communication through colleges, online programs, and continuing education platforms. Although these efforts to improve and measure communication skills are abundant, you must take the time to seek them out and complete the training. In the interim, the barriers to effective communication between patients, pharmacists, and other health care professionals continue to grow. Further, hurdles arising from linguistic and cultural differences, same gender marriages, and electronic communication modes are already changing rapidly and will continue to evolve in coming years as the population demographics shift and technology advances.

This edition of California Pharmacist includes several articles focused on improving and understanding communication for a diverse population. Bridging the Gap: Effective Communication Despite Barriers (page 21) is an enlightening article and area that is seldom addressed - communication challenges pharmacist face working with deaf and blind patients. The article Patient Centered Labeling: How to Make Prescription Labels Work for our Patients (page 35) addresses cultural issues with current labeling and other written material for various diverse patient populations. Transgender Patients & Communication Pearls for Pharmacists (page 26) focuses on communicating with Transgender patients and includes a mini scenario that will take the pharmacist through some thought provoking questions regarding communication. Although the concepts in these articles can be applied to inter-professional healthcare team communication, Effective Communication is Fundamental to Inter-professional Collaborative Practice (page 12) focuses primarily on the importance of effective communication with our healthcare colleagues. This area faces many of the same challenges as the communication challenges presented by the changing patient population as practitioners themselves become more diverse and the need for inter-professional collaboration increases. Adapting our Communication for the Generations (page 17), penned by my colleagues at California Northstate University, is applicable to both patient and health care team members. The article brings to light the changing generational landscape of pharmacy practice and the need to modify communication for a new era of patients.

The articles in this publication bring many patient and inter-professional healthcare team communication challenges to the reader’s attention to help enlighten and educate pharmacists with communication skills for the 21st century.

About the Author
Cyndi Porter Fraser, MBA, MS is the Associate Dean for Student Affairs & Admissions and faculty member at California Northstate University College of Pharmacy, a current member of the CPhA Leadership Development Institute who has over twenty years of experience in health professional education. Associate Dean Porter has no bias to report.

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Objectives

After reading article, you should be able to explain:

• Why effective communication is essential to the practice of pharmacy
• The importance of interprofessional collaboration
• Structure and organization affecting communication
• Tools and techniques of communication

Communications Continuing Education

Effective Communication is Fundamental to Interprofessional, Collaborative Practice

By Dr. William Gordon

Abstract

The international conversation about collaborative and interprofessional teams in healthcare compels every discipline to address its pre-licensure and continuing education programs. Pharmacists must be prepared with solid science education as well as elevated skills in interdependent teamwork and communication. Creating functional interprofessional teams focused on patient safety demands intentional and rigorous focus on interpersonal skill development at all levels of the profession.

For some, it begins with a doctor’s slap. Others, it seems, start without such provocation. However it happens, we communicate with the world within a few minutes of our arrival, making known our preferences and our presence.

We tend to believe we are good communicators, having more experience in this skill set than any other, and to a large degree, we are right. Given the number of communication events that occur over the course of a typical day, most of us have a pretty good average of successes. Those events, however, are not the ones that stand out for us. We notice most what happens when communications fail; sadly, these events occur during times of stress, when the stakes are very high, opinions are opposing, and emotions are strong.1

As pharmacists, effective and efficient communication is essential to practice. Pharmacists, by the nature of their work, must be skilled in giving and receiving information accurately in interactions that involve other health care providers, patients, and their families. Increasingly, as information and health care issues become more complex, we find ourselves needing to work with other providers (both within and outside direct healthcare) in interprofessional teams. In contrast to our interpersonal or casual conversations, our
ability to effectively communicate and collaborate across professional boundaries has profound consequences for healthcare consumers at all levels.

The concept of interprofessional collaboration is not new, but has been receiving renewed attention in the past decade following revelations of unacceptably high patient harm (including deaths). Movement toward collaborative interprofessional teamwork spans the spectrum of health care professions, and with good reason. While there has been increasing focus on development of clinical skills, training health care providers about best practices in team work and communication has not received similar emphasis.

“Teamwork training for interprofessional collaborative practice in health professions education has lagged dramatically behind these changes in practice, continually widening the gap between current health professions training and actual practice needs and realities.” As a result, practitioners may emerge from education programs as skilled pharmacists from the standpoint of science, and may remain unskilled in interpersonal relationships. Regardless of how good the pharmacist is clinically, a failure to communicate could have devastating effects on patient outcomes. The emerging need in health professions education “is to prepare all health professions students for deliberately working together with the common goal of building a safer and better patient-centered and community/population oriented U.S. health care system.”

It is important to distinguish between the two terms interprofessional and collaborative. An interprofessional team is composed of members from two or more disciplines, and the term relates to how that team is structured. That is, health care teams that function in traditional hierarchical models (where, for example, a physician has assumed primacy, and directs the actions of the team with little or no input from its members) may indeed be interprofessional in that they are composed of members from multiple health care disciplines. The term relates to structure, but not to team functioning.

Collaborative refers to the behavior of individual team members and the team as a whole. When the team members are working together interdependently, sharing information, knowing and respecting boundaries of scope of practice, being responsible and accountable to the team, and communicating clearly and respectfully with one another, they may be considered to be collaborative. A team of people from one profession could meet these expectations; this would be a collaborative team that is not interprofessionally structured.

Both the ideal and the most likely situations in which pharmacists work will be interprofessional teams (with doctors, nurses, Physician Assistants, Nurse Practitioners, etc.) that are also collaborative.

Structure and organization affect communication and collaboration within and across the team. Hierarchical teams (see Fig. 1) function with information and authority resting at the top of the pyramid and flowing down and out to other team members. Flexibility and rapid responses are not characteristic of such structures in that team members are dependent upon the person at the top to make decisions.

In alternative team models, including heterarchies (see Fig. 2), information flows more freely and flexibly within the network, allowing teams greater opportunities for interdependence, and thus true collaboration. Ultimately, interdependence among team members refers to both the relationships among team members and the environment in which the team functions. The quality of relationship between and among team members as well as between individual team members and the team as a whole both affects and is affected by the communication skills of the practitioners involved.

To educate the pharmacists that will work in this team-based, collaborative and interprofessional environment, it is necessary to expose both those coming through our educational system and those already in practice to additional opportunities to develop these relational skills. It is not enough to simply add these topics to an already full pre-licensure curriculum. They must become
integrated into didactic and clinical educational experiences as well as continuing education opportunities. In other words, we must not diminish the academic preparation within the sciences of pharmacy; instead we must find ways to integrate and include communication and relational strategies and tools into all aspects of pharmacy education programs. Collaborative, interprofessional, interdependent skills and strategies must become part of the expectation we set for all graduates and practitioners, not simply superfluous options.

What do learners need to know to function in interprofessional, collaborative, and interdependent teams? First, they must be experts in the discipline of pharmacy. Because these teams are both collaborative and interdependent, other team members will be looking for the pharmacist to share crucial insights and information, respectfully and effectively calling out errors or complications that may result in harm to patients. Nothing can substitute for this contribution.

In addition, pharmacists must learn to utilize a variety of tools and techniques related to communication. For example, using a complex name of a drug with a patient may tell them very little. Telling them what the drug is used for, along with its potential benefits and side-effects de-codes the message and opens the communication between consumer and pharmacist. Similarly, other disciplines may require explanations and conversations that are different than what one may experience in working with other pharmacists. What is said matters less than what is heard, as it is the latter that will determine how a case moves forward. Each profession utilizes its own verbal shorthand, jargon, lingo, or acronyms. We must be certain we articulate our messages in a manner that can be easily processed and understood by colleagues and patients.

To assess a care plan and how well one’s own messages have been received, active listening and appropriate feedback become essential in closing the loop of communication. Experienced pharmacists recognize that they may gather information in speaking with a customer over the counter that was not revealed in the doctor’s office. Pharmacists often see patients on a continuing basis and may develop levels of trust within the relationship that other health care professions cannot achieve. For these relationships to be effective, the pharmacist must be capable of both listening and sharing information in the clearest ways possible. For that information to be helpful, it must be shared with others in a timely, effective, and efficient manner.

We must teach pharmacy students who may have a somewhat monocular enthusiasm for their chosen profession that they are part of a larger team. They are not alone in their practice; they cannot act alone in their practice. While they have
part of the answer, they don’t have all of the answers. Pharmacists, like all other health care providers, must provide their services from a place of humility, and must articulate the importance of their intentional, interprofessional and collaborative teamwork to patients and families.

Inevitably, conflicts may arise, particularly at the worst times of stress. All communications become more difficult during those periods, and conflicts either deepen or arise more easily. We help patients and families understand and negotiate the conflict between benefits and side effects, and are involved in situations where knowledgeable and well-meaning professionals may not agree on the next course of action. As a result, we must also be accountable and responsible. In this case, accountability is related to holding individuals to the team’s vision and goals, and clearly identifying when behaviors chosen may not be in the best interest of the team and its purpose. Such skills are developed and sharpened in both low and high fidelity simulations and can be captured in both primary and continuing education venues.

Ultimately, pharmacists must understand how teams are formed and function, and how they dysfunction. We must become experts in translating that information and conveying it to others. We must be able to diagnose and work to correct poor team functioning, particularly for the sake of patient safety. All team members, including pharmacists, must remain committed to collaborative, interdependent, interprofessional interactions, utilizing effective and efficient communication as a means to that end.

**About the Author**

Dr. William Gordon is the Associate Director of the DeWitt C. Baldwin Institute for Interprofessional Education and is a faculty member at Rosalind Franklin University of Medicine and Science in North Chicago, IL. Dr. Gordon has no bias to report.

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1. Eisenberg, E., and Goodall, H.L. Organizational communication, 6th ed. Boston, MA: Bedford/St. Martin’s, 2010; 5, 82.
CONTINUING EDUCATION QUIZ
Effective Communication is Fundamental to Interprofessional, Collaborative Practice

1. Pharmacist must be skilled in giving and receiving information accurately with
   a. Other Health Care Professionals
   b. Patients and their family
   c. Providers outside of the healthcare team
   d. A and B
   e. All of the above

2. The concept of interprofessional collaboration has received new attention due to unacceptably high patient harm in recent years.
   a. True
   b. False

3. The need in the health care professions today is to have graduates who are
   a. Clinically sound
   b. Unskilled in interpersonal relationships
   c. Experienced in teamwork
   d. A and C
   e. All of the above

4. Interprofessional Team is not:
   a. How a team is structured
   b. Members are from the more than one discipline
   c. How a team functions
   d. Hierarchical

5. Being collaborative means:
   a. Respecting boundaries
   b. Behavior of individuals only
   c. One individual directs the actions of a team
   d. One person is accountable for the actions of the team

6. Flexibility and rapid responses are not characteristics of:
   a. Collaborative Team
   b. Pyramid Team

7. Interdependence allows for
   a. Information to flow freely
   b. Collaboration
   c. Flexibility
   d. All of the above

8. Adding communication topics to a pharmacy curriculum is all that is needed in order to educate pharmacists to work in a team-based approach.
   a. True
   b. False

9. The most important tool for successful communication is:
   a. Listening
   b. Being an expert
   c. Being able to read people
   d. Using technical words

10. If a team that are collaborative, interprofessional and interdependent create work environments where there is never conflict.
    a. True
    b. False

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Adapting Our Communication for the Generations

By Sonya Frausto, PharmD, MA; Rachel Lowe, PharmD, BCPS; and Velliyur Viswesh, PharmD, BCPS

Abstract
As the landscape of pharmacy practices transforms, pharmacists are prepared to adapt to a host of changes. Communication techniques will need to be modified as we address a new era of patients. With four generations of patients requiring our advice, guidance and recommendations, we must be prepared to adapt quickly to their needs to ensure the best possible health outcomes. This starts with pharmacists understanding differences in communication preferences between the generations, the impact of technology on communication, and our ability to continue to build relationships with our patients through appropriate and professional communication.

Introduction and Background
Over the years, the field of healthcare has endured many changes and challenges. Pharmacy in particular has made significant strides towards increased responsibilities and the recognition of pharmacists as members of the healthcare team. However, with this expansion of pharmacists’ responsibilities has come a unique challenge. With more direct interactions with patients, the archetypal pharmacist must be versatile and savvy in their communication skills. For the first time in history, there are four different generations that currently comprise the majority of our patient population and they differ significantly in their preferred methods of interaction. With pharmacists and patients spanning the entire spectrum of generations, effective communication across these generations represents a unique challenge for our profession.

The oldest of our patients form the ‘Silent Generation,’ also known as the ‘Veteran Generation,’ represent those who were born between the years of 1925 and 1945 (currently ages 69-89). The term was originally coined by an article in *Time* magazine from 1951 which described the generation as ‘withdrawn’ and ‘cautious’ upon experiencing the Great Depression.1 Next comes the generation known as the ‘Baby Boomers,’ born between 1946 and 1964 (currently ages 50-68). The term was due to the significant increase in birth rates in the United States during this era; subsequently this generation comprises the greatest percentage of our current population.2 The ‘Baby Boomers’ are followed by ‘Generation X,’ born between 1965 and 1980 (currently ages 34-49), and ‘Generation Y,’ also known as the ‘Millennial Generation’ born between 1981 and 2000 (currently ages 14-33).

