Nov 2016

Volume 3, Issue10

New York State Council Health-system Pharmacists



President's Message

Dear NYSCHP Members,

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Office Staff Abby Curro The NYSCHP 2016 Fall Leadership Weekend was held in the Council's new Albany office on October 22nd and 23rd. Our leadership spent the first day working on development of the Council's next strategic plan. Once finalized, the strategic plan will guide our organization for the next three years. Day two was dedicated to a face-to-face meeting of the Board of Directors. The officers, directors and committee chairs provided reports regarding the numerous facets of NYSCHP.

Now that Election Day 2016 is behind us, our Vice President of Public Policy, Monica Mehta, will have a clearer picture as to the players in the New York State Legislature. With the expertise and guidance of our lobbyist, James Lytle, Esq., Dr. Mehta can better focus our advocacy efforts in anticipation of the next legislative session commencing in January 2017. However, the Council's advocacy efforts have been ongoing throughout the year. Our Executive Director Shaun Flynn and President Joe Pinto have maintained an open dialogue on our legislative priorities with leaders from our fellow New York State pharmacy organizations and stakeholders. Dr. Mehta identified opportunities to make strategic contributions with PAC (political action committee) funds to key New York legislators thereby increasing our visibility and highlighting our efforts to improve patient care for the residents of our state.

Joe Pinto and myself participated in the 2016 ASHP State Affiliate Presidential Officer Retreat in Dallas, Texas on November 14th and 15th. It increased our exposure to issues and trends in our profession across the country. We had the opportunity to interact and exchange ideas with colleagues from more than 20 state associations affiliated with ASHP. We look forward to discussing our findings with our Board of Directors and sharing ideas with our members.

With the holiday season approaching, I implore everyone to plan ahead and take the opportunity to spend some quality time with your loved ones.

Christopher Jadoch
President Elect, NYSCHP

Westchester Chapter Spotlight

You never know how many people would actually participate in a flash mob dance if you make such an impulsive request. I am happy and relieved to say that many of our members are not only well-accomplished and smart, but they are creative and fun-loving too! During the Westchester inauguration party in June, many of our members (and also some members from the NYC chapter) danced to the song "We Go Together" from the movie Grease and everyone had a blast! It was a magical night and I will always be grateful for the love and support that everyone has given me as I was inaugurated to be the president of the Westchester chapter.

As president, some of my goals are to continue our tradition of providing excellent CE programs to our members, to be more active in the participation of community events, and to collaborate more often with our neighboring chapters. I wondered, "What better way to accomplish these goals than to combine them and achieve all of them at the same time?" We have so many talented pharmacists within our own chapter and in the neighboring chapters. Therefore, it would be great to involve everyone in our CE and networking programs. In July, we participated in a fun and enjoyable social mixer hosted by the Royal Counties chapter. In August, the Westchester chapter volunteered at God's Love We Deliver and helped to prepare meals for people who are living with life-altering illnesses. In mid-October, we participated in the Making Strides Against Breast Cancer walk along with the NYC chapter and raised \$2,100 for the American Cancer Society! At the end of October, we participated in a fun-filled hiking trip hosted by the NYC chapter.

We also had a great start with our Fall CE programs and were honored to have Dr. Karen Berger, president-elect from the NYC chapter, as our CE speaker in September. She gave an excellent lecture on anticoagulation reversal in critically ill patients and everyone enjoyed her talk tremendously. In October, we were once again very fortunate to be able to invite our CE speaker from a neighboring chapter. Dr. Robert Berger, treasurer of the Long Island Chapter, gave us a poignant and impactful lecture on the importance of empathy. Since pharmacists are very much involved with the direct care of patients these days, Dr. Berger's lecture on empathy was particularly timely and appropriate for our CE program during Pharmacy Week.

Yes, I believe that we are stronger when we work together! I am excited that more members from our neighboring chapters will be speaking at the Westchester chapter events. Moreover, I am looking forward to many more joint CE programs, networking, as well as social events. I can't wait to see the many more things that we can accomplish when our chapters work together. After all, we are only limited by our own imagination!

