

the Rheumatologist

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EXERCISE to Improve Outcomes in Knee Osteoarthritis

An exercise program can improve functionality and quality of life

>> By Marian A. Minor, PT, PhD

The effects of knee osteoarthritis (OA) on an individual can go far beyond having to live with a stiff and painful knee. People with symptomatic knee OA are less active than their peers and are at increased risk for inactivity-related diseases such as hypertension, diabetes, obesity, and cardiovascular disease. Inactivity produces general deconditioning as well as increased pain, weakness, stiffness, and functional loss. Knee OA is a major cause of disability, and prolonged inactivity adds to the loss. Fortunately, many of the sequelae of knee OA are modifiable through exercise.

As shown in Table 1 (p. 17), guidelines for the management of hip and knee OA consistently recommend exercise as an integral component of management.¹ Both strengthening and aerobic exercises show positive results in

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Water exercise—shown here in a therapeutic bath in Budapest, Hungary—is safe and effective for patients with OA.

STOP THE RA CASCADE EARLY

Early arthritis clinics pioneered diagnosis and treatment to prevent disease progression

>> By Sue Pondrom

This is Part One of a two-part series on early arthritis clinics.

Early arthritis clinics (EACs) and the huge research databases amassed over the past 20 to 30 years in Europe and other countries have vastly improved physicians' understanding and treatment of the early stages of rheumatoid arthritis (RA).

The pioneering EACs, many of which are in Europe, were established by rheumatologists seeking an earlier intervention in RA. The EACs were largely responsible for current criteria used to predict persistent RA

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Are You INFORMED ABOUT CONSENT?

Physicians walk a fine line between informed consent and patient trust

>> By Kurt Ullman

This is Part One of a two-part series focusing on the clinician's role in clinical trials. Part Two will explore the ethics of recruiting patients for Phase 1 trials.

In July of 2007, trials for a gene-based intervention for arthritis were temporarily suspended following the death of Jolee Mohr, a participant. Although investigations by both the Food and Drug Administration and the company resulted in findings that the investigational treatment was not at fault and the trial has been restarted, some questions were raised about the nature of the informed consent and the role the patient's community-based physician played in her recruitment.

At one time, clinical trials in the United States were almost entirely within the purview of

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Rheum and Race: Where Are We?



It is time to examine the role of race in the care we provide >> By David A. Fox, MD

A paper by Fry and colleagues published in *Arthritis Care & Research (AC&R)* deserves the attention of ACR members.¹ The title is a mouthful: "Racial/ethnic disparities in patient-reported nonsteroidal antiinflammatory drug (NSAID) risk

awareness, patient-doctor NSAID risk communication, and NSAID risk behavior." The message, however, is simple: African American patients who were prescribed NSAIDs received less education about medication toxicity and fewer prescriptions for med-

ications to prevent gastrointestinal complications than did white patients. While income and educational levels were important, these factors did not account for much of the racial disparity that was found.

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Several other recent papers in *AC&R* have documented additional examples of racial disparities in both the impact of rheumatic diseases and the utilization of rheumatologic and orthopedic care. A recent paper in the *Journal of Rheumatology* reported that the median time from the diagnosis of rheumatoid arthritis to the initiation of disease-modifying anti-rheumatic drugs was seven years for non-white versus one year for white patients.² This discrepancy represents, in part, differing approaches to treatment in a "private clinic," which took care of a patient population that was mostly white, versus a "public clinic," where primarily minority patients were treated.

Multiple barriers limit access to medical care, and these barriers affect different portions of our society asymmetrically. However, what these studies report bears on what happens *after* patients reach a physician. Moreover, the results could not be attributed to patients of different racial groups

receiving care from different physicians.

Race a Pervasive Issue for Medicine

These disparities are not unique to the practice of rheumatology. Similar results have been repeatedly documented in many domains of healthcare, and appear to be narrowing only slowly. And, as reported by ABC News, the disparities in healthcare delivery are also mirrored in the spectrum of patients who participate in clinical research trials.³

Superimposed on this problem is the healthcare crisis manifested by the expanding number of Americans who lack medical insurance. According to January's *Congressional Quarterly*, which summarizes a study performed by the Urban Institute, 27,000 Americans were estimated to have died in 2006 because they did not have health insurance, compared to 18,000 in 2001.⁴ A 50% increase in five years is a statistic that is both sobering and shameful.

A recent editorial published in *AC&R*, titled "Articulating a justice ethic for rheumatology: A critical analysis of disparities in rheumatic diseases," also addresses equity in healthcare.⁵ Rom and colleagues trace the axiom that preservation of health is the foundation for a just society back to the French philosopher Rene Descartes and argue that ensuring equitable access to healthcare is a fundamental issue of social justice. They further argue that disparities in outcomes of rheumatic disease are, in substantial measure, "avoidable, unnecessary, and unfair."

