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New York State Council Health-system Pharmacists



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President's Message

Dear NYSCHP Members,

I hope everyone is enjoying the summer and staying cool as we work through the heat wave. I have to be honest, I have writer's block. I've been trying to come up with a topic to write about and share with you, but I have nothing. I think my brain left for vacation before my body. So I asked one of the manager's, Alina Levitsky here at Mount Sinai Beth Israel, to give me an idea. I said, "Levitsky, what should I write about for the NYSCHP News Brief?" "What were you thinking of?" Levitsky replied. I said, "I don't know, I have nothing," to which she responded, "then write about nothing." I thought, if Jerry Seinfeld and George Costanza can write a fictional sitcom about nothing, then I should be able to write an article in a News Brief about nothing.

I'm sure by now you have seen that Peyton Manning will be giving the keynote address at the ASHP Midyear Conference in Las Vegas. Personally, I think they read my News Brief piece from February, 2016 where I wrote about Manning, his leadership, and said Peyton would be a great keynote speaker. But I may be biased.

There is an editor's note from a Harvard Business Review article; *Leading Change: Why Transformation Efforts Fail*, written by John Kotter. The note reads, "Guiding change may be the ultimate test of a leader- no business survives over the long term if it can't reinvent itself." As you know, the NYSCHP has started our remodeling project of reinventing our self. As we announced at the end of June, we have entered into an agreement with Capitol Hill Management to assist Shaun in managing the day-to-day operations of the Council. This will allow Shaun to network and promote the organization with our legislators and other stakeholders. We have begun the process of reaching out to local media outlets and educating them on what we, Health-System Pharmacists, have to offer when there are questions about medications and healthcare in general. I hope you are ready when we call you to put your face on the big screen or your James Earl Jones voice on the radio! Have you started to work on submitting an entry for our new logo competition? Get your crayons and markers out. I know we have some creative members out there. Lastly, the Board of Directors will be meeting in October to construct our strategic plan for the next three years. This will serve as our compass guiding us to our future state.

As I have mentioned numerous times both in print and at meetings, I really want to see involvement from our membership. Please share your ideas either locally at your chapters or email me, or any one of our board members about how we may improve our organization. We want to be the best, and we want you to experience the best, but that will not happen unless we all get involved.

Have a great rest of the summer. I hope to see you at one of our upcoming programs or when I get to one of your chapter board meetings or educational programs.

So were the first 2 paragraphs about nothing as good as Seinfeld?

Joseph Pinto
President, NYSCHP

Legislative Update

One Step Forward, Two Steps Back...Then Sprint!

By Monica Mehta, PharmD, MPH, BCPS
Vice President, Public Policy
NYSCHP



As more states achieve pharmacy practice expansion throughout the country (e.g. provider status in Colorado, pharmacy technician certification in New Jersey, and ability to dispense oral contraceptives without a prescription in California – just to name a few), we in New York continue to stand watching and waiting our turn. *Always the bridesmaid...*

You may be aware that NYSCHP's legislative priority for the spring/summer 2016 legislative session was to establish pharmacy technician registration and certification. At present, we have no registration, education, competency, or age requirements for folks to practice as pharmacy technicians. In the context of medication errors and drug diversion, this remains a troublesome fact to many of our members. Also, if we can mobilize technicians to a higher standard, we can be liberated to do more clinical work (less dispensing and more educating and driving pharmacotherapy).

We were unsuccessful at passing the legislation. However, we made great strides that we hope to capitalize on in the coming year! To review, the bill was a bifurcated one in which pharmacy technicians in community settings required registration only (a minimum standard), but those who worked health-systems or conducted compounding required certification (a higher standard). The division was one of many sticking points between the pharmacy groups: Pharmacists Society of the State of New York (PSSNY) vs. New York State Council of Health System Pharmacists (NYSCHP), but we collaborated to iron out our differences and reach a mutually accepted bill. This is a triumph to be proud of.

Our profession will not move forward if we continue to be divided. Even in college, we are routed to “retail” or “hospital,” which I believe to be a false dichotomy – both misleading (there are so many more options!) and divisive. Plus, community pharmacists are the face of our profession. When we walk into the office of a legislator, they see us as pharmacists (like the one on their corner). When we meet someone at a party and they ask what you do (to which you reply “pharmacist”) their next question is, “which store?” – almost invariably! We stand or fall together.

All this is to say – we can stand taller and create an impact (read: pass legislation) if every NYSCHP member and PSSNY member had the same voice and used that voice.