Warmly,
Angela Cheng-Lai, PharmD, BCPS
President, Westchester Chapter



Inauguration Party June 2016



Breast Cancer Walk October 2016



God's Love We Deliver



Joint Hiking Trip



Joint Hiking Trip

Clinical Corner

(About: The Clinical Corner is dedicated to the sharing of innovative ideas in pharmacy. It is a way for members to share information that advances the profession of pharmacy. This includes but is not limited to "Best Practices," "Medication Error Prevention," "New Medication Review," "Pharmacy Operational/Systems Enhancements," and many more. We welcome members to submit ideas to the Director of Communications at cmillaressipin@gmail.com.)

Going Bananas over Potassium-binding Agents: Spotlight on Patiromer

By Betty N. Vu, PharmD

Hyperkalemia is an asymptomatic, serious electrolyte abnormality characterized by serum potassium elevation greater than or equal to 6 milliequivalents per liter. Complications of this electrolyte disturbance include arrhythmias and eventually cardiac arrest and death. Hyperkalemia is commonly due to reduced renal excretion of potassium due to acute kidney injury or chronic kidney disease (CKD). Although it occurs in 3.2% of the general population in the United States, the risk of hyperkalemia markedly increases in patients with worsening CKD, particularly in conjunction with heart failure or type 2 diabetes. dispersion of the general population in the United States, and the property of the general population in the United States, the risk of hyperkalemia markedly increases in patients with worsening CKD, particularly in conjunction with heart failure or type 2 diabetes.

For the first time in over 50 years, clinicians now have another option for the treatment of hyperkalemia that is efficacious and appears to be well-tolerated. Patiromer sorbitex calcium, also known as Veltassa®, is a non-absorbed, cross-linked synthetic polymer that selectively binds to potassium and exchanges it for calcium in the distal colon of the gastrointestinal tract, increasing fecal potassium excretion.¹ It was approved by the Food and Drug Administration (FDA) in November 2015 for the treatment of hyperkalemia and was released by the manufacturer in early 2016. Prior to the approval of patiromer, optimal treatment options were lacking. Sodium polystyrene sulfonate (SPS) was the only available potassium binder, approved before the enactment of the Kefauver-Harris Drug Amendment in 1962.²,³ Hence, there are limited randomized controlled trials demonstrating its efficacy and growing concerns of safety, particularly regarding patient tolerance and colonic necrosis.⁴-8 Patiromer's unique mechanism of action and physical properties allow for it to be a useful tool in chronic management of certain patient populations.

A major challenge that many clinicians face in managing these high-risk patient populations is the potential hyperkalemia that may result from the use of renin-angiotensin-aldosterone system (RAAS) inhibitors. The risk of hyperkalemia occurs in approximately 11% of outpatients within one year of initiation of RAAS inhibitors. ¹⁰ In addition, a 2012 national Veterans Affairs surveillance survey estimated that about 36% of patients with diabetic nephropathy have never received RAAS inhibitor therapy, which has been shown to significantly delay progression of CKD. ^{11,12} Diuretics and SPS have been used to increase potassium excretion in these clinical scenarios, although are associated with limitations for chronic use. ¹³

Patiromer was studied in various patient populations on concomitant RAAS inhibitor therapy in several small clinical trials, including patients with heart failure, CKD stage 3 or 4, and diabetic nephropathy in the PEARL-HF, OPAL-HK, and AMETHYST-DN trials, respectively. ¹⁶⁻¹⁸ Across all studies, patiromer demonstrated efficacy in significantly decreasing serum potassium levels compared to placebo. However, both PEARL-HF and OPAL-HK studies were restricted to 12 weeks of treatment. ^{16,17} The AMETHYST-DN study is the longest trial to date, which showed significant reductions of serum potassium levels from baseline that were maintained throughout the 52-week study. ¹⁸ However, discontinuation of patiromer resulted in increased serum potassium levels after three days. Overall, patiromer was well tolerated with low rates of discontinuation secondary to drug-related adverse events. However there were several limitations of the studies

used to evaluate patiromer, including small sample sizes, extensive exclusion criteria, necessity for longer duration of treatment, lack of comparator studies to SPS, and lack of routine management of a low-potassium diet. Even though data in CKD patients is comparable, the role of patiromer in hemodialysis patients is also unclear, as they were excluded from published studies. Further studies are needed to evaluate these patient populations, since they are also at risk of hyperkalemia.

