



PROFESSIONAL PERSPECTIVES

ICA FOUNDER STEPS DOWN BARBARA GORDON IS NEW EXECUTIVE DIRECTOR

New Leadership Brings Strong Healthcare, Management Experience



The Interstitial Cystitis Association (ICA) recently announced that after almost 25 years as its guiding force, its President, Vicki Ratner, MD, has stepped down from her staff position.

Barbara Gordon was appointed Executive Director, effective March

3, 2008. Gordon brings with her a wide range of healthcare and managerial experience, as well as a deep understanding of the special challenges confronting people who suffer from chronic diseases like interstitial cystitis.

"The ICA is profoundly grateful to Dr. Ratner for her tireless efforts on behalf of IC patients worldwide. Her work has had direct impact on the quality of life for all people

with IC. From its beginnings in her living room at a time when very few clinicians were aware of IC, the ICA has grown to become the authoritative and highly respected advocacy organization it is now, and with Dr. Ratner's constant encouragement there now exists a large international group of superb clinicians and researchers dedicated to studying and treating IC," said Marianne Schuster, co-chair of the ICA's Board of Directors.

"I am proud that the ICA has been able to attract Barbara Gordon to serve as Executive Director. She has the perfect qualifications to lead the ICA," said Dr. Ratner.

During her 25 year career, Gordon has held senior management positions at the Association of American Medical Colleges and at consulting firms that focus on healthcare, including Eagle Design and Management. As a consultant, she has worked closely with the National Institutes of Health, the Centers for Disease Control and Prevention, and other federal agencies, and has advised and guided multidisciplinary teams at healthcare advocacy groups and nonprofit organizations.

Gordon has degrees in social work and nutrition, an MBA from Johns Hopkins, and postgraduate management training at the Harvard Business School. "Barbara brings extraordinary managerial and leadership capabilities to the ICA, and we believe that after an exhaustive search we have found in her the ideal executive director," said Minna Schrag, Board co-chair.

"I am thrilled to work with such an effective and well-respected organization as the ICA, especially because of the breadth of its programs, from disseminating up-to-date information to patients and caregivers to promoting scientific research. I look forward to working with its superb and dedicated staff and to helping it expand its reach to become even more effective," said Gordon.

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NIDDK JUNE SYMPOSIUM: DEFINING THE UROLOGIC PELVIC PAIN SYNDROMES

The purpose of this symposium, which will be held on June 16 and 17 in Bethesda, Maryland, is to enlist expert opinion related to the multiplicity of factors involved in defining the urologic pelvic pain syndromes. Updates will be given on such topics as:

- ◆ classifying urologic chronic pain syndromes
- ◆ advanced diagnostic studies for characterizing the pain syndromes
- ◆ epidemiological data for overlap of chronic pelvic pain syndromes
- ◆ developing biomarkers for the chronic pain syndromes, and many other topics

The meeting will explore the pros and cons of developing a unifying definition, as well as the need for phenotyping persons with these disorders. Interactive discussions will be strongly encouraged among speakers, participants, and the panel of consultants. The meeting will be informative for clinicians, basic scientists, patients, advocacy groups, pharmaceutical representatives, and the public interested in developing a further understanding of the urologic chronic pelvic pain syndromes and associated disorders.

A major outcome will be development of a definition of these diseases and their phenotypes, which will be used in future NIDDK-funded research studies and the upcoming network for a Multidisciplinary Approach to the Study of Pelvic Pain (MAPP). The meeting is open to all; however, preregistration is required because of seating limitations.

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NIH TERMINATES ICCRN CELLCEPT STUDY

The NIDDK has notified the ICA that its Interstitial Cystitis Clinical Research Network (ICCRN) CellCept (mycophenolate mofetil) clinical trial, which was launched in the spring of 2007, has been terminated. The ICCRN clinical trial was being conducted to study the potential use of CellCept, an immunosuppressive drug that is frequently used for organ transplants, in the treatment of severe interstitial cystitis/painful bladder syndrome (IC/PBS) that is unresponsive to other therapies.