Of course "avoidable" is not the same as "easily avoidable," and we need to systematically consider the barriers to equity in healthcare. Some disparities in disease are genetic and may truly be unavoidable. Others are rooted in deep-seated social problems that lead to economic and educational shortfalls. But what about the barriers that our healthcare system itself has created? Let me give some examples.

Challenges for Rheumatologists and Patients

An ACR member recently told me of her concern about the restrictions on access to outpatient care that have been imposed by a renowned—and wealthy—academic medical center in New York on patients who live in their immediate vicinity, but whose insurance coverage is suboptimal. After caring for a hospitalized scleroderma patient, this rheumatologist was informed that her patient, who is African American, would be permitted to return for only one follow-up visit in her clinic, but after that could instead be sent to another hospital's outpatient clinic that was far enough away to be difficult for this patient to access, but was willing to accept her insurance coverage.

This vignette, which is far from unique, exemplifies the extent to which many—maybe most—of our elite academic health centers have transformed themselves from social institutions that once fostered medicine as a profession into businesses that are thinly—and falsely—disguised as nonprofit entities. The rheumatologist in this case is trapped in an irreconcilable conflict between her duty to her patient and the constraints imposed by her provider. In the process, she has morphed from a physician who practices a profession to a "healthcare provider," an agent of a "health system." The consequence is fragmented medical care and disparities in disease outcomes.

At the same time, it would be a mistake to ignore the tremendous economic pressures faced by many rheumatologists, especially those engaged in solo practice who are beleaguered by denials of payment for their services, pre-authorizations for not only biologics but also methotrexate and prednisone, rising costs, and Medicare fee scales that have been declining in relation to practice expenses. In order to survive, some practices have had to cap the percentage of patients under their care whose insurance coverage is poor. This compromises access to healthcare and undoubtedly creates disparities in outcome, but is preferable to the alternative of rheumatologists being forced to close their practices. At the same time, when our larger and more successful practices and—especially—our wealthiest academic centers (that spend millions of dollars on advertising) engage in patient cherry-picking, we had better take a long, hard look in the mirror.

What Can We Do?

Another barrier to equitable care for

We have an opportunity to take a stand this year on the need for adequate racial diversity in rheumatology, and, more importantly, to take action.

patients with rheumatic diseases may lie within the workforce composition of our specialty. Recently, the ACR's Young Investigator Subcommittee, led by John Fitzgerald, MD, PhD, surveyed rheumatology fellows' perceptions about training and careers in academia. The interesting report of this survey is currently being prepared for publication, but I want to point out the demographic composition of the rheumatology fellows who responded to the survey: 57% female *but only 2% African American!* And this 2% figure is not just the proportion among current fellows—a quick glance around the room at any ACR meeting quickly reveals that this figure reflects the composition of our specialty, within which African Americans are more poorly represented than in most other fields of medicine.

Now, it's unlikely that this is due to a practice of deliberate exclusion, but it seems to me that this is a topic that gets far too little attention from the ACR. If disparities in the composition of our profession have anything to do with disparities in the outcomes of our patients, then neglect of this issue is not a tenable option. We have an opportunity to take a stand this year on the need for adequate racial diversity in rheumatology, and, more importantly, to take action as the ACR constructs its plan to deal with the well-documented and growing shortage of rheumatologists in the United States.

These are challenging times for the practice

of rheumatology and for our academic rheumatology units, but let's not shortchange our accomplishments, our strengths, and—most important—our values. Our character, as individuals and as a profession, is defined much more clearly in times of stress than in times of comfort. How we address disparities in the outcomes of rheumatic diseases will be an important element of that definition.

Epilogue: The rheumatologist from New York mentioned earlier in this column now works for a different institution. THE RHEUMATOLOGIST

Dr. Fox is president of the ACR. Contact him via e-mail at fox@rheumatology.org.

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- Are you passionate about the work of the ACR?
- Are you always thinking of ways to improve things?
- Would you enjoy collaborating with others to better your professional association?

Volunteer for your professional association to help lead the ACR's work in shaping the future of rheumatology.

The ACR and the REF are now accepting volunteer nominations for standing committees. Positions are available in all areas of the College's work – including education, research, training and advocacy. To nominate yourself or a colleague, simply complete the online nomination by visiting www.rheumatology.org.

The deadline for nominations is June 1, 2008.

>> For more information, contact Rachel Myslinski, senior specialist, administration & governance at rmyslinski@rheumatology.org.



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To Document or to Doctor? That is the Question

Is paper pushing taking away from patient care?

>> By David S. Pisetsky, MD, PhD

“If you don’t document it, it didn’t happen.” How many times have we all heard this in a conversation or committee meeting, or seen it a memo?