Although clinical trials suggest that the new potassium binder appears to be an efficacious and relatively safe treatment, there were several caveats. Maintenance of normokalemia using patiromer appears to require chronic use as potassium levels elevated within 3-4 days following withdrawal of this agent. Even when compliance is not a barrier, patients will need to be monitored for drug-drug interactions during treatment since patiromer may affect the absorption of other orally-administered medications. Currently, there is a boxed warning that recommends separation patiromer from other oral agents by six hours. Recent studies currently under review by the FDA suggest that three hours may be adequate to avoid any drug-drug interaction with patiromer. Additionally, there is some minimal effect on magnesium absorption observed in rare reports of hypomagnesemia that were non-severe and without electrocardiogram changes. Administration of this medication for emergency, life-threatening severe hyperkalemia situations is not recommended because of its delayed onset of action (~7 hours).

Patiromer is an off-white to light-brown powder for oral suspension, supplied in single dose packets in the following strengths: 8.4 grams, 16.8 grams, and 25.2 grams. Oral dose packets should be stored in the refrigerator or used within 3 months after being removed from refrigeration. The FDA dosing recommendation is as follow: initiate 8.4 grams once daily, with titration in increments of 8.4 grams daily at 1-week intervals to target a desired serum potassium level with a maximum recommended daily dose of 25.2 grams. The average wholesale price of patiromer oral packets is approximately \$35 per packet, which equates to an estimated \$1,050 per month. Oral packets is approximately

As the first novel agent for the treatment of hyperkalemia in over 50 years, patiromer demonstrates a promising and potential revolutionary role in the chronic management of hyperkalemia, particularly in patients with CKD, heart failure, and/or diabetic nephropathy. Its enhanced physical properties, efficacy, and tolerability makes it a favorable option to reduce and sustain potassium levels, while allowing patients on RAAS inhibitors to continue therapy. Further studies are needed with larger sample sizes to determine the full extent of safety concerns and clinical outcomes as well as drug interactions.

About the Author: Dr. Betty Vu wrote this article when she was a PGY1 pharmacy resident at Montefiore Medical Center. She is now a PGY2 pharmacy resident in Infectious Disease at Midwestern University

References

- Veltassa® (patiromer) for oral suspension [package insert]. Redwood City, CA: Relypsa, Inc.; October 2015. US Food and Drug Administration website. http://www.accessdata.fda.gov/ drugsatfda_docs/label/2015/205739s000lbl.pdf. Accessed 2016 Oct 11.
- 2. Greene JA and Podolsky SH. Reform, regulation, and pharmaceuticals The Kefauver-Harris amendments at 50. *N Engl J Med.* 2012; 367:1481-3.
- 3. Kayexelate (sodium polystyrene) [package insert]. Bridgewater, NJ: Sanofi-Aventis US LLC; revised December 2010. US Food and Drug Administration website. http://www.accessdata.fda.gov/drugsatfda_docs/;abe;/2001/011287s023lbl.pdf. Accessed 2016 Oct 11.
- 4. Sterns RH, Rojas M, Bernstein P, Chennupati S. Ion-exchange resins for the treatment of hyperkalemia: are they safe and effective? *J Am Soc Nephrol*. 2010;21(5):733-5.
- 5. Gerstman BB, Kirkman R, Platt R. Intestinal necrosis associated with postoperative orally administered sodium polystyrene sulfonate in sorbitol. *Am J Kidney Dis* 1992;20(2):159-61.
- 6. Flinn RB, Merrill JP, Welzant WB. Treatment of the oliguric patient with a new sodium-exchange resin and sorbitol: a preliminary report. *New Eng J Med* 1961; 264:111-5.

