PCSANM and COVID-19, Part 2

As COVID-19 pandemic continues, the Prostate Cancer Support Association of New Mexico (PCSANM) would like to inform our members and the public about our approach to promoting health and safety. As many of those who visit us are particularly vulnerable to COVID-19, taking special precautions is essential.

As an initial response, in March 2020 we closed our office to prevent direct contact between people. We continued our services of supporting patients by phone and web-based references. In addition, our bi-monthly, in-person meetings were transformed into web-based meetings, allowing a space for members to share their experiences and for medical professionals to present on prostate cancer treatments.

On September 1, PCSANM re-opened its office, maintaining regular Monday-Thursday, 10 a.m.-2 p.m. hours. By following CDC and New Mexico Department of Health (DOH) safety precautions and protocols, such as asking standard COVID-related questions, taking visitors’ temperatures, requiring face coverings at all times, providing hand sanitizer, and limiting the number of visitors allowed in the office, we strive to create a safe environment for all.

Many aspects of the support members need is best provided in person. We, therefore, have re-opened our library and made our conference room available for use by those needing to meet with one of our trained facilitators. Only three persons at a time are permitted in this space, and all safety protocols must be followed. Appointments are preferred.

For the foreseeable future, we will continue to meet virtually on the first and third Saturdays of the month using GoToMeeting. When large group gatherings are permitted and venues become available, we will reconsider the possibility of in-person meetings.

PCSANM is dedicated to following CDC and DOH guidelines to protect members and guests from infection by COVID-19. When the guidelines change, whether they become more relaxed or more stringent, we will comply. Check our website, pcsanm.org, for current information.
Special thanks to Presbyterian Healthcare Services for its generous support of this newsletter.

Board Members

Rod Geer, Chair
Charles Rowland, Vice-Chair
David Turner, Treasurer
Audrey Sniegowski, Secretary
Lou Reimer, Programs Chair
Gene Brooks
Kat Lopez
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Prostate Cancer Support Contacts Around the State

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PCSANM provides education, information and support, not medical advice. Please contact your physician for all your medical concerns.

PCSANM does not endorse or approve, and assumes no responsibility for, the content, accuracy, or completeness of the information presented.

Articles are selected from a variety of sources to give as wide a range of content as possible.

They are provided for information only and are not endorsements. Information expressed in this newsletter are not recommendations for any medical treatment or course of action by PCSANM.
The Prostate Cancer Support Association of New Mexico will hold its ninth annual conference for the purpose of providing knowledge to our members and the public regarding the latest developments in the diagnosis and treatment of prostate cancer. The conference will focus on the needs of two groups of potential conference attendees: 1) those wanting to learn about the options for prostate cancer diagnosis and treatment, and 2) physicians, nurse practitioners and physician assistants serving in remote practices in New Mexico.

Unlike previous conferences, and in compliance with COVID-19 pandemic guidelines, our 2020 conference will be virtual with pre-recorded and live presentations using ZOOM Webinar.

This FREE program will be held on two Saturdays in November, the 7th and 14th. The first day of the program will cover the signs of prostate cancer and the tools available to the primary care provider, followed by pathologists’ reading of biopsies, and wrapping up with a talk on how the medical community puts all information together to create a risk assessment for the prostate cancer patient. The program continues on the second day with an overview of the potential treatments available for prostate cancer. The final presentation will be a review of New Mexico’s attempts at promoting and increasing medical coverage in remote parts of the state.

### Saturday November 7

- **9:00 AM** – Welcome:
  - Ground rules for virtual conference
  - PCSANM history/mission/method
  - Steve Denning, Conference Chair

- **9:15** – Early Detection of Prostate Cancer
  - Jerome Baca, PA
  - Lovelace Urology

- **9:55** – Break

- **10:00** – Gleason Score and New Grading Groups
  - Larry Massie, MD, Pathologist
  - Veterans Administration

- **10:30** – Risk Stratification
  - Satyan Shah, MD, Urologist
  - University of New Mexico Comprehensive Cancer Center

- **11:15** – Break

- **11:25** – Q & A Panel for submitted questions –
  - Presenters live: Jerome Baca,
    - Dr. Massie, Dr. Shah

