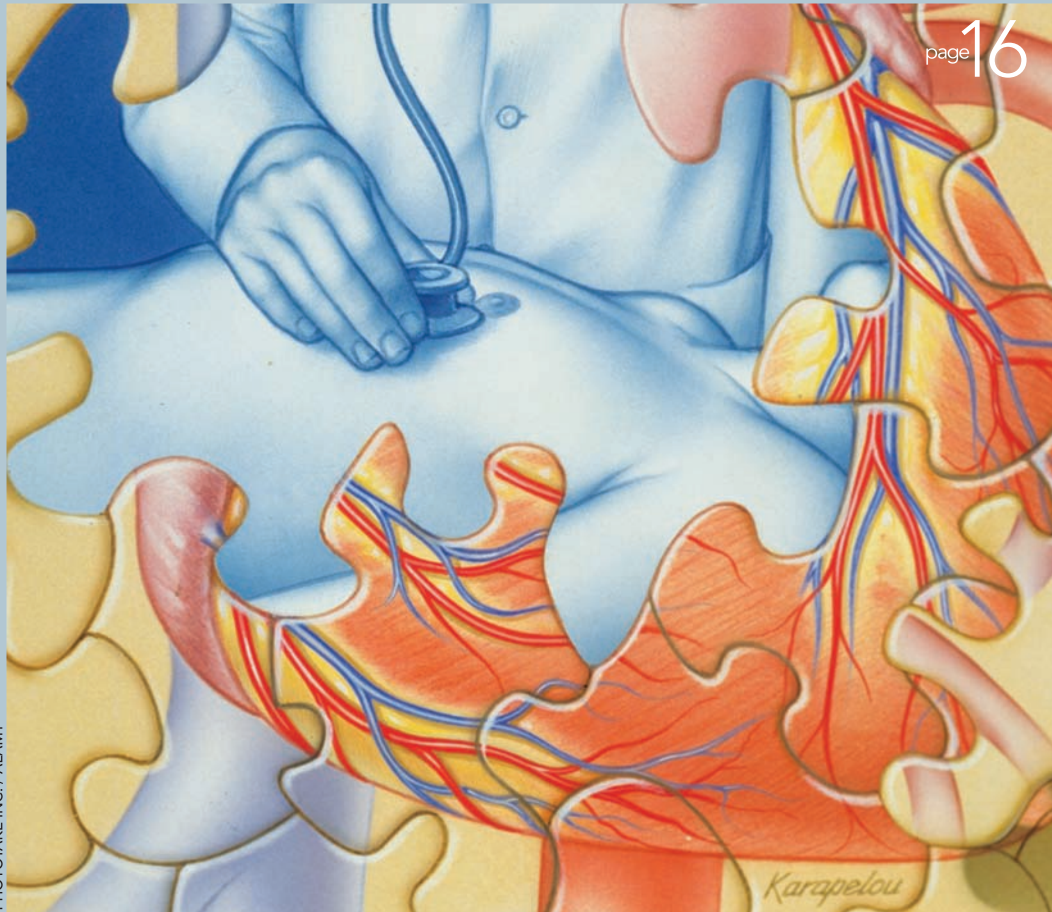
the Rheumatologist
An official publication of the ACR and the ARHP serving rheumatologists and rheumatology health professionals
VOLUME 3 NUMBER 5
MAY 2009



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the heart SSc PUZZLE

Identifying and treating cardiac involvement in systemic sclerosis can be a challenge

>> By Olga Kaloudi, MD, and Marco Matucci Cerinic, MD, PhD

Systemic Sclerosis (SSc) is a complex systemic illness that is characterized by a heterogeneous mix of serious and sometimes life-threatening clinical manifestations. Because of the extensive involvement of internal organs (e.g., lung, heart, kidney, gastrointestinal system), patient care requires a comprehensive approach and a solid preparation to manage the clinical picture. Of manifestations in SSc, cardiac involvement is often clinically silent or occult and, indeed, may be missed without special study. The main signs and symptoms, however, are usually related to cardiomyopathy, pericarditis, conduction and rhythm disturbances, or vascular disorders.[1] The impact of the cardiac disease on morbidity and mortality in SSc makes understanding of this manifestation a top priority for the rheumatologist caring for patients with this disease.

In the clinic, the evaluation of heart involvement in SSc can be difficult, since a variable pattern of symptoms like dyspnoea upon exertion, palpitations, dizziness, atypical chest pain, and syncope may occur. These features may overlap with other problems in SSc (e.g., lung disease) creating a dangerous "puzzle" associated with increased mortality—one that may challenge the physician's skills. In addition to primary heart involvement, pulmonary hypertension and renal involvement can induce a secondary cardiac disease and dysfunction that are a harbinger of poor prognosis. By diagnosing heart involvement in SSc early in its course, timely and effective treatment measures can be initiated, optimizing the clinical outcome. Here we focus on the diagnosis of the different "puzzle" components of heart involvement in SSc as well as the available treatment.

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HARD WORK Behind the Scenes

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My first ACR board meeting gives an insider's view

>> By Alfred E. Denio, MD

I thought that ACR members might appreciate an unsolicited experiential report of the recent board of directors (BOD) meeting from the perspective of a practicing rheumatologist. Because this was my first meeting, I was filled with many impressions. Although I will share some highlights of the meeting, this article will not be a catalogue of all the issues that were discussed, because on March 24th members were sent via e-

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Drug UPDATES

INFORMATION ON SAFETY, LABELING CHANGES, AND PHARMACEUTICAL RESEARCH

>> By Michele B. Kaufman, PharmD, BSc, RPh

Safety Warnings and Label Changes

A possible market withdrawal may be imminent for **propoxyphene-containing products.** In December 2008, the American Society of Health-Systems Pharmacists (ASHP) sent a petition to the Food and Drug Administration (FDA) asking for the removal of propoxyphene-containing products from the US market due to poor effectiveness and safety profiles.[1] On March 2, 2009, the ASHP reported a close vote of 14 to 12 in favor of the removal of propoxyphene-containing products from the US market based on testimony from a joint meeting of the FDA's Drug Safety and Risk Management and Anesthetic and Life Support Drugs Advisory Committees on January 30.[2] Issues included are its relationship to drug-related deaths,

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The Rheumatologist
John Wiley & Sons
111 River Street
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MAY 20
- > **Audioconference/Webcast:** Reconditioning Hearts and Muscles: The Fit and Strong! OA Evidence-Based Program
- > **Exam:** ABIM Rheumatology Maintenance of Certification

MAY 22
- > **Registration Opens:** ACR/ARHP Annual Scientific Meeting Housing and Registration Open to Members

JUNE 1
- > **Deadline:** ACR and REF Volunteer Applications
- > **Open:** 2009 ACR Slide Competition

JUNE 2
- > **Deadline:** ARHP Graduate Student Award Proposal

JUNE 5
- > **Registration Opens:** ACR/ARHP Annual Scientific Meeting Housing and Registration Open to Non-members

JUNE 9
- > **Audioconference/Webcast:** Managing Office Infusions: From Biologics to Bones

JUNE 26
- > **Deadline:** ACR/ARHP Annual Meeting Abstract Submission

the Rheumatologist
VOLUME 3 NUMBER 5 | MAY 2009

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The Rheumatologist is published monthly by John Wiley & Sons on behalf of the American College of Rheumatology. Editorial, business, and production offices located at 111 River Street, Hoboken, NJ 07030; (201) 748-6696; (201) 748-7791 fax. Printed in the United States by Cadmus Specialty Publications, Easton, Pa. Copyright 2009 American College of Rheumatology, administered by John Wiley & Sons. No part of this publication can be reproduced without the written permission of the publisher.

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Communications Line to the Top

The Affiliate Society Council brings local concerns to the ACR leadership

>> By Sherine Gabriel, MD

"The ACR's Affiliate Society Council is a two-way communications conduit, to and from the rheumatology practice community, tackling the big issues of the day and the problems we confront daily." —Alex Limanni, MD, Chair, ACR Affiliate Society Council

Communication is the key to success and this perfectly explains the role of the Affiliate Society Council (ASC). The ASC was started in 2008 to expand on the concept of the Regional Advisory Council (RAC), which was first formed in 2004. The RAC had eight to 10 council members who were asked to monitor various regions of the United States and respond to problems that affected patient care, including insurance carrier policies. Dan Fohrman, MD, served as the first RAC chair and was instrumental in leading the RAC's evolution to the ASC model, which now represents all state and local societies who apply for membership. The ASC currently has 21 state/local societies. If your society is not a member, please encourage them to join.

As Dr. Limanni states above, the ASC is designed to enhance communication by serving as a "two-way conduit" between the rheumatology practice community and the ACR in order to discuss problems and share solutions. To ensure that they have a good understanding of both the issues facing practitioners as well as the issues and potential solutions ACR can offer, ASC members regularly meet with and provide presentations to the community.

The ASC at Work

One of the first major problems brought to the attention of the RAC—and ultimately acted upon by the ASC—was problematic antinuclear antibody test (ANA) results. John Goldman, MD, who was then serving as the RAC's Southeast region advisor, was notified by some ACR members of erroneous and misleading ANA results stemming from suboptimal techniques used in these labs. The RAC recommended to the Committee on Rheumatologic Care (CORC) that a task force be formed to investigate this issue. CORC's ANA Task Force was formed, and a position statement on ANA studies was recently finalized; it is now available online at www.rheumatology.org. The ANA Task Force continues to work on the ANA issue and recently sent a letter to the Food and Drug Administration regarding this issue. The group has also co-signed a letter sent by the College of American Pathologists addressing this topic.

Another problem recently addressed by the ASC was the downcoding of infusion claims in Michigan. The ACR quickly notified the Michigan Rheumatism Society, and both groups contacted the insurer to register a complaint. The insurer responded by explaining that these were errors, the result of mistakes made by claim auditors. It is now retraining its staff to ensure that these mistakes don't happen again. This successful and rapid outcome was possible due to the ASC working closely with ACR staff and leaders. The ACR is also currently working with state societies in Pennsylvania and Delaware on local issues.

Unfortunately, every insurance notification we've received about a problem policy isn't as easily resolved. Noridian, a Medicare carrier, has also created problems regarding infusion payment policies. The ACR has sent numerous letters and has worked with the state and local societies to encourage members to support our confrontation of this carrier. The ACR remains vigilant and continues to apply pressure encouraging the insurance company to adjust their policies for appropriate reimbursement and to maintain needed access for patients.

If you have problematic insurance policies in your state, I encourage you to contact the ASC delegate from your state society, and the ACR will work with you to help resolve the issue. We have found that it definitely helps to have a letter of support from both the ACR and your local state society as you address these issues.

State/Local Society Membership in the ASC

By becoming an affiliate society, you not only have representation in the ASC, but your society also receives these benefits:

> **Presentations at your local meetings:** An ACR board member will attend your society meeting to provide an update on ACR activities that may be of interest. This gives local society members an opportunity to interact with an ACR board member, who can in turn bring local-level concerns from the state back to the ACR Board. ACR staff are also available for presentations.

> **Regular ASC meetings:** the ASC met in March, and the agenda contained several controversial topics, including quality initiatives, patient-centered medical home, and tier-4 pricing. Dan Solomon, MD, MPH, past chair of the ACR Quality of Care Committee, attended to discuss the ACR's quality initiatives. The dialogue provided an opportunity to clear up some confusion about the ACR's initiatives, hear concerns about these efforts, and opened lines of communication even further. The council ran out of time because of the intense discussion, but agreed to continue the conversation on the ASC list serve, where they could invite many others to participate.

> **Networking:** Membership in the ASC provides an opportunity for networking with other members from across the country. Many ACR members are busy outpatient specialists, often in small practice settings, and thus have little opportunity to interact with colleagues to discuss challenges affecting rheumatology across the US. The ASC membership provides an opportunity to brainstorm about these challenges and consider what may be done in response.

> **Supporting affiliate society activities:** Through participation in the ASC, affiliate societies receive help with Web site development, communications via list serves and other methods, meeting space at the ACR Annual Scientific Meeting, and much more. The California Rheumatology Alliance took advantage of its meeting room at the 2008 ACR Annual Scientific Meeting in San Francisco and invited insurance carriers to discuss a variety of issues affecting California physicians. The meeting provided this group of members a rare opportunity network with colleagues and to ask questions of the carriers. Predictably, the discussion was animated and the room was packed.