Ultimately, the bill came to a screaming halt because we did not have total support of 1199. They wanted more liberal grandfathering than we were comfortable with. This is where ongoing discussions begin. We are engaging stakeholders earlier for next year. But you have to do your part...



It's easy to be disappointed in lack of practice expansion in New York, but we are all responsible for that. When is the last time you wrote your local legislator? Or visited them? Pharmacists may tend to be introverted, but I know us to be powerful when we feel strongly about something. Like calling a prescriber when we know that an order can be deleterious to our patient. I believe that not practicing at the height of our license is deleterious to our patients. And leads to ADRs, readmissions, and inadequate management of disease (all the stuff you already know). You took pharmacology and pharmacotherapeutics for a reason!

My wish list for our organization:

- ✓ Every one of our ~2,000 members writes a letter to a legislator
- ✓ Every one of our ~2,000 members signs this form for pharmacy federal provider status under Medicare Part B: <http://cqrcengage.com/ashp/app/write-a-letter?0&engagementId=76964>
- ✓ Every chapter host a fundraiser for our PAC
- ✓ Every chapter gets groups together to visit legislators (seasoned folks take newbies)
- ✓ Academic institutions and novel practices invite legislators to their workplace

If you're doing any of these things, please let me know. I would love to hear these stories. And support your work. Remember; ask not what NYSCHP can do for you, but what you can do for NYSCHP.



Royal Counties Spotlight

Hello from the Royal Counties Chapter of Brooklyn, Queens, and Staten Island! I would like to congratulate and welcome our new executive board members, President-Elect Deep Patel, Secretary Nina Chhabra, Treasurer Natalie Ho, and Director-at-Large Sal Ventrice- I am confident that we will have a great year! I would also like to acknowledge our outgoing board, Ashley Galla, Elizabeth Chung, Miri Mineh, Sal Ventrice, and Agnes Cha, and everyone else on our board for their fresh ideas and tireless dedication.

Thank you to all that participated in our educational programming this past year. The Quad Meeting, held this April at the Astoria World Manor, was a successful event and a fun time. It was complete with great networking opportunities as there were over 200 guests in attendance, informative booths from approximately 17 exhibitors, and a continuing education presentation given by Fernando Gonzalez on the topic of pharmacy law. We continued with the tradition of holding our installation ceremony at Russo's on the Bay in Howard Beach, where we recognized our chapter's residents with a photo montage, lovely words from their preceptors, and small gifts. This year, we rounded out the evening by having four of these residents each discuss a new drug. We are excited to see this program continue to grow as new ideas are put into play and more members become involved. The Regional Residency Conference was also held this June at Long Island University, with collaborative efforts between Royals, NYC, and Long Island Chapters. It was a rewarding day with excellent presentations by more than 90 residents, keynote presentations, raffles, and outdoor lunch.

Last winter we hosted a coat drive with drop off locations at Long Island Jewish Medical Center, the Brooklyn VA, and The Brooklyn Hospital Center. We successfully donated 50 coats to New York Cares. We are planning to make involvement in NY Cares an annual project and we would love to reach even more New Yorkers and participate in service events around the community.

Royals is excited to kick the year off by joining our neighboring chapters (NYC, LI, Westchester) in a "Quad Social Mixer" that we are hosting in Queens, filled with arcade and table games, food, and a great chance to mingle with new and old friends alike! We are also hosting a networking event at Fushimi in Williamsburg, which will have a presentation on an increasingly important topic – transitions of care. In the spirit of these events, one of our goals this year includes increasing our collaboration with our neighboring chapters. We are also planning to expand the locations of our meetings so that we can better serve our geographical region- so look out for more programs in your area!

Happy summer!

Jaclyn Scott, PharmD

President, Royal Counties Chapter

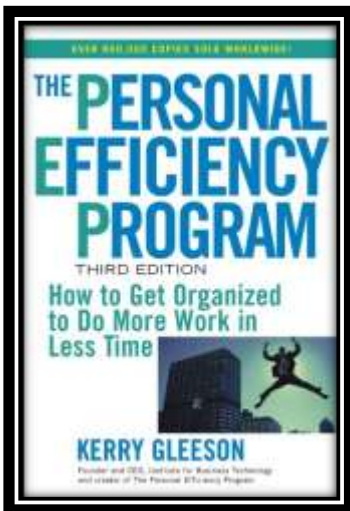


Book Review

The Personal Efficiency Program: How to Get Organized to Do More Work in Less Time

By Kerry Gleeson

Review by: Catherine A. Millares-Sipin



Most of us would agree that time management is one of the most challenging skills to master. Whether you are a student, professor, clinical pharmacist, pharmacy manager, executive, or director, time management is key to becoming successful. But how can we be more efficient with our time?