Certainly, this is wise advice, especially in an era when reimbursement depends on the demonstration that a host of items have been performed in the clinical setting: history and physical, review of systems, review of records, complex decision making, and so on. In the realm of education, documentation also abounds and includes needs assessments, written goals and objectives, and disclosure statements, among others.

To meet the requirements for documentation, institutions have acquired computer systems that far exceed in power those that got Apollo 7 to the moon. No doubt about it, modern medicine is equipped to document.

I have a question that is somewhat different. “If you document it, did it happen?”

I am not talking about fraudulently billing for services. I am talking about the real world and the extent to which honest and conscientious people deliver care in the spirit and not just the letter of the law.

Documenting in Action

I began to ask this question while visiting my mother in the hospital. This was a fine, well-established community hospital. Indeed, in the elevator, there was a sign indicating that this hospital was the only one in the area that was ranked in the top 100 by some rating service. I have no idea how this assessment was made, but it is reassuring to know that a loved one is in the hands of good people.

When I was not with my mother, I paced around the ward, which had an old-fashioned nurs-



PHOTODISC/GETTY IMAGES

men was her name and she was clearly a great nurse, the kind you love to work with when you are a house officer, especially in the ER.

At one point, Carmen came into my mother’s room to do patient education with a wizened old lady in the next bed. The woman was about to be discharged after a bout of heart failure and Carmen did a terrific job. In about a minute flat, she hit the high points of salt restriction, daily weights, and medication adherence. She then apologized to the patient because there was a code down the hall and her services were urgently needed.

Some time during the course of the shift when the ward settled down, Carmen would no doubt go to the nursing station and spend many minutes or hours documenting what she had done that day. I am positive that the documenting took more time than the doctoring or—in this case—the nursing.

Documenter’s Dilemma

We are living in a time when there are critical shortages in the provision of medical services and a failure to attract and adequately compensate healthcare providers—especially nurses—who do heroic work under very trying circumstances.

If there is a finite amount of time that can be spent on each patient, what would be the best allocation: documenting care or providing it?

Fortunately, Carmen’s patient picked up on the essentials on heart failure. Given Carmen’s furious schedule, I wonder what would have happened if the patient had questions about what kind of scale to use or how much salt is in a bag of potato chips. Seeing how Carmen worked, I suspect that she would have returned after the code to explain again and then stayed late to document while her family ate their dinner without her.

In my own practice, I am spending more and more time documenting and less and less time doc-

toring. The need for rheumatology services grows. There are not enough of us to care for patients or to teach. An increasing amount of time is consumed with writing about what we do and a decreasing amount of time is devoted to doing it. In this onslaught of documentation, I would include obtaining permission from payers to prescribe certain treatments.

During my house staff training, one of my co-interns relayed his experiences on a rotation in the African bush. The time was

well before AIDS but malaria and tuberculosis were rampant as were the other parasitic diseases that caused incredible devastation. Suffice it to say, sub-Saharan African did not—and does not—have a lot of money to spend on healthcare, and they could not use precious dollars on medical records.

“How did you know what had happened to the patients?” I asked my friend.

“They wore little wooden amulets around their necks with notations like ‘TB 1968 Rxed with INH,’ ” he said.

“That’s it?”

“What more do you need?” he said, a wise comment I have always remembered.

Bonus Care

The computer hardware and software manufacturers would be bereft if we slowed down on the documentation; informatics is touted as the answer to all that ails modern medicine, and that is their business.

Personally, however, I would like to doctor more and document less and—God forbid—have the regulators trust me that I am delivering the services for which I am billing, even if I do not dot every “i” and cross every “t.”

There is a Southern word, lagniappe, which I always associate with New Orleans and its cuisine. Lagniappe is something extra, a bonus, an embellishment that makes life better.

In their interaction with the healthcare system, patients need lagniappe—a quiet, unhurried conversation with the doctor, a dietician describing how to spice up a low-salt diet with some Texas Pete hot sauce, a nurse washing an old lady’s thin gray hair.

In medicine, what can provide lagniappe?

Doctoring? Absolutely.

Documenting? Get real. | 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.

If there is a finite amount of time that can be spent on each patient, what would be the best allocation: documenting care or providing it?

ing station where scores of people were charting, scribbling notes, or clacking at computer keyboards. From the intensity of their activity, they appeared to be documenting up a storm.

On the other hand, there appeared to be only a few people actually with patients, and those who were seemed variously frazzled or frenzied. I watched one nurse in the middle of her 13-hour shift speed around the ward with the moves of Barry Sanders in his prime days with the Detroit Lions. In her white Adidas sneakers, the nurse dodged right near a med cart, broke left past an old man drooling in a wheel chair, and then did a quick