With the exponential growth in technology over the last two decades, many novel means of communication have been introduced. With the advent...
of internet, email, texting, social media and others, the diversity in communication methods is unprecedented. However, the preferred means of communication varies greatly with generations, with older generations generally accustomed to face-to-face interactions and younger generations increasingly dependent on technology. The way we as pharmacists communicate with our patients should therefore be individualized to specific patients to most efficiently educate them on their medications and healthcare. The means by which we accomplish this hinges on a deeper understanding of the characteristics and differences between the various generations that comprise our patient population. Table 1 provides a brief glimpse of some of the general characteristics of these four generations.

### Communication Characteristics and Differences for Each Generation

The Silent generation tend to prefer face-to-face conversations and do not like or utilize technology to a significant extent.³⁴ This silent generation is less likely to send an email or text message in place of a face-to-face conversation. They work well with authority, and this does not impact their performance in the workforce. This group does not like change, and may respond slower to specific change than other generations.³ The group may be less technology savvy, and may take longer to adapt. Written instructions are likely to be preferred over internet/web-based instructions when it comes to learning a new product or instructions on a project.³

The Baby Boomers are more accepting of change and technology.³ They still prefer the face-to-face conversation, or even a phone call instead of an email. Given their ability for change and knowledge of technology, some individuals in this group are willing to learn while others may be slower to adapt to newer technologies.³ Having clear, written instructions for those individuals who may be slower to adapt newer technologies may help, if there is a need to implement new technologies for work performance.

Generation X is the first generation to be ‘computer literate.’³ This group is usually willing to adapt to new technology when it comes out.³ They tend to communicate through email instead of the face-to-face conversations, and conversation may often be short and to the point. Visual assignments are more appealing to this generation compared to long written reading assignments. This generation often likes feedback from supervisors and to be kept informed.

Generation Y enjoy new technology.⁴ This generation is the most savvy when working with new technology and tends to implement it in all forms of communication. This group is less likely to engage in a face-to-face or phone call conversation, and would prefer a quick text message or email conversation.³ They learn well from audiovisual, multimedia presentations and are less likely to read long written instruction manuals.⁵ This generation is most likely to use new phone applications for different forms of communication, although other generations feel this has made conversations less personable. Generation Y works well with others in a group and does not respond well to authority, as they prefer to see everyone on the same level working together.

### Communication Strategies

The challenge for pharmacists in all settings is to understand that their patients will span this spectrum of generations. This may be difficult because our practicing pharmacists will also span the generational spectrum. Therefore, understanding the uniqueness in communication styles among all generations is key to a beneficial patient-pharmacist relationship. Communication with our patients should not be static but rather a dynamic discussion utilizing many.

---

Table 1: Example of Generation Differences³

<table>
<thead>
<tr>
<th>Dates</th>
<th>Silent Generation</th>
<th>Baby Boomers</th>
<th>Generation X</th>
<th>Generation Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>1925-1945</td>
<td>Loyal</td>
<td>Optimistic</td>
<td>Team mentality</td>
<td>Self confident</td>
</tr>
<tr>
<td>1946-1964</td>
<td>Less likely to change</td>
<td>Independent</td>
<td>Prefer flexibility</td>
<td>Strive for success</td>
</tr>
<tr>
<td>1965-1980</td>
<td>Cautious</td>
<td>Value Creativity</td>
<td>Outspoken</td>
<td>Value work-life balance</td>
</tr>
<tr>
<td>1981-2000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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different methods available to us to enhance medical care. We should strive to understand the preferred method of communication that our patients desire and then we should adapt to those preferences.

Adaptation in communication methods may be difficult for many pharmacists for a variety of reasons. Age differences, lack of exposure to different generations, or work restraints and technology limitations may impede their flexibility. However, these challenges should be viewed as opportunities to enhance communication and allow pharmacists to be innovative in their delivery. The more flexible pharmacists are in acknowledging that communication methods may vary, the more successful they will be at positively affecting the health outcomes of their patients. This will lead to less frustration and more satisfaction in communication with patients.

There are several tactics that can be employed to enhance the communication relationship with our patients. While face-to-face communication is an ideal situation that allows the healthcare provider the opportunity to identify and respond to concerns that many patients possess, in some situations this may not be possible. Therefore, applying newer technology such as emailing, texting, or online video conferencing may be integrated into healthcare delivery that can possibly lead to optimized outcomes. Using a blend of communication styles will ultimately benefit the patient. For example, when addressing the ‘Silent Generation,’ direct face-to-face communication is the preferred method, although automated phone call reminders may help improve health outcomes, such as improving medication adherence thereby leading to optimal pharmacotherapy regimens and disease state control. On the contrary, ‘Millennial’ or ‘Generation X’ patients would likely prefer to download an app to manage their pharmacy services or prefer a text message or email to inform them of any medication issues. The ‘Baby Boomers’ along with ‘Generation Y’ would prefer a blend of face-to-face communication enhanced by technology to manage their medications.

Therefore, utilizing the tools available in many pharmacies such as text message alerts, phone call reminders, or email messaging will be most advantageous to all generations, if used appropriately. Pharmacists should embrace the variable communication methods and identify ways that these communication tools can be incorporated into daily interactions with patients. One step would be to allow patients to select their preferred method of communication and allow alerts to be sent through their preferred means.

As we incorporate more technology into our arsenal of communication abilities we should keep in mind that no matter what generation we are addressing, the basic foundations of communication are constant. The

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communication that we have with our patients, regardless of the format that we use or the generation that we address, must be individualized, respectfully crafted and professionally delivered. The tenets of basic communication such as identifying the type of information that is to be delivered, who that message is being delivered to, and how the message will be delivered will guide the pharmacist on the best method to deliver healthcare needs.

Pharmacists are uniquely positioned to guide patients through healthcare services. With the changing landscape and enhanced scope of practice that our profession will face in the near future, pharmacists must keep in mind that technology will affect our practice and most importantly will change the way we communicate with our patients. Understanding the different characteristics of these four generations will allow us to better serve our patients and develop communication platforms that will enhance our connectivity with them while improving their healthcare.

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Bridging the Gap: Effective Communication Despite Barriers

By Jennifer Thu Pham, PharmD and Jessica Huang, PharmD

Abstract
The number of educational tools created to strengthen pharmacist patient counseling skills is increasing; however, some of the more challenging communication scenarios such as having a patient who is a non-English speaker, deaf, or blind have consistently been underaddressed. Many studies suggest that members of these populations experience health disparities due to communication barriers. Healthcare providers report discomfort and low confidence in providing culturally and linguistically competent care for these groups. In an effort to bridge the gap and reduce disparities for these disadvantaged populations, this article will reintroduce the concept of patient-centered communication (PCC), highlight considerations regarding cultural identity, and provide practical suggestions to facilitate rapport. Providing PCC allows the pharmacist to individualize care and create personal relationships to ensure proper and safe medication use for all patients.

Introduction to Patient Centered Communication (PCC)
Imagine yourself fully expressing your thoughts to another person, but unable to get your message across to him or her. This scene is not imaginary but reality for millions of patients including those who are non-English speakers, deaf, or blind. How can quality health care be given if a healthcare provider-patient relationship is plagued by language and cultural barriers?

As pharmacists evolve into positions of direct patient care, the concept of PCC must be consistently taught and practiced. Per the APhA Code of Ethics for Pharmacists, PCC is defined as communication that is respectful and responsive to patients’ preferences, needs and values. Effective medication counseling has been increasingly cited as a key element of improving the public health issue of medication adherence. The role of the pharmacist is to ensure at minimum that each patient understands the following about a medication: 1.) what it is for, 2.) how to take it, and 3.) what to expect, despite what barriers stand in the way.

Language Barriers
America is known for its diversity in culture and language. According to recent Census data, 8.7%, over 25 million Americans self-rated their ability to speak English less than very well. According to the California Board of Pharmacy Laws and Regulations:

The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label, [...] identify the patient’s language and to provide interpretive services in the patient’s language.

Thus, pharmacists need to understand how to use available language lines and interpretative services to adequately fulfill these requirements. When using a medical interpreter it is important to speak directly to the
patient in first person in order for the interpreter to seem invisible. This tightens the patient-pharmacist bond and limits filtering of the message.

Not preferred: “Please tell her this medication is for an infection so she should take 2 tablets three times a day until there are no remaining pills.”

Preferred: “Ms. Jones, your doctor prescribed this medication to treat an infection. Take 2 tablets by mouth three times a day until there are no remaining pills.”

Family or friends who serve as interpreters may filter information and can present a serious ethical dilemma. One possible scenario is a family member interpreter shielding the patient from bad news of a diagnosis so the patient doesn’t fully grasp the importance of compliance and does not adhere to medication regimen. It is important to remember that family members may not be adequately trained in medical terminology may not have enough health literacy to convey the message accurately. Further, this is a violation of patient’s confidentiality and should be avoided.

To effectively engage in cross-cultural communication, the pharmacist must convey a positive attitude, be aware of their own culture and biases, and have adequate knowledge to be accepted by a member of a specific culture. One of the most frequently cited models used in cross-cultural communication in health care is the RESPECT model. It is as follows:

Rapport: Connect on a social level, seek the patient’s point of view, recognize and avoid making assumptions.

Empathy: Remember the patient has come to you for help, verbally acknowledge and legitimize the patient’s feelings.

Support: Ask and understand barriers to care, help patient overcome barriers, involve family members if appropriate, reassure the patient your availability to help.

Partnership: Be flexible with regards to issues of control, negotiate roles when necessary, stress that you will be working together to address medical problems.

Explanations: Check often for understanding, use verbal clarification techniques.

Cultural Competence: Respect the patient, his or her culture, and beliefs, be aware of your own biases and preconceptions, understand that patient’s view of you may be informed by ethnic or cultural stereotypes, know your limitations in addressing medical issues across cultures, understand your personal style and recognize when it may not be working with a given patient.

Trust: self-disclosure may be an issue for some patients who are not accustomed to Western medical approaches, take the necessary time and effort to establish trust.

This was first developed for non-English speakers with alcohol and drug dependency, but since has been widely used by all health professions to establish clinical relationships and better patient care. The RESPECT model should be applied to all patient populations especially when conversations become difficult.

Deaf and Hard of Hearing

Hearing loss is a very common condition in the United States. An estimated over 37 million Americans, or 9% of the population, have some degree of hearing loss. Among this population, it is estimated that more than 28% have either been deaf since birth or during the early years of life.
Because hearing loss affects access to information, people with hearing loss often have limited knowledge about a variety of health conditions, and knowledge of health information is an important component in health decision-making and overall well-being. In addition, research suggests that patients with hearing loss often experience communication difficulties with their health provider. When there is a lack of effective communication, it can impact provider-patient relationship and patients’ overall healthcare utilization. Studies have shown that some patients with hearing loss seek medical care more frequently than do people with normal hearing. People who have more severe hearing loss and communicate primarily in sign language utilize healthcare services less often. In terms of access to health information and healthcare utilization, people with hearing loss are considered a medically underserved population. Thus, it is important for health professionals to be aware of their health needs, and be knowledgeable about communication with deaf and hard-of-hearing patients.

Successful communication between provider and patient depends on the environment, patient’s current level of health knowledge, and communication method used. People with hearing loss are usually categorized as 1) hard-of-hearing people who still has some residual hearing, 2) oral deaf people who read lips and communicate orally, and 3) deaf people who use sign language as the primary mode of communication. In the U.S., American Sign Language (ASL) is the primary language used by deaf people who communicate primarily by signing. It is important to keep in mind that ASL has a different sentence structure and grammar than English; it is not an exact manual gesture of English. Thus, a deaf patient may communicate in ASL more fluently compared to spoken or written English. Using printed material in English solely to communicate with an individual who uses primarily the visual, conceptual ASL is no different from speaking only English to communicate someone who speaks a completely foreign language. Pharmacists must make every effort to tailor their interaction to the deaf patient’s communication and information needs. It is important to note that printed materials should not substitute a pharmacist-patient interaction.

For all patients with hearing loss, the first thing to do in a patient encounter is to ask the patient what is the best way to communicate with him or her, and ensure that the patient can see your face. This can be done by making eye contact and making sure your face and lips are not obscured by a shadow or physical barrier. Do not rush. Take time to communicate. Below are communication strategies that community and health-system pharmacists can utilize with patients from any category:

- Ask the patient for the most preferred communication method. When possible, use a qualified ASL interpreter with patients who use ASL.
- If working with an ASL interpreter, speak directly to the patient and address him/her; do not speak to the interpreter and refer to the patient as “him/her.” Look at the patient, not interpreter, while interpreter relays information. This will allow you to observe patient’s expression and understanding.
- Utilize a pharmacist or another health professional who is fluent and can communicate in ASL in a full medical capacity so as to preserve the original intent and context of information.
- Use a computer and keyboard as a tool to communicate. Keep message simple and easy to understand.
- Note-writing or drawing may be helpful to clarify ambiguous information, however it should not be the sole method of communication.
- If communicating verbally, minimize background noise. Speak at a volume that can be comprehended by the patient.
- Look directly at the patient when speaking. Speak clearly at a pace that is neither too fast nor too slow. No need to over-enunciate or exaggerate words as it can distort words and make lip reading more difficult.
- Repeat or summarize information communicated by patient to ensure understanding.
- Ask patient to repeat information back to you to check accuracy and patient’s understanding.
- Repeat information that is not understood. Rephrasing may be helpful.
Most deaf people use telephone- or video-based relay service interpreters (e.g. TDD or VRS) for phone calls. Be available to take the phone call and speak directly to the patient as with any other phone call.

