EXECUTIVE SUMMARY

UroGPO
2017 Fall
National Urology Conference

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UroGPO’s Fall 2017 National Urology Conference was in Houston, Texas on October 5-7. Topics of the meeting were: 1) to discuss new initiatives, 2) converse about new clinical treatments available, and 3) develop new programs to help keep urology practices in business.

UroGPO is a urology-centric group purchasing organization (GPO) that uses the combined purchasing power of its members to create powerful legislative and regulatory advocacy and to secure product contracts. UroGPO also facilitates communication between and within practices, and allows for the delivery of consistent, streamlined care. Member practices are also assisted with developing new opportunities, enhancing revenue streams, reducing costs, and networking across the urology specialty.

The talks presented at the UroGPO conference covered a range of topics, and provided updated guidelines, best-practice recommendations, and announcements of new, promising drug treatments.

A quick overview of the entire meeting is as follows:

Presentations focused on updates within the healthcare continuum (“CEO Welcome: UroGPO Update” and “UroGPO CVS Caremark and USP 800 Update”), new guidelines (“UroGPO Benign Prostatic Hyperplasia (BPH) Guideline”), the future of the field (“UroVision 2017 and Beyond”), and marketing in general (“The Obstacle is the Way”).

Additional opportunities were also available at the conference, including a presentation by Folds of Honor (“A Patriots Calling: Living between Fear and Faith”) about their organization, their work giving back to the children of fallen or wounded soldiers, and motivational messages about giving back through charity and a continual focus on ‘doing the right thing’ when no one is looking.

From an industry perspective, Dendreon/Provenge presented on new information from a pivotal clinical trial and study.

Each of these seven presentations are summarized in this document, organized by overall topic:

**Best Practices:** (“The Obstacle is the Way”, “UroVision 2017 and Beyond,”)

**Changes and Updates:** (“CEO Welcome: UroGPO Update,” “UroGPO CVS Caremark and USP 800 Update,” “UroGPO Benign Prostatic Hyperplasia (BPH) Guideline,”)
In an unstable medical environment, keeping track of the business end of medicine is very important. When medical teams are coordinated through the use of technology and communication with each other and the patients, they become more efficient and effective, and are more likely to stay in business. Reducing costs and improving quality relies on technology that is well integrated into the care system, good staff training, and consistent protocols. In addition, the goals and methods of the medical staff, administrative staff, and the patient must be aligned.

UroGPO network members continue to be pragmatic and focused as they tighten operational processes, add service lines and expand staff to support patient ID and navigation – ultimately generating better patient care and reducing costs. APC Champs programs, Nurse Navigator programs, and Medical Advisory Round Table summits have provided key assistance to UroGPO partners in creating more efficient and effective public health organizations.

“UroVision 2017 and Beyond”

This presentation detailed UroGPO programs and their effectiveness, over time, in using staff and resources to their fullest potential. Emphasis was made on improving practices in four different areas:

- Clinical – the care that is received by patients of the facility.
- Financial – the money the practice brings in and spends.
- Operational – the effectiveness of the organization as a whole.
- Vocational – the quality of the medical care professionals and employees.

Technology is used as a powerful tool to manage patient care and insurance claims, with full integration and web capability a necessity for the changing modern world. EHR technology is also accompanied by training programs in financial stewardship and risk management and the solidifying of good leadership and communication methods. This helps practices to stay afloat financially, make good business decisions for the future, and work better as a team for the patient.

There are three key drivers of positive changes in healthcare organizations:

- Patient Consultation and Treatment Pathways
  Streamlining and standardizing the process of treatment for patients and
providers to ensure consistent care and reduced errors in medications (and associated patient satisfaction and health costs). Addressing potential barriers to care and providing guidelines allows clinical care to be efficient, prompt, and accurate.

• Triage and Communication Between and Across Groups
  Better communication leads to better work culture and politics, removes barriers to effective care, improves medical processes, and leads to improved treatment. The right person will see the patient, provide the right advice, and the patient will be given the right tools to support them in self-managing their treatment.

• Identification and Navigation of Treatment
  Optimizing the cost and process of treatment makes it easier for patients and caregivers to adhere to a line of treatment. This leads to improved drug compliance and utilization, as well as improved results as follow-ups catch symptoms and identify the best way to manage those symptoms.