- **12:10** – End of November 7 program

### Saturday November 14

- **9:00 AM** – Welcome Back:
  - Ground rules for virtual conference
  - Steve Denning, Conference Chair

- **9:05** – Active Surveillance
  - Aaron Geswaldo, MD, Urologist
  - Lovelace Urology

- **9:35** – Treatment Modalities
  - Thomas Schroeder, MD, Radiologist
  - University of New Mexico Comprehensive Cancer Center

- **10:25** – Break

- **10:28** – Rural Health Care Challenges
  - Barbara McAneny, MD,
    - Oncologist/Hematologist
  - New Mexico Cancer Center

- **11:10** – Break

- **11:15** – Q & A Panel for submitted questions –
  - Presenters live: Dr. Geswaldo,
    - Dr. Schroeder, Dr. McAneny

- **12:00** – End of November 14 program

If you wish to participate in this conference, you will have to pre-register to get the link. Pre-register by sending your info to the PCSANM office (pchelp@pcsanm.org) or calling 505-254-7784. Also see our website (pcsanm.org) for possible changes and other registration information and updates.

We look forward to you joining us on November 7 and 14.
The objective of androgen deprivation therapy (ADT) in men with prostate cancer is to maintain very low levels of testosterone so that the hormone does not promote tumor growth. But a new analysis found that drugs commonly used to achieve this are administered later than the recommended 28-day regimen, and this late dosing was associated with ineffective suppression of testosterone.

"Evidence suggests achieving and sustaining T levels <20 mg/dL with ADT is desirable and correlates with improved disease-specific survival in patients with advanced prostate cancer," lead author David Crawford, MD, professor of urology, University of California, San Diego, and colleagues point out. They looked at administration schedules for luteinizing hormone-releasing hormone (LHRH) agonists and found that they were frequently (84%) administered later than the recommended 28-day regimen, and this late dosing was associated with ineffective suppression of testosterone.

They looked at administration schedules for luteinizing hormone-releasing hormone (LHRH) agonists and found that they were frequently (84%) administered later than the recommended schedule of every 28 days. Nearly half of the late testosterone values for the extended month were greater than 20 ng/dL, and mean testosterone was almost double the castration level, they report.

"Considering the presumed clinical benefits of maintaining effective T suppression throughout the course of ADT, clinicians should administer treatments within approved dosing instructions, monitor T levels, and consider prescribing treatments with proven efficacy through the dosing interval to maintain T below castration levels," they emphasize.

The analysis was published in the Journal of Urology and was presented during the virtual American Urological Association 2020 annual meeting.

Now, in the COVID-19 era, the interval between when men are scheduled for their next injection and when they actually get it may well be growing longer. Crawford says he recently saw one patient who waited 3 months before getting his next "monthly" injection.

28-day Injection Cycle
For the review, Crawford and colleagues examined electronic health records (EHRs) and associated insurance claims for a total of 85,030 injections to evaluate the frequency of late dosing.

When the pivotal registration trials for LHRH agonist were done, a 1-month injection of an LHRH formulation was defined as every 28 days, and not 30 or 31 days as per calendar months.

The current analyses were done using 2 definitions of a month: a 28-day month with late dosing defined as injections given after day 28, and an "extended" month with late dosing defined as injections given after day 32, for products that are dosed once-monthly. The analyses also looked at products that are dosed once every 3 months, once every 4 months, and once every 6 months.

The team also evaluated how often testosterone exceeded the castration level of 20 ng/dL, as well as mean T levels and frequency of T tests and prostate specific antigen (PSA) tests taken by physicians prior to administering the injection.

Results showed that 84% of the 28-day dosing interval and 27% of the extended-month dosing administrations were late.
ADT for Prostate Cancer: Concern That Injections Often Given Late

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Furthermore, "when LHRH agonist dosing was late, both the proportion of T tests with T >20 ng/dL and mean T were higher compared to when the dosing was early or on-time," Crawford and colleagues point out. For example, 43% of T values exceeded 20 ng/dL when injections were late compared to only 21% of T values when injections were given early or on time.

Furthermore, mean T values were 21 ng/dL when injections were given early or on time, but they rose to a mean of 79 ng/dL when injections were late.