- 7. Harel Z, Harel S, Shah PS et al. Gastrointestinal adverse events with sodium polystyrene sulfonate (Kayexelate) use: a systemic review. *Am J Med* 2013; 126:264.9-24.
- 8. FDA. Kayexalate (sodium polystyrene sulfonate) powder detailed view: safety labeling changes approved by FDA Center for Drug Evaluation and Research (CDER). 2011. http://www.fda.gov/safety/medwatch/safetyinformation/ucm186845.htm. Accessed 2016 Oct 11.
- 9. Weiner ID, Wingo CS. Hyperkalemia: A potential silent killer. J Am Soc Nephrol. 1998; 9:1535-43.
- 10. Einhorn LM, Zhan M, Walker LD, Moen MF, Seliger SL, Weir MR, et al. The frequency of hyperkalemia and its significance in chronic kidney disease. *Arch Intern Med.* 2009;169(12):1156-62.
- 11. Albert NM, Yancy CW, Liang Li, Zhao X, et al. Use of aldosterone antagonists in heart failure. JAMA. 2009;302(15):1658-65.
- 12. Xie X, Liu Y, Pekovic V, Li X, Ninomiya T, et al. Renin-angiotensin system inhibitors and kidney and cardiovascular outcomes in patients with CKD: a Bayesian network meta-analysis of randomized controlled trials. *Am J Kidney Dis*. 2016; 67(5):728-41.
- 13. Centers for Disease Control and Prevention (CDC). Chronic Kidney Disease Surveillance System United States. Website. https://nccd.cdc.gov/ckd/detail.aspx?QNum=Q606 . Accessed 2016 Oct 11.
- 14. Pitt B, Zannad F, Remme WJ, Cody R, Castaigne A, Perez A, Palensky J, Wittes J; Randomized Aldactone Evaluation Study Investigators: The effect of spironolactone on morbidity and mortality in patients with severe heart failure. *N Engl J Med.* 1999;341: 709-17.
- 15. Palmer BF. Managing hyperkalemia caused by inhibitors of the renin-angiotensin-aldosterone system. *N Engl J Med*. 2004;351(6):585-592.
- 16. Pitt B, Bakris GL, Bushinsky DA, Garza D, Mayo MR, Stasiv Y, Christ-Schimdt H, Berman L, Weir MR. Evaluation of the efficacy and safety of RLY5016, a polymeric potassium binder, in a double-blind, placebo-controlled study in patients with chronic heart failure (the PEARL-HF) trial. *Eur J Heart Fail*. 2011;32(7):820-8.
- 17. Weir MR, Bakris GL, Bushinsky DA, Mayo MR, Garza D, Stasiv Y, Wittes J, Christ-Schmidt H, Berman L, Pitt B. OPAK-HK Investigators. Patiromer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors. *N Engl J Med*. 2015;372(2):211-21.
- 18. Bakris GL, Pitt B, Weir MR, Freeman MW, Mayo MR, Garza D, Stasiv Y, Zawadzki R, Berman L, Bushinsky DA, AMETHYST-DN Investigators. Effect of patiromer on serum potassium level in patients with hyperkalemia and diabetic kidney disease: The AMETHYST-DN randomized clinical trial. *JAMA*. 2015;314(2):151-61.
- Arnold C. Relypsa announces results from Veltassa drug-drug interaction studies in healthy volunteers. Relypsa. Jan 25 2016. http://investor.relypsa.com/releasedetail.cfm?releaseid=951581. Accessed 2016 Oct 11.
- 20. Bushinsky DA, Williams GH, Pitt B, Weir MR, Freeman MW, Garza D, Stasiv, Li E, Berman L, and Bakris GL. Patiromer induces rapid and sustained potassium lowering in patients with chronic kidney disease and hyperkalemia. *Kidney Int*. 2015;88: 1427-33.
- 21. Patiromer: drug information. UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed 2016 Oct 11.

NYSCHP Downstate Critical Care Symposium

On October 14, 2016, Mount Sinai Beth Israel Medical Center hosted the 5th annual NYSCHP Downstate Critical Care Conference. In attendance was a mix of critical care pharmacists, residents, and students. All lectures and sessions throughout the day were led by pharmacists from our local New York City area hospitals. The event opened with a series of continuing education presentations.