Of note all of the above topics are also addressed in the APC Champs program and the Nurse Navigator Summits.

The effectiveness of the APC Champs program and the Nurse Navigator Summits can be seen in their high attendance and the increase in systemic therapy by the UroGPO group since 2015. As use of these programs has increased, member practices of UroGPO have seen significant benefits, including better, safer, higher-quality care, reduced extraneous costs, and more cohesive medical teams. Use of these programs will be increased in 2018, to 50 (Champs Program) and 16 (Nurse Navigator APC and BPH/OAB), with further benefits expected.

“The Obstacle is the Way”

Ryan Holiday presented on the concepts found in his books “The Obstacle is the Way” and “Ego is the Enemy,” which are about how to be successful in business and marketing. He has also written books on media relations and manipulation.

The “Ego” aspect of the talk was about how the biggest problems facing organizations often come from within – from poor attitudes, selfishness, and self-absorption. This, he explained, causes internal strife and politics problems in an organization, and prevents its members from being rational, objective, and clear headed.

However, the “Obstacle is the Way” portion is about having the personal and organizational confidence to take a failure or a setback and turn it into a success. Not being discouraged by a situation, Holiday explains, is key to adapting to the situation.
Holiday also referred to books by Robert Greene ("The 48 Laws of Power," "The 50th Law") who writes about success, manipulation, and power. His books use psychological theory, quotations, and studies of historical figures to create cutthroat but effective advice.

In essence, Mr. Holiday’s talk was about incorporating best practices into business, and balancing confidence, in oneself and in the organization, with humility and positive attitudes, in order to set up a medical practice up for success.

CHANGES AND UPDATES

“CEO Welcome: UroGPO Update”

UroGPO is a group purchasing organization that helps its members deliver services, procure fair product contracts, and optimize their practices to produce better business and medical outcomes. It has been in operation since October 2013 and quickly formed productive contracts with pharmacological and medical device companies (Zytiga, Xtandi, Xofigo, Eligard.) Membership has steadily increased, and presently includes practices in most US states (with the exception of North Dakota, South Dakota, and Hawaii.)

Part of the collective power of the GPO is to help insulate healthcare providers from being influenced by product vendors; such influence is illegal under the federal Anti-Kickback statute, but a small practice on its own would be highly vulnerable. Instead, with UroGPO, the power rests with the healthcare providers, allowing them to carry savings and benefits on to their patients and themselves, while remaining compliant with regulations.

The current priorities of UroGPO are, firstly, to produce guidelines for the effective and streamlined treatment of bladder cancer, renal cancer and OAB. Then, they will switch gears to organizing regional payor services. They will, of course, continue to provide access to APC Champs programs, Nurse Navigator programs, and Medical Advisory Round Table summits.

“UroGPO CVS Caremark and USP 800 Update,”

CVS Caremark – the second-largest prescription benefit manager in the US -- has recently re-opened its applications to healthcare practices that fall within UroGPO’s membership. These applications are long and require a lot more information than most prescription benefit managers require about the practice. Response time is usually 7-10 days, and carries a $875 application fee.
UroGPO is offering its assistance in creating the necessary documents and ensuring that everything that is needed is sent in. Currently (as of the time of the presentation) 70 of the GPO’s members are dispensing practices, 17 of which have CVS contracts and 20-25 of which are in the process of getting CVS contracts. UroGPO hopes to expand this range, and is also working with the Community Oncology Alliance (COA) to expedite the CVS application process.

Also in this presentation was a brief overview of the USP 800 rules on handling hazardous products, effective July 2018. It impacts all personnel who are involved in handling, storing, preparing, or transporting drugs such as Leuprolide, Abiraterone, Enzalutamide, Medroxyprogesterone, Acetate, Estrogens, Dutasteride, Finasteride, and Testosterone. UroGPO members are advised to identify whether they are using any applicable drugs and discuss how this new policy affects their practice.