Blind
In 2011, over 6.6 million Americans reported a vision disability which encompasses a wide spectrum of blindness; approximately three-quarters have some residual vision. The appropriate terminology to use in referring to the part of the population with visual disparities is “people who are blind” rather than “blind people” or “the blind.” There are sensitivity considerations to be aware of but there is no need to feel overly conscious about avoiding common expressions that seem to relate to a disability like, “good to see you,” “watch television,” or “see you later.”

Upon entering, introduce yourself, your position, and why you’re there. Offer help before taking action: “Is there anything I can do to assist you?” Do not be offended if your help is not needed. Often patients are well accustomed to their vision loss and can effectively communicate what resources or specific assistance they require. If the patient is unable to direct your help or unsure what assistance is required, make an effort to assist in non-condescending ways. Speak in normal conversation tones directly facing the patient and help your patient by not moving around or speaking away from them. Orally narrate what you plan to do so the patient knows what to expect: “Mr. Jones, I am going to wrap a cuff around your arm to measure your blood pressure now.” Be descriptive when mentioning steps of the process and inform the patient when you leave the room.

The key to PCC is having information delivery methods that can accommodate the needs of any blind patients despite the varying extent of vision impairment. Be prepared to read forms or pamphlets with medication information upon request while being cognizant of patient privacy. For some, there may be accommodations that need to be large print (at least 18 pt. bold). In other scenarios, different tools can be used such as: audio recordings, different sized bottles, rubber bands or paper flag labels, Braille labeled pill boxes, liquid medication bottles with tactile measuring lines, or talking medication bottles. The ScripTalk System is a widely used talking medication bottle system that includes a microchip embedded in the prescription label that is printed by a pharmacy computer system. At home, the patient uses a handheld device that speaks the information contained on the label to the patient. The Veteran Affairs Hospital system has used this system for many years and increasingly more retail chains and certain pharmacies are adopting this technology. As a pharmacist, it is prudent to understand that this technology is available, how to use it, and advocate for its accessibility if necessary.

When Communication is Difficult
Regardless of language or communication barriers, conversations can become difficult. The most basic recommendation is to prepare for a difficult conversation long before the interaction happens. To limit frustration, provide an environment where patient’s privacy is protected and noise and distractions are limited. A rushed demeanor or divided attention in a busy pharmacy can make a patient feel like they are not being respected. Even a barrier as commonplace as a counter can divide the conversational space and restrict a patient encounter significantly. More than half of communication is active listening.
and engaged body language which requires life-long self-reflection and self-awareness. In the end, the goal is effective communication. The diversity in patient populations requires a significant adaptability on the part of the pharmacist.

Communication tools like the RESPECT framework can be applied to any situation. When frustration is building up on both sides, take a moment to recollect and recall that the end goal is to create a therapeutic alliance to promote adherence and safe medication use. Be patient and rephrase the key points as many times as necessary to get a clear message across. Do not be afraid to be resourceful and creative: use drawings, gestures, props (clocks, calendars), or technology in your patient interactions. At the end of the interaction, review take-home points and actions the patient needs to take. Often times this is the best opportunity to use the teach-back method and ask the patient to reiterate the highlights you emphasized to assure that the information has been retained accurately.

Be mindful that a poor interaction is one where the patient walks away without sufficient information subsequently putting the patient at significant risk. It requires a coordinated effort of the healthcare team to bridge the gap of health disparities experienced by patients who experience communication barriers. To improve as a communicator beyond this article, continue to seek opportunities to garner insight into patient perspective and implore pharmacy teams to consciously practice PCC consistently. Communication, like many other skills of a healthcare provider, is a life-long process to develop.

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Transgender Patients

Communication Pearls for Pharmacists

By Emmanuelle Schwartzman, PharmD, BCACP, CDE and Thomas Kleyn, PharmD, BCPS, AAHIVP

Abstract

Understanding the unique communication needs of transgender patients is critical in order to minimize health disparities and patient barriers to care. As this population gains more social and political acceptance, pharmacists must be equipped to provide medical acceptance through knowledge of how to appropriately communicate with these patients through active listening, empathy, and sensitivity, while maintaining a high standard of respect and privacy.

A recent Time magazine article featuring Laverne Cox from Netflix’s Orange Is the New Black has thrust issues affecting the transgender population into mainstream American conversation. In addition, the medical community is increasing its focus on this patient population and initiating dialogues about assessing and addressing the unique challenges providers may face when caring for this population. Currently, an estimated 3.5% of adults in the United States identify as Lesbian, Gay, or bisexual and 0.3% of adults are transgender according to a recent study conducted by the Williams Institute. Pharmacists need to be at the forefront of discussions regarding the health needs of transgender patients as we are a highly accessible provider and can be a critical patient advocate. In addition to understanding the pharmacological needs of transgender patients, pharmacists need to have effective communication skills to garner trust and build relationships with these patients to become effective advocates.

A patient scenario* from a Los Angeles HIV clinic illustrates the patient and provider barriers to communication that could arise during a visit with a pharmacist:

“I don’t understand why I keep getting sick,” Jess stated as she wiped away tears. Jess, whose legal name is Michael Ancell, has had AIDS for over 15 years, and has struggled to maintain adherence to her antiretrovirals, and has been in and out of the hospital with pneumonia, most recently leaving early against medical advice. “I just got out of the hospital for the fourth time this year. I had a bad experience there, they kept calling me Michael and referring to me as ‘he.’ I felt like the people there were more interested in what was in my pants than my pneumonia. My medications aren’t working, and I’m not sure why. My son came up to me in the hospital with one of my pill bottles, and said, ‘Mommy, please take this.’ He’s such a sweet child. I adopted him when he was three months old. And I adopted his biological sister when she was just a few days old, so she’s known no other mother but me. They’re out in the waiting room right now with my husband. When asked about her oral estrogen during medication reconciliation with the clinic pharmacist, she stated, ‘I was castrated fifteen years ago.’

*This scenario is modeled after a combination of real patient cases, however, the names depicted here are fictitious.

Patient Barriers

Due to societal stigma, transgender patients can feel a tremendous amount of insecurity, anxiety, and...
marginalization. Many transgender patients feel that the medical community is hostile to their status and unique needs and therefore, they avoid medical care altogether.\textsuperscript{3-6} Many studies have demonstrated that large health disparities exist among transgender populations. A study assessing suicide rates in the U.S. revealed 41\% of transgender adults in the U.S. have attempted suicide.\textsuperscript{7} Transgender women have 49 times greater odds of HIV infection than other populations.\textsuperscript{8} Transgender patients have increased cardiovascular risks due to the use of exogenous hormones.\textsuperscript{9-10} Disease states commonly associated with the opposite gender such as breast cancer for women go undiagnosed or untreated in males who transition to females. In addition, physical exams such as pelvic exams become more complex or are skipped in trans women, or exams for other diseases such as human papillomavirus-associated anal neoplasia are overlooked.\textsuperscript{11} Other alarming trends seen among transgender patients are an increase in tobacco use, alcohol and substance abuse.\textsuperscript{11} Appropriate care provided by informed providers along with accessible patient advocates can play an important role in decreasing health disparities, reducing patients’ anxieties and providing a link between transgender patients and vital resources.

Addressing the Patient

A. Definitions:

To communicate effectively with any patient it is important to understand the culture and self-identity of that individual. The first step is to become familiar with appropriate terminology with the understanding that preferred terminology shifts and a provider must stay abreast of the most recent terms. Let’s review some terms below:

- **Sex** - an individual is assigned to either a female group or male group based on anatomical features of the sex organs.\textsuperscript{12}
- **Gender** - a societal classification into either female or male based on mannerisms, characteristics, and appearance.\textsuperscript{3,12}
- **Gender identity** - an individual’s self-classification as a man or woman which may or may not correspond with their gender assigned at birth.\textsuperscript{13}
- **Sexual orientation** - “the inclination of an individual with respect to heterosexual, homosexual, and bisexual behavior.”\textsuperscript{12} Sexual orientation is not related to gender identity.
- **Transgender** - “a term inclusive of a range of transgender, transsexual, and gender variant identities of people who no longer express or identify their genders with their birth sex. Sometimes abbreviated as ‘trans.’”\textsuperscript{3}
- **Transgender man or trans man** - “natal females with masculine gender identities, often referred to as Female-to-Males, FTMs.”\textsuperscript{3}
- **Transgender woman or trans woman** - “natal males with feminine gender identities, sometimes referred to as Male-to-Females, or MTFs.”\textsuperscript{3}

**Transvestite** - “Trans” meaning to change and “Vest” meaning attire. Transvestite indicates an individual who adopts the dress and occasionally the behavior of the opposite sex.\textsuperscript{12}

**Genderqueer** - a person who does not conform to the conventional gender binaries of male and female, also known as “gender nonconforming.”\textsuperscript{14}

**Gender dysphoria** - clinical distress within an individual whose gender at birth is contrary to the one identified with.\textsuperscript{15}

**Intersex person** - “is a general term used for a variety of conditions in which a person is born with a reproductive or sexual anatomy that doesn’t seem to fit the typical definitions of female or male.”\textsuperscript{16} Includes intersex conditions such as sex chromosome disorders, gonadal anomalies, reproductive duct dysfunction, malformed genitalia. A male or female orientation
A Model of Gender Affirmation

Gender affirmation is a process in which a person’s chosen gender is recognized and respected by others. This process can be facilitated through various means, including the use of preferred pronouns, the avoidance of derogatory language, and the provision of resources and support. The goal of gender affirmation is to recognize and respect one’s gender identity and to create a welcoming and affirming environment for all individuals.

A. Preferred Pronouns:

Preferred pronouns should be used whenever possible to respect one’s gender identity. This can include the use of pronouns in conversation, on medical records, and in any other written or spoken communication. It is important to use the pronouns that the patient chooses, as this can make them feel more affirmed and respected.

B. Pronoun /Proper Name Use:

To establish a trusting and comfortable environment for the patient, the pharmacist must be comfortable with addressing the patient appropriately. Regarding the above case, our patient’s name in the EMR is her legal name Michael Ancell. Should the pharmacist address the patient as Mr. Ancell or Ms. Ancell; Michael or Jess? The best approach is to find out how the patient prefers being addressed.

Although Jess is not her legal name, it is the name she prefers and is the name she should be called. In addition, since the patient identifies as a male, when speaking to or about a patient, pronouns should be used which correspond with the patient’s identified female gender. It may feel uncomfortable having to clarify someone’s gender, but it will make future interactions smoother for all involved parties. Some example questions of how to ask a patient about their gender include: “In order to respect your desires, please let me know how you would like to be addressed?” or “I see your name is written as Mr. Michael Ancell, what name would you prefer to be called?”

What name would you put in your electronic medical record (EMR) and on the prescription? The legal name should be put in the EMR, and the preferred name can be added to an additional “AKA” field (if one exists), or put in quotation marks after the legal name. A prescriber should use the legal name, with or without the preferred name, but, as with all patients, should always use a second patient identifier (such as date of birth) on the prescription to minimize risk of medication errors or duplicate patient profiles in a pharmacy information system.

A Model of Gender Affirmation

A Model of Gender Affirmation has been developed which states that when a transgender woman places a high personal value on whether her gender identity is affirmed by others, she will intentionally look for opportunities to receive this affirmation, while similarly avoiding situations where gender identity affirmation is not received. Referring back to the case above, Jess, when she was referred to by her legal name “Michael” or with male pronouns by providers at the hospital, felt that her gender identity was not being affirmed. This introduced an unnecessary barrier which may have contributed to her leaving the hospital against medical advice.

In addition, if you provide patients with intake forms in your pharmacy or practice setting, it may be beneficial to make the form friendlier towards transgender patients. Consider modifying your forms to provide space for patients to fill in their sex assigned at birth and their currently identified gender, as well as a place to indicate preferred name.

Just as utilizing preferred pronouns is important to foster a caring environment, so is the avoidance of disparaging or derogatory language around the workplace. However, due to the fluidity of language and rapidly changing cultural views, it can sometimes be difficult to know exactly which terminology has fallen out of favor for whatever the reason. For example, use of the term “trannie” is no longer viewed as acceptable, and instead the terms “trans” or “transgender” are preferred. Ultimately, the best practice is to ask patients what their preferences are, validate their choices, and not draw unnecessary attention to it afterward.

B. Pronoun /Proper Name Use:

To establish a trusting and comfortable environment for the patient, the pharmacist must be comfortable with addressing the patient appropriately. Regarding the above case, our patient’s name in the EMR is her legal name Michael Ancell. Should the pharmacist address the patient as Mr. Ancell or Ms. Ancell; Michael or Jess? The best approach is to find out how the patient prefers being addressed.
sive and sensitive which may not add a clinical benefit to the patient.\textsuperscript{18}

\textbf{Are You Listening?}

One major component to effective communication is the ability to listen. Although this sounds natural and seems as though it is an innate skill, it is perhaps one of the most challenging patient communication skills to master. Listening requires the ability to truly see and hear the patient free from bias and to empathize with the patient.

Some useful tools to enhance the ability to effectively listen include summarizing and paraphrasing.\textsuperscript{19} Throughout the interaction with the patient, it is helpful to provide a summary of what you have heard, which will make the patient feel heard and provide an opportunity for the patient to correct information that was unclear. While providing a summary, it is important to keep a neutral demeanor and to avoid interjecting personal beliefs, morals or biases into the conversation. Personal bias is unavoidable as it is built up over our lifetime consisting of our personal experiences, morals, beliefs, and religious views. To have a meaningful interaction with the patient, we must recognize our biases and areas of discomfort. Once we are able to recognize what makes us uncomfortable or affects our view of the patient we can make a conscious effort to see the patient through a neutral lens and hear them free from our judgments. Challenge yourself by asking the following question: “Does a patient’s appearance, sexual orientation, or personal values make me uncomfortable and distract me from hearing the patient or influence how I provide treatment?”