Do you typically do this? You have a long list of things to do for the day, but when you get to your office the first thing you do is check your email inbox. Then, you immediately feel the need to respond to these emails right away. Next thing you know, you've spent most of your time replying to emails and not getting to your to-do list. Guess what, you are not alone. Many of us have this bad habit. In fact, we develop many bad habits like this at work: texting, checking emails on smartphones, writing and rewriting to-do lists, working on a cluttered desk with files that need to be stored or addressed, etc.

With the advent of technology, email at our fingertips, and the ability to text and call anyone at anytime, it is surprising we get anything done! The constant interruption, the need to respond immediately to emails, and the overwhelming amount of data that we need to process on a day-to-day basis causes a lot of stress and slows down our productivity. But this is just the tip of the iceberg.

In my quest to find a better way to manage my time, I stumbled upon this book. It was available at the public library as an e-book and audio book (score!). I downloaded both versions. At first I was skeptical about what I would learn that I have not heard or read before, like keeping a log book (which was suggested), keeping a to-do-list, keeping a calendar, etc. Well, I was pleasantly surprised with the tools the author suggested.

The book contained many mantras such as the 4Ds, which stands for "Do it now," "Delegate," "Designate," and "Discard." **Do it now** if the work can be done right away, **Delegate** the work that should be done by another party, **Designate** a time to work on projects that require more time, and **Discard** (or store) data/email or projects that are no longer needed. The book provides more detail on the 4D approach and ways one can apply it to one's workflow. After a month of applying the 4D approach to my work, I can honestly say that I feel more accomplished and less overwhelmed.

The book also provided some great suggestions on how to manage and store electronic and paper data, like the tickler file and the monthly file, which I also applied to storing my own electronic data. Once again, I was pleased to find that these ideas actually work. How about handling of emails and phone calls? The author has some wonderful suggestions on how to better handle them so that they won't cause many interruptions in your workflow, like setting set scheduled times when they should be handled.

I thought that the book was very useful. It is easy to follow and can be applied to many situations. If you are a busy bee like me, consider reading this book!



Nominations Committee

Do you want to be at the forefront of advancing pharmacy as an essential component of health care in New York State? The Nominations Committee is beginning its task of identifying the next round of candidates for future roles on the NYSCHP Board of Directors. All Board positions have a two-year term of office, except the President, which is a 3-year term (President-Elect, President and Immediate Past President). Although it seems counter-intuitive, the Nominations Committee will be seeking candidates to fill the positions below, for which members were just installed at the 2016 Annual Assembly. This ballot will be sent to members during the summer of 2017 and the elected members will be installed at the Annual Assembly in 2018. The only exception is the Vice-President of Public Policy who is voted into office by the 2017 House of Delegates, and will resume the office immediately thereafter.

- Vice-President of Public Policy (2017-19)
- Director of Education and Workforce Development (2018-20)
- Director of Industry Affairs (2018-20)
- Director of Pharmacy Practice (2018-20)

And of course -

- President-Elect (2018), who will also be President (2019) and Immediate Past President (2020)

When identifying potential candidates for NYSCHP Board of Director positions, the following qualities are given the utmost consideration:

- Demonstrated leadership qualities and exemplary practice
- Demonstrated interest in the affairs of NYSCHP
- Experience as an officer of a local chapter

We are seeking at least two qualified candidates for each position and we are especially looking for future leaders, mentors and role models for health-system pharmacy in New York State. Duties, responsibilities and time commitment are described in the document **NYSCHP Candidate Guide to Nominations** on the NYSCHP website (under About Us/Board of Directors). If you would like to nominate yourself or someone else for any of these positions, please send an email to sseyse@kaleidahealth.org no later than October 1.

Stephanie Seyse

Immediate Past President, NYSCHP



Clinical Corner

(About: The Clinical Corner is dedicated to sharing of innovative ideas in pharmacy. It is a way for members to share information that advances the profession of pharmacy. This includes but 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 Catherine.millares-sipin@touro.edu.)