Networking, sharing, discussing, and learning are

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Join the ASC

Societies interested in being a member of the ASC are invited to apply, and membership information is available online at www.rheumatology.org under Practice Support. You may also visit the Web site to see a complete list of ASC benefits and view a list of current ASC members. If you have questions about the ASC, contact Antanya Chung at (404) 633-3777, ext. 818, or achung@rheumatology.org.

VOLUNTEER

Volunteer for the ACR and help shape the future of rheumatology!

The ACR is now accepting nominations for ACR and ACR Research and Education Foundation committees. Positions are available in all areas of the College's work, including education, practice support, research, training and advocacy.

To nominate yourself or a colleague, complete the online nomination at www.rheumatology.org

For more information or questions, contact Rachel Myslinski, director, administration and governance, at rmyslinski@rheumatology.org.

Nominations accepted through June 1

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Let's Get Personal

Finding cost-effective solutions in the quest for personalized medicine

>> By David S. Pisetsky, MD, PhD

As recent history shows, research advances are not cheap, and focusing on the individual can be very expensive and, indeed, can skew healthcare funding and detract from outcomes for the population as a whole. As is well documented, despite healthcare expenditures that, on a per capita basis, dwarf those of other Western countries, American life expectancy is lagging, and childbirth mortality is shockingly high. In the absence of a comprehensive vision for allocation of healthcare resources, focusing on the individual can be very, very expensive, as reflected in the relentless growth of healthcare expenditures that outstrip inflation.

Except for vaccines, most new therapies or interventions to improve health outcomes increase, not decrease, costs. Often, it takes a bunch of smart pharmacoeconomists to develop models and juggle the math of quality-adjusted life years to demonstrate that certain treatments are worth the costs in a dollars-and-cents way. For new oncology drugs with price tags that are in the six-figure range, there is sometimes not even an effort to justify costs by standard metrics, likely because cost-effectiveness would be impossible to show.

As discussed *ad nauseum* by the experts, the healthcare industry (at least in the United States) is unlike any other industry, and the usual rules of the competitive marketplace do not pertain. Although the cost of countless consumer items has dropped, even plummeted—witness computers—the costs of medicines have gone in the opposite direction. Many reasons account for this phenomenon, including the enormous costs of research and development, regulations, and pressure from Wall Street to create blockbuster drugs. However, it could be exacerbated if emphasis on a personalized approach continues unabated.

Focusing on the individual leads to products to fill smaller and smaller niches as drugs are designed to target much more selective genetically and genomically distinct variants of a disease. Developing drugs for a market that looks fractal-like in its complexity takes big bucks, and, unless the market is constrained or regulated in a new way, costs will continue to skyrocket.

Alas, the rocket is running low on fuel. The world flounders in economic uncertainty as words like *meltdown*, *crises*, and *depression* fill the daily lexicon. With a budget deficit soaring into the trillions as the government takes over banks and tries to rescue automakers, the pressure on budgets will be fierce. Money is scarce, and I cannot imagine that funding for federal programs for healthcare will rise. I suspect that it will contract. Furthermore, with unemployment increasing and the automakers try to jettison the insurance obligations of their retirees, the well could go dry.

RUSTYCLOUD / ISTOCK.COM

What should be done for Joe the Plumber's aching shoulder?

A Possible Solution?

One approach to lowering healthcare costs would be to make medical care less personal and to have patients and physicians accept outcomes, which, while good, may not be optimized for every individual. Consider the treatment of rheumatoid arthritis (RA), where individual responses to tumor necrosis factor (TNF) blockers may differ among the currently available agents. Until we know a lot more about the determinants of responses, one approach would be try each of the TNF blockers until an effective one is found, or the decision is made to go on to something else.

Such an approach can be justified, but it is expensive because it involves a lot of trial and error. By its inefficiency, this approach can keep drug prices high, require larger inventories, and limit competitive bidding. If, by some chance, I ran a pharmacy service for a healthcare organization, I would like to purchase drugs in bulk and bargain for discounts for the size of the purchase. Under the circumstances, I might stock only two of the five TNF blockers, choosing the ones whose manufacturers give the best price. This is Costco care, not that of Neiman Marcus.

The Costco care strategy would likely work for 95% of RA patients and would save money. Some patients, however, would no doubt have less than fully satisfactory results because they would lack access to the drug that worked best for them. The personal loss would be counterbalanced by the public gain to the extent that it is worthwhile to decrease healthcare expenditures overall (especially in a weak economy) or allow money saved on RA to fund other priorities in the system. In a time of fiscal constraints, something has to give, and I would rather that patients and providers make the choices rather than the pressures of the marketplace or arbitrary decisions of the bean counters.

Making Personalized Medicine Personal

Imagine now that Joe the Plumber has decided to move from cold and cloudy Ohio to the sunny, verdant, and congenial state of North Carolina. Joe has heard that homes are still going up in Holly Springs and Fuquay Varina and that plumbers are needed to install showers (times are tough here, too—no more Jacuzzis). Joe has also seen the light in sports and will forsake the Buckeyes for the Blue Devils or Wolfpack.

In his newfound home in the South, Joe works like a demon and, in a hurry one day, he yanks hard on his wrench and suddenly his shoulder erupts with pain. Joe comes to see me, and my exam shows limited range of motion and signs of impingement. Joe says that he wants an MRI because one of his buddies on the job with similar complaint had one and got better.

What should I do to provide the most cost-effective care to soothe the pain in Joe's throbbing shoulder? Do I think only about Joe? What is the place of systems-based practice? Where do I factor in the reluctance of some to spread the money around as required by any insurance system, whether supported by taxes or healthcare premiums?

In my mind, I can see a few options that I can frame as a multiple-choice question. What should be done for Joe the Plumber's aching shoulder?

a. Prescribe a nonsteroidal anti-inflammatory drug and teach Joe some exercises;
b. Inject the subacromial space with methylprednisolone (DepoMedrol);
c. Perform an ultrasound, and then do the injection;
d. Send Joe for the MRI that he requests; or
e. None of the above.

Let's get personal. I know what I would do for Joe. What would you do? | THE RHEUMATOLOGIST |

Dr. Pisetsky is physician editor of The Rheumatologist *and professor of medicine and immunology at Duke University Medical Center in Durham, N.C.*

PRESIDENT'S PERSPECTIVE | continued from page 5

the communication methods that allow the ASC to be successful. ASC delegates are encouraged to provide real, unvarnished feedback from the practicing community directly to the ACR Board and committees. Such feedback helps the ACR to better understand and respond to the challenges members face and to grow and improve as an organization.

I encourage you to become a member of your state and local society. Partnering through the ASC, we are a stronger force for addressing issues that affect you and your day-to-day practice of medicine. | THE RHEUMATOLOGIST |

Dr. Gabriel is president of the ACR. Contact her via e-mail at gabriel@rheumatology.org.

Hard Work Behind the Scenes

First ACR Board Meeting gives an insider's view

>> By Alfred E. Denio, MD

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mail a summary of the board meeting. Instead, this report will focus on a process with which members may be unfamiliar.

The meeting was held over three full days, Thursday through Saturday, from February 19–21, 2009, in Miami Beach, Fla. When you add an additional day for travel, this quarterly meeting was a four-day major commitment of time and energy for the approximately 30 volunteer physicians and allied health professionals and 19 ACR staff who participated. Thankfully, I am told that the three other meetings this year will not be as long.

The agenda notebook sent to me for reading prior to the meeting filled a very thick binder that occupied half of my carry-on bag and added greatly to its weight. Despite the location of the meeting—in a hotel with a beautiful sandy beach on the Miami Beach ocean boardwalk—we had very little opportunity to enjoy the weather because the meeting ran from 8 A.M. to 6 P.M. each day. This was not an activity for people with sore backs or difficulty sitting in chairs for hours at a time.

At the meeting, the 13 board members, 11 committee chairs, six executive committee members, and ACR's legal counsel and executive vice president sat around the inner U-shaped table; the staff and other invited guests and speakers sat around the outer table. The executive committee members and executive vice president were backlit by the bright Florida sun piercing through a wall of windows behind them. This had the effect of creating halos around their heads, and I wondered if this effect was intentional.

FRANCK-BOSTON / ISTOCK.COM

Eager Discussions

One was immediately struck by the diversity of rheumatology backgrounds and constituencies present: education, research, and practice were all well represented. Sherine Gabriel, MD, president of the ACR, did her best to keep the meeting moving along, but compulsive rheumatologists seemed eager to discuss the nuances of every issue, and her job was extremely difficult, if not impossible. This trait, compulsiveness, which is common among rheumatologists, must be some type of passively acquired immune response that is activated whenever a rheumatologist is in close proximity to another rheumatologist. Of interest, there were no shy members, and all the board members actively participated in the sometimes lengthy debates.

As one might have expected, this was a business meeting that ran on an agenda with more time allotted to items of greater controversy or importance. The ACR divides its activities into three categories: survival functions, core functions, and discretionary functions. One of the survival functions is the yearly scientific meeting, and there was considerable discussion about how to improve the quality of the meeting. *SessionSelect*, a reproduction of scientific presentations available online after the meeting, was judged a great success, although it was expensive. Rosalind Ramsey-Goldman, MD, DrPH, chair of the Committee on Education, submitted a discretionary project to fund *SessionSelect*, and I hope it will be funded again for this year's meeting.

Likewise, the poster tours had such high demand with great reviews that they will be expanded this year. Dr. Ramsey-Goldman also announced her committee's commitment to increase the number of practicing rheumatologists on the meeting planning committees from the current 20% to 33%, which should help ensure that the meeting fully addresses the needs of our practice members.

Checking on Quality, Task Forces

Perhaps the largest block of time was devoted to a discussion of quality issues. Quality of Care Committee Chair Daniel Solomon, MD, MPH, reviewed ongoing strategies that the ACR has pursued to help reduce the work of reporting quality measures. The committee budget and projects were presented and debated. The issue of an ACR quality-recognition program was reviewed at great length. The thinking here is that rheumatologists, not carriers, may be best qualified to decide who provides quality rheumatologic care. Because this was such a controversial item that raised many difficult questions, it was felt a task force was needed to examine the feasibility.

We heard a presentation from the American Society of Clinical Oncology on how they approach quality in oncology and later heard that the Rheumatology Clinical Registry will be rolled out later this year. This will be an online tool that members can utilize to help record and store data for American Board of Internal Medicine practice improvement modules (also known as PIMs), Medicare Physician Quality Reporting Initiative, and various other quality-measure reporting requirements.

There were a number of task force reports presented, including Pain Management and Diversity. After strengthening the language, we approved a position statement submitted by the Antinuclear Antibody (ANA) Task Force regarding the proper methodology for the ANA test. The position emphasizes the preeminence of the immunofluorescent ANA as the gold-standard methodology. The adoption of this position by the ACR should help advocacy efforts to encourage clinical laboratories around the country to improve their methodology. The issue had come up because a practice member, John Goldman, MD, had complained to the ACR that many laboratories in the country were performing the ANA with methodology that did not have the specificity or sensitivity of the immunofluorescent ANA.

Reports from American Medical Association delegates, Arthritis Foundation, ACR Research and Education Foundation, and ARHP were heard. Sharad Lakhanpal, MB, MD, chair of government affairs, reported the ACR advocacy issues for this year and the date for the Advocates for Arthritis event which was held March 9–10 in Washington, D.C. Karen Kolba, MD, chair of the Committee on Rheumatologic Care (CORC), gave her update on all the various CORC subcommittees and issues confronting practicing rheumatologists.

ACR and the Medical Home Model

The BOD members also discussed the Medical Home Model. The ACR has been asked by the American College of Physicians (ACP) to support the Medical Home Model. The ACP, American Academy of Family Physicians, American Academy of Pediatrics, and others have proposed a major overhaul of the American healthcare delivery system, emphasizing primary care. In this Medical Home model, where the primary care provider becomes the central healthcare provider, it is hoped that healthcare would be better coordinated, more efficient, and more effective. There was spirited debate over the plight of primary care and also perceived shortcomings in that model from a rheumatology standpoint. For instance, it was noted that rheumatologists already provide primary care coincident with specialty care for patients with serious complex immunologic diseases. The Medical Home model, as currently constructed, would discourage that activity if reimbursement policies required that the patient go back to the primary care physician for every primary care problem. Patient care would suffer in that scenario.

Each of the chairs then presented new discretionary projects for funding consideration. The projects were graded by each board member. The grades will be tallied, projects ranked, and decisions made at the next BOD meeting in May as to which projects will be funded based upon the available funds. Because every project seemed thoughtfully developed and important, it is unfortunate that there will not be enough money to fund all of them.