An honest self-assessment is the first step to fostering a safe and welcoming environment where patients can feel that they have been sufficiently heard.

Empathy is another key skill in listening. Put yourself in the shoes of the patient to try to understand their challenges, and why their values of personal health may be different from yours. Making empathetic statements such as “That situation must have been very hard for you,” or, “I hear what you are saying,” can be very affirming. Particular attention must also be paid to non-verbal communication. A majority of human interaction occurs through non-verbal communication. It is important to be aware of personal body language clues. Avoid negative facial reactions or creating an unusually large distance from patients. Even something as simple as main-

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Pharmacists need to be at the forefront of discussions regarding the health needs of transgender patients as we are a highly accessible provider and can be a critical patient advocate.

Conclusion
Pharmacists should intentionally seek to utilize effective communication strategies such as addressing the patient per patient’s desires, being mindful of appropriate terminology, listening free from personal bias, and responding with empathy and affirmation. Pharmacists should strive to create a safe and confidential space for open dialogue with the aim of minimizing the barriers transgender patients face within the healthcare system.

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Emmanuelle Schwartzman, PharmD, BCACP, CDE is an Associate Professor of Pharmacy Practice and Administration at Western University of Health Sciences and Director of Fellowship and Residency Training. Dr. Schwartzman has a research and teaching focus in communication skills and Diabetes. She is a certified diabetes educator through the National Certification Board for Diabetes Educators and a Board Certified Ambulatory Care Pharmacist. Dr. Schwartzman has no bias to report.

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References
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Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with the extent of smoking (in epidemiologic studies, 15 or more cigarettes per day was associated with a significantly increased risk) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

INDICATIONS AND USAGE
Lomedia™ 24 Fe is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

CONTRAINDICATIONS
Oral contraceptives should not be used in women who currently have the following conditions: •thrombophlebitis or thromboembolic disorders, •past history of deep vein thrombophlebitis or thromboembolic disorders, •cerebrovascular or coronary artery disease (current or history), •valvular heart disease with thrombogenic complications, •severe hypertension, •diabetes with vascular involvement, •headaches with focal neurological symptoms, •major surgery with prolonged immobilization, •known or suspected carcinoma of the breast or personal history of breast cancer, •carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia, •undiagnosed abnormal genital bleeding, •cholestatic jaundice of pregnancy or jaundice with prior pill use, •hepatic adenomas or carcinomas, or active liver disease, •known or suspected pregnancy, and •hypermobility to any component of this product.

WARNINGS
THROMBOEMBOLIC DISORDERS AND OTHER VASCULAR PROBLEMS
Myocardial Infarction
An increased risk of myocardial infarction has been attributed to oral contraceptive use. This risk is primarily present in women who already have other risk factors for coronary artery disease such as hypertension, hypercholesterolemia, morbid obesity, and diabetes. The relative risk of heart attack for current oral contraceptive users has been estimated to be two to six. The risk is very low under the age of 30.

Thromboembolism
An increased risk of thromboembolic and thrombosis disease associated with the use of oral contraceptives is well established. Case control studies have found the relative risk of users compared to non-users to be 3 for the first episode of superficial venous thrombosis, 4 to 11 for the vein thrombosis or pulmonary embolism, and 1.5 to 6 for women with predisposing conditions for venous thromboembolic disease. If feasible, oral contraceptives should be discontinued at least four weeks prior to and for two weeks after elective surgery of a type associated with an increase in risk of thromboembolism and during and following prolonged immobilization. Since the immediate postpartum period is also associated with an increased risk of thromboembolism, oral contraceptives should be started no earlier than four to six weeks after delivery in women who elect not to breastfeed.

Cerebrovascular diseases
Oral contraceptives have been shown to increase both the relative and attributable risk of cerebrovascular events (thrombotic and hemorrhagic strokes) although, in general, the risk is greatest among older (>35 years), hypertensive women who also smoke. Hypertension was found to be a risk factor for both users and nonusers, for both types of strokes, while smoking interacted to increase the risk for hemorrhagic strokes.

Dose-related risk of vascular disease from oral contraceptives
A positive association has been observed between the amount of estrogen and progestogen in oral contraceptives and the risk of vascular disease. The amount of both hormones should be considered in the choice of an oral contraceptive. New acceptors of oral contraceptive agents should be started on preparations containing the lowest estrogen content which is judged appropriate for the individual patient.

Persistence of risk of vascular disease
There are two studies which have shown persistence of risk of vascular disease for ever-users of oral contraceptives. In these studies, the increased risk persisted for up to or more than nine years.

ESTIMATES OF MORTALITY FROM CONTRACEPTIVE USE
One study concluded that with the exception of oral contraceptive users 35 and older who smoke and 40 and older who do not smoke, mortality associated with all methods of birth control is low and below that associated with childbirth. The Fertility and Maternal Health Drugs Advisory Committee recommended that the benefits of oral contraceptive use by healthy nonsmoking women over 40 may outweigh the possible risks.

CARCINOMA OF THE REPRODUCTIVE ORGANS AND BREASTS
Women who currently have or have had breast cancer should not use oral contraceptives because breast cancer is a hormone-sensitive tumor. Some studies suggest that oral contraceptive use has been associated with an increase in the risk of cervical intraepithelial neoplasia or invasive cervical cancer in some populations of women. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors.

HEPATIC NEOPLASIA
Benign hepatic adenomas are associated with oral contraceptive use. An estimate of the attributable risk is 3.3 cases/100,000 for users and the risk increases after four or more years of use. Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage.

Studies have shown an increased risk of developing hepatocellular carcinoma in long-term (>8 years) oral contraceptive users. However, the attributable risk of liver cancers in oral contraceptive users approaches less than one per million users.

OCULAR LESIONS
Oral contraceptives should be discontinued if there is an unexplained partial or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal vascular lesions.

ORAL CONTRACEPTIVE USE BEFORE OR DURING EARLY PREGNANCY
Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies also do not suggest a teratogenic effect, particularly in so far as cardiac anomalies and limb reduction defects are concerned, when taken inadvertently during early pregnancy (see CONTRAINDICATIONS section). The administration of oral contraceptives to induce withdrawal bleeding should not be used as a test for pregnancy.

GALLBLADDER DISEASE
Studies suggest a small increased relative risk of developing gallbladder disease among oral contraceptive users.

CARBOHYDRATE AND LIPID METABOLIC EFFECTS
Oral contraceptives have been shown to cause glucose intolerance in a significant percentage of users. Prediabetic and diabetic women should be carefully observed while taking oral contraceptives. A small proportion of women will have persistent hyperglyc cereidemia while on the pill.

ELEVATED BLOOD PRESSURE
Women with significant hypertension should not be started on hormonal contraceptives. An increase in blood pressure has been reported in women taking oral contraceptives, and this increase is more likely in older oral contraceptive users and with continued use. The incidence of hypertension increases with increasing concentrations of progestogens.

Women with a history of hypertension or hypertension-related diseases, or renal disease should be encouraged to use another method of contraception. If women elect to use oral contraceptives, they should be monitored closely and if significant elevation of blood pressure occurs, oral contraceptives should be discontinued (see CONTRAINDICATIONS section).

HEADACHE
The onset or exacerbation of migraine or development of headache with a new pattern which is recurrent, persistent, or severe requires discontinuation of oral contraceptives and evaluation of the cause (see Thromboembolic Disorders And Other Vascular Problems in WARNINGS).

BLEEDING IRREGULARITIES
Breakthrough bleeding and spotting are sometimes encountered in patients on oral contraceptives, especially during the first three months of use. If bleeding persists or recurs, nonhormonal causes should be considered and adequate diagnostic measures taken to rule out malignancy or pregnancy as in the case of any abnormal vaginal bleeding. If pathology has been excluded, time or a change to another formulation may solve the problem. Absence of a withdrawal menses may also occur. In the event of amenorrhea for two cycles or more, pregnancy should be ruled out. In the clinical trial with Lomedia™ 24 Fe, 31 to 41% of the women using Lomedia™ 24 Fe did not have a withdrawal menses in at least one of 6 cycles of use. Some women may experience post-pill amenorrhea or oligomenorrhea (possibly with anovulation), especially when such a condition was preexistent.

PRECAUTIONS
SEXUALLY TRANSMITTED DISEASES
Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.
PHYSICAL EXAMINATION AND FOLLOW-UP
A periodic personal and family medical history and complete physical examination are appropriate for all women, including women using oral contraceptives. The physical examination should include special reference to blood pressure, breasts, abdomen and pelvic organs, including cervical cytology, and relevant laboratory tests. Women with a strong family history of breast cancer or who have breast nodules should be monitored with particular care.

LIPID DISORDERS
Women who are being treated for hyperlipidemias should be followed closely if they elect to use oral contraceptives. In patients with familial defects of lipoprotein metabolism receiving estrogen-containing preparations, there have been case reports of significant elevations of plasma triglycerides leading to pancreatitis.

LIVER FUNCTION
Discontinue oral contraceptives if jaundice develops. Steroid hormones may be poorly metabolized in patients with impaired liver function.

FLUID RETENTION
Oral contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention.

EMOTIONAL DISORDERS
Women with a history of depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.

CONTACT LENSES
Contact lens wearers who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist.

DRUG INTERACTIONS
Changes in contraceptive effectiveness associated with co-administration of other products:

Anti-infective agents and anticonvulsants
Contraceptive effectiveness may be reduced when hormonal contraceptives are coadministered with antibiotics, anticonvulsants, and other drugs that increase the metabolism of contraceptive steroids. This could result in unintended pregnancy or breakthrough bleeding. Examples include rifampin, barbiturates, phenylbutazone, phenytoin, carbamazepine, felbamate, oxcarbazepine, topiramate, and griseofulvin.

Anti-HIV protease inhibitors
Several of the anti-HIV protease inhibitors have been studied with co-administration of oral combination hormonal contraceptives; significant changes (increase and decrease) in the plasma levels of the estrogen and progestin have been noted in some cases. The safety and efficacy of combination oral contraceptives given in the postpartum period may interfere with lactation by decreasing the quantity and quality of breast milk. If possible, the nursing mother should be advised not to use combination oral contraceptives but to use other forms of contraception until she has completely weaned her child.

PEDIATRIC USE
Safety and efficacy of Lomedia™ 24 Fe have been established in women of reproductive age. Safety and efficacy are expected to be the same in postpubertal adolescents under the age of 16 years and in users age 16 years and older. Use of this product before menarche is not indicated.

GERIATRIC USE
This product has not been studied in women over 65 years of age and is not indicated in this population.

ADVERSE REACTIONS
The most common adverse events reported by 2 to 6% of the 743 women using Lomedia™ 24 Fe were the following, in order of decreasing incidence: headache, vaginal candidiasis, upper respiratory infection, nausea, menstrual cramps, breast tenderness, sinusitis, vaginitis (vulval), vaginal discharge, acne, urinary tract infection, mood swings, weight gain, vomiting, and menstrual irregularity. Among the 743 women using Lomedia™ 24 Fe, 46 women (6.2%) withdrew because of an adverse event. Adverse events occurring in 3 or more subjects leading to discontinuation of treatment were, in decreasing order: abnormal bleeding (0.9%), nausea (0.8%), menstrual cramps (0.4%), increased blood pressure (0.4%), and irregular bleeding (0.4%). An increased risk of the following serious adverse reactions has been associated with the use of oral contraceptives (see WARNINGS section): thrombophlebitis, arterial thromboembolism, pulmonary embolism, myocardial infarction, cerebral hemorrhage, cerebral thrombosis, hypertension, gallbladder disease, and hepatic adenomas or benign liver tumors.

There is evidence of an association between the following conditions and the use of oral contraceptives: mesenteric thrombosis and retinal thrombosis.

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug related: nausea, vomiting, gastrointestinal symptoms (such as abdominal pain, cramps and bloating), breakthrough bleeding, spotting, change in menstrual flow, amenorrhea, temporary infertility after discontinuation of treatment, edema/fluid retention, melanoma/chloasma which may persist, breast changes (tenderness, pain, enlargement, and secretion), change in weight or appetite (increase or decrease), change in cervical ectropion and secretion, possible diminution in lactation when given immediately postpartum, cholestatic jaundice, migraine headache, rash (allergic), mood changes (including depression), vaginitis (including candidiasis), change in corneal curvature (steepening), intolerance to contact lenses, decrease in serum folate levels, exacerbation of systemic lupus erythematosus, exacerbation of porphyria, exacerbation of chorea, aggravation of varicose veins, and anaphylactic/anaphylactoid reactions (including urticaria, angioedema, and severe reactions with respiratory and circulatory symptoms). The following adverse reactions have been reported in users of oral contraceptives, and a causal association has been neither confirmed nor refuted: acne, Budd-Chiari syndrome, cataracts, colitis, changes in libido, cystitis-like syndrome, dizziness, dysmenorrhea, erythema multiforme, erythema nodosum, headache, hemorrhagic eruption, hemolytic uremic syndrome, hirsutism, impaired renal function, loss of scalp hair, nervousness, psychotic neuritis (which may lead to partial or complete loss of vision), pancreatitis, and premenstrual syndrome.

OVERDOSAGE
Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdose may cause nausea, and withdrawal bleeding may occur in females. Please see package insert for full prescribing information.