This action was taken upon the recommendation of the Data Safety Monitoring Board which reviewed interim data at its meeting on January 23, 2008. Early results found a "lack of efficacy of the drug vs. placebo" suggesting that it would be futile to continue the trial. The Data Coordinating Center demonstrated the futility of continuing the trial.

In addition, during the trial, problems with CellCept began to surface. In October 2007 the US Food and Drug Administration (FDA) and the pharmaceutical firm Roche (the supplier of CellCept) issued an alert to physicians regarding CellCept. In short, CellCept was linked with fetal malformation and was also more directly linked with lymphoma. Both of these issues affected the ability of the trial to proceed effectively.

All CellCept study participants have been or are being notified. In addition, any actual results or information gleaned from the CellCept trial in regard to IC/PBS are embargoed until these results are published.

Please Inform Your IC Patients! TAMPA REGIONAL IC FORUM

**Sunday, July 13, 2008
Sheraton Tampa Riverwalk Hotel**

Featured Speakers are Robert Evans, MD of the ICA's Medical Advisory Board and Board of Directors, and Chief of Surgery for the Moses Cone Health System in Greensboro, NC, and Molly Miller, PT, a Tampa-area pelvic floor specialist.

Watch the ICA's website at www.ichelp.org for registration info.



IC RESEARCH, OUTREACH TAKE BOLD NEW DIRECTIONS

That patients with IC often have other pain conditions has long been recognized. But the IC research community has realized that it needs to look beyond the bladder to find the possible common causes and more effective treatments for all of these conditions. Now, researchers and patient groups focused on the different conditions are joining forces, thanks in large part to the ICA's advocacy. That should bring not only more fruitful research and better treatment but also stronger awareness of these conditions and how to treat them among a broad range of healthcare providers.

ICA advocacy helped bring about the NIDDK-funded Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network initiative, which will be funding six research sites at \$7.5 million for five years. This new program will foster research partnerships between urologists, rheumatologists, neurologists, infectious disease experts and more, not just at their own institutions but across the country. The research interest in this new direction is so high that the NIH was overwhelmed by the response to the MAPP Request for Applications, with worthy applications far exceeding the currently available funding, noted ICA Government Affairs Consultant Libby Mullin.

That's good news for research, but that also has highlighted the need for other institutes at the NIH to provide financial assistance for these crossdisciplinary studies in addition to technical assistance, and the ICA will be working toward that goal. To bolster the effort in the future, the ICA is already developing language for the next appropriations cycle to increase funding for MAPP and is reaching out directly to NIDDK Director Griffin P. Rodgers, MD, to ensure the effort continues to be funded substantially.

ICA advocacy has already brought considerable NIH focus to the epidemiology of IC, and, as a result, you should be hearing new information about the prevalence of IC this fall. Indications are that it is significantly higher than past estimates.

Regarding the recent controversy over how to name the disease, the NIH has definitively stated it has no plans to adopt any change. In the plain language materials that they produce, however, the NIDDK will use interstitial cystitis/painful bladder syndrome. That should help you avoid confusion about reimbursement from Medicare, Medicaid, and other third-party payers and will help your patients avoid more difficulties when you support them in their applications for Social Security disability or assistance.

Discussions continue, however, on the definition of IC and pelvic pain syndromes. There seems to be increasing consen-

sus on the core components of the definition, recognizing that pain is central but that urgency and frequency still are hallmark symptoms.

To help clarify research directions and further define pelvic pain syndromes, the NIDDK will hold a symposium, *Defining the Urologic Chronic Pain Syndromes*, in June. Researchers, clinicians, patients, advocacy groups, and industry will all be able to give their input on classification of the syndromes, advanced diagnostic studies to clarify them, epidemiologic data on their overlap, biomarkers, and more.

Another important development that should help improve urologic care of IC patients in the more immediate future is the development of guidelines for diagnosis and treatment. The American Urological Association recently announced it is developing these guidelines, and the ICA has been invited to be a part of that effort.