A practicing rheumatologist has few other opportunities to meet and get to know many of the ACR staff and board members that represent other constituencies and functions within the organization. Thus, the lunches, breaks, and dinners were critical to network. It gave me the opportunity to present a "practice" perspective on issues to staff and other board members, as well as to hear other viewpoints that affect all of us involved in rheumatologic care.

The breadth and depth of the ACR's activities became more apparent to me from attending this meeting, along with the remarkable abilities and intellect of the people responsible for these activities. Flying home from the meeting, I reflected upon the progress the ACR has made over the past six years of my personal involvement. What previously was an organization devoted primarily to education and research has evolved to become the guardian shepherd of our specialty. Rheumatology faces many challenges, and my involvement in the ACR's attempts to confront the challenges facing the practice of rheumatology has been one of the most sustaining and fulfilling accomplishments of my professional life. To my colleagues in practice who feel the ACR does not do enough, I say the ACR needs you to get involved. We need your ideas and, just as importantly, we need your passion for our profession. We need a few good men and women.

If you have concerns that you think should be brought to the BOD's attention, feel free to contact me at adenio@cox.net. If I cannot directly help, I will try to find within the organization the person who can.

THE RHEUMATOLOGIST

Dr. Denio is a rheumatologist at the Center for Arthritis in Chesapeake, Va.

From the COLLEGE

NEWS FROM THE ACR AND THE ARHP

This month in From the College:

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LEADERSHIP

Use Communication Style Clues to Manage Your Employees

Over the last two months, "From the College" provided insight on the Five Rs of physician leadership: recruitment, realization, recognition, redirection, and retention. The Five Rs give great guidance in managing the leadership process, yet they will be far less effective if you lack the ability—or willingness—to successfully communicate with your employees.

PHOTOCANAL25 / ISTOCKCOM

There are four main communication styles: sensor, feeler, thinker, and intuitor.

Whether managing a small practice or a large department, highly successful physician leaders have learned how to communicate effectively with their staff members. They have discovered and embraced the fact that not everyone communicates—or responds to communication—in the same way, and they have taken the time to adjust their own communication styles to ensure their employees will help them successfully manage their practices, departments, and institutions. The challenge? There are many communication styles, and each of your employees is uniquely different from the others. The good news, according to Timothy J. Keogh, PhD, is that a physician leader can place most employees, supervisors, and coworkers into four categories. Once you learn about these communication types, you will be able to maximize your conversations for the most effective practice or department.

Dr. Keogh is assistant professor of Citadel School of Business Administration in Charleston, S.C.; adjunct associate professor of Health Systems Management at Tulane University School of Medicine in New Orleans; and featured speaker at the American College of Physician Executives' 2008 Annual Spring Institute. He is also a contributor to the book, *Enhancing Physician Performance: Advanced Principles of Medical Management*, where he writes, "Insight into our own style begins to give us the fundamental skill of how to adjust, or flex, our style to the style of others. Without this insight, we often create the personal barriers to communication, which causes us to think, 'I don't know what it is about this person, but we just don't see eye-to-eye.' This invisible barrier comes between two people with different styles and creates a shield through which our words fail to pass."

Dr. Keogh suggests that there are four main communication styles, and it is the responsibility of the physician leader to identify his or her style and then work to flex to the styles of each of his or her employees.

Four Styles

1 The **Sensor** is a person who likes to be seen as powerful. He or she is often busy and will likely greet someone who enters his or her office with a short, to-the point salutation like, "What do ya got?" To others, the Sensor can be seen as impatient and dominant. To communicate with the Sensor, a physician leader should get right to the point, have a bottom line, emphasize action, and give concrete examples.

The Sensor does not want to be bothered with social chit-chat or minute details. He or she wants to know just enough to make a decision and move on. When communicating with a Sensor, Dr. Keogh says it is important to use balance and, "skip the preliminaries, skip the details, include steps [to take action], and bring something to hand over [such as a chart or graph]."

2 The **Feeler** likes to be seen as popular among peer groups. He or she is a master at networking and wants to be involved and liked on many different levels. The Feeler will engage people in chit-chat and can be seen by others as disorganized or as someone who makes decisions based on gossip.

To communicate with the Feeler, Dr. Keogh says, "An approach that is too abrupt will be unsuccessful." Starting with social conversation will engage this person from the start of a conversation. Making a lot of eye contact, appealing to passion, and dropping the names of others in the organization are all successful techniques to use when communicating with a Feeler.

3 The **Thinker** likes to gather and organize information. He or she loves systems and plans (charts and graphs really speak to a Thinker). The Thinker wants to be to be seen as perfect and has very high internal standards. He or she will be humiliated in the wake of a mistake but will never show it. The Thinker can be seen as overly critical of himself or herself as well as others and will often give unsolicited feedback.

To communicate with the Thinker, Dr. Keogh suggests being organized and prepared with a specific plan. Additionally, Dr. Keogh warns to not expect the Thinker to make a quick decision, as this person is more likely to prefer selecting from a number of choices in a methodical way.

4 The **Intuitor** is the person who likes to mull things over in his or her head. The Intuitor wants to be seen as patient and will take the time to explore all avenues before making a final decision. He or she often goes along easily with the group to avoid appearing aggressive. Because the Intuitor is often quiet, he or she can be seen as unenthusiastic.

To communicate with the Intuitor, Dr. Keogh suggests using patience and politeness while allowing him or her ample time to digest and mull over the conversation (either during or afterwards). Dr. Keogh also suggests being inventive when communicating with this type of person. "[Intuitors] like to challenge themselves by learning new things and by solving problems which stretch their existing skills," he says. "Offering a way to expand their horizons and produce some rational solution can be persuasive to this type."

Dr. Keogh's research has shown that most physicians are either Sensors or Thinkers, but the physician leader should be prepared to communicate with—and manage—all four types. Some may think this suggestion is asking a physician leader to cater to his or her employees' quirks, but the savvy leader will understand that different communication styles are part of life, and understanding how to elicit a positive response from different people will only help the leader in the long run.

There are several ways to determine your communication style and that of your employees, with the Myers–Briggs test being among the most popular. Research on trusted Internet sites or at your local library or university can help you determine how to best identify your employees' communication styles.

No matter how you go about identifying your communication style, it is important to understand that establishing open, proactive internal communication is one of the greatest assets a physician leader can have (or can obtain) to lead a successful practice, department, or institution.

Three Questions To Open the Door of Communication

According to Dr. Keogh, asking the following questions, either in person or via a quick, anonymous survey, will give you a wealth of knowledge about the current climate of your practice or department:

1. What is good around here?
2. Who do we need to recognize?
3. What are some of the barriers we are encountering?

By asking these types of questions, physician leaders open the door of communication with their employees and gain a starting point for conversations about their practice, department, or institution.

PRACTICE UPDATES

The Dos and Don'ts of Documentation

In order for a physician to be reimbursed for his or her services, those services must be documented. Your

continued on page 10

documentation should be able to stand on its own; it is your story of the visit. Just imagine if the news reported, "two people found dead" and nothing else. You would want to know who, when, where, and possibly why. A good news story gives all pertinent information, and your documentation should do the same.

Every year, rheumatologists lose thousands of dollars because of insufficient documentation, and understanding what you should and shouldn't do will help you prevent this loss.

> DO Use Templates to Assist in Documentation

The history and exam portions of are often where rheumatologists are lacking in their documentation. When reaching the history level, there are three components you have to touch on: history of present illness, review of systems, and past family and social history. Many times, physicians will not document the past family and social history. This will automatically mean the history cannot be graded higher than "expanded problem focused." Having a template will help to remind the rheumatologist to document everything.

> DON'T Misuse Templates

Don't let templates make your practice complacent. Each visit should not be the same because each patient is not the same.

> DO Sign and Date Every Entry

Each page of the medical record should contain the patient's name or identification number. Each author should be identified on each entry, and all entries should be dated. Also, make sure the documentation is legible to someone else besides the author. If these rules are not followed, there is a risk that the medical records could be disregarded, leaving no support for medical necessity of the encounter.

> DON'T Change a Medical Record

Don't try to replace or add any information to medical records as if it was there in the beginning. If something needs to be added to the records, the date and explanation should be clearly noted to as why the addition was made.

In the end, the good documentation of each encounter is the only tool used to determine what happened during the physician's services. Your documentation should be clear, concise, and accurate enough to stand up in any legal setting. There is an old saying in the coding world: "If it is not documented, it is not billable."

For more information on how proper documentation can help save your practice time and money, contact Melesia Tillman, CPC, CCP, at (404) 633-3777, ext. 820 or mtillman@rheumatology.org.

ANNUAL MEETING

PHOTO BY R. KENNEDY FOR GPTMC

Liberty Bell Center

New Reasons to Get Excited About the 2009 ACR/ARHP Annual Scientific Meeting

Practicing clinicians and basic and clinical investigators alike will benefit from the expanded offerings and the return of ever-popular sessions and features at this year's ACR/ARHP Annual Scientific Meeting, to be held in Philadelphia October 16–21.

The most popular sessions from previous years, including "The Year In Review," "The Great Debate," "Curbside Consults—Ask the Professors," the series of "Immunology Updates for Clinicians," and an entire spectrum of Clinical and Translational Science Symposia, Medical Aspects of Disease, and State-of-the Art lectures will be offered again this year.

Major additions to the program this year include a new series of sessions aimed at clinical challenges in daily practice. These presentations, which compose an entire new Clinical Practice track, will focus on the clinical care of difficult rheumatologic issues. In addition, the "Thieves' Market," a presentation of interesting and unique cases, is being introduced this year as a forum for practicing rheumatologists to share their best cases with their colleagues. This session will consist of five to six cases solicited from ACR practicing members.

Other highlights of this year's meeting include:

New session types: The REF will debut two new lectures: the REF Memorial Lecture, created to honor deceased physicians who made significant contributions to the field of rheumatology, and the REF *Within Our Reach* Lecture, created to promote the REF Within Our Reach campaign and highlight the work of these grant recipients.

Expanded poster tours: Back by popular demand, the guided poster tour will return with expanded offerings. Thirty-six tours (12 each day) will be offered during this year's meeting.

Plenary program: The plenary sessions have been redesigned to improve general interest and to ensure that the very best new science is presented. Each of the three plenaries will have a separate focus:

- First plenary: Translational research results;
- Second plenary: Highest-ranked abstracts describing basic science advances; and
- Third plenary: Highest-ranked abstracts describing clinical advances.

Opening lecture: In celebration of the ACR's 75th anniversary, the opening lecture will focus on the history of rheumatology. Bonnie Dorwart, MD, will discuss arthritis and medicine in 19th century America; Ralph Schumacher, MD, will review the development of rheumatologic knowledge through the 20th century; and Charles Christian, MD, will present the first 75 years of the ACR.

The ACR Annual Meeting Planning Committee and the ARHP Program Committee have worked to develop a program that will be of great interest to all attendees. For more information on the 2009 meeting, visit www.rheumatology.org/annual.

CODING CORNER!

May's Coding Challenge:

A 68-year-old female returns to the office for her monthly abatacept infusion treatment. She has an established diagnosis of moderate rheumatoid arthritis. The patient is currently on a nonsteroidal anti-inflammatory drug and also takes glucosamine–chondroitin. She reports pain, stiffness, and swelling in both knees and states the pain is a six on a scale of one to 10. She denies any other complaints.

On exam, the patient was alert and oriented, vital signs were normal, and there was no lymphadenopathy. Her lungs were clear, and her heart rate and rhythm showed no murmurs or friction rubs. Her abdomen was soft with epigastric tenderness on palpation, and there were no masses or hepatosplenomegaly.

A musculoskeletal exam revealed bony proliferation and crepitus in the right knee, as well as irritability, large effusion, warmth, and decreased flexion in left knee without erythema. All other joints are unremarkable with full range of motion.

Plan: After discussion of therapeutic options with the patient, the infusion was performed. The patient was infused with 750 mg of abatacept for a total of 29 minutes. Her medication was left unchanged, and a complete blood count and a MRI of the knee were ordered.

How should this encounter be coded?

See page 21 for the answer.

QUALITY MEASURES

PQRI Now Includes RA Measures Group

By Salahuddin Kazi, MD, Melesia Tillman, CPC, CCP, and Amy S. Miller

In 2008, the only Physician Quality Reporting Initiative (PQRI) measure that applied to rheumatoid arthritis (RA) was disease-modifying antirheumatic drug therapy. For 2009, five new RA measures were included, for a total of six measures in the new RA Measures Group. The five new measures were developed in 2008 by the National Committee for Quality Assurance in collaboration with the ACR and the American Medical Association's Physician Consortium for Performance Improvement and were subsequently adopted by Medicare.