More detailed information is available upon request.

For more information about Lomedia™ 24 Fe contact: Amneal Pharmaceuticals at 1-877-835-5472. Date of Issue: October 2013. Manufactured by: Watson Laboratories, Inc., Corona, CA 92880 Distributed by: Amneal Pharmaceuticals, Glasgow, KY 42141

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"Take two pills twice daily." For the approximately 90 million U.S. adults with limited functional health literacy (FHL), understanding such directions may prove to be a formidable task. FHL, or the ability to interpret basic health information in order to make appropriate health decisions, is a significant determinant in the effectiveness of an individual’s care and ultimately a “predictor” of their health. Examples of areas where FHL is needed is in interpreting medical forms, bills, instructions etc. Patients with limited FHL are more likely to report their overall health status as poor compared to those with higher FHL. Furthermore, limited FHL is linked to higher rates of emergency room visits, longer hospital stays, adverse drug reactions, and non-adherence to treatment. Limited FHL is not only problematic to patient care and healthcare providers but also carries its own economic burden of an estimated $73 billion on the U.S. healthcare system. The impact of FHL in patient care is such a concern that it is considered by the Institute of Medicine (IOM) as one of the top 20 priorities in improving U.S. healthcare. Although FHL levels can be influenced by several factors including culture, socioeconomics and educational background, the strongest impact on FHL is an individual’s general literacy, familiarity with the healthcare system, and how the health information is presented. A factor which is particularly relevant within our profession is the last factor mentioned, i.e., presenting health information to patients in a manner that is understandable to them and useful in their care. Pharmacists can play a pivotal role in communicating to patients on how they should take their medications. Verbal communication provides patients with clarity but often patients, particularly those using multiple medications, have difficulty remembering specific information. It is approximated that 80% of the medical information provided to patients will be forgotten once they go home. Hence, there is need to have a simple, easy to understand, form of communication at the point of use that serves as a reminder as well as helps patients obtain information specific to each medication. Although technology is slowly helping customize information to each patient, Rx labels still remain the legally mandated communication element accompanying medications. Rx labels are an important example.

Abstract:
Clarity in verbal communication (counseling) of medication instructions by pharmacists is essential; however, information recall may be an issue with patients. The prescription label remains an important form of written communication used within the profession to remind patients to take a medication and how and when to take it. However, there have been concerns that current labels have led to misunderstanding of instructions, hence, there is a need for patient-centered labels. Our team designed such a label with adjusted font sizes, a table of administration times and indications on the label, and previously found it was “preferred” for content, convenience, and cosmetics compared to current labels. The current study demonstrated that the redesigned label also fared significantly better in terms of patient comprehension of label instructions and functional health literacy compared to current labels. In addition, a simple label-focused education provided by student pharmacists improved both these outcomes significantly more than with current labels. Combining such a redesigned, patient-centered label along with verbal label education is recommended for improving patient use of medications as prescribed.
of written patient communication that are regularly seen by the patient at point of use and serve as a reminder of how, why, and when to take their medications. Nonetheless, how an individual interprets an Rx label influences how closely they follow instructions related to medication use in accordance to how it was prescribed. Previous research has shown that misunderstanding of label information is fairly common (42%) with current Rx labels, especially in those with low FHL. Therefore, there is a need to make prescription labels more user-friendly.

In exploring how labels influence patient’s interpretation of medication information, it would be prudent to first review the U.S. Pharmacopeia (USP) standard of Rx labeling developed in 2009. The main objective of the USP label recommendations (Table 1) is to provide patients with sufficient information to understand how to take their medication in an easy and concise manner as possible. Our team developed a patient-centered (PC) label taking into consideration the USP recommendations, labeling requirements proposed by California Board of Pharmacy, and our previous research on patient needs from a label perspective. Our next step was to test the usability of this label in populations of differing FHL levels, when combined with a simple label education by a pharmacist.

We defined usability as Rx label comprehension. Accordingly, our study objectives were to compare label comprehension and FHL with the PC label compared to a current standard label; and then compare label comprehension and FHL with (intervention group) or without (control group) a label focused education provided by student pharmacists. This multisite randomized controlled trial (RCT) was conducted at various senior centers in Southern California after it was approved by the Institutional Review Board at Western University of Health Sciences in Pomona, California.

First, the study randomized participating senior centers to the use of current standard labels or redesigned PC labels. Second, the study further randomized study participants into either a control group, which did not receive educational intervention, or an intervention group, which received the education. Third, participants in both the intervention and control groups were assessed for FHL using the Short Test of Functional Health Literacy in Adults (STOFHLA); and for label comprehension using a Modified LaRue Medical Literacy Tool (MLT). Inclusion criteria for the study were age (55 years old or above), regular Rx medication use (two or more), and English language (read, understand, and speak). The study excluded those with visual, hearing or cognitive impairment that precluded them from adequately interacting with the study investigators or completing assessments. STOFHLA, a reading comprehension test, was used to test a participant’s level of FHL by their ability

<table>
<thead>
<tr>
<th>USP Standards for Prescription Labels</th>
<th>Current Prescription Label</th>
<th>Redesigned Patient-centered Prescription Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Organize the label to be patient focused with only pertinent information.</td>
<td>• Patient name, medication name, directions in bolded font.</td>
<td>• Patient name, medication name, directions, quantity, refills in bolded large font</td>
</tr>
<tr>
<td>• Highlight or “prominently display” important information.</td>
<td>• Require patients to turn Rx bottle around to read the full directions.</td>
<td>• Full directions on one side of Rx bottle to minimize the need to turn around.</td>
</tr>
<tr>
<td>• Keep the language concise.</td>
<td>• Include the purpose of the medication if indicated on the prescription.</td>
<td>• A timetable of administration to assist patient with when to take medications.</td>
</tr>
<tr>
<td>• Give explicit instructions.</td>
<td>• Limit auxiliary information.</td>
<td>• Warnings that are listed horizontally on one side of Rx bottle.</td>
</tr>
<tr>
<td>• Include the purpose of the medication if indicated on the prescription.</td>
<td>• For improving “readability”:</td>
<td></td>
</tr>
<tr>
<td>• Keep auxiliary information.</td>
<td>• Use high contrast print.</td>
<td></td>
</tr>
<tr>
<td>• For improving “readability”:</td>
<td>• Use familiar fonts with large font size (e.g. using a minimum of 12-point Time New Roman or 11-point Arial).</td>
<td></td>
</tr>
<tr>
<td>• Allow sufficient white space between label sections.</td>
<td>• Keep highlighted colors to no more than two.</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Comparison of the two prescription label designs and the USP standard for labeling
to read a passage with commonly encountered information in a healthcare setting. The test consists of 36 fill in the blank questions in which participants select a correct answer from four possible options. The participant is allowed seven minutes to complete the questions. A score is then assigned based on the total number of correct answers; and the participant can be categorized as having either adequate, marginal, or inadequate FHL.\(^\text{10}\)

The modified LaRue Medical Literacy tool (MLT) that was administered to assess participants’ comprehension of Rx labels consisted of a total of 25 open-ended and multiple choice questions. These questions assessed pertinent components of Rx comprehension, such as medication name, direction, indication, number of refill, expiration date, and quantity. Rx bottles with labels for five commonly prescribed medications (simvastatin, metformin, glipizide, lisinopril and hydrocodone/acetaminophen) were used in our study to simulate real-life settings.

Educational intervention for the intervention group consisted of label-focused education highlighting where to locate key elements in a label and how to interpret each label component (Table 2). Such education is publicly available through the Agency for Healthcare Research and Quality (AHRQ). Participants also received information relevant to each of the four disease states in the study, as needed. To facilitate the learning process during the educational intervention, the participants were given self-assessment questions for two more sample Rx labels.

The study focused on comparing the difference in label comprehension and FHL between the current labels and redesigned PC labels.

### Results

As seen in Figure 2, key results were:

1. PC label showed better label comprehension compared to current standard label both before and after educational intervention.
2. Label comprehension and FHL (statistically) significantly improved after educational intervention in the intervention groups compared to the control groups, for the redesigned Rx label, but not for the current Rx label.

### Implications

A PC label was found to be superior not only due to stronger patient preference as seen in our previous study, but also due to demonstrated positive improvement in comprehension at each level of FHL. The results also strongly suggest that a simple label-focused educational intervention can help improve label comprehension and FHL in all patients regardless of their FHL level. Therefore, a similar approach of label-focused education using a PC label may be something to consider incorporating into a routine pharmacy consultation.

### Pharmacists Role in FHL

The aging population, advances in medicine, and changes in healthcare policy (ACA and SB493) will increase the need for healthcare providers to play an active role in helping patients manage their care. This increased demand provides an opportunity for healthcare team members to advance the quality and outcomes of patient care while reducing disparities.

As the healthcare team member at the last line of communication before patients begin a medication regimen, pharmacists play an integral role in impacting patients’ medication use. A pharmacist can greatly improve how patients should interpret their Rx labels by providing clarity through tailoring communication to an individual’s level of literacy and providing patients with a brief overview of Rx label components.\(^\text{6}\) As seen above, our research has shown that using a patient-centered label and simple label-focused education can improve both label comprehension and FHL.
thereby potentially improving long term medication self-care, adherence and outcomes.

Authors

Alana Zapata is a 2015 PharmD Candidate at Western University of Health Sciences College of Pharmacy and was an APPE student in an Outcomes Research Selective Elective with Dr. Law when she wrote this manuscript. Ms. Zapata has no bias to report.

Bik-Wai Bilvick Tai, PharmD, AE-C, was a Health Outcomes Research Fellow at Western University of Health Sciences College of Pharmacy, under the mentorship of Dr. Law during the preparation of this manuscript. He was central to the development of this research project, data collection and analysis. Dr. Tai has no bias to report.

Anandi V. Law, B.Pharm., 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. She has been working on prescription labels since 6 years and has presented thrice on this issue to the BOP. Dr. Law has no bias to report.

References

8. Effectiveness of an educational intervention to improve prescription label comprehension and functional health literacy: A multisite randomized control trial
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The California Pharmacists Association receives sponsorship fees for insurance programs that offset the cost of program oversight and support member benefits and services.
Antibiotic Stewardship programs exist frequently in hospitals and health management organizations in order to optimize patient health outcomes, control costs, ensure correct utilization, and, most importantly, minimize the emergence of bacterial resistance to preserve the effectiveness of current antibiotic medications. There are few established antibiotic stewardship programs that formally exist in community pharmacy despite the fact that up to 50 percent of all antibiotics are dispensed through community pharmacies. Among that percentage, it is estimated that a significant portion of those antibiotics were prescribed inappropriately to treat symptoms of viral infection rather than a true bacterial infection. As a result, populations and individual patients who use the same antibiotic, or class of antibiotic, repeatedly are more likely to develop resistance. Community pharmacists are the most frequently seen health care provider and the final check in the delivery-of-care line. The regular correspondence that community pharmacists have with patients, as well as the training and knowledge they possess, creates a tremendous opportunity to perform interventions for patients in order to slow resistance, verify appropriate usage, recommend alternative over-the-counter (OTC) medications, and educate physicians and patients.

The purpose of this article is to offer a program to provide recommendations for how community pharmacists can act as antibiotic stewardship proponents. This program offers an evidence-based formulary, accredited organizational-based practice guidelines, and relevant clinical pearls for continued education and awareness. It is composed of program principles (Table 1), a formulary (Table 2), and guidelines for treatment (Table 3). While there is no consensus to implementing a community-based antibiotic stewardship program, we propose the following (further detailed in Table 1):