Physicians were also far less likely to measure T levels at the time of administering the injections when compared to measuring PSA levels, the team found. T levels were assessed only 13% of the time, whereas PSA levels were assessed 83% of the time while administering LHRH injections. "All of the package inserts say clinicians should measure T periodically when men are on these drugs, yet urologists don't do it most of the time. They are more interested in PSA because that is what the patient wants to know," Crawford commented in an interview with Medscape Medical News. The thinking is that "so as long as the PSA is fine, everything else is fine too," he added.

That, however, is not necessarily the case. As Crawford and his colleagues explain, rising PSA levels can reflect disease progression to castrate-resistant prostate cancer but they may also simply reflect late ADT dosing or other technical issues such as inappropriate dosing for a patient's body weight.

With a number of new therapies now available for castrate-resistant prostate cancer, it's important that physicians ensure that T levels remain below castration levels in order to not wrongly diagnose a man with castrate resistance disease as subsequent changes in management could be entirely inappropriate.

More of an issue, Crawford suggests, is that every time a patient receives an injection of an LHRH agonist, not only do his T levels flare, but so does his PSA.

Crawford suspects that levels of follicle-stimulating hormone (FSH) are also going up in response to LHRH agonist injections.

"We know that hormone therapy is associated with a lot of side effects but the big one for us right now is cardiovascular, so you may be doing the patient a significant disservice by allowing these 'mini-flares' to occur with late injections," Crawford said.

As to why men are receiving their injections beyond recommended intervals, Crawford feels that many urologists are not taking the timing of dosing as seriously as they should. "There may also be scheduling issues and patient compliance issues as well," he said.

Disturbingly, however, if a man does show up in a timely way for his next injection, "insurance companies may refuse to reimburse him unless he comes back on days 30 or 31," Crawford observed.

For men who are concerned about COVID-19 and reluctant to attend the clinic for the next injection, there are ways to deliver healthcare that can facilitate timely dosing. For example, some big urology clinics are having men drive up to their parking lots and receive their next injection in the car, by appointment only of course. Some centers are trying out at home administration. The other solution to the late dosing problem is to prescribe longer-acting depot formulations so men need less frequent injections. "It is simply not acceptable to be giving drugs out of their indication and time frame for which they were approved, so people need to take this more seriously," Crawford said. "We need to administer these drugs on time," he emphasized.

"We need to monitor T levels because some patients will still experience escapes even if they are getting the drug on time," Crawford explained, "and we now have evidence that when patients do have these T failures, this is reflected in rising PSA levels and that may be an indication of disease progression, which we clearly don't want to happen."

Relugolix Superior to Leuprolide in Advanced Prostate Cancer

For men with advanced prostate cancer, the oral gonadotropin-releasing hormone (GnRH) antagonist relugolix maintains testosterone suppression compared with the GnRH agonist leuprolide, while enzalutamide is associated with improved survival versus placebo in nonmetastatic, castration-resistant prostate cancer, according to two studies published online May 29 in the New England Journal of Medicine to coincide with the American Society of Clinical Oncology Virtual Scientific Program.

Neal D. Shore, M.D., from the Carolina Urologic Research Center in Myrtle Beach, South Carolina, and colleagues randomly assigned patients with advanced prostate cancer to receive relugolix (orally once daily) or leuprolide (injections every three months) for 48 weeks (622 and 308 patients, respectively). The researchers found that 96.7 and 88.8 percent of men receiving relugolix or leuprolide, respectively, maintained castration (sustained testosterone suppression to castrate levels) through 48 weeks. The difference indicated non-inferiority and superiority of relugolix. The superiority of relugolix over leuprolide was also demonstrated in all other key secondary end points.

Cora N. Sternberg, M.D., from Weill Cornell Medicine in New York City, and colleagues conducted a double-blind study in which men with nonmetastatic, castration-resistant prostate cancer and a rapidly rising prostate-specific antigen level who were receiving androgen-deprivation therapy were randomly assigned to receive enzalutamide or placebo (933 and 468 patients, respectively). The researchers found that median overall survival was 67 and 56.3 months in the enzalutamide and placebo groups, respectively (hazard ratio for death, 0.73).

"These results add to the growing body of evidence that androgen-receptor inhibitors not only delay the time to metastasis but also improve overall survival among men with nonmetastatic, castration-resistant prostate cancer," the authors write.