The new measures are tuberculosis screening prior to beginning anti–tumor necrosis factor therapy, periodic assessment of disease activity, functional status assessment, assessment and classification of disease prognosis, and glucocorticoid management. Other measures on which rheumatologists can report include osteoporosis, osteoarthritis, assessment of pain, back pain, falls, and health information technology. With the exception of back pain, these measures can be reported individually or as part of a measures group.

PQRI is voluntary and involves payment for participation in the program. Currently, the incentive to participate is a two-percent bonus on all allowable 2009 Medicare Part B fee-for-service charges during the reporting period, with no cap. It is anticipated that in future years this incentive may increase substantially or that penalties for nonparticipation may be implemented, so rheumatologists and other eligible health professionals are encouraged to get in the habit of reporting now.

There are two methods that practices can employ to report individual PQRI measures or measures groups to Medicare. The first includes claims-based reporting, which involves submitting CPT II codes or numerator codes along with the usual services for the visit. The second involves registry-based reporting, and there are several commercial vendors that facilitate registry-based reporting.

To assist its members with PQRI reporting, the ACR has partnered with Outcome Sciences to develop a Web-based quality-measures recording and reporting tool—the Rheumatology Clinical Registry (RCR). The RCR will be available to ACR members in June 2009 and will provide additional resources including the ability to record patient history, complete the ACR practice-improvement modules (PIMs; used primarily for maintenance of certification), and

Why Use the RCR Instead of Claims-Based Reporting?

Using the RCR for PQRI reporting provides several advantages over claims-based reporting:

- Users can collect clinical information at a pace that suits their clinical workflow.
- Users can print forms to incorporate into the paper record until Web-based data entry can be done.
- Information can be collected by a downloadable Excel spreadsheet that can be subsequently uploaded to the RCR.
- Because registry reporting does not need to occur at the same time as submitting claims for patient visits, users will have the option to employ batch reporting for 2009 PQRI as late as February 2010.
- There is no need to report any CPT II codes.
- Office managers or other designated personnel can complete the forms for the providers, who can then review and sign the forms for submission.
- The RCR is being developed to integrate with major electronic medical records.
- Outcome Sciences, the RCR development company, is a registered vendor with the Centers for Medicare and Medicaid Services. This makes reporting for PQRI using the RCR an easy, streamlined process that will have fewer errors and be more likely to be reimbursed fully than claims-based reporting would.

PATIENT FACT SHEET

MYOPATHIES

Myopathy is the medical term for muscle disease. Patients with myopathy develop weakness in the large muscles around the neck, shoulders, and hips. This causes difficulty in climbing stairs, getting up from a chair or toilet seat, or reaching for objects overhead. Some patients with myopathy develop weakness of the throat muscles involved in swallowing, and this may cause choking or aspiration of food into the lungs when eating. Others may experience shortness of breath and cough due to inflammation of the lungs.

Two types of inflammatory myopathies are polymyositis and dermatomyositis. Polymyositis is an inflammation of the muscle tissue that leads to weakness, and dermatomyositis is characterized by immune inflammation of muscles, as well as by the presence of a rash. This rash, which appears as a purple or red discoloration of the upper eyelids, is present in almost all children with inflammatory myopathy. "People with dermatomyositis may also have lung inflammation (pneumonitis), and children may have an inflammation of the blood vessels and calcium deposits in the skin referred to as calcinosis," explains patient fact sheet author Marc Miller, MD, of Rheumatology Associates in Portland, Maine.

Inflammatory myopathies are rare diseases, and polymyositis and dermatomyositis occur in approximately one person in 100,000. All age groups are affected, with peak incidence between the ages of five and 10 in children and between the ages of 40 and 50 in adults. Women are affected about twice as often as men, all ethnic groups are affected, and it is not possible at this time to predict who will develop an inflammatory myopathy.

A diagnosis of myopathy is suspected when patients complain of difficulty performing tasks that require muscle strength or when they develop certain rashes or respiratory problems. To establish a diagnosis, perform a muscle-strength examination to determine if true muscle weakness is present. This likely will be followed by a blood test to measure the level of various muscle enzymes, an electromyogram to gauge electrical activity in muscle, and finally a biopsy of a weak muscle. Sometimes MRI scanning can help to establish the presence of abnormal muscle.

Treatment depends on the type of myopathy diagnosed. Polymyositis and dermatomyositis are usually treated with medications. An oral corticosteroid, such as prednisone, is usually administered in high doses once the diagnosis has been established. "Methotrexate or azathioprine are usually added to ensure better long-term control of the disease and to avoid long-term side effects of cortisone," explains Dr. Miller. In severe or treatment-resistant cases, additional measures may include intravenous immunoglobulin and other immunosuppressive medications.

Since the myopathies are chronic diseases, it is important for patients to practice good general health measures, including a well-balanced nutritional diet, maintenance of normal weight, and proper management of any other chronic illnesses. Physical therapy and regular exercise to regain and maintain muscle strength are also important in the treatment of myopathy.

Download the complete myopathies fact sheet and other patient-education materials at **www.rheumatology.org** by following the links to patient education from the Practice Support Menu.

track data related to supplementary ACR quality measures that are not currently part of PQRI. These include measures related to gout management and drug safety.

With the RCR, the ACR has created a user-friendly, intuitive Web-based platform that allows its members to enhance the care they provide to their patients. Anyone with Internet access can record and retrieve the essential elements of PQRI and PIMs or enter and record patient demographics and history. Future enhancements will include the ability to record a physical examination and clinical decision-making elements of the patient encounter.

For the practicing rheumatologist and other health professionals who are committed to improving patient care, interested in the integration of quality reporting and performance improvement for recertification purposes, or who would like to participate in quality reporting, the RCR provides a timely, optimal tool that has been developed based on the input of clinical rheumatologists.

Further details on PQRI can be found on the ACR Web site at www.rheumatology.org/practice. Information about the ACR quality measures can be found at www.rheumatology.org/practice/qmc/quality.asp.

For more information about the RCR, contact Amy S. Miller at amiller@rheumatology.org, and for additional PQRI information, contact Melesia Tillman at mtillman@rheumatology.org.

REF NEWS

Streamlined Funding Portfolio Increases Efficacy

The ACR Research and Education Foundation recently completed a comprehensive review of its core awards and grants portfolio to assure that it was effective in meeting the needs of junior or early career physician-scientists and health professionals.

"Typically, support for initial training comes from NIH-sponsored training grants and from REF development awards," explains REF president Leslie J. Crofford, MD. "As research experience and accomplishments increase, young scientists continue to require mentoring, but with an eye towards developing a more focused area of research that will take them to independence."

Over the last several years, funding for the rheumatology research community has been in serious decline, threatening the advancement of care for rheumatology patients. Therefore, the REF convened a task force and charged it with carefully and thoroughly reviewing the REF core awards and grants portfolio with respect to the efficacy and need for each award currently offered, as well as to consider needs for new grant mechanisms.

After careful consideration, and with input from various constituencies, the task force concluded that it was necessary to reduce the number of awards offered by combining several mechanisms and making the application process more clear.

The streamlined portfolio represents the same commitment and the same balance of dollars between education and research that the REF has provided in the past—over $4 million—but in a more simplified way that provides a clear path for young scientists to make the transition from postdoc to independent researcher. (See "REF Support for Building a Career in Rheumatology," below.)

The hope is to encourage medical students to enter the field of rheumatology, strengthen rheumatology training programs, advance rheumatology research, and bring findings from bench to bedside—ultimately improving patients' lives.

APPLY NOW!

The REF is now accepting applications for its core awards and grants program. The deadline to apply online is August 3, 2009. Visit www.rheumatology.org/REF/Awards for complete information.

ADVOCATING WITH YOU

The Future of Medicine Is in Washington—You Should Be, Too

On March 10, the ACR hosted its 2009 "Advocates for Arthritis" fly-in. During this event, over 100 rheumatologists, rheumatology health professionals, and patient advocates walked the halls of Congress to lobby legislators on important issues affecting the rheumatology community. Advocates urged Congress to support:

> The "Arthritis Prevention, Control, and Cure Act";

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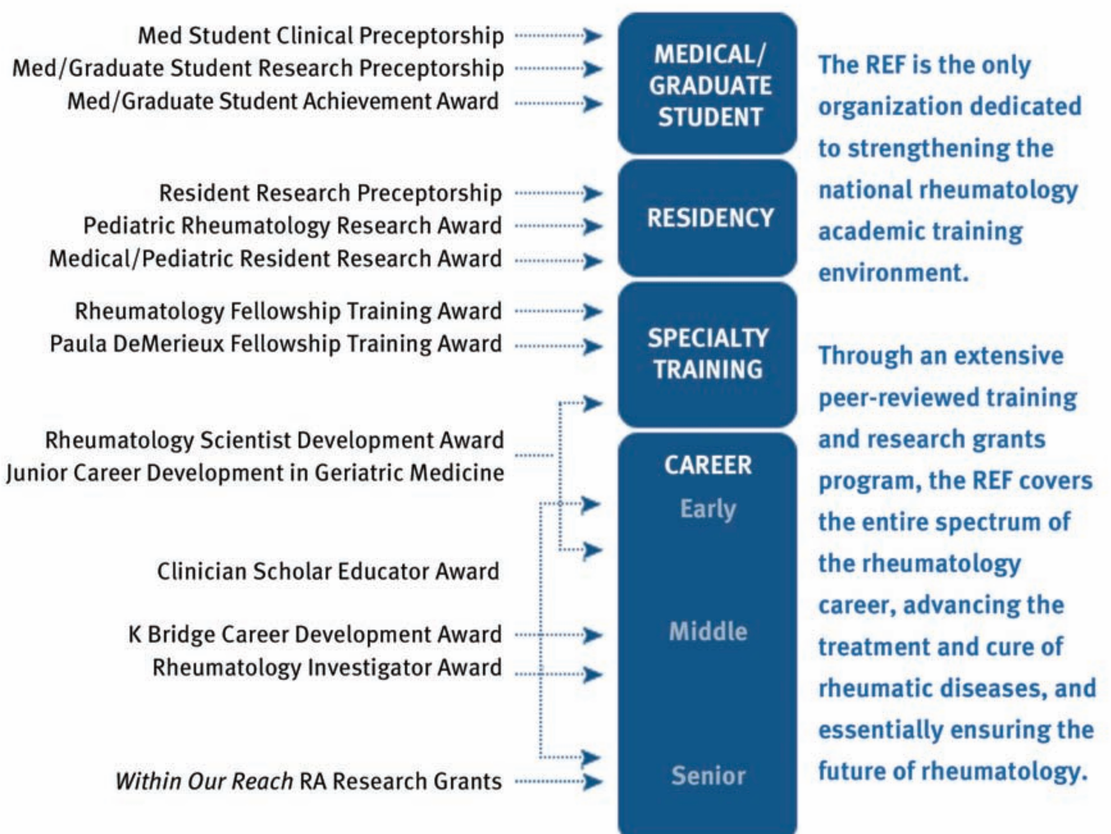

> Legislation to restrict Tier IV pricing;
> A permanent fix to the Sustainable Growth Rate;
> Legislation to ensure access to osteoporosis testing; and
> Continued increases for arthritis research funding.

Improving public policy starts with educating lawmakers on the problems affecting their constituents.

Prior to "Advocates for Arthritis," the ACR hosted an educational session where leaders in Washington addressed healthcare reform, comparative effectiveness, and ACR health policy priorities. Additionally, advocates attended a training session in preparation for their congressional visits.

RheumPAC Committee Chair Gary Bryant, MD, also gave a presentation about RheumPAC, the bipartisan political action committee created to support legislators who support rheumatology, and its role in enhancing the ACR's advocacy activities.

Everybody Is Doing It: Are You an Advocate?

This month, the ACR board of directors is on Capitol Hill. As leaders of the organization, they have heard the cry of their membership and are dedicating time to address the concerns of the rheumatology community with Congress.

Advocacy is fun, easy, and essential to ensuring that issues affecting your practice, profession, and patients are priorities of the lawmakers in Washington, D.C.

Become an advocate by:

> Contacting your U.S. representative and senators and educating them on the issues affecting the rheumatology community;
> Visiting your legislators at home or in Washington, D.C.;
> Attending town hall meetings and becoming a voice your legislator knows;
> Inviting your U.S. representative to visit your office;
> Urging other rheumatology professionals and patients to advocate; and
> Contributing to RheumPAC.