Table 1. Community-Based Antibiotic Stewardship Program & Principles

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Implementation</th>
</tr>
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<tbody>
<tr>
<td>Increase pharmacist's awareness of regional antibiotic resistance patterns</td>
<td>Contacting the CDC or WHO to obtain information and resources regarding current high-risk organisms and antibiotic resistance trends. A list of such organisms and antibiotics should be compiled by the pharmacist in charge or a designated team member, and all team members should be educated for what drugs and organisms to look out for. The list should be updated regularly, i.e., yearly or seasonally. Pharmacists should also be aware of the most common misdiagnoses, such as pharyngitis, common cold, bronchitis, sinusitis, etc.</td>
</tr>
<tr>
<td>Increase pharmacist’s knowledge of treatment guidelines for diseases/infections for which antibiotic therapy is appropriate and ensure sufficient coverage and duration of therapy</td>
<td>Provide quick-reference brochures for commonly dispensed antibiotics and indications. These brochures should be easy to refer to and contain information such as diagnosis, appropriate antibiotics and alternatives, recommended length of therapy, and adjunct drugs necessary. The quick-reference guides should include the most commonly outpatient diagnoses: pharyngitis, sinusitis, bronchitis, upper respiratory tract exacerbation, urinary tract infection, non-tuberculosis mycobacterium, and organisms such as S. pneumoniae, H. influenza, and M. catarrhalis.</td>
</tr>
<tr>
<td>Community pharmacies should limit and adjust their inventory of antibiotics to minimize overuse of broad-spectrum antibiotics and maximize usage of narrow-spectrum antibiotics</td>
<td>Pharmacy should carry limited supplies of the broadest spectrum antibiotics to discourage overutilization or flag such antibiotics as high-alert medications for dispensing pharmacist to verify appropriateness of usage. Narrow-spectrum antibiotic inventory should be maintained as appropriate for patient population served by the pharmacy, seasonal infection patterns by year, and resistance trends by pharmacy region. High-resistance risk/alert antibiotics should typically include: azithromycin, cephalexin, and high-dose amoxicillin-clavulanate.</td>
</tr>
<tr>
<td>Antibiotic-stewardship-focused prospective and retrospective drug utilization review</td>
<td>Pharmacists should ask patients or physicians what the antibiotic is for if the drug prescribed is a broad-spectrum antibiotic and verify if the information is missing or unclear in order to ensure completeness and appropriateness of the prescription. Any refills for antibiotics should be verified for appropriate continuation of the medication for a treatment regimen. Pharmacists should periodically review patient profiles for antibiotics that are being refilled or new but repeat orders of the same antibiotic or class. Pharmacists should also schedule follow-up calls for patients during or after their antibiotic course to ensure successful completion and better patient compliance, and to monitor for adverse drug events, sudden discontinuation, or physician revisit for new antibiotics. The pharmacy should also run reports that find physician antibiotic prescribing patterns to determine whether there are any physicians who may be overprescribing inappropriate broad-spectrum antibiotics who could benefit from a pharmacist intervention or educational reminder call.</td>
</tr>
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<tr>
<td>Pharmacists should prioritize and promote immunizations</td>
<td>Train and certify that all pharmacists are capable of administering immunizations. Pharmacists should be up to date on their own immunizations. Ensure that pharmacy is stocked with correct inventory of immunizations and that they are the current batch for the year. Vaccines stocked and administered should include: Annual influenza, pneumococcal, hepatitis A/B, chickenpox, meningitis, measles, mumps, rubella, shingles-herpes zoster, tetanus Td, and Tdap. An increased number of vaccinations in the community will increase herd immunity, decrease physician visits, and lower the likelihood of developing symptoms that result in antibiotics prescribed for viral causes.</td>
</tr>
<tr>
<td>Mandatory counseling and counseling guidelines for all antibiotics by pharmacists</td>
<td>All antibiotics including new prescriptions and refills (only for appropriate long-term continuation therapy) must be dispensed with a pharmacist counseling of what the medication is for, how long to take the medication, what side effects to look out for, and clinical pearls such as to take all pills until finished. Pharmacists must also clarify the difference between a side effect, adverse reaction, or drug allergy and firmly instruct patient to continue taking antibiotic to completion even if they start feeling better. Antibiotic counseling should be prioritized especially during cold and flu season.</td>
</tr>
<tr>
<td>Pharmacists should recommend OTC products to treat symptoms first before referring patient to a physician for antibiotic; actively educate patients on viral vs. bacterial infections and the dangers of antibiotic overuse and resistance.</td>
<td>For patients with the following symptoms, recommend that they try these OTC products first before going to physician for an antibiotic: Sore throat: throat spray and lozenges Ear pain: warm moist cloth over ear or acetaminophen (APAP) Runny nose: decongestant, saline spray Sinus pain/pressure: warm compress, decongestant, nasal spray, steam cough: humidifier, rest, fluids Note: APAP formulations specific for children under 6 months only Community pharmacists should look for the following symptoms in adult patients as appropriate to refer to physician: extreme lethargy, stiff neck, difficulty breathing, high fever, and seizures. Remind pharmacists to look for and educate patients who may have viral infections and should try an OTC product first. Be able to distinguish between appropriate OTC drugs for pregnancy, infants, children, hypertensive, diabetic, etc. Recommend community hygiene practices such as washing hands correctly before handling food and after using the bathroom; practices such as covering one’s mouth when sneezing, and using a face mask to minimize spread to others in confined areas.</td>
</tr>
<tr>
<td>Pharmacists should educate physicians and bring awareness to antibiotic resistance from inappropriate expectations from patients</td>
<td>Physicians commonly cite patient expectations and demands as reasons for prescribing antibiotics in the ambulatory setting. Educate patients that antibiotics have no benefit if for the wrong organism and are likely to wipe out natural healthy protective bacteria and give patients side effects such as diarrhea and secondary infections. Identify particular local physicians with prescribing habits that demonstrate overuse of broad-spectrum antibiotics and/or inappropriate use of antibiotics, and create list with which to perform interventions and antibiotic switching to narrower spectrum when appropriate by pharmacist judgment. Inform physicians of local antibiotic resistance trends and ask if their facility has policies and procedures in place for antibiotic stewardship.</td>
</tr>
<tr>
<td>Pharmacists should ensure that all patient profiles accurately contain true patient drug allergies; pharmacists should counsel patients on true drug allergies vs. adverse events or side effects</td>
<td>Patient profiles should contain up-to-date and accurate patient information on true allergies to antibiotics, especially beta lactams and sulfas. True drug allergic reactions will involve skin rashes, hives, breathing problems, edema, swelling, changes in blood pressure. Anaphylaxis occurs quickly after taking medication and causes responses such as severe swelling, bronchoconstriction and difficulty breathing, nausea/vomiting, sudden drop in blood pressure, loss of consciousness, and possible shock and organ damage. Pharmacists should use their clinical judgment to determine whether a patient has a true allergy and is prescribed a related antibiotic to the stated allergy. Policies and procedures should be in place in the event of an antibiotic drug allergy event. These policies and procedures will be outlined in a way to cover actions such as informing the physician, providing supportive and reversal agents to an allergic reaction, and providing appropriate alternative antibiotic in a timely manner.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Indication</td>
</tr>
<tr>
<td>-------</td>
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</tr>
<tr>
<td>Cefdinir</td>
<td>Bronchitis: S. pneumoniae, H. influenzae, M. catarrhalis, Pneumonia, Pharyngitis, Sinusitis</td>
</tr>
<tr>
<td>Cephalexin</td>
<td>Dental infection: Streptococci, anaerobes, Otitis Media, Streptococcal Pharyngitis, UTI</td>
</tr>
<tr>
<td>Amoxicillin / Clavulanate</td>
<td>Pneumonia: S. pneumoniae, Mycoplasma pneumoniae, H. influenzae, Bacteroides, Peptostreptococcus, fusobacterium; Dental infection: beta-lactamase producing organisms; Sinusitis (symptoms &lt; 14 days) S. pneumoniae, H. influenzae, M. catarrhalis, Group A strep, anaerobes; Bronchitis: S. pneumoniae, H. influenzae, M. catarrhalis</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>Dental infection: Streptococci, anaerobes, Bronchitis: S. pneumoniae, H. influenzae, M. catarrhalis</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>Respiratory Tract Infection, GI Tract Infection, Genitourinary Infection</td>
</tr>
<tr>
<td>Dicloxacillin</td>
<td>Infection due to S. aureus</td>
</tr>
<tr>
<td>Penicillin VK</td>
<td>Pharyngitis: Strep (pyogenes, group C and G), A. hemolyticum, C. diphtheriae; Respiratory Tract Infection</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>Pneumonia: S. pneumoniae, Mycoplasma pneumoniae, H. influenzae; Sinusitis + penicillin allergy (symptoms &lt; 14 days) S. pneumoniae, H. influenzae, M. catarrhalis, Group A strep, anaerobes; Bronchitis: S. pneumoniae, H. influenzae, M. catarrhalis</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>Pneumonia: S. pneumoniae, Mycoplasma pneumoniae, H. influenzae; Dental infections: Streptococci, anaerobes</td>
</tr>
<tr>
<td>Drug</td>
<td>Indications</td>
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<tr>
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<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>Pneumonia: S. pneumoniae, Mycoplasma pneumoniae, H. influenzae Pharyngitis: Strept (pyogenes, group C and G), A. hemolyticum, C. diphtheriae Sinusitis + penicillin allergy (symptoms &lt; 14 days) S. pneumoniae, H. influenzae, M. catarrhalis, Group A strep, anaerobes Bronchitis: S. pneumoniae, H. influenzae, M. catarrhalis</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>Urethritis + penicillin allergy (symptoms &lt; 14 days), Rocky Mountain Spotted Fever Bronchitis: S. pneumoniae, H. influenzae, M. catarrhalis</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>H. pylori, Use for high resistance risk or patient who tried/failed prior triple course</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>Bronchitis: S. pneumoniae, H. influenzae, M. catarrhalis Lower respiratory tract infection</td>
</tr>
<tr>
<td>Levofoxacin</td>
<td>Pneumonia: S. pneumoniae, Mycoplasma pneumoniae, H. influenzae Sinusitis + penicillin allergy (symptoms &lt; 14 days) S. pneumoniae, H. influenzae, M. catarrhalis, Group A strep, anaerobes UTI: Enterobacteriaceae (includes E. coli, serratia, klebsiella, enterobacter, citrobacter), S. saprophyticus, enterococci Bronchitis: S. pneumoniae, H. influenzae, M. catarrhalis</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>Pneumonia: S. pneumoniae, Mycoplasma pneumoniae, H. influenzae Bronchitis: S. pneumoniae, H. influenzae, M. catarrhalis</td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>UTI: Enterobacteriaceae (includes E. coli, serratia, klebsiella, enterobacter, citrobacter), S. saprophyticus, enterococci</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Bacterial vaginosis, Trichomoniasis, H. pylori infection</td>
</tr>
<tr>
<td>Infection Type</td>
<td>Organisms</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Rhinosinusitis</td>
<td>S. pneumoniae, H. influenza, M. catarrhalis, S. pyogenes, S. aureus, Enterobacteriaceae, Bacteroides, Fusobacterium, Peptostreptococcus</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>Group A Streptococcus S. pyogenes Group C Strep</td>
</tr>
<tr>
<td>Community-Acquired Pneumonia (Outpatient)</td>
<td>S. pneumonia, Mycoplasma pneumonia, H. influenza, Chlamyphilia, pneumoniae</td>
</tr>
<tr>
<td>Condition</td>
<td>Pathogens</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td><strong>Acute uncomplicated cystitis (UTI)</strong></td>
<td>E. coli, Proteus mirabilis, Klebsiella pneumonia, S. aureus</td>
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<tr>
<td><strong>Bronchitis</strong></td>
<td>Most cases due to virus</td>
</tr>
<tr>
<td></td>
<td>S. pneumonia, H. influenza, S. aureus, M. catarrhalis, Mycoplasma pneumonia, Chlamyphila pneumonia, Bordetella pertussis</td>
</tr>
<tr>
<td><strong>Nontuberculosis Mycobacterium</strong></td>
<td>Mycobacterium avium, Complex</td>
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<tr>
<td><strong>H. pylori Infection</strong></td>
<td>H. pylori infection</td>
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<td></td>
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<tr>
<td><strong>Acute Otitis Media</strong></td>
<td>Infants &lt; 6 months 6 months-2 years if severe illness or positive diagnosis &gt; 2 years if severe illness or observe</td>
</tr>
</tbody>
</table>
DISSEMINATE: Dissemination of the program with all three tables to pharmacy staff and prescribers

DISPLAY: Posting the tables in the pharmacy and in the provider exam rooms

PORTABLE: Lamination of the tables for ease of transport by prescribers and pharmacists in their lab coats

CLINICAL PEARLS: Regular and continuing educational interactions between prescribers and pharmacists based on clinical pearls drawn from the three program tables

EDUCATION: Short educational articles for dissemination to patients and interested organizations

LABELS: Include treatment guidelines for specific therapies in computer labels and ancillary Web-based communications

REVIEWS: Monthly review of antibiotic and corollary prescriptions (e.g. cough and cold medications, antihistamines, analgesics, etc.) with a pharmacist follow-up to prescribers focusing on improvement of appropriate antibiotic prescribing habits.

FEEDBACK ON PERFORMANCE: Announce to prescribers, pharmacy staff, and patients successes and improvements to the program

There is a critical need for improving antibiotic prescribing. It is the authors’ hope that this program can provide guidance for community pharmacists and managers to address this problem at the site of the largest volume of prescriptions. We would be very interested in feedback provided from local programs and their successes.

About the Authors
Christopher Lee, PharmD, is a newly graduated pharmacist from Midwestern University Chicago College of Pharmacy and received his B.S. in Biology from the University of California, Irvine. Dr. Lee has no bias or conflict of interest to report.

Michael Pazirandeh, PharmD, is a Sr. Clinical Pharmacist at Blue Shield of California in the Outcomes & Analytics department. He received his PharmD at the University of Southern California and his B.S. Biology at the University of Notre Dame. Dr. Pazirandeh has no bias or conflict of interest to report.

Craig Stern, PharmD, MBA, is President of Pro Pharma Pharmaceutical Consultants, Inc. and serves as the Chairperson of the CPhA Editorial Review Committee. Dr. Stern has no bias or conflict of interest to report.

References
4. Infectious Diseases Society of America (IDSA)
5. IDSA Guidelines: Community-Acquired Pneumonia http://cid.oxfordjournals.org/content/44/Supplement_2/S27.full.pdf+html
7. IDSA Guidelines: Rhinosinusitis http://cid.oxfordjournals.org/content/early/2012/03/20/cid.cir1043.full.pdf+html
11. Globalrph: Clinician’s Ultimate Reference (Globalrph.com)
17. Micromedex: ciprofloxacin, ampicillin, dicloxacillin
18. UpToDate: American College of Gastroenterology-First Line H. pylori regimens, Non-Tuberculosis Mycobacterium Treatment
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Linagliptin for Patients aged 70 years or older with type 2 diabetes inadequately controlled with common antidiabetes treatments

By Michael Wong, PharmD; Kevin Wu, PharmD; Justin Yu 2014, PharmD; and Craig Stern, PharmD, MBA, FCPhA

Introduction

This study was conducted to evaluate the efficacy of linagliptin in outpatients aged 70 years or older with type 2 diabetes inadequately controlled with common antidiabetes treatments. The study compared linagliptin versus placebo on select background antidiabetes medications such as metformin, sulfonylureas, basal insulin, or combinations of these drugs. The primary endpoint is the HbA1c change from baseline at 24 weeks.