The Shore study was funded by Myovant Sciences; the Sternberg study was funded by Pfizer and Astellas Pharma.
Among the men with unfavorable intermediate-risk prostate cancer, the 10-year overall survival was 59.2% for those who started radiotherapy 0 to 60 days before ADT initiation, 57.9% for those who did so 1 to 60 days after ADT initiation, 62.3% for those who did so 61 to 120 days after ADT initiation, and 58.9% for those who did so 121 to 180 days after ADT initiation. None of these differences were statistically significant.

Similarly, among men with high-risk or very-high-risk prostate cancer, 10-year overall survival did not differ significantly among those who initiated radiotherapy 0 to 60 days before ADT (58.9%), 1 to 60 days after ADT (51.7%), 61 to 120 days after ADT (54.8%), or 121 to 180 days after ADT (52.4%), the researchers report in JAMA Oncology.

"The decisions that go into the timing of therapy should be made while taking into consideration the whole context, now complicated by the added risk of COVID-19 and the threat posed to many patients with cancer," Dee said. "We hope our findings help nuance how treatment is timed, given evidence suggesting no survival decrement if treatment is delayed for particular patient subgroups."

"Ultimately, this decision should be made in partnership between patient and provider," he said.

Dr. Amar U. Kishan of the University of California, Los Angeles, who has researched various aspects of radiotherapy for prostate cancer, told Reuters Health by email, "I think these results are reassuring, and, as the authors state, are consistent with two randomized trials evaluating the sequencing of hormonal therapy, though there are some differences. Overall, however, we know that patients with prostate cancer are thankfully expected to have a good outcome with treatment, and given the success of what we call salvage treatments in the event the first treatment doesn't work, it would be surprising to find a large overall survival difference."

"This should reinforce to patients and providers that, during this pandemic situation, delaying the start of radiation by initiating hormone therapy appears to be safe with respect to overall survival, even for patients with high-risk prostate cancer," he said. "These findings can likely be generalized to any other instance in which radiation might be delayed, such as having another medical problem that requires treatment or having other personal or professional obligations that preclude radiation treatment at the time being."

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According to the news reporters, the research concluded: “Treatment decisions for elderly men with prostate cancer require consideration of the risk posed by the cancer coupled with an understanding of the patient’s general health status.”

For more information on this research see: Risk Assessment and Considerations for Proper Management of Elderly Men with Advanced Prostate Cancer: A Systematic Review. European Urology Oncology, 2020
Guest Column: What Are Your Options for Urinary Incontinence After Prostate Cancer Treatment?

Yooni Yi, MD - Assistant Professor, University of Michigan Department of Urology, Genitourinary Trauma & Reconstructive Surgery

Urinary incontinence, or the loss of ability to control urination, is a well-known consequence of prostate cancer treatment (surgery or radiation). It is a highly distressful situation for both the patient as well as their loved ones. Incontinence can affect many aspects of life, such as avoidance of activities, fear of intimacy, financial burden, and mental well-being.

There are two main types of urinary incontinence—stress incontinence and urge incontinence. Stress incontinence is urine leakage that occurs with changes in intra-abdominal pressure, like sneezing, coughing, or heavy lifting. Urge incontinence refers to urine leakage that occurs with a sudden strong desire to urinate that is unable to be suppressed. Stress incontinence is more common after prostate surgery and will be the main focus in this article. However, urge incontinence can also occur after prostate cancer treatment and this should be discussed with a physician as this may change the treatment options.

If you suffer from incontinence after prostate cancer treatment, you are not alone. Incontinence rates after prostate cancer treatment vary in studies, but it has been shown that a majority of men improve in the first six months following treatment.

Initially after surgery, the first step to becoming dry is beginning pelvic floor muscle exercises or therapy. This promotes muscle awareness and strengthens the urinary sphincter (the muscle that controls continence). It’s also an opportunity for a man to have some control over his outcomes. The exercises improve the time to recovery, but it is important to remember that this takes time and effort to complete.

After six to 12 months, only a minority of men will show further improvement in urine leakage. Therefore, if urinary leakage persists at this point, you should discuss your symptoms and level of bother with a urologist to determine your options.