For more information about the results of "Advocates for Arthritis," or to learn how you can become an advocate, visit www.rheumatology.org or call Aiken Hackett at (404) 929-4811.

ARHP NEWS

Graduate Student Award Mentors Needed

Are you looking for an opportunity to make a difference in the life of a graduate student? If so, consider mentoring someone through the ARHP Graduate Student Award Program. This is a great way to start the mentor–mentee relationship and will give you the opportunity to positively affect your subspecialty. For details, visit to www. rheumatology.org/arhp or contact an ARHP staff member at (404) 633-3777.

ARHP Member-Get-a-Member Campaign

Strengthen your professional association and see the benefits of growth by recruiting new members. Every new member you recruit places you closer to winning a $500 airline gift certificate that can be used to travel anywhere in the United States. For more information, visit to www.rheumatology.org/ arhp or contact an ARHP staff member at (404) 633-3777.

Managing Office Infusions: From Biologics to Bones

On June 9, Josh Brinks, BSN, MSN, FNP, will address the management of office infusions during the ARHP June audioconference/webcast.

Brinks began his career working in a level-1 trauma center, which led him down the rheumatology path several years later. As a rheumatology health professional, Brinks has built infusion protocols, managed infusion reactions, and trained staff on the issues surrounding infusions.

"There are a wide variety of health professionals who are administering, or assisting with, infusions, from medical assistants to registered nurses and even mid-level providers," explains Brinks. "Staff members must be trained and aware of the procedures regarding infusions to allow for continuity. Many times with retiring staff, the message gets lost; therefore it is important for health professionals to be aware of the processes related to infusions."

As Brinks began developing the infusion audioconference/webcast, he realized there were many components that needed dedicated attention. "There is not one perfect way to administer infusions every time," he says. "This depends on the individual, their health history, and what medicine they are currently taking. One of the great challenges is that patients switch medications, and each biologic is infused over a different amount of time; there is an art to figuring out how this process will be handled."

During the ARHP's audioconference/webcast, Brinks will share his knowledge of infusions, focusing on the core elements of infusion protocols, what the benchmarks should be for infusion center productivity, the appropriate response to infusion reactions, and the current reimbursement practices for infusions.

To register for this audioconference/webcast, visit www. rheumatology.org/arhp, or contact Sharon Ross at (404) 633-3777, ext. 802. CME and certificates of participation will be offered to paid registrants.

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Mentoring Makes the World Go 'Round

>> By Marian T. Hannan, DSc, MPH, and Catherine L. Backman, PhD, OT(C)

After a decade each of serving on many committees and presidential working groups, our work in the ARHP is not over. In fact, we have discovered that our educational and professional motivation to improve research and educate our students has nearly one hundred-percent overlap with the ongoing goals of the ARHP to support the graduate students and young investigators and to sponsor new members. The ARHP offers several opportunities for you to mentor a student, colleague, or non-member through the ARHP Graduate Student Award Program, the Member-Get-a-Member Campaign, and the REF grants programs for health professionals.

Dr. Backman   Dr. Hannan

As much as we value the benefits of being mentees, we know it is also vitally important that we serve as mentors to the next generation of rheumatology health professionals.

A Cycle of Give and Take

Over the years, we have spent a fair amount of time on the front lines of research—working on other people's projects, collecting data, interviewing patients, and programming and conducting statistical analyses—and, through our ARHP membership, we have also benefited from the mentorship of colleagues who are senior researchers in our fields.

As much as we value the benefits of being mentees, we know it is also vitally important that we serve as mentors to the next generation of rheumatology health professionals. Coming to this realization led us to a commitment of mentoring, which is simply reaching out to those who are at various stages in their careers (e.g., graduate students, medical students, postdocs, new investigators, and non-members) and offering guidance based on your own knowledge and experience.

You may wonder, "If this is an unfunded activity, what motivates a researcher to educate and mentor?" As research mentors, we are enthusiastic about recognizing the creative research of junior investigators and students as their efforts merge evidence, theory, and clinical practice in assessing and improving the lives of patients with rheumatic diseases. Their wonderfully inspired ideas allow us to hone our own research skills by commenting on their ideas and work as they grow and evolve.

In addition to helping our mentees with specific projects and offering advice based on our own knowledge and experience, we know that another important aspect of mentoring is serving as a source of guidance for our mentees' career paths. As mentors, we find it very important to encourage students to participate in the ARHP Graduate Student Award Program, and if they're not a member, to join the ARHP. We encourage membership and involvement in the ARHP because we have experienced, firsthand, the value of the ARHP and the many benefits it offers.

Mentors place these benefits high on the list of opportunities they want for their mentees because they come at a reduced price that is much more economical than any other "tuition" they will ever pay.

Why We Still Make Time to Mentor

As mentors, we expand our students' world of learning as we guide and educate them and as we introduce them to our own mentors in the field. As National Institutes of Health/Canadian Institutes of Health Research–funded researchers and educators at our own institutions, we find our role as mentors to be rewarding and exactly what is needed in today's challenging funding arena.

We are at a juncture where it is crucial to enthusiastically support research training to recruit and retain young, promising researchers in the field and help them establish a track record of grants and publications. We fully believe that the seeds planted early in a research career will bear bountiful and continuing returns over time.

We follow the careers and successes in clinical research of each of the young researchers we have mentored with great pride, and it is safe to say that not one mentee has ever let us down in his or her quest for answers. We marvel at their capacity to set and surpass goals.

We appreciated having the ears (and brains) of accomplished, senior investigators interested in our research, and aim to foster collegial exchanges among all levels of researchers to support the growth of young investigators. The future of rheumatologic care and research is in the hands of the talented young professionals who join our association and who walk the halls of your institutions. Their research and teaching efforts hold great promise for our field and our future, and we are proud to serve as mentors to the next generation.

For more information on how you can mentor the next generation of rheumatology health professionals, visit www.rheumatology.org/ARHP.

Dr. Hannan, of the Institute for Aging Research at Hebrew SeniorLife and Harvard Medical School in Boston, served as ARHP president in 1997–1998. Dr. Backman, of the University of British Columbia, Vancouver, served as ARHP president in 2005–2006.

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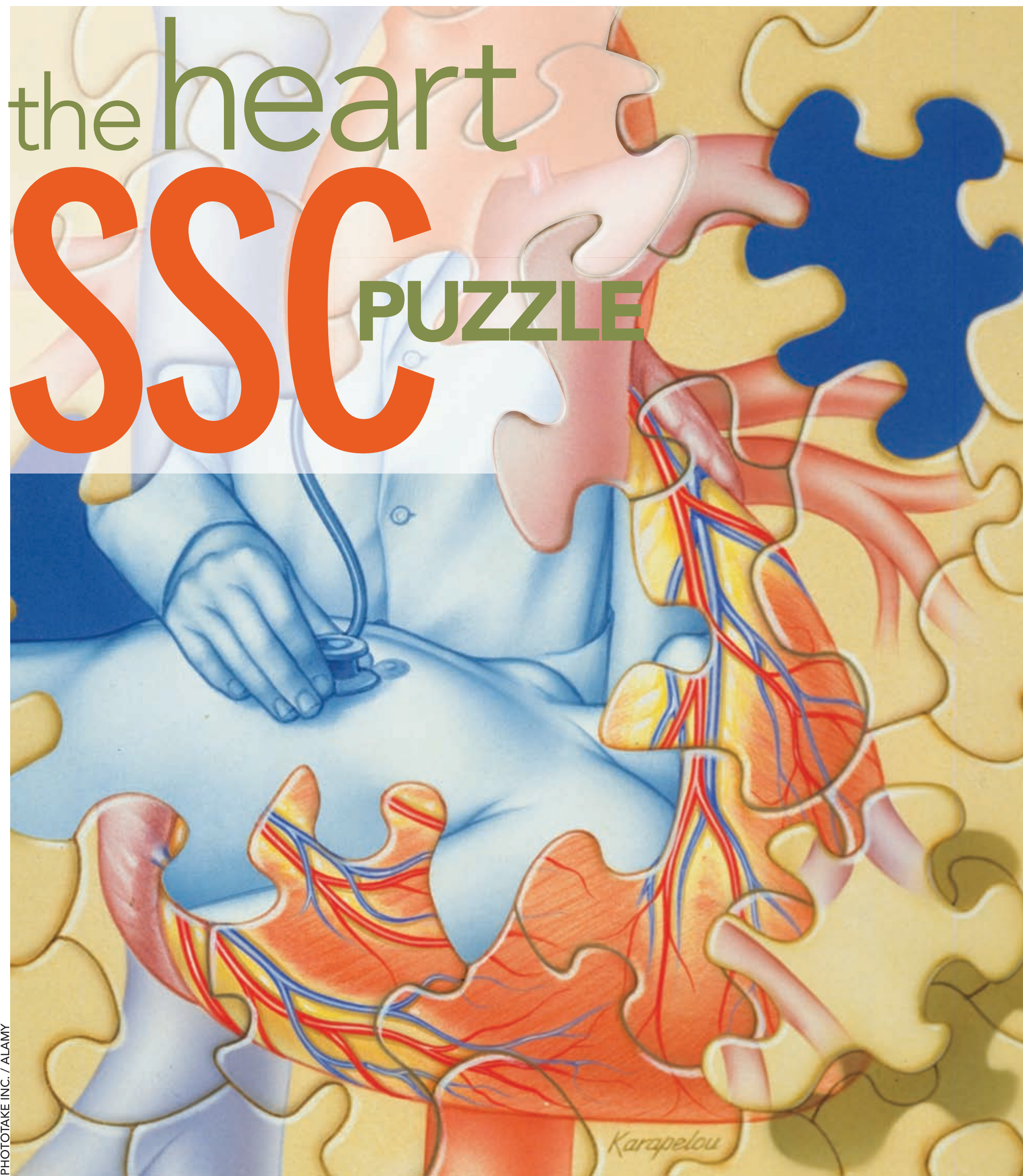


PHOTOTAKE INC. / ALAMY

Identifying and treating cardiac involvement in systemic sclerosis can be a challenge

>> By Olga Kaloudi, MD, and Marco Matucci Cerinic, MD, PhD

Electric Piece of the Puzzle

Conduction defects and arrhythmias occur frequently in SSc as a result of fibrosis or ischemia of the conduction system. Arrhythmias may be a manifestation of early cardiac involvement and may be detected during ambulatory monitoring.[2] Palpitations or syncope may occur, but usually patients are asymptomatic. Ventricular arrhythmias and sudden cardiac death are the most serious and dreaded complications. Pathological studies have shown diffuse patchy myocardial fibrosis that may favor ventricular arrhythmias by a re-entry mechanism or by activity of trigger areas. Another arrythmogenic substrate results from small (millimeter) ischemic areas (contraction band necrosis) created by repeated abnormal vasospasm of small coronary arteries and arterioles mimicking Raynaud's phenomenon of the myocardium.[3]

The most frequent conduction abnormalities in SSc are P-R interval prolongation (first-degree heart block), left anterior fascicular block, right and left bundle branch block, and nonspecific intraventricular conduction defects. With the same pathophysiological substrate, the most common arrhythmias occurring in SSc are premature ventricular contractions in the form of couplets multifocal, premature atrial contractions, and supraventricular tachycardia. Particular attention must be directed to sustained ventricular tachycardia that represents a poor prognostic factor for sudden death.

In SSc, the incidence of sudden cardiac death is higher than that in the general population. Postmortem studies of SSc patients who die suddenly show a history of ventricular arrhythmias, documented ventricular tachycardias, and frequent multifocal premature ventricular contractions.[4] Currently, there is no evidence that drug therapy lowers mortality in SSc patients. In fact, the outcome may be even worse with treatment because of a proarrythmic effect of drugs; the use of drugs, however, may represent a marker of severity of arrhythmia rather than a cause of increased mortality. Whatever the basis for this association, these data suggest that use of anti-arrhythmics in SSc patients should be closely monitored with repeated ambulatory electrocardiography.

Diagnosis

1 Standard 12-lead electrocardiogram (EKG): At baseline, a standard 12-lead EKG with serial studies at intervals is the most simple, inexpensive, and rapid method for initial cardiac evaluation (see Figure 1, p.17). In SSc, an EKG can detect hidden arrhythmias, asymptomatic conduction defects, and previous ischemic defects. In a large EKG study, ventricular ectopy occurred in 67% of patients and was strongly correlated with total mortality and sudden death, independently from other indexes of severity of disease and organ involvement.