Andexanet Alfa – A Potential Antidote for the Reversal of Factor Xa Inhibitors

by Bejoy Maniara, Sweta Patel, and Caitlyn Cummings
PGY-1 residents, Long Island Jewish Medical Center

For many years, the world of anticoagulation has been faced with a conundrum. A variety of patients require anticoagulation, whether for stroke prevention in atrial fibrillation, treatment and secondary prevention of venous thromboembolism (VTE), or prevention of VTE after total hip or total knee arthroplasty. Regardless of the indication, the benefit of reduced mortality must be weighed against the risk of bleed. Unfortunately, not all anticoagulants currently have an antidote to reverse bleed, but this may change in the near future.¹

There are currently several pharmacologic options for routine anticoagulation approved by the U.S. Food and Drug Administration (FDA), including a vitamin K antagonist (warfarin), heparin, low molecular weight heparins (enoxaparin, dalteparin, tinzaparin), a direct thrombin inhibitor (dabigatran), and factor Xa (fXa) inhibitors (rivaroxaban, apixaban, edoxaban, fondaparinux). If any of these anticoagulants are inappropriately used, negative outcomes may occur. Doses that are too low may increase the risk of developing a clot, while doses that are too high may increase the risk of bleed, though bleeding can occur at any dose.¹ If bleeding occurs, it is important to be able to reverse the bleed. Although many of the FDA-approved anticoagulants currently have antidotes to reverse bleeds, there are currently no FDA-approved agents to reverse the anticoagulant effects of fXa inhibitors.²

Portola Pharmaceuticals has developed andexanet alfa, a recombinant protein, to reverse the anticoagulant effects of both direct fXa inhibitors (rivaroxaban, apixaban, edoxaban) and indirect fXa inhibitors (enoxaparin, dalteparin, tinzaparin, fondaparinux). This medication would be intended for patients who experience serious uncontrolled bleeding, or for patients who require immediate surgery while on a fXa inhibitor. Although andexanet alfa has not yet been FDA-approved, it addresses an unmet need and has the potential to save the lives of individuals who bleed while using direct or indirect fXa inhibitors.³

In order to understand how andexanet alfa works, it is imperative to understand the common pathway of the coagulation cascade, and the mechanism of action of fXa inhibitors. fXa is a serine protease that catalyzes prothrombin (fII) to thrombin (fIIa). fIIa then catalyzes fibrinogen (fI) to fibrin (fIa). Factor XIIIa finally converts fibrin to a stable cross-linked fibrin clot, allowing for natural endogenous coagulation. fXa inhibitors work by

inhibiting fXa, thereby reducing the formation of fIIa and fIa, ultimately reducing natural endogenous coagulation by decreasing stable cross-linked fibrin clot formation. It is important to note that fXa inhibitors must bind to fXa in order to prevent fXa from catalyzing fII to fIIa. Low molecular weight heparins and fondaparinux function as indirect fXa inhibitors, as they regulate antithrombin III, a serine protease inhibitor, to inhibit fXa. Andexanet alfa works by acting as a “decoy receptor,” binding to the fXa inhibitor, and reducing unbound plasma levels of the anticoagulants, subsequently preventing fXa inhibition. Once fXa inhibitors bind to andexanet alfa, the fXa inhibitors are unable to bind to and inhibit endogenous fXa. This would enable the natural coagulation cascade to continue forming stable cross-linked fibrin clots.^{4,5}

Two phase 3 randomized, double-blind, placebo-controlled studies (ANNEXA-A and ANNEXA-R) were conducted in reasonably healthy, older subjects (n=145: apixaban – 48, rivaroxaban 53, placebo - 44) to assess the use of andexanet alfa in the reversal of the anticoagulant effects of rivaroxaban and apixaban. Outcome measures were similar in both studies, with a primary outcome of anticoagulant effect measured by mean percent change in anti-fXa activity, both after a bolus and after a bolus plus 2-hour continuous infusion. Secondary outcomes included unbound plasma concentration of the fXa inhibitors and incidence of thrombin generation. Patients exhibited substantial and rapid decreases in anti-fXa activity within 2 to 5 minutes with the use of andexanet alfa bolus compared to placebo in both the apixaban study ($93.9 \pm 1.7\%$ vs. $20.7 \pm 8.6\%$, $p < 0.001$) and the rivaroxaban study ($92.2 \pm 10.7\%$ vs. $18.4 \pm 14.7\%$, $p < 0.001$). Effects on anti-fXa activity were similar with the bolus plus infusion strategy compared to placebo. The results of the primary and secondary outcomes of the ANNEXA studies are provided in Table 1. There were no severe adverse events or thrombotic events reported. Mild adverse events included constipation, dysgeusia, and sensations of warmth and flushing. It is important to note that the doses of andexanet alfa used in ANNEXA varied by which fXa inhibitor was used.⁵