Awareness and outreach to a broad range of health professionals will also be bolstered by the continuing CDC/ICA partnership. Despite cuts for many other programs, Congress increased funding for this campaign in the appropriations bill that passed last December, thanks to ICA advocacy on Capitol Hill. Outreach on IC to obstetrician/gynecologists and nurse practitioners and the work to make "IC" a household phrase will continue.

TULSA PRACTICE STAYS EFFICIENT AND GIVES IC PATIENTS ACCESS

Urologists are busy surgeons and can see the extensive medical and follow-up care of IC patients as a drain on their practice. But it doesn't have to be that way.



Sandra L. Seidel, APRN-BC

A Tulsa, Oklahoma, practice has made efficient and effective use of their allied health staff to give IC patients easy next-day, same-day, and walk-in access to care when they need it, keeping the practice profitable and keeping the patients out of the emergency room.

The key is having allied health staff who are experienced in IC counsel IC patients up front and offer clinic time every day, explained Sandra Seidel, a board certified advanced practice registered nurse who works with John Forrest, MD, at Urologic Specialists of Oklahoma. At this practice, two nurse practitioners have clinic time every day for IC patients, and each urologist has a primary assistant who may be a nurse, nurse practitioner, or physician's assistant who can help as well.

The arrangement has been so successful for this practice that, instead of turning IC patients away, the practice has increased that share of its practice. In fact, the 3 urologists who do IC care in the 16-urologist practice have an IC patient population of more than 500. Seidel estimated that about half the patients have taken advantage of the walk-in and same-day clinic at some time.

“Between those two groups of allied staff, pretty much anytime during the normal working hours from 8 to 5, patients come in if they need help,” she explained.

Right from the diagnosis, the allied staff works closely with IC patients on diet and lifestyle practices and self-help techniques that will get them feeling better and help prevent flares in the first place. The nurses and assistants and their physicians also help ensure that patients have the appropriate medications for all aspects of IC, including pain control, which keep flares and crises to a minimum. “We get very few calls in the middle of the night,” remarked Seidel.

As soon as their IC is diagnosed, Seidel and her colleagues help patients learn to do all they can to stay out of flares and feel better. Although many patients can recognize their triggers, not all do. For example, when a patient with a flare comes into the clinic for an instillation, Seidel will review with them what they recently ate and drank, and that’s often revealing. Sometimes, patients don’t realize that coffee or tea or tomatoes, or even that great Mexican food that’s available in Tulsa, will cause trouble.

“We talk a lot about things they can do to make things better—ice packs and heat packs and the need to be communicating with their partners if they had pain with intercourse—a lot of behavioral things that they do have control over.”

If that acute flare does happen in the middle of the night, the practice’s IC patients know what to do. “They’re going to take their Pyridium, they’re going to take their pain medications, and they’re going to use ice and heat. Then, they’re going to call us that next morning and come in.”

But a trigger that brings even those who manage their IC well into the clinic are spring and fall allergens. “We have bigtime flares then,” Seidel noted.

Because the staffers who see IC patients have become well versed in IC care, they can perform more high-level IC care than many allied health professionals. For example, they can adjust settings on sacral nerve stimulators (InterStim). That’s a boon for patients who would otherwise have to just turn off the stimulators and make do with medications until they can see the doctor.

Stimulator programming experience and new techniques have contributed to the practice’s success with stimulators, noted Sandra. “We’re getting good results with chronic pelvic pain. We put those settings a little bit differently, and patients seem to get results with their urgency, their frequency, and with their pelvic pain, even though there’s not an indication for pain yet with IC.”

Although new techniques help, the bottom line at this practice is giving IC patients good access to care. “That’s our main goal,” said Seidel.

Having a clinic that builds ancillary staff experience with IC also means that the staff can steer patients to the right diagnosis faster, too. Sandra recalled a number of cases that might have gone undiagnosed. Once, a woman come in to learn about self-catheterization for urinary retention, but it became clear as the staff started talking to her that she likely had IC. She got her diagnosis and got on her way to feeling better. Sandra also recalled another patient—a man who didn’t have an IC diagnosis, likely because he was a man, who had symptoms she suspected were IC. She put him on the doctor’s schedule for a cystoscopy and hydrodistention under anesthesia, and he got his diagnosis and a treatment plan.