Non-Surgical Management

Non-surgical management can be a way to manage the incontinence in the recovery period, but can also be used as a long term management option. Treatment that falls under this category include:

- Pads/briefs
- Penile clamps/occlusive devices (Cunningham Clamp). During the day, it is important to remove this device every two hours to allow blood flow to the area. Men with decreased sensation in the genital area should not use penile clamps as they will not be able to sense any pressure wounds forming from the device. These devices are not to be worn overnight.
- Condom catheters. A condom catheter is an external device in which a condom is connected to a small urine collection bag. It is different from the catheter that is used after prostate surgery. This is ideal for men with severe incontinence.
- Indwelling catheters. This is usually a last resort for severe incontinence. Leaving an indwelling catheter in place is only an option if all others have been exhausted and/or are not possible.

Surgical Management

In a recent study, less than 4% of men who had their prostate removed pursued surgery for incontinence, even though reported rates of incontinence after prostate removal are much higher. In addition, they pursue surgery on average two years after their prostate removal, even though recommendations state that it is ok to have surgery for urinary incontinence as early as six months after prostate surgery. The reasons for this are many, but education is the first step!

Prior to any surgical intervention, it is important that the urologist evaluates if you are a good candidate for any of the therapies. They should also discuss what to expect during and after surgery and the risks/benefits of each procedure prior to moving forward. The goal of these therapies is to improve the incontinence, but the

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Guest Column: What Are Your Options for Urinary Incontinence After Prostate Cancer Treatment?

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degree of improvement may vary from patient to patient depending on the severity of incontinence, radiation history, and more.

Currently available surgical therapies include the male urethral sling, artificial urinary sphincter and adjustable balloon devices. The descriptions below are brief overviews of the treatment and are not comprehensive by any means. Other therapies are considered investigational and not listed here. It is important to discuss with your urologist the specific details of each therapy.

Male Urethral Sling (AdVance XP or Virtue Sling)
- **Description:** A sling is a synthetic material that is placed on the urethra to help support the urethra when you have increases in abdominal pressure, like with coughing and sneezing, to minimize leakage. The sling works right away. This is a passive therapy meaning the patient does not have to actively do anything to urinate.
- **Surgical Expectations:** The surgery can be performed as an outpatient surgery or the patient can be observed overnight depending on the urologist.
- **Possible Complications:** Urinary retention or inability to urinate, lack of improvement in incontinence, infection, and very rarely erosion.
- **Comments:** If this surgery is not effective, other options are still possible. This is often used in patients with mild stress incontinence and no history of radiation treatment.

Artificial Urinary Sphincter (AMS 800)
- **Description:** This is considered the gold standard for stress urinary incontinence in men. This has been in use since the 1970s. It is a three-piece device with a cuff, pump and a balloon. Everything is implanted and there are no external devices. The cuff sits around the urethra and provides compression of the urethra. To urinate, the patient presses the pump in the scrotum, which then opens the cuff for the patient to urinate. The cuff then closes on its own.
- **Surgical Expectations:** During the recovery period, men are advised not to perform any heavy lifting or any straddle activities. The device is then activated at six weeks and the patient can start to use the device. This means that for the first six weeks after surgery, the leakage will be the same as it was before surgery.
- **Possible Complications:** Infection requiring removal of the device, urethral erosion, device malfunction, and very rarely urinary retention. After 10 years with the device, 50% of patients had a failure of the device and revisions or replacements can be pursued.

Adjustable Balloon Device (ProACT)*
- **Description:** ProAct has been commercially available in the USA since 2017. This device consists of two silicone balloons that are placed next to the urethra where it joins the bladder. The balloons are inflated to compress the urethra on either side. These balloons are attached to thin tubing with ports that are in the scrotum. This is also a passive therapy as there are no actions a patient needs to take to urinate.
- **Surgical Expectations:** This is usually an outpatient surgery with effects seen immediately after surgery. In follow-up, the urologist can access the ports in the scrotum and adjust the balloon volume in clinic to get an optimal compression on the urethra.
- **Possible Complications:** Device erosion, infection, lack of efficacy, urinary retention.
- **Comments:** Studies have shown a higher rate of failure and complications in men with a history of radiation. In addition, only certain centers provide this procedure. Having this procedure does not exclude other treatment options in the future.