2 Holter monitoring: Holter monitoring is a noninvasive method with high predictive value that permits the early detection of cardiac involvement. Analysis of Holter monitoring data can detect arrhythmias and conduction defects not seen on a standard EKG. Patients with significant abnormalities on Holter monitoring should have further investigations (see Figure 1, p.17). In SSc, Holter monitoring may add valuable information about the autonomic nervous system, assessing the heart rate variability and the QT interval. Recently, abnormalities of heart rate variability and increased QT dispersion have been reported in SSc patients. Autonomic dysfunction represents the cardiac vulnerability resulting from an autonomic imbalance and is a marker for arrhythmic death or an indicator of disease severity. We strongly recommend performance of a Holter at least twice a year in patients with SSc.

3 Invasive electrophysiologic studies: Invasive electrophysiologic studies are indicated when spontaneous arrhythmias are frequent and when a serious sustained arrhythmia is suspected. Electrophysiologic studies can detect the mechanism generating the arrhythmias and allow the selection of patients who can be treated by transcatheter ablation; in this selection, the guidelines are similar to those employed in the management for ventricular tachycardia due to coronary disease.[5]

Treatment

At present, the management of cardiac involvement in SSc remains largely empirical and derives mainly from evidence obtained from other diseases. There is no evidence that antiarrhytmic drug therapy lowers mortality in SSc patients. Successful treatment with ablation, both surgical cryoablation and catheter ablation, has been reported. Implantation of a cardioverter defibrillator and/or a pacemaker may be a treatment of choice for patients with life-threatening ventricular arrhythmias and conduction defects.

Myocardial Piece of the Puzzle

Primary myocardial involvement in SSc is characterized by patchy fibrotic lesions distributed in both ventricles. Although advanced myocardial fibrosis may lead to congestive heart failure, systolic or diastolic dysfunction can occur early in the disease, before becoming symptomatic years later. When clinically evident, myocardial involvement is recognized as a poor prognostic factor since the overall mortality rate at five years of SSc patients with proven cardiovascular impairment is over 70%. Usually, physical findings are nonspecific and include signs of congestive heart failure. For this reason, a timely diagnosis is highly recommended.

Recently, increased interest has been devoted to left ventricular diastolic dysfunction. Some authors suggest that this type of dysfunction occurs only in SSc patients with systemic and/or pulmonary hypertension, ventricular hypertrophy and pericardial disease. Other authors believe that diastolic abnormalities in SSc reflect primary involvement of the myocardium that may precede systolic dysfunction or may relate to subclinical myocardial involvement occurring even as early as the onset of Raynaud's phenomenon.[6] This frequent symptomless coronary vasospasm may contribute to myocardial dysfunction.

Diagnosis

1 Echocardiography: In SSc, baseline and serial echocardiography with Doppler should be performed to achieve important information about left and right ventricular morphology and function, valvular function, and/or pericardial effusion. Using improved echochardiographic techniques, like tissue Doppler imaging, regional systolic diastolic abnormalities and direct measures of myocardial velocities can be detected, offering the opportunity of more

accurate follow up and earlier treatment. One recent study suggests that the presence of diastolic dysfunction in SSc patients reflects an early asymptomatic myocardial fibrosis, identifying those patients with higher risk for cardiac impairment. Left ventricular diastolic dysfunction is expressed by an inverted E/A ratio that represents early and late ventricular filling during atrial contraction.[7] Recently, the use of TDI techniques may improve the detection of heart involvement showing the depression of left and right ventricular systolic and left ventricular diastolic function.[8]

2 Magnetic resonance imaging (MRI): MRI is superior to other techniques for the assessment of ventricular size, function, and mass because it is non-invasive and has high spatial resolution, high reproducibility, and low inter-observer and intra-observer variability. High-resolution perfusion MRI techniques can identify small subendocardial defects and may allow a non-invasive determination of coronary reserve and the evaluation of fibrotic myocardium compared with viable tissue. Two recent studies indicate that MRI may detect subclinical right heart involvement and can identify myocardial fibrosis in a significant percentage of SSc patients.[9] MRI is a valuable tool but the high cost still limits its use.[10]

3 Myocardial biopsy (MB): In clinical practice, the use of MB is limited by invasiveness of the procedure and high rate of sampling errors as shown by its relatively low diagnostic yield compared with that of autopsy. MB is indicated when there is clinical concern for the presence of other cardiac pathologies that might overlap with SSc. An immunohistological study of MB revealed myocarditis and an increased amount of fibroblast, suggesting that more frequent use of MB might lead to more differentiated therapies. In fact, in this study, an increased amount of AS02-positive fibroblast was found in the myocardium of both SSc patients in comparison with the controls, suggesting that fibroblasts are over-represented in the SSc myocardial tissue of patients in comparison with other myocardial diseases. However, the utility of MB is significantly limited by risks and the possibility of sampling error due to patchy heart involvement.[11]

Treatment

Early treatment with vasodilators such as calcium channel blockers and angiotensin converting enzyme inhibitors has been shown to be beneficial on myocardial perfusion and function and may help to limit the progression of major life-threatening complication of the disease. Up to now, no antifibrotic therapy has been shown to preview or control myocardial fibrosis.

Vascular Piece of the Puzzle

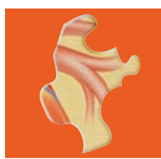
In SSc, despite of the prominence of vascular abnormalities and documented ischemia, the incidence of coronary artery disease does not seem different from that of the general population.[12] Characteristic SSc vascular lesions result in major impairment of the microcirculation. Histological examinations reveal concentric intimal hypertrophy associated with fibrinoid necrosis of intramural coronary arteries. In addition, vasospasm of the small coronary arterioles mimicking a myocardial Raynaud's phenomenon induce contraction band necrosis that are ischemic tiny fibrotic areas of the myocardium. Two recent studies using enhanced transthoracic Doppler before and after adenosine infusion have confirmed the reduction of coronary reserve in SSc patients without clinical evidence of cardiac involvement. The functional and structural abnormalities of the small coronary circulation are now considered the first pathologic step of the disease that leads to late fibrotic patchy ischemic lesions.

Diagnosis

1 Single photon emission computed tomography (SPECT): The acquisition of perfusion scintigraphy using gated SPECT is an important development of nuclear medicine. Gated SPECT allows the automated calculation of left ventricular ejection fraction (LVEF) and the assessment of regional function using perfusion images. A good correlation exists between resting gated SPECT and other imaging techniques for the calculation of LVEF and the assessment of regional wall motion and thickening. The simultaneous assessment of perfusion and function is helpful for the diagnostic and prognostic assessment of patients with chronic coronary artery disease like SSc patients.

The addition of functional data to stress and rest perfusion images significantly improves their specificity and reduces the uncertainty in test interpretation, with a better separation of normal from abnormal studies SPECT allows the assessment of myocardial perfusion, providing evidence of associated reversible ischaemia. Using pharmacological stress (dipyridamole) with SPECT, decreased heart perfusion was observed in 82% of SSc patients.[13] This technique is important in differentiating myocardial stunning from inducible ischemia or necrosis, using the endothelium-dependent vasodilating effect of dipyridamole. SPECT is considered relatively safe, inexpensive, and easy to perform. SPECT can be applied in scintigraphy with thallium-201 and with perfusion markers like Tc-99m. We recommend performance of SPECT as a baseline exam even in asymptomatic patients.

2 Coronary angiography: Coronary angiography offers the most accurate visualization of the coronary arteries and remains the gold standard when a stenotic coronary lesion is suspected. Angiography is not recommended for screening asymptomatic patients.[14]



Pericardial Piece of the Puzzle

Pericardial effusion is a harbinger of a poor prognosis and is more frequent in patients with the diffuse subset of the disease.[15,16] Pericardial effusion is also a useful predictor of scleroderma renal crisis.[17] In autopsy studies, SSc patients commonly have asymptomatic pericardial abnormalities with a prevalence estimated from 33% to 72%. Recently, it has been reported that pericardial abnormalities are associated with echocardiographically defined pulmonary arterial hypertension (PAH).[18]

Diagnosis

1 Echocardiography: Echocardiography is the most widely used imaging technique in the evaluation of suspected pericardial disease. Transthoracic echocardiography represents the gold standard for diagnosis of pericardial abnormalities, demonstrating the location and amount of even minimal pericardial effusion. The echocardiographic features of pericardial effusion are the pericardial layer separation with an echo-free space and the decrease in the parietal pericardial motion.

2 Pericardiocentesis and biopsy: Pericardiocentesis and biopsy are limited by their invasiveness. Cytology, bacteriology, and virology may be performed on the fluid and can be of important diagnostic value. If tamponade develops, emergency pericardiocentesis is needed.

Treatment

Low-dose steroids may be helpful for the control of pericardial involvement. The addition of colchicine can be an effective treatment for acute and recurrent pericarditis. This combination may be helpful in preventing recurrences in almost 90% of cases.[19]

Diagnosis and Management

Clinical signs suggesting cardiovascular involvement in SSc are often nonspecific. The first step in practice is to obtain a detailed history, a thorough physical examination and a standard EKG. Thereafter, the baseline evaluation consists of a 24 Holter monitoring, Doppler echocardiography, and SPECT. Assessment of Pro-BNP may be useful for the diagnosis of cardiomyopathy because its concentration is altered in patients with myocardial structural impairment even if asymptomatic: usually, pro-BNP levels are used to monitor patients with PAH.

If baseline studies are normal and the patient has no complaints, we recommend a biannual assessment with Holter and Echo-Doppler (See Figure 1, above). If Holter monitoring provides evidence of arrhythmias or conduction defects, further investigations are necessary and should be guided by the arrhythmic pattern. If the echocardiogram re-

continued on page 18

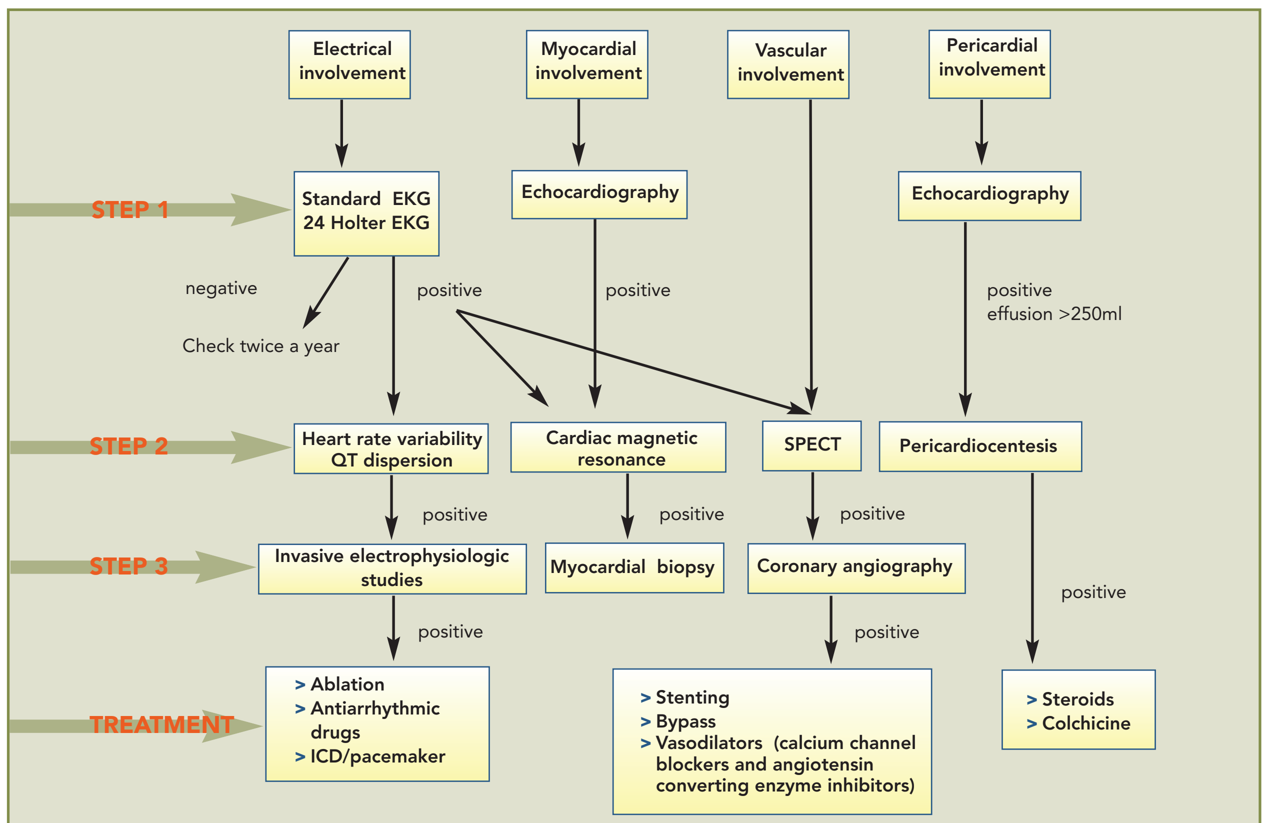


FIGURE 1: An algorithm for the diagnosis and management of cardiac involvement in SSc.