Seidel, who is the immediate past president of the Society of Urologic Nurses and Associates (SUNA), is aware of negative attitudes toward IC patients on the part of some of her own colleagues. But she knows that getting all this experience in IC care builds a team and a practice that understands IC patients well and doesn’t dismiss them or treat them as burdens.

“Some of the ancillary staff made comments like ‘Those patients are so difficult to work with,’ and ‘I don’t really like that type.’ But now, I have a lot of believers of ancillary staff because they see the patients who were so uncomfortable get so much better. Then, they say, ‘Wow, there really is something to this.’”

STAY ALERT TO DRUG ALERTS

You need to stay on top of drug safety recalls, warnings, and significant labeling changes for your patients’ sake and yours. But it can take weeks for you to get notices from FDA and pharmaceutical companies by snail mail. Then, when they arrive, you and your staff often don’t have the time to get through the piles of mail you receive to open, read, and act on those “Dear Doctor” letters immediately.

Now, there’s a better way. You can sign up online in just two minutes at www.hcnn.net to get email delivery of notices through the new Health Care Notification Network (HCNN). A collaboration between US medical societies, liability carriers, health plans, consumer advocacy groups, government, and industry, the network is governed by a

nonprofit, the iHealth Alliance, and is operated by Medem, Inc., a for-profit company. The network sends notices free, and there is no pharmaceutical company advertising. Notices are sent to you and can also be sent automatically to staff you designate. Once you sign up, you will no longer receive the same notices by mail.

“The goal of the HCNN is to deliver these product recall warnings to physicians in a more timely fashion,” Edward Fotsch, MD, Medem’s CEO, told *ICA Professional Perspectives*. “Doctors already get these alerts, or at least they are sent them, but whether they ever see them is another issue because they come in the mail and are mingled with marketing pieces and so much else.”

You won’t be inundated with every alert, explained Dr. Fotsch. The alerts will be targeted to specialties in the same way that snail-mail “Dear Doctor” letters are now. You will get no more and no fewer, but “it will probably increase the number you actually get and read but get them two weeks sooner,” said Dr. Fotsch. “The simple solution is go to HCNN and enroll.”

Pharmacists and some other practitioners who are interested in getting every alert will be able to do that through a service HCNN will call the “All-Alert” system. It is possible now to get every alert through FDA’s *MedWatch*, but the HCNN system will be faster.

Once you receive an alert by email, you can link to the HCNN website to read it. Not only will you be able to read the information that would have been in a traditional “Dear Doctor” letter, you will also be able to read more background on the alert and even be able to enter a discussion area on the website to share experiences and ask questions of other concerned providers. You can also access the alert information again if you need to, since notices will be archived for a year. An advantage for your practice is that the site records the visit, which can help protect your practice from liability.

If you haven’t heard about this service yet, you will soon because most carriers of malpractice insurance are asking their physician clients to sign up to improve patient safety, reduce claims, and reduce premiums. Not only are most liability carriers encouraging doctors to be on the system but also health plans, medical societies, and the FDA, said Dr. Fotsch.

Doctors themselves have wanted this kind of service, too. HCNN cited surveys of practicing physicians showing that more than 90 percent want safety alerts sent immediately online instead of by snail mail and that more than half want copies of the alerts also sent online to office staff.

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According to a March 25 article in *The Wall Street Journal*, five major drug makers have already requested contracts to use the system. Dr. Fotch said that all the major pharmaceutical companies are interested and willing to use the network. Alerts are expected to begin flowing through the network in about two months.

IC NUMBER FIVE ON NIDDK SEARCH ENGINE REQUESTS

In 2007, interstitial cystitis was number five among all the items people searched on the information service website of the National Institute of Diabetes and Digestive and Kidney and Urologic Diseases (NIDDK). The third most popular publication the information service sent out was *Interstitial Cystitis/Painful Bladder Syndrome*. And the service has just published a new, easy-to-read booklet, *What I need to know about Interstitial Cystitis/Painful Bladder Syndrome*.