Andexanet alfa has portrayed swift and substantial reductions in anti-fXa activity and in unbound concentrations of rivaroxaban and apixaban, facilitating the return to normal endogenous coagulation through the formation of stable cross-linked fibrin clots. Despite these positive surrogate markers, and the great promise it delineates, the true efficacy and safety of andexanet alfa in patients who require urgent reversal of fXa inhibitor activity has not yet been studied.⁵ However, there is currently an ongoing study (ANNEXA-4: ClinicalTrials.gov number NCT02329327) that is recruiting patients who experience acute major bleed requiring reversal of anticoagulation, to study the effects of andexanet alfa in patients receiving an indirect or direct factor Xa inhibitor. Patients receiving apixaban, rivaroxaban, edoxaban, or enoxaparin within 18 hours prior to andexanet alfa infusion are all included in the study, and the primary outcome is the proportion of patients with excellent or good hemostasis. ANNEXA-4 is expected to be completed by November 2022.⁶

As of February 2016, the Center for Biologics Evaluation and Research of the U.S. Food and Drug Administration has accessed the Biologics License application for andexanet alfa. The FDA is expected to take action on the application by August 17, 2016.³ According to the drug manufacturer (Donna Hesari, in-person communication, July 14, 2016), if andexanet alfa were to be approved by the FDA, it is likely that distribution and criteria for use of the medication may be limited, as the medication is difficult and expensive to produce.

Table 1: Primary & Secondary Outcomes

Primary Outcome	ANNEXA-A				ANNEXA-R			
	Bolus		Bolus + 2-hour infusion		Bolus		Bolus + 2-hour infusion	
	Andexanet (n=24)	Placebo (n=9)	Andexanet (n=23)	Placebo (n=8)	Andexanet (n=24)	Placebo (n=14)	Andexanet (n=26)	Placebo (n=13)
Percent change in anti-factor Xa activity (mean \pm SD reduction)	-93.9 \pm 1.7%	-20.7 \pm 8.6%	-92.3 \pm 2.8%	-32.7 \pm 5.6%	-92.2 \pm 10.7%	-18.4 \pm 14.7%	-96.7 \pm 1.8%	-44.8 \pm 11.7%
	P<0.001		P<0.001		P<0.001		P<0.001	
Secondary Outcomes	Andexanet (n=24)	Placebo (n=9)	Andexanet (n=23)	Placebo (n=8)	Andexanet (n=24)	Placebo (n=14)	Andexanet (n=26)	Placebo (n=13)
Mean (SD) change in FXa inhibitor free fraction to nadir (ng/mL)	-9.3 (3.2)	-1.9 (1.6)	-6.5 (2.8)	3.0 (1.2)	23.4 (6.2)	-4.2 (2.9)	-30.3 (8.1)	-12.1 (5.3)
	P<0.001		P<0.001		P<0.001		P<0.001	
Mean (SD) change in thrombin generation to peak (nM \cdot min)	1323.2 (335.4)	88.2 (125.8)	1193.1 (263.3)	189.4 (184.8)	1314.2 (331.2)	173.9 (104.2)	1510.4 (344.8)	264.4 (140.7)
	P<0.001		P<0.001		P<0.001		P<0.001	

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6. Portola Pharmaceuticals. A Study in Patients with Acute Major Bleeding to Evaluate the Ability of Andexanet Alfa to Reverse the Anticoagulation Effect of Direct and Indirect Oral Anticoagulants. In: *ClinicalTrials.gov* [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-2016 Jul 28. Available from: <https://clinicaltrials.gov/ct2/show/NCT02329327>.

NYSCHP and Local Chapter Upcoming Events

August

- August 10th: Royal Counties Networking Event
- August 11th: NYCSHP Networking Program
- August 18th: NYCSHP CE Program
- August 25th: NYCSHP CE Program
- August 26th: NYSCHP Downstate Student Program: Staying “A Step Ahead”

September

- September 8th: NYCSHP Networking Program
- September 13th: LISHP CE Program
- September 13th: Royal Counties CE Program
- September 20th: Royal Counties CE Program
- September 28th: NYCSHP Industry Relations
- September 30th: Tri-State Meeting

October

- October 13th: NYCSHP Networking Program
- October 20th: NYCSHP Networking Program
- October 14th: Downstate Critical Care Program
- October 15th: Upstate Critical Care Program
- October 27th: LISHP CE Program
- October 27th: Royal Counties CE Program
- October 27th: NYCSHP CE Program

April

- April 28th: NYSCHP 56th Annual Assembly





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 their logo.
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!

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

Deadline is November 30th, 2016

Submit your entry to: Catherine.millares-sipin@touro.edu or
sflynn@nyschp.org