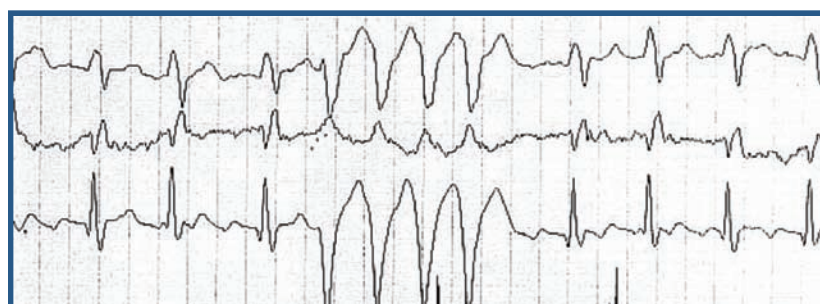


FIGURE 2: A Holter surface EKG with complex ventricular tachycardia before ICD implantation.

 continued from page 17

veals cardiac hypertrophy, a reduced ejection fraction, or a diastolic dysfunction (inverted E/A ratio), more invasive investigations like left- and right-heart catheterization or angiography are needed. If SPECT reveals areas of inducible ischemia, coronary angiography should be performed.

CASE REPORT

A 53-year-old SSc patient with esophageal and muscle involvement (weakness, elevated CK) developed dyspnea on exertion. Pulmonary function tests and high-resolution computed chest tomography were normal. Cardiac color-Doppler echocardiography PAP was normal, but a left ventricular asynergy with normal ejection fraction (56%) was detected. Cardiac scintigraphy demonstrated an apical–septal area of inducible ischemia. Coronary angiography was performed demonstrating a slow contrast washout representing a microcirculation pathology with no occlusions of the extramural coronary arteries. Cardiac Holter showed the presence of 7.567 monomorphic ventricular extrasystolic beats with 237 pairs and 13 runs of bigeminy despite antiarrhythmic drug (amiodarone) therapy (see Figure 2, p. 17). For this reason, an intracardiac defibrillator (ICD) was implanted.

Six months later, the analysis of the ICD showed that it has been activated with deliverance of four shocks to stop episodes of malignant ventricular tachycardia. This case shows that a prompt diagnosis of arrhythmia and the implantation of an ICD can prevent sudden cardiac death in an SSc patient and this clearly illustrates the value of a comprehensive diagnostic work-up and the benefits of an aggressive patient management.

Conclusion

Cardiac findings—ranging from fatal arrhythmias to congestive heart failure—remain serious manifestations of SSc and important sources of morbidity and mortality. These manifestations, which may reflect electrical, vascular, and myocardial pathology, are frequently asymptomatic and can occur alone or together. The rheumatologist must therefore confront the puzzle of cardiac involvement in SSc with a broad array of diagnostic approaches and, by determining which piece of the puzzle is jeopardizing the patient's life, apply the right treatment. Hopefully, with a more aggressive approach and development of new modalities of treatment, improvements in patient outcome will occur and thereby change the course of this dangerous and puzzling complication of the disease. THE RHEUMATOLOGIST

Dr. Kaloudi is in the Division of Rheumatology at the University of Florence. Dr. Matucci Cerinic is professor of rheumatology and medicine and director of Division of Medicine and Rheumatology at the University of Florence.

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From the COLLEGE continued from page 12

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Drug UPDATES

INFORMATION ON SAFETY, LABELING CHANGES, AND PHARMACEUTICAL RESEARCH

>> By Michele B Kaufman, PharmD, BSc, RPh

continued from page 1

limited analgesic usefulness, and unfavorable risk-to-benefit ratio. At press time, a final decision had not been made.

Wearing **medicated transdermal patches** while undergoing magnetic resonance imaging (MRI) scans can cause skin burns on the direct patch area.[3] Some transdermal patches contain metallic backing or other layers that can overheat during an MRI scan. Patches have many indications including anti-emetics (e.g., granisetron), antidepressants (e.g., selegiline), hormone replacement (e.g., estrogen, testosterone), analgesia (e.g., fentanyl), and smoking cessation (e.g., nicotine). The FDA is evaluating patch contents and labeling to ensure that patients receive this warning about burns. Until the FDA makes a final decision, healthcare providers are asked to warn patients wearing a medicated patch to remove and dispose of it prior to undergoing an MRI. After the scan, the patch should be replaced. When filling out the health history questionnaire at the time of an MRI, patients should include information about medicated transdermal patches.[4]

Genentech is voluntarily withdrawing **efalizumab (Raptiva)**, a medication for treatment of psoriasis, from the U.S. market due to a potential risk to patients of developing progressive multifocal leukoencephalopathy (PML).[5] The phased withdrawal will run through June 8, 2009, at which time the drug will no longer be available in the United States. Physicians are being asked not to start any new patients on efalizumab and to discuss alternate therapies with their patients currently taking efalizumab.

Bisphosphonate-associated Osteonecrosis

Around the time that Sedghizadeh et al were conducting and reporting on bisphosphonate-related osteonecrosis of the jaw (BRONJ) [See "Reading Rheum," p. 20], the American Dental Association Council on Scientific Affairs updated their recommendations for managing patients taking oral bisphosphonates.[6-7] They note that the risks of developing BRONJ from oral bisphosphonate therapy remains small compared with the risk associated with IV bisphosphonates, a comparison of approximately 0.04% and 20%, respectively. Management of general dentistry for patients taking oral bisphosphonates should include routine dental examinations and routine dental care. Those patients taking oral bisphosphonates who do not receive regular dental care should and would benefit from a comprehensive oral examination. Patients taking oral bisphosphonates should be informed of the following:

- That they are at a low risk of developing BRONJ of the jaw (estimates of zero to 1 in 2,260 cases);
- The low BRONJ risk may be minimized but not eliminated;
- The optimal approach to lowering BRONJ risk *may* be via good oral hygiene practices and usual care;
- No validated diagnostic techniques are available to determine who is at increased risk of BRONJ;
- Discontinuing bisphosphonates may not eliminate the risk of BRONJ;
- A dentist should be consulted if there are any oral cavity–related problems that develop while receiving bisphosphonate therapy; and
- Any discussions about whether or not to continue bisphosphonate therapy should be held with the prescribing physician. The risk–benefit ratio of oral bisphosphonate therapy should be evaluated, because the benefit often might outweigh the risk.

The goal in BRONJ prevention is to limit the possibility of extensive involvement. The advisory statement discusses management of periodontal disease, implant placement/maintenance, and other dental-related procedures. It is available at http://jada.ada.org/cgi/reprint/139/12/1674.

Bisphosphonates and Esophageal Cancer

In the January 1, 2009 issue of the *New England Journal of Medicine*, Diane Wysowski, PhD, from the FDA, reported on information regarding esophageal cancer in U.S. patients treated with bisphosphonates. Data from October 1995 through mid-May 2008 were analyzed.[8] Dr. Wysowski reported that there have been 23 cases (eight of them fatal) of esophageal cancer associated with alendronate. Alendronate was the suspect drug in 21 cases and used as concomitant therapy in two. No other esophageal cancer cases were reported with other oral bisphosphonates. Abroad, an additional 31 cases (six of them fatal) were reported in Europe and Japan. In these cases, alendronate was the suspect drug in 21 cases. For remaining cases, the following drugs were implicated: risedronate, ibandronate, etidronate, or a combination of these. Four cases noted "bisphosphonates" without specifying the drug. The majority of cases were women (>71%) with median ages of 74 years (US) and 68.5 years (abroad). The median exposure time from alendronate use to diagnosis was 2.1 years (US) and 1.3 years (abroad). Barrett's esophagus was diagnosed near the time of the esophageal cancer diagnosis in three patients. Five patients had squamous-cell carcinoma and six had adenocarcinoma.

The author noted that esophagitis has been associated with oral bisphosphonates and this usually occurs when drug administration directions are not closely followed. Additionally, crystalline material that looked like ground alendronate tablets was found on the biopsies of patients with erosive esophagitis, and ongoing mucosal irregularity had been seen in some of these same patients.[9] This information suggests a potential for carcinogenic effects.

Dr. Wysowski recommends that physicians not prescribe oral bisphosphonates to patients with Barrett's esophagus. Merck has stated that over 150-million prescriptions for alendronate have been written in the US. They note that in their clinical database of pre- and post-marketing patients that received the medication for three to 10 years (n=3,800), the data do not suggest an association between alendronate and esophageal cancer.

Further studies need to be performed that include oral bisphosphonates as a possible risk factor for esophageal cancer.

FDA Drug Safety Efforts

In an ongoing effort to improve drug safety and pursuant to Title IX, Section 921 of the FDA Amendments Act (FDAAA) of 2007, each quarter the FDA will be publishing a new list of potential signals of serious risks and new safety information for drugs identified. The FDAAA directs the FDA to regularly screen the Adverse Event Reporting System (AERS) database for any new safety in-

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Pipeline UPDATE

On January 5, the FDA issued a complete response letter to UCB for their certolizumab pegol (Cimzia) Biological License Application to treat rheumatoid arthritis.[16] On February 6, UCB announced that the FDA is requiring additional analysis of their existing data and a new safety update, but no additional clinical or nonclinical studies are needed.[17] The planned submission date is now in the second quarter of 2009. Certolizumab pegol is the first pegylated anti–tumor necrosis factor (TNF) agent. It is already FDA approved to treat patients with moderate to severe Crohn's disease.

Acura and King Pharmaceuticals submitted a New Drug Application (NDA) to the FDA for **oxycodone hydrochloride/niacin tablets (Acurox)**, which was accepted as a priority review.[18] The proposed indication is treatment of moderate to severe pain. Acurox utilizes a proprietary Aversion technology designed to deter common methods of misuse and abuse, including: intentional swallowing of excess tablet quantities; dissolving tablets and then injecting them via the intravenous (IV) route; and crushing tablets and then nasally snorting the contents.

New Approvals

- **Febuxostat (Uloric)** was FDA approved for treating hyperuricemia in gout patients.[12] Febuxostat is a potent, non-purine, selective, xanthine oxidase inhibitor, structurally different from other xanthine oxidase inhibitors. Availability will be in 40- and 80-mg tablets (once-daily dosing). It is not recommended for patients with asymptomatic hyperuricemia, and does not require dosage adjustment for patients with mild to moderate hepatic or renal impairment.
- **Hylan G-F 20 (Synvisc-One)** has been FDA approved as a single, intra-articular injection viscosupplement for treating knee osteoarthritis.[13]
- **Morphine sulfate extended-release capsules (Avinza)** are now also available in 45- and 75-mg dosage strengths. This is in addition to the 30-, 60-, 90-, and 120-mg capsules already available. Avinza is FDA approved for treating moderate to severe chronic pain in patients needing around-the-clock analgesia.[14]
- **Topical coal tar foam 2% (Scytera)** has been FDA approved for treating chronic psoriasis. It contains an odor neutralizer and spreads easily.[15]

Reading RHEUM

HANDPICKED REVIEWS OF CONTEMPORARY LITERATURE

BISPHOSPHONATES

Should Rheumatologists Watch for Osteonecrosis of the Jaw in Oral Bisphosphonate Users?

>> By Daniel Hal Solomon, MD, MPH

Sedghizadeh PP, Stanley K, Caligiuri M, Hofkes S, Lowry B, Shuler CF. Oral bisphosphonate use and the prevalence of osteonecrosis of the jaw: An institutional inquiry. J Am Dent Assoc. *2009;140:61-66.*

Background: Initial reports of osteonecrosis of the jaw (ONJ) secondary to bisphosphonate (BP) therapy indicated that patients receiving BPs orally were at a negligible risk of developing ONJ compared with patients receiving BPs intravenously. The authors conducted a study to address a preliminary finding that ONJ secondary to oral BP therapy with alendronate sodium in a patient population at the University of Southern California was more common than previously suggested.