Based on the results of a 24-week randomized, double-blind, placebo-controlled trial, the authors concluded that linagliptin was efficacious in lowering glucose with a safety profile similar to placebo in elderly patients with type 2 diabetes. The purpose of this evidence-based evaluation is to determine the validity of the evidence presented for linagliptin in the aforementioned patient population and to determine the drug’s clinical relevance. 

Grade: B-U

<table>
<thead>
<tr>
<th>Element</th>
<th>Criteria</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Study Design Assessment          | • Is the design appropriate to the research question? Is the research question useful?  
  • For efficacy, use of experimental study design (meaning there was no choice made to determine intervention)  
  • Clinically significant area for study (morbidity, mortality, symptom relief, functioning and health-related quality of life) and reasonable definitions for clinical outcome such as response, treatment success or failure  
  • If composite endpoints used, reasonable combination used — and used for safety if used for efficacy | Threat: Concomitant medications used with varying dosages and baseline medications were not balanced across both groups (e.g. metformin plus sulfonylurea plus insulin = 9/162 (5.6%) for the linagliptin arm, 0/79 (0%) for the placebo arm), making it difficult to assess the efficacy and safety of linagliptin alone versus placebo in this population. |
| Internal Validity Assessment     | • Can bias, confounding or chance explain the study results?  
  • Ensure prespecified and appropriate 1) research questions, 2) populations to analyze, and 3) outcomes | Threat: In the study, 241 patients were randomized; randomization of about 243 patients was needed, assuming a 5% dropout. Ultimately 220 (linagliptin = 146, placebo = 74) completed the study. Hence, the study was less than 90% powered (because 231 patients were needed) and deviated from protocol.  
  Threat: Doses of background treatments were maintained for the first 12 weeks of randomized treatment, after which dose adjustments were permitted. This allows for selective adjustment of treatment arms as they are not controlled or monitored. This introduces bias and removes randomization between the two arms by allowing the investigator to selectively adjust a patient’s treatment.  
  Threat: Criteria for rescue medication for hyperglycemia differed during weeks 1-12 (>240 mg/dL) and weeks 13-24 (>200 mg/dL), which creates inconsistencies in patient management over different time periods. |
| Selection Bias | Groups are **appropriate** for study, of appropriate size, **concurrent** and similar in prognostic variables  
- Methods for generating the group assignment sequence are truly **random**, sequencing avoids potential for anyone affecting assignment to a study arm and **randomization remains intact**  
- **Concealment of allocation** strategies are employed to prevent anyone affecting assignment to a study arm | **Threat:** The two groups were not equal to begin with. There were more men in the linagliptin group versus the placebo group (71.6% vs. 62%). The linagliptin group also tended to have more people with more severe HbA1c values (in the ≥8% to <9% group and ≥9% group). It should also be noted that the types of concomitant antidiabetics used were not equal between the two groups. |
| Performance Bias | **Double-blinding** methods employed (i.e., subject and all working with the subject or subject’s data) and achieved  
- Reasonable **intervention** and reasonable **comparator** used (e.g., placebo)  
- No bias or difference, except for what is under study, between groups **during course of study** (e.g., intervention design and execution, care experiences, co-interventions, concomitant medication use, adherence, inappropriate exposure or migration, cross-over threats, protocol deviations, measurement methods, study duration, changes due to time etc.) | **Threat:** Patients in the study concomitantly received metformin, sulfonylureas, basal insulin, or combinations of these drugs at various dosages, which could have confounded the results. Investigators remain blinded to treatment assignments and adjusted only concomitant drug dosages after 12 weeks to target patient-specific HbA1c goals. A clinical endpoint committee (CEC), consisting of three academic cardiologists and three academic neurologists and masked to assignment, reviewed events suspected to be stroke or cardiac ischemia. Other assessments were performed by individual, respective investigators who were masked to treatment assignment throughout study. No formal committee was mentioned to provide confirmation of initial assessments. |
| Attrition Bias | **Might attrition**, including missing data, discontinuations or loss to follow-up, have resulted in distorted outcomes? | **Threat:** Last observation carried forward (LOCF) was used to impute missing variables for patients that discontinued treatment (placebo = 5, linagliptin = 16) and no HbA1c levels were reported at time of discontinuation. This dropout discrepancy introduces potential bias favoring the control arm as more patients discontinued due to adverse events (n=8) compared to placebo (n=1). Using LOCF for a greater number of dropouts in the control arm can lead to an apparent decrease in efficacy of linagliptin compared to placebo. Patients that drop out before linagliptin is able to exert its full therapeutic effect will have a higher A1c carried forward, thus decreasing the treatment difference between linagliptin and placebo and biasing results toward non-significance. |
| Assessment Bias | **Assessors are blinded**  
- Low likelihood of findings due to chance, false positive and false negative outcomes  
- Non-significant findings are reported, but the confidence intervals include clinically meaningful differences  
- Intention-to-Treat Analysis (ITT) performed for efficacy (**not safety**) (all people are analyzed as randomized + reasonable method for imputing missing values which puts the intervention through a challenging trial or reasonable sensitivity analysis) or missing values are very small.  
- If **time-to-event analysis** performed, appropriate, transparent and unbiased.  
- Evaluate censoring rules.  
- **Analysis methods** are appropriate and use of modeling only with use of reasonable assumptions  
- No problems of selective reporting or selective exclusion of outcomes | **Threat:** The full analysis set consisted of 238 patients. As 241 patients were randomized, that would indicate that three patients were excluded and no ITT analysis was performed. The treated set, defined as all those who received a dose (n=241), was used to assess safety. Since the study was powered for efficacy, it is unlikely that it was adequately powered to assess all the safety endpoints.  
**Threat:** While there was no issue with selective reporting, the conclusions related to the incidence of hypoglycemia would have been stronger had they mentioned what concomitant antidiabetic drugs the patients were on when these adverse events occurred. |
| Usefulness | **Clinically significant area + sufficient benefit size** = meaningful clinical benefit (consider efficacy vs. effectiveness) | **Threat:** A change in HbA1c of -0.64% versus placebo represents a change in a surrogate marker of disease. This change is of unknown clinical significance and may not justify the use of this drug over other efficacious pharmacologic and non-pharmacologic options (e.g., diet and exercise) given the high costs. |
| External Validity | • How likely are research results to be realized in the real world considering population and circumstances for care?  
• Review n, inclusions, exclusions, baseline characteristics and intervention methods—this is a judgment call.  
  | Threat: Majority of the patients studied were White, which limits the external validity of the study considering the majority of patients suffering from diabetes are non-White (per American Diabetes Association statistics). Baseline included ~96% White, 56.9-66.7% with HbA1c ≥7 and <8%, ~70% men, 83-88% taking metformin at screening, mean weight 86 kg and BMI 30 kg/m², and did not include cardiovascular characteristics which are pertinent in diabetic patients.  
|  
| Patient Perspective | • Consider benefits, harms, risks, costs, uncertainties, alternatives and satisfaction  
  | Threat: Linagliptin is currently a branded drug that costs approximately $913.61 for 90 days (Medi-Span). Depending on a patient’s co-pay, the high cost of the drug may limit access to patients.  
• The clinical benefit of a change in HbA1c of -0.64% may also be questionable. This change may in fact be achievable through diet and exercise alone or using the other drugs that were excluded (i.e. a thiazolidinedione, alpha-glucosidase inhibitor, meglitinide, GLP1 analogue, DPP4 inhibitor, or anti-obesity drug). The risk of hypoglycemia with linagliptin is a concern, especially in combination with other unknown hypoglycemic agents such as sulfonylureas.  
  |  
| Provider Perspective | • Satisfaction, acceptability (includes adherence issues, potential for abuse, dependency issues), likely appropriate application and actionability (e.g., FDA approval, affordability, external relevance, circumstances of care, able to apply, tools available)  
  | Threat: Linagliptin is a costly new DPP4 inhibitor that shows minimal reduction in HbA1c (i.e. -0.64).  
• Other PO alternatives, such as alpha-glucosidase inhibitors, are less expensive albeit with a different side effect and tolerability profile. A one-month supply of acarbose (Precose), a drug class with equal HbA1c lowering efficacy ~0.5% that also does not have to be renally adjusted, is about $90-$200 a month depending on the dosage strength.  
• Sitagliptin and saxagliptin can still be used with very low CrCl and in hemodialysis. There are no contraindications for renal function for sitagliptin and saxagliptin, although greater monitoring may be warranted to optimize dosing.  
  |

**Author’s Results and Conclusions**

The placebo-adjusted mean change in HbA1c with linagliptin was -0.64% (95% CI, -0.81 to -0.48, p<0.001). Patients in both the linagliptin and placebo groups reported a 75.9% adverse event rate, although the rate of serious adverse events was higher in the linagliptin group versus the placebo group (8.6% vs. 6.3%). Adverse events such as non-fatal ischemic stroke, unstable angina, and neoplasms were deemed unrelated to linagliptin by the investigators. The treatment arm had a nonsignificant higher rate of hypoglycemia compared to the placebo arm (24.1% vs. 16.5%, 95% CI, 0.78-3.78, p=0.2083), which was attributed to the greater number of sulfonylurea users in the linagliptin group.

**Reviewer’s Conclusions**

In the study population, linagliptin had a modest effect on the reduction in HbA1c compared to placebo, which calls into question its clinical efficacy and value in a real-world patient population. Furthermore, approximately 96% of the patients in the study were White, potentially limiting the external validity of the study. This is particularly important because the American Diabetes Association (ADA) states that African Americans are 1.8 times more likely to develop diabetes than their Caucasian counterparts. According to 2007-2009 statistics from the ADA, diabetes prevalence in people ages 20 or older was 7.1% in non-Hispanic whites, 8.4% in Asian Americans, 12.6% in non-Hispanic blacks, and 11.8% in Hispanics. Additional studies in non-White elderly populations may also reveal additional information on the efficacy, safety, and tolerability of linagliptin. Referencing the primary outcome, a 0.64% decrease in HbA1c can likely be achieved by diet and exercise alone, although the population studied was one with longstanding diabetes inadequately controlled with metformin, sulfonylureas, basal insulin, or combinations of these drugs.

One of the greatest weaknesses of the studies was that the two treatment arms were not equal.
in relation to their baseline characteristics; although unstated, there appeared to be clinically meaningful differences between them. The treatment arm, for example, had more males and more severe HbA1c values compared to the placebo arm. Additionally, the two arms were not equal in terms of concomitant glucose-lowering drugs, which may have confounded the study results. In addition, dosage adjustment after 12 weeks was allowed and rescue medication criteria for hyperglycemia changed after 12 weeks to be less strict (240 mg/dl vs. 200 mg/dL) and together may have led to inconsistent patient management.

Based on the above findings, recommendations for linagliptin’s place in therapy are more clear. Although linagliptin possesses several advantages, including a lack of need for renal adjustment and evidence for efficacy and safety in a rarely studied population, the impact of this drug may be limited due to the aforementioned statements and due to its high cost ($913.61 for a 90-day supply, per Medi-Span). Although there is no need for renal dosing with linagliptin, it would not provide linagliptin with a significant advantage over other DPP4 inhibitors in the setting of moderately decreased but stable renal function. Lastly, alternative medications such as alpha-glucosidase inhibitors provide a comparable HbA1c lowering efficacy while also possessing no need for renal dosing. These agents are less expensive, with costs ranging from $89.94 to $203.92 (per Medi-Span) for slightly more than one month’s supply.

**About the Authors**

Michael Wong is a 2014 PharmD Candidate at the USC School of Pharmacy.

Kevin Wu is a 2014 PharmD Candidate at the USC School of Pharmacy.

Justin Yu is a 2014 PharmD Candidate at the USC School of Pharmacy.

Craig Stern, PharmD, MBA is president of ProPharma Pharmaceutical Consultants, Inc. and Chair of the CPhA Editorial Review Committee. Dr. Stern has no bias to disclose.

**References**


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**Delfini Evidence Grading Scale**

<table>
<thead>
<tr>
<th>Grade A Evidence: Useful</th>
<th>The evidence is strong and appears sufficient to use in making health care decisions – it is both valid and useful (e.g., meets standards for clinical significance, sufficient magnitude of effect size, physician and patient acceptability, etc.).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade B Evidence: Probably Useful</td>
<td>The evidence appears potentially strong is probably sufficient to use in making health care decisions. Some threats to validity were identified.</td>
</tr>
<tr>
<td>Grade B-U Evidence: Possible to Uncertain Usefulness</td>
<td>The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B and the uncertainty is not great enough to fully warrant a Grade U. Study quality is such that it appears likely that the evidence is sufficient to use in making health care decisions; however, there are some study issues that raise continued uncertainty. Health care decision-makers should be fully informed of the evidence quality.</td>
</tr>
<tr>
<td>Grade U Evidence: Uncertain Usefulness</td>
<td>There is sufficient uncertainty that caution is urged regarding its use in making health care decisions.</td>
</tr>
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</table>
University of California, San Francisco

By Valdy Tjong, CPhA Board of Directors Representative

With the new academic year just beginning, the campus is buzzing with activity. First-year students are getting adjusted to life in pharmacy school, while second-year students are busy planning many of the extracurricular activities. On the other hand, third-year students are buckling down getting ready for rotations in the spring, while the occasional fourth-year student can be seen walking the campus grounds. Before discussing some of the events we have planned for the Fall, there were a couple of important events our chapter was working towards during the Spring and summer.