Urologists recognize the importance of quality of life after prostate cancer treatment and can discuss these options with you in further detail.
Newswire: Published July 20, 2020

Treatment Hope as Scientists Find Gene that Powers Spread of Prostate Cancer

Mark Waghorn

A GENE that fuels the spread of prostate cancer has been discovered by scientists.

The protein makes tumours more aggressive, helping them migrate to other organs, according to research. Experiments on human cells and mice found turning it off stopped the disease in its tracks, so opening the door to new treatments.

Lead author Dr Lisa Moris, of the University of Leuven, Belgium, said: “We were able to show the regulation of the AZIN1 gene is closely associated with the risk of the tumour spreading.

“What we can say is this finding applies to the patients we tested, who were followed up over a period of 10 years, as well as our mouse and in-vitro models.”

She added: “We are looking at what exactly this gene does, to see if we can find a way of regulating it in real-life cancers. Opening a way to controlling whether tumours risk spread would be a significant step towards controlling prostate cancer.”

Her team based the finding on 44 “high-risk” men with tumours likely to spread, or metastases—19 of whose did.

A DNA analysis showed they had many more copies of the AZIN1 gene than the 25 others who were cured after treatment.

To test this the researchers changed its activity in cells grown in the lab and rodents genetically engineered to develop prostate cancer.

Reducing the activity, or expression, of the gene resulted in less spread.

Ms. Moris said: “We need to do a lot more research on AZIN1 to see if the relation with metastases is generally applicable to prostate cancers.

“There are many different types and causes of prostate cancer, so this finding is still a long way from any clinical application.”

It is also believed AZIN1 plays a role in other cancers, offering hope of developing a drug for multiple forms including those of the breast, bowel and lung.

Latest figures show prostate cancer is now the most commonly diagnosed cancer in England, overtaking breast cancer for the first time.

In 2018 there were nearly 50,000 registered cases, around 8,000 more than in 2017. Public Health England says it is because more men are getting tested.

Celebrities such as actor Stephen Fry and broadcaster Bill Turnbull have raised awareness by speaking out about their own experiences.

The findings were presented at an European Association of Urology virtual congress. It had been scheduled to be held in Amsterdam.

In the UK, about 11,000 men die from prostate cancer every year. Prostate cancer is the most common cancer amongst men in Scotland.

One in 10 men north of the border are likely to develop the disease.

Special thanks to Presbyterian Healthcare Services for its generous support of this newsletter.
Supporting information for this research may be obtained from:
Holden H. Wu, University of California Los Angeles (UCLA), Dept. of Radiological Sciences, David Geffen School of Medicine University of California Los Angeles (UCLA), 300 UCLA Med Plaza, Suite B119, Los Angeles, CA 90095, United States. Additional authors for this research include Zhaohuan Zhang, Sohrab Afshari Mirak, Sepideh Shakeri, Amirhossein Mohammadian Bajgiran, Melina Hosseiny, Afshin Azadikhah, Kyunghyun Sung, Steven Raman, Dieter R. Enzmann, Alan Priester, Robert E. Reiter, Clara Magyar and Anthony E. Si.
A Message from the Chair

October 2020

The first order of business as the new person typing these comments is to offer more salutes to our four recently retired, long-serving, board members. Steve Denning led PCSANM the past four years as board chair. He joined the board four years before that. Although Dave Ball left the board about a month ago, he’ll continue to periodically answer out-of-hours and weekend calls. He served 11 years. Eli Maestas stepped down from the board about two months ago with six years of tenure. He remains on our outreach committee. Jan Marfyak joined the board in 2007. His name remains on our Buddy List. If you were counting you came up with 38 combined years of service! Cue virtual applause.

Next is to introduce myself as the recently installed board chair. I learned of this group in early 2016 after being diagnosed but before I know squat about what was getting ready to happen. Luckily, a cousin-in-law, then active in PCSANM, urged me to promptly take myself up to a small office that’s home to our group. About a year after that I queried a board member about that body, which I joined.

Well, 2020 surely has been different. There’s been notable impact on how we conduct business. Our office hours went away. They’ve now returned, but in a COVID-19 appropriate way. Those twice-monthly Saturday group meetings at a senior center now occur virtually via GoToMeeting. If you haven’t joined one, do so. They’ve been very interesting. Our free annual early-November conference will have new format. See details on page 3.

Rod Geer

Chair of the Board, PCSANM