- Dr. Caroline Der-Nigoghossian of New York-Presbyterian Hospital, The Allen Hospital, gave a talk titled "Endocrine Emergencies" and very expertly covered a broad array of endocrine topics, notably pancreatic (diabetic ketoacidosis vs hyperosmolar hyperglycemic state), thyroid (thyroid storm/thyrotoxicosis vs myxedema coma), and adrenal (adrenal insufficiency vs adrenal crisis).
- Dr. Henry Cohen, Dean of the Touro College of Pharmacy, presented a segment called "Pharmacy Administration Primer: Medication Safety in the ICU" and discussed examples of medication errors vs adverse drug reactions vs adverse drug events, using real-time examples from programs implemented at Kingsbrook Jewish Medical Center to illustrate these key concepts.

New to this year's programming was the resident Hot Topics talks, featuring 15-minute clinical pearls presentations given by three local PGY2 Critical Care pharmacy residents. This was a hugely successful part of the day's events, and it will hopefully get adopted into next year's programming too!

Our resident presenters and their topics were:

- Diana Gritsenko, PGY2 Critical Care pharmacy resident at Touro College of Pharmacy/Mount Sinai Beth Israel, "A Breath of Fresh Air: Inhaled Antibiotics for Hospital-Acquired and Ventilator-Associated Pneumonia"
- Brittany (Kalemkarian) Verkerk, PGY2 Critical Care pharmacy resident at New York-Presbyterian Hospital, "Alteplase for Submassive Pulmonary Embolism"
- Rebecca Fletcher, PGY2 Critical Care pharmacy resident at Kingsbrook Jewish Medical Center, "Should We Be Using the VSE (Vasopressin-Steroids-Epinephrine) Bundle?"



The afternoon programming wrapped up with two additional sessions, venturing first into toxicology and then into infectious diseases.

- Dr. Gabrielle Procopio of Hackensack University Medical Center presented a segment titled "Tox Tidbits: Antidotes and Beyond," where she effectively highlighted how toxicology management concepts permeate many areas of pharmacy practice, especially critical care, and how all clinical pharmacists can benefit from knowledge of basic toxicology concepts and antidotes for gastric contamination i.e., activated charcoal.
- Dr. George Rodriguez of New York-Presbyterian Hospital, Queens Hospital, presented about "New and Emerging Therapies for Gram Negative Infections," a concept of much interest given the relative lack of any new antimicrobials in development, especially new agents with a novel mechanism of action. He focused on agents in Phase II and III development as well as agents that specifically target the beta-lactamases and other hydrolytic enzymes that have traditionally been very difficult to counteract with our existing antibiotics.

These talks represented concepts that we can use at our clinical sites, in our own daily practice, and when educating others.

Melissa Santibañez, PharmD PGY2 Critical Care Pharmacy Resident New York-Presbyterian Hospital



Are you creative? Do you doodle a lot on paper? Do you want to be part of history?

NYSCHP is seeking to rebrand, redesign, and revitalize our logo.

It's time for a change and we need you!

You do not have to be a computer graphics designer to submit an entry.

A hand-drawn idea of a logo will work!

Just scan or take a photo of it with your phone, and submit.

It's that simple.

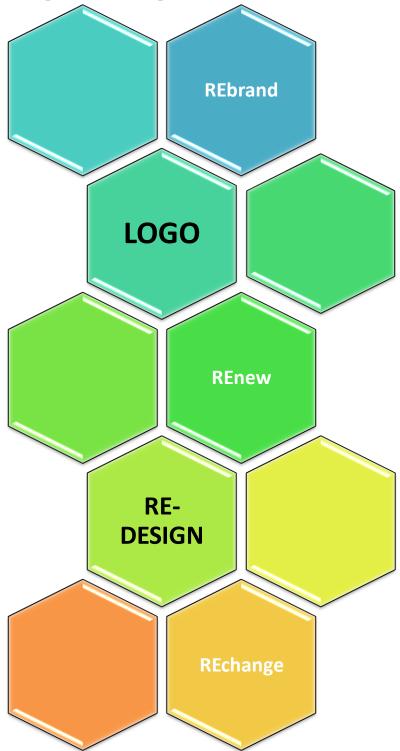
The winning design will be enhanced by a professional graphic designer for NYSCHP use. The winner's prize: one-year FREE membership or FREE registration to the Annual Assembly!

STUDENTS are welcome to enter this contest. Submit your entry soon!

For contest rules and information, please visit http://www.nyschp.org/page/2016LogoRedesign

Deadline is November 30th, 2016
Submit your entry to: sflynn@nyschp.org or cmillaressipin@gmail.com

Will your Logo Design Be the One?