The first of these events was our very first CPhA-ASP/APhA-ASP Ambulatory Care Pharmacist Panel, which was held in the spring. The growing interest in this career field prompted the event, and we invited several ambulatory care pharmacists working in diverse settings. Each pharmacist spoke about their role, their daily responsibilities and how they got to where they are today. Moreover, it was an intimate setting where students could discuss any questions or concerns they had about the career field. The event received a very positive response, and we will be sure to repeat this event in future years!

Another important event for our chapter was our push over the summer to set up a meeting with our federal legislator regarding HR 4190. This federal bill is very important to the pharmacy profession and focuses on attaining provider status for pharmacists at the federal level. In many ways, we have already started down this road with the recent passage of SB 493 in California, so it would be a huge accomplishment to establish something at the national level. That is why we and many other pharmacy students are helping to set up meetings with local legislators in order to gain more support for the bill. We hope to set one up this Fall and are looking forward to a strong showing from members of our student body.

Needless to say, a lot of our current focus is on the activities we have planned for the upcoming Fall. We will be holding many of our popular events again this year such as our annual Wine and Cheese night where students get an opportunity to network with pharmacy professionals in an intimate setting. Additionally, we’ll be holding joint events with other organizations with a focus on student professional development. Many of these events have been well-received in previous years as many students view them as a wonderful learning opportunity. However, we’re also working on new events involving collaborations with one of our local CPhA associations. With this mix of new and traditional events planned for the quarter, we look forward to welcoming new and old members at our annual student body information session. It’s sure to be another exciting year for our chapter!

California Northstate University

By Alice Kwok, CPhA Board of Directors Representative

This past summer, the CNU-CPhA’s newly elected board worked on upcoming events and fundraiser ideas that will be hosted this Fall. The new board is determined to get more students involved within CPhA and has started working on a CNU-CPhA newsletter, which will be distributed to students on campus. The goal of the newsletter is to keep students informed about our advocacy efforts and mission. Recently, our CPhA-ASP chapter participated in our school’s Club Day, where we introduced CPhA for the first time to the Class of 2018. The board members spoke to students about our upcoming events, such as our First CPhA General Meeting, the Alzheimer’s Walk, and American Heart Walk with APhA. We gave a brief overview of what CPhA is about and answered any questions they may have about CPhA. We hope that both the CNU-CPhA Newsletter and Club Day will interest students in joining CPhA and to become active members within our student chapter. We are looking forward to meeting and talking to the students interested in CPhA during our first General Meeting!
Loma Linda University
By Jerry Chen, CPhA Board of Directors Representative

The summer season for students at Loma Linda was anything but uneventful. Although Loma Linda is still in its summer break and the Autumn quarter is still a few weeks away, the students have still been nonetheless busy. From studying abroad and interning in new pharmacies to volunteering in Diabetes camp and mission trips to Cambodia and Romania, CPhA members at LLU hardly have time to stop and take a breath.

The board at Loma Linda has also been working hard to prepare for the new academic year. CPhA already has a few health fairs lined up for the students as well as a few welcoming events to ring in the new year. We are so excited to meet the new class of 2018 and are planning a special event just for the new class to prepare them for our annual job fair. The Student Panel will consist of older students, who have successfully navigated through the confusion of a job fair, who will give advice to the P1 class.

This year, Loma Linda has also decided to host a Leadership retreat before the start of the quarter. The entire CPhA board will be participating in this retreat where major school events will be planned. The Leadership retreat will be most certainly be productive, but it will also be a good bonding experience since the CPhA Board consists of students from different academic years.

The LLU CPhA Board of 2014-2015.

The speakers of the Student Panel in 2013.

University Southern California
By Akemi Meguro, CPhA Board of Directors Representative

The CPhA chapter from the University of Southern California (USC) School of Pharmacy had a fruitful summer. Several projects participated in the Schweitzer/ChAPSA Health education fair at a Chinese Senior community center on August 13, providing educational services to 74 participants. The participants were geriatric Chinese and predominantly Mandarin or Cantonese speaking and many projects tailored their educational materials to meet their needs. The Body Fat analysis project screened participants’ body fat percentage and body mass indexes, and also had an educational poster in Chinese. Project Hypertension and Project Cholesterol educated participants on how to maintain blood pressure/cholesterol and adopt lifestyle changes to improve their health to prevent cardiovascular diseases. Smoking cessation educated about the effects of second hand smoke and the environment on lungs, while Asthma Awareness educated about managing asthma and asthma medications. Arthritis Awareness spread awareness about osteoarthritis and cleared misconceptions such as muscle pain being the same as arthritis. Sleep hygiene is a new project, which debuted its educational poster board and handed out complimentary sleep kits, which included sleep masks, earplugs and stress balls.

Through this health fair, students not only gave back to the community but also learned about cultural competency and how to address barriers that patients may face. Since participants were predominantly Mandarin or Cantonese speaking, some posters were made in Chinese, and educational materials such as brochures or flyers were provided in Chinese. There were students who helped with Mandarin and Chinese translations so that participants could have their questions answered. With the Asian community, there is a high emphasis on homeopathic medica-
tions and therefore, it is crucial to be aware of such remedies so that they can be properly counseled. In addition, this health fair was conducted in collaboration with students from Keck School of Medicine, which gave pharmacy students an opportunity to communicate with other health professionals and develop leadership skills.

The USC Chapter held a summer board retreat and went over our themes and objectives for the following year. Our focus includes interdisciplinary collaboration, legislative advocacy and collaboration with pharmacy schools and local associations. With that in mind, we discussed and brainstormed upcoming events that would fit those themes, which we would promote this upcoming year. On August 25, a couple of USC student pharmacists attended the SGBPhA Board Meeting at the Western University of Health Sciences. They were able to learn more about upcoming events from the local associations, network with fellow student pharmacists at Western and local pharmacists, and exchange leadership ideas with CPhA/APhA-ASP board members. The next SGBPhA Board Meeting will be held at the USC School of Pharmacy. With the start of the school year, our enthusiastic board is looking forward to our membership drive in September and to implement our projects!

Western University of Health Sciences
By Diana Jeon, CPhA Board of Directors Representative

This spring, the Western University chapter of APhA-ASP/CPhA continued to give students the opportunity to be involved and to learn about the profession of pharmacy. In August, APhA-ASP/CPhA hosted the mixer with incoming students at the park. It was memorable event for both incoming students and current students.

August 8, 2014 APhA-ASP/CPhA Mixer
At the SGVPhA meeting, more than 200 students participated to watch the board meeting and they had chance to get to know the association and the importance of participating in local associations. Dr. Victor Law gave speech about the important rules of pharmacy and Dr. Marie Martinez encouraged students to get involved with local associations to get to know more of people in the pharmacy.

August 25, 2018 SGVPhA Local Association Meeting at Western U
Another big event that APhA-ASP/CPhA board hosted was ‘Price is Right’. Many P1’s and P2’s were able to participate in the program where few students come up to the stage to guess on the price of over the counter medications. It was good way to learn about the prices of over the counter medications. There will be elections for the board members for the next year in late September. We are looking forward to meeting new faces in September.
University of the Pacific

By Tinh An (April) Nguyen, CPhA Board of Directors Representative

It’s the start of a new year and the University of the Pacific student pharmacists wear their orange polos with tiger pride as we pounce on new opportunities! Wrapping up the end of a successful year with multiple local legislative visits, student programming that promoted leadership in our profession, and showcasing the talents of our individual students, we look forward to celebrating American Pharmacists Month and the upcoming year!

Programming to Kick Smoking Habit

Second year student pharmacist Saranpreet Nagra was featured on Pharmacy Times for his up-and-coming smartphone app to help patients quit smoking! By combining his passions for computer programming and pharmacy, he focused on improving patients’ health through new technology. With a rapid growth in technological advances, the focus of the project was to “create momentum that will drive scientists and health care providers to create even more innovative patient oriented applications that have a positive effect”, with an emphasis on developing technology that will provide personalized health care for our patients.

Guiding them through several questions to determine the best product for their current life style, it also provides product information so that the patient has access to the common side effects and directions of use, as well as setting up a reminder on their quit date to determine the effectiveness of this application. He hopes to apply the information from making this iOS app to other chronic disease states and continue integrating technology and health care to provide positive patient outcomes.

Women Leaders in Pharmacy Panel

Following the tradition of encouraging active leadership in the profession of pharmacy, a dedicated group of 15 first- and second-year student pharmacists collaborated with faculty to hold the second annual Women Leaders in Pharmacy Panel. Exploring the evolving role of women in pharmacy to highlight the unique opportunities for growth and diversity, we addressed challenges that they faced in professional settings and inspired both male and female students to advance their professional development.

Including professionals from a variety of fields, students welcomed the following pharmacists to our campus: CPhA President Kathy Hill-Besinque, CVS District Manager Diane Dwyer, Associate Director of Women’s Health and BioOncology at Genentech Cathy Sterk, Division President at Ransell Corporation Colleen Higgs, and extensive researcher in Parkinson’s disease Katerina Venderova. Many of them alumni from the University of the Pacific, students were eager to be inspired by their stories of maintaining a healthy work-life balance while pursuing their pharmacy career.

Local Legislative Visits

On Friday, June 20, 2014, two pharmacists and 11 first- and second-year pharmacy students met with field staffer Gary Prost from Congressman McNerney’s office to share their stories and highlight the importance of H.R. 4190 for the constituents in District 9. After explaining how this legislature helps pharmacy take a significant step towards provider status, students shared their experience on how we can improve patient care for some of our nation’s most vulnerable patients.

Recognizing pharmacists as healthcare providers in settings located in health professional shortage areas, medically underserved areas, or with a medically underserved population, approximately 40% of the population in District 9, including many of the community in Stockton, will be able to benefit from wider access to pharmacists care.

Focusing on the great strides that pharmacists have taken in California and our own community, 3 pharmacists and 10 pharmacy students discussed S.B. 493 and its implications with field staffer Tony Wong from Assemblymember Susan Talamantes Eggman’s office. Students were able to highlight how their experiences in school have made a direct impact on the patients that we serve through the numerous health fairs and outreach events over the last several months.

We were able to successfully carry on the momentum and contacted Congresswoman Doris Matsui, who agreed to sign on as a cosponsor to H.R. 4190. These events highlight the impact of student pharmacists, and we look forward to coordinating future legislative visits with other student organizations to continually advocate and advance our profession.

We continue to encourage all students to stay involved in the legislative process and shape the future of our career!
Touro University

By Ravi Shah, CPhA Board of Directors Representative

Touro University of California student pharmacists began the 2014-2015 academic year by organizing an interprofessional event held on August 28 to discuss the rise of prescription drug abuse. The APhA-ASP/CPhA (ASP) chapter at Touro used the Generation Rx Initiative to host an event that would educate future healthcare professionals on the importance of medication stewardship. Over 100 pharmacy, doctor of osteopathy, physician assistant, and nursing students were in attendance.

The featured speakers included people such as Dr. Matthew Willis (Marin County Public Health Officer), Ramón Castellblanch (California Board of Pharmacy Member), and April Rovero (CEO of National Coalition Against Prescription Drug Abuse). The discussion focused on how the prescription drug abuse epidemic could be attacked from both the prescribing and dispensing standpoints. Touro students will continue to build partnerships with community leaders, and spread awareness and education to local schools and additional at-risk groups.

Besides advocating for the community, students in ASP promoted membership in their chapter. From August 25th to the 29th, information sessions and a membership drive were held on the Touro campus. New members joined because of the amount of student programming offered between the two associations, and because of the focus on advocacy for the profession of pharmacy.

The next event for Touro ASP members is scheduled for mid-September.

First-year pharmacy school students will be able to refine their resume and get advice on balancing work and school commitments.

University of California, San Diego

By Victor Ramos, CPhA Board of Directors Representative

While classes remain out of session at UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS), our CPhA student chapter continues to make its presence felt in the community by making active inroads to improve the health of the public. The 27th annual VA Stand Down was held from July 18th to 20th to benefit the homeless veterans of San Diego. The event was a large, collaborative endeavor that provided shelter, food, clothing, and medical care. It also provided other services like VA and Social Security benefits counseling and programs for employment counseling, housing, and substance abuse treatment. Student pharmacists from SSPPS were able to provide medication reconciliation, medication counseling, and hypertension screenings. The United States Armed Forces has a strong presence in the San Diego community and it was a privilege for SSPPS to attend and provide pharmacy services to those who have served. In the same vein, Operations Cholesterol and Diabetes continued their efforts through the summer. Operation Cholesterol held screenings at the Seventh Day Adventist Church, while Operation Diabetes participated in a summer camp for diabetic children held by the American Diabetes Association. Student pharmacists were able to provide assistance in monitoring of blood glucose while ensuring that the campers had a great time.

As the new school year approaches, UCSD CPhA looks to continue improving and growing. UCSD CPhA’s President and President-Elect became certified CPR trainers over the summer to provide training to incoming first year student pharmacists and student pharmacists who are required to renew their CPR certification. This allows our CPhA chapter to teach student pharmacists essential life-saving skills while also raising money for outreaches that will benefit the community. In anticipation of all the great programming that CPhA will provide throughout the year, board members will be meeting September 6th for strategic planning. It is our hope and goal that we will continue CPhA’s streak of excellence in providing pharmacy services to the public while also advancing the profession of pharmacy.
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