Those were some of the things the ICA's Executive Director Barbara Gordon learned at the National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC) Coordinating Panel Meeting in late March that demonstrated the importance that the NIDDK plays in getting information about IC out to the American public and the medical community as well as in funding IC research.

And, you may recall that thanks to the ICA's work on Capitol Hill and with the NIDDK, the NKUDIC announced that part of their budget for a five-year contract was devoted to an IC awareness campaign to meet the needs that the American public has made so clear. The NIDDK has completed these special efforts—which included the NKUDIC conducting targeted mailings to urologists, placing stories about IC in US newspapers, and disseminating their new IC publications at numerous professional meetings. The NIDDK's goal was to educate “intermediary audiences” composed of those health professionals such as doctors, nurses, and physicians' assistants who can get the information out to the public. Each one of these professionals not only gets educated him- or herself but may also be able to reach 100 or more patients who need the information. On behalf of IC patients, families and friends, as well as the healthcare community, the ICA thanks the NIDDK and NIH for their success in increasing awareness about IC.

As former project manager of the NKUDIC, Gordon understands that strategy well and also knows how important it is to take opportunities like this one to keep your needs in front of the NIDDK and remind them to stay focused on IC research and awareness. Along with other key nonprofit organizations concerned with urologic issues, the ICA is a member of the NKUDIC Coordinating Panel. The panel meets every year, giving the ICA an opportunity to converse with NIDDK officials and network with other nonprofits. The NIDDK and these organizations, such as the American Urological Association Foundation and the Simon Foundation for Continence, share information about the research the institute is sponsoring, the needs of the organizations' members, and the organizations' activities. This year, Gordon shared the news about the new look and feel for the ICA's publications and website.

The meeting gave Gordon her first opportunity as ICA Executive Director to meet with Griffin Rodgers, MD, who became the NIDDK's Director in April last year, and with the newly appointed Director of the Division of Kidney, Urologic, and Hematologic Diseases, Robert Star, MD.

READ THE NKUDIC PUBLICATIONS ABOUT IC ONLINE

Interstitial Cystitis/Painful Bladder Syndrome

<http://kidney.niddk.nih.gov/kudiseases/pubs/interstitialcystitis/>

What I need to know about Interstitial Cystitis/Painful Bladder Syndrome

http://kidney.niddk.nih.gov/kudiseases/pubs/interstitialcystitis_ez

TWO IMPORTANT IC RESEARCH APPLICATION DEADLINES! SEPTEMBER 15, 2008

Two research grant programs that are administered by the ICA have grant application deadlines that are rapidly approaching. The **ICA Pilot Research Program** and The **Fishbein Family IC Research Foundation** both have grant application deadlines of **September 15, 2008**.

If you are a researcher interested in obtaining funding for your IC research, please visit our website to find out more about each program including how to apply.

The **ICA Pilot Research Program grant application instructions** and The **Fishbein Family IC Research Foundation grant application instructions** can be accessed by visiting www.ichelp.org and clicking on the **RESEARCH CENTER** menu.

“Dr. Star was a wonderful host and was very, very gracious,” said Gordon. She was pleased that he shared with her that the NIDDK hopes to continue the Institute’s long and positive relationship with the ICA.

LATEST IC PUBLISHED RESEARCH HIGHLIGHTS

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Just send an email to ICAmail@ichelp.org with “Office Copies” in the subject line and give us your preferred office mailing address.

The nonprofit Interstitial Cystitis Association (ICA) is the leading provider of information and services assisting people with IC in the management of their condition.

Our mission is:

- ◆ To provide the most comprehensive and up-to-date information on IC
- ◆ To provide IC patients, their families, and friends with a support network
- ◆ To educate the medical community and the public about IC
- ◆ To advocate in the public and private sectors for research funding and patients' rights
- ◆ To promote and provide research funding to find effective treatments and a cure for IC

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Be sure to visit us in New Orleans
at our ICA Booth
1141

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