“UroGPO Benign Prostatic Hyperplasia (BPH) Guideline,”

The new clinical guidelines presented in this session were for the treatment of Benign Prostatic Hyperplasia (BPH). The UroGPO medical advisory group, an advisory team of medical professionals and administrators, produced flowcharts for treatment to represent the recommendations of this team. These flowcharts are intended to streamline and standardize care and evaluation of this condition. However, it is noted that medical professionals conducting the evaluation should exercise their professional discretion at all points in the evaluation process. And, of course, any treatment plans should be discussed with the patient first. Depending on observation and on the patient, the guidelines may be modified on a case by case basis.

Upon initial evaluation of the patient, their symptoms and current drug therapy regimen should be checked. If the treatment is not optimal and “bothersome” symptoms persist, other treatment options can be suggested along with follow-up visits (with possibly PUR and urinalysis) within the next 2-6 weeks. If there are no troubling symptoms, then the next evaluation should be scheduled in 6-12 months, depending on the patient.

When evaluating the drug therapy that the patient is using, discuss switching a nonspecific α-blocker for a selective α blocker, due to side effects, if their disease symptoms persist. After any changes, follow up in 2-6 weeks with urinalysis. If symptoms have improved from the last check-in, continue therapy and normal assessment.

If there is no symptom improvement after treatment change, additional tests need to be performed; annual uroflowmetry, urodynamics, and pressure flow cuffs should be considered. Alternative drug therapies should be discussed with the patient, as appropriate; blockers, reductase inhibitors, phosphodiesterase, and antiholinergic
medications are recommended by the guidelines. After treatment change, continue to evaluate the patient for symptoms on a regular basis.

Finally, during routine prostate exams, the guidelines standardize what should be done based on the size of the gland and the degree of obstruction it is causing. If it is over 80cc, then prostatectomy and other interventions should be considered. If it is of a lesser size, not a cancer risk, and not impeding ejaculation or urinary function, then the evaluation should move on to further tests.

Again, these guidelines are just a way to deliver consistent care across practices, and it should be emphasized that these updated guidelines need to be tailored to fit the patient’s individual needs, and rely completely on the professional opinion of medical personnel.

CLINICAL HOT TOPICS

Three drugs were presented at the conference:

- Pfizer and Astellas announced that results of the phase-3 PROSPER trial for XTANDI (enzalutamide) were positive, and that they would be extending the label to patients with CRPC.
- UroGen announced that the FDA was fast-tracking Mitogen, their drug currently being evaluated in the OLYMPUS phase 3 clinical trial, aimed at treating low-grade upper tract urothelial carcinomas as an alternative to surgery of the kidney and upper urinary tract.
- Provenge presented promising early disease survivorship benefits for their immunotherapy drug Siluleucel-T.

Provenge’s talk is described in greater detail below:

“Provenge: Potential Subgroup Survival Benefits”

Dr. Paul F. Schellhammer, Professor of Urology at Eastern Virginia Medical School, presented Provenge’s survivorship study of their drug Silpuleucel-T.

Silpuleucel-T is designed to prime the immune system into targeting the epitope sites of prostate tumors. The survivorship study showed effects amounting to a median benefit of 4.5 months more survival than placebo across the whole population in the study.

Greater benefit (13 months) was seen in men with lower PSA levels (less than or equal to 22.1) than men with high PSA levels (greater than 134.1) with only an average of
2.8 months over the placebo. PSA levels between 22.1 and 134.1 found a 5.4-7.1 month (half year) improvement over placebo.

These findings indicate that Silpuleucel-T may be a good first line drug option, as it provides higher benefits at the early stages of the disease. The presentation discussed how the use of a long-term benefit treatment such as immunotherapy, combined with more aggressive short-term therapies (such as chemotoxicity therapy) could be a good strategy for extending life and reducing the tumor burden and progression of patients.

OTHER

“A Patriots Calling: Living between Fear and Faith”

Major Dan Rooney came to present on his book, “A Patriot’s Calling: Living Between Fear and Faith”, and his organization, “Folds of Honor.” Folds of Honor provides educational scholarships to the families of fallen or disabled military service members who would not otherwise qualify for federal academic scholarships.

The book itself is about his experiences in warfare, and the talk was, primarily, an explanation of his organization and a raising of awareness for the families left behind by war.