Methods: The authors queried an electronic medical record system to determine the number of patients with a history of alendronate use and all patients receiving alendronate who also were receiving treatment for ONJ.

Results: The authors identified 208 patients with a history of alendronate use. They found that nine had active ONJ and were being treated in the school's clinics. These patients represented one in 23 of the patients receiving alendronate, or approximately 4% of the population.

Conclusions: This is the first large institutional study in the United States with respect to the epidemiology of ONJ and oral bisphosphonate use. Further studies along this line will help delineate more clearly the relationship between oral BP use and ONJ.

Clinical implications: The findings from this study indicated that even short-term oral use of alendronate led to ONJ in a subset of patients after certain dental procedures were performed. These findings have important therapeutic and preventive implications.

Commentary

ONJ has been increasingly described in relation to the use of bisphosphonates (BRONJ). The original reports of BRONJ focused on patients receiving intravenous (IV) bisphosphonates to treat osseous manifestations of a variety of cancers. In addition, numerous case series have been reported, some including patients using bisphosphonates at the lower dosages to treat osteoporosis. In the last two years, both the American Academy of Oral and Maxillofacial Surgeons (AAOMS) and the American Society of Bone and Mineral Research have put out major position papers regarding BRONJ.[1,2] The AAOMS has established a case definition that includes three criteria: **1)** An area of exposed bone within the oral cavity; **2)** No predisposing conditions (such as oral radiation therapy); and **3)** Prior use of a bisphosphonate. In addition, a grading system has been established by the AAOMS and general treatment recommendations have been put forward.

Among cancer patients, the epidemiology of BRONJ has been well defined. Large epidemiologic studies with careful follow-up and structured dental questionnaires and/or examinations have described an incidence of BRONJ ranging from 2% to 11%.[3] Risk factors for BRONJ among cancer patients appear to be the concomitant use of glucocorticoids as well as several chemotherapies. Recent dental extractions strongly associate with BRONJ. However, the epidemiology of BRONJ among osteoporosis patients is much less clear.

Several sources suggest that the incidence of BRONJ among patients using these agents for osteoporosis is between 1 in 10,000 and 1 in 100,000.[4] This estimate is based on sparse data, including the lack of BRONJ observed in randomized controlled trials with oral bisphosphonates. This number may be an underestimate because most trials did not formally assess for oral lesions. In fact, a postal survey conducted in Australia found a rate of BRONJ among oral bisphosphonate users between 0.01% and 0.04%. Rates increased 10-fold among persons with recent dental extractions.[5]

This more recent study by Sedghizadeh et al reported an even higher risk. Investigators at the USC dental school clinic collected a sample with all oral bisphosphonate users (n=208) and found nine cases of ONJ. None of the cases was referred to the clinic for ONJ, and all were at least stage 2 or 3 (painful or infected site of exposed bone). All cases of BRONJ occurred after a simple tooth extraction or denture trauma and all cases were among older women. No case occurred prior to 12 months of bisphosphonate exposure.

There were several limitations to the study by Sedghizadeh and colleagues. The dental school clinic population may not be representative of a typical population using bisphosphonates. The authors give us no information about the total source population. Also, the authors do not calculate the rate of ONJ among patients not using bisphosphonates. Thus, it is difficult to know whether the source population was uniquely at risk for ONJ.

Despite these potential limitations, the calculated rate of BRONJ of 4% is many times higher than other estimates. While it seems unlikely that the rate is actually this high, it is also likely that initial estimates of 1 per 100,000 were too low. However, without large well-conducted studies, there are no good estimates of the rates of BRONJ among osteoporosis patients. For now, it seems prudent to warn patients about this potential risk, to encourage them to have dental work prior to starting bisphosphonates, and then to include the oral cavity in one's review of systems and physical examination of patients using bisphosphonates. If a patient needs dental work while on a bisphosphonate, they should have it done, but what to do with the bisphosphonate is unclear. The

TABLE 1:

DXA Results and Clinical Follow-Up of Patients Who Completed Screening

Condition (T-Score)	n (%)	Clinical follow-up, %
Osteoporosis (≤ -2.5)	31 (12.7)	93.5*
Osteopenia (-2.0 to -2.4)	41 (16.8)	78.0†
Osteopenia (-1.1 to -1.9)	88 (36.1)	100.0††
Normal (≥ -1.0)	84 (34.4)	88.1§
Total	244 (100.0)	

* All patients received follow-up contact; one patient never scheduled and one patient cancelled a recommended follow-up PCP appointment.

† Four patients had no follow-up contact (three of these were patients of medical residents); five never scheduled a recommended follow-up PCP appointment.

†† 20% random sample.

§ In 20% random sample, 2/17 patients had no follow-up contact.

DRUG UPDATES

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formation or potential signals of serious risks identified within the last quarter. This information may include new safety information such as that derived from postmarketing adverse-event reports or from drugs with Risk Evaluation and Mitigation Strategy (REMS).[10] However, an identified safety issue does not mean that causality has been identified between the drug and the listed risk.[11] The FDA will communicate new information identified from their review as it completes each evaluation.

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ASBMR task force noted that some experts suggest a period off of bisphosphonates before and after dental extractions.[1] However, there are little actual data to guide decision making for such patients. As more patients have used bisphosphonates for longer periods, more cases of BRONJ are likely to surface. Based on potential toxicities and lack of clear benefit beyond five years, it may be prudent to limit bisphosphonate use to 60 months.

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Increasing Bone Densitometry Testing Through an Outreach System

>> By Gail C. Davis, RN, EdD

Denberg TD, Myers, BA, Lin, CT, Libby, AM, Min SJ, McDermott MT, Steiner JF. An outreach intervention increases bone densitometry testing in older women. JAGS. *2009; 57:341-347.*

Abstract

Objectives: To evaluate the performance of a patient recall intervention that relies on an outreach coordinator with a bachelor's degree to prompt women by mail and telephone about their eligibility for bone densitometry (dual-energy X-ray absorptiometry [DXA]) screening and allow them to schedule an examination without a medical provider visit ahead of time.

Design: Observational.

Setting: Academic general internal medicine practice.

Intervention: Mail- and telephone-based patient recall for DXA.

Participants: Five hundred sixty-four women aged 65 to 79 at average risk for osteoporosis without a history of DXA.

Measurements: Rates of DXA completion and the change in proportion of screened women during a seven-month intervention period, case finding for clinically significant bone loss, frequency of appropriate clinical follow-up, DXA no-show rates compared with usual care, and clinician satisfaction.

Results: Through patient recall, rates of DXA screening rose significantly ($P<.001$), and the proportion of the eligible clinic population screened increased 13%. Thirty percent of patients had clinically significant bone loss, with almost all of these receiving follow-up, DXA no-show rates were comparable with usual care, and provider acceptance was high.

Conclusion: A patient recall intervention substantially increased DXA screening, allowing pharmacological therapy to be started much earlier in some women with significant bone loss. It imposed minimal burden on providers and enhanced patient convenience. This type of program may have utility for additional preventive services.

Commentary

The article provides a description of a "health promotion outreach system" designed to "improve the delivery of preventive and chronic disease care in the outpatient setting."[1]

Specifically, this outreach system was developed to increase DXA testing of bone density in women between the ages of 65 and 79 who were patients in an academic ambulatory medical practice. The recommendation of the US Preventive Services Task Force (USPSTF) is that DXA screening should routinely begin for postmenopausal women at age 65, and at age 60 for those who are at increased risk for osteoporotic fractures (e.g., low weight and no current hormone replacement therapy).[2] Women aged 80 and over were excluded from the study because primary care providers (PCPs) preferred to see them prior to a DXA referral, assuming they might have more comorbidities than younger women. Women were also excluded if they were currently taking a bisphosphonate or had active cancer or a terminal diagnosis.

The authors make a case for the importance of the study, noting that the disability, mortality, and direct care costs associated with osteoporotic fractures could be reduced if screening were increased and treatment begun to maintain or increase bone density. They note that 50% of women aged 50 and older will have a future osteoporosis-related fracture.[3] Further evidence pointing out the incidence and the issues associated with osteoporotic fractures is available and compelling.[4,5]

Prior to implementation of the intervention, it was approved by all of the PCPs in the system. An invitation letter was sent to 564 eligible patients that informed them of the USPSTF recommendations and encouraged them to call for a DXA appointment. Along with the letter, a prepaid postcard was included that individuals could return to indicate if they had had a previous DXA outside this agency, no longer received primary health care within this system, were not interested in receiving a DXA, or would like to be called at a given time and number. If there was no response to the first letter within two weeks, the coordinator called the patients up to three times over an eight-week period. If no response was received, a voice message was left only the first time. If the woman was reached, the coordinator reviewed the DXA recommendations and scheduled an appointment, if this was desired. An electronic order for the DXA was then requested from the PCP. When the DXA results were received, the PCP decided whether to follow up by mail, phone, or an office visit. A call center was available for patients to request a callback.

Results support the use of such an intervention in primary care. Almost half (n=244, 43.3%) of those contacted had a bone scan. Table 1 (p. 20) shows the results of those found to have osteoporosis, advanced osteopenia (defined as a T-score of less than -2.0), less severe osteopenia, and normal bone mass, as well as the follow-up activities. These numbers show that 72 women (29.5%) of those screened had clinically significant bone loss requiring pharmacological therapy. The treatment criteria of the National Osteoporosis Foundation indicate that pharmacological therapy should be started for those with a T-score equal to or less than -2.5 of the hip (femoral neck) or spine.[6]

This prevention model offers a feasible, positive approach to increasing patient participation in a potentially preventive activity such as DXA screening. The intervention was found to be valuable when outcomes were measured, and it was viewed as beneficial by the PCPs. The notes following Table 1 show that most patients received clinical follow-up, though nine of those with advanced osteopenia did not. Lack of follow-up was most often related to patients not following advice to make an appointment or to resident physicians not communicating with patients. In addition to increasing the preventive screening, such an intervention could promote education about the health-related condition while, at the same time, allowing more time during the office visit for discussion of the person's more immediate health issues. The authors note that additional testing is needed in a variety of practice environments.

Implementation of such an intervention could be planned individually for different environments (e.g., rheumatology clinics and private practices). Because the cost of mailing and having staff available for calling may be prohibitive without additional funding, settings can at least take steps to insure that patients receive information as they make office visits. For example, a nurse or nurse practitioner could be designated to make a quick risk assessment and provide counseling before or after the patient sees the physician. Discussion might be prompted by signs placed in the waiting area (in English and other appropriate languages). In addition to the USPSTF recommendations, cost considerations should also be discussed with patients. Medicare will cover DXA every two years[3]; other insurers may vary. Not only women should be targeted; men with risk factors (e.g., aged 70 and older, low weight, and minimal exercise) should also be assessed.[7]

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CODING CORNER!

May's coding answer (question on p. 10): 99213-25, 96413, J0129 x 75

Diagnosis: 714.0

Modifier -25 is used to indicate that the patient required a significant, separately identifiable E/M service on the same day as the patient received a minor procedure. E/M services that result in the decision to perform a procedure on the same day are considered to be part of the evaluation for the procedure and are not separately billable. However, this patient had a separate problem (pain and swelling of the knees), which required E/M services, therefore the portion of the encounter related to the diagnosis and treatment of the patient's pain are separately billable with the use of modifier -25.

The E/M services related to the patient's knee pain included:

- Expanded problem-focused history;
- Detailed exam; and
- Low complexity decision making—established problem; worsening, lab and X-ray ordered, and one or more chronic illness with mild exacerbation.

The abatacept infusion would be coded as 96413, not 96365. The CPT definition states that, "chemotherapy services are typically highly complex and require direct physician supervision for any or all purposes of patient assessment, provision of consent, safety oversight, and intra-service supervision of staff. Typically, such chemotherapy services require advanced practice training and competency for staff who provide these services; special considerations for preparation, dosage, or disposal; and commonly, these services entail significant patient risk and frequent monitoring."

Abatacept falls under this portion of the definition because it requires direct physician supervision. There have been rare cases of anaphylaxis or anaphylactoid reactions in patients receiving abatacept, as well as other events potentially associated with drug hypersensitivity such as hypotension, urticaria, and dyspnea. Physicians should exercise caution when considering abatacept in patients with recurrent infections and underlying conditions that may predispose them to infections, or chronic, latent, or localized infections. Specially trained staff should be available to monitor these patients and should be able to deal with potential reactions.