It's not too late to submit your design

Submit your entry to: SFlynn@nyschp.org OR cmillaressipin@gmail.com

It's that time again... to submit your resolutions

Deadline for Submission: February 3rd, 2017

RESOLUTIONS*

Actions of the New York State Council of Health-system Pharmacists are expressed as resolutions submitted in writing according to the Regulations of the NYSCHP House. Resolutions may register an opinion or may recommend action be taken by the NYSCHP. The resolution should be clear, concise and specific. The substance should be well researched, and reflect the character and interests of the NYSCHP and the pharmacy profession.

Each resolution should be written in a common format. Each resolution has three (3) parts: the heading, the preamble and the operative clause. It is one long sentence with commas and semicolons throughout the resolution, with a period at the very end. All operative clauses end with a semicolon except the final clause, which ends in a period.

HEADING

Committee: i.e. the committee in which the resolution is introduced.

Topic: the topic of the resolution

Sponsored by: List the sponsors whose signatures appear at the bottom of the resolution.

PREAMBLE

The purpose of the preamble is to demonstrate that there is a problem that needs to be solved or resolved. The preamble of the resolution does everything but propose the action or make any substantive statement in the topic at hand. Each clause of the preamble begins with "Whereas" followed by a comma and the next word should begin with a capital letter. The preamble, regardless of how many paragraphs should never contain a period. The last paragraph of the preamble should close with a semicolon, after which a connecting expression, such as "therefore, be it: or "now therefore be it" can be added. The statements contained in the "Whereas" clause have no legal effect.

OPERATIVE CLAUSE

Operative clauses are set to achieve the NYSCHP's main policy or goals on the topic. Each operative clause ends with a semicolon and the final clause ends with a period. Operative clauses should be organized in a logical progression and each clause should contain a single idea or policy proposal. The word resolved is printed in italics and is followed by a comma and the word "That" should begin with a capital "T". If there is more than one resolving clause, each clause should be in a separate paragraph. Each paragraph begins with the word "Resolved, That". A resolving paragraph should not contain a period within the paragraph.

Whereas, The... [text of the preamble]; now, therefore, be it *Resolved* That ... [stating action to be taken].

*The Standard Code of Parliamentary Procedure; Alice Sturgis, The New Robert's Rules of Order.

Sample Resolution

Roy Guharoy Russell Yandon

Committee: Central New York Chapter of Health-system Pharmacists Topic: Certification of technicians in New York State Sponsored: Roy Guharoy, Russell Yandon Registration of Pharmacy Technicians Whereas, Hospital pharmacists have moved into clinical patient-care roles requiring more freedom from distribution, dispensing and manual tasks, and, Whereas, Pharmacy technicians are being increasingly used to perform such work, and, Whereas, There are large numbers of technicians working in hospitals in New York State over the past couple of decades; many in long-term employment, and, Whereas, Pharmacy technicians give valuable support which enables pharmacists to use their cognitive services for better patient care, and, Whereas, While not requiring knowledge framework of a pharmacist, the duties performed by technicians are often crucial; involving precision, trust, risk and excellence, and, oversight and regulation would be helpful for patient safety and quality of care, and, Whereas, More technician participation and recognition should increase progress, accountability, efficiency, and job satisfaction in pharmacy practice, therefore, be it Resolved That: The New York State Council of Health-system Pharmacists supports registration of all pharmacy technicians in New York State. Date: _____

Resolutions should be emailed to Shaun Flynn, sflynn@nyschp.org.

NYSCHP and Local Chapter Upcoming Events

November

- November 19th: RASHP CE Program
- November 20th: NYCSHP Brown Bag Event
- November 30th: Westchester CE Program

December

- December 13th: NYCSHP CE Program
- December 14th: WCSHP CE Program

January 2017

• January 18th: LISHP CE Program

February 2017

• February 15th: LISHP CE Program

March

• March 14th: LISHP CE Program

April 2017

• April 28th: NYSCHP 56th Annual Assembly

June 2017

• June 27th: LISHP Installation Dinner and CE Program



From NYSCHP
Board of Directors and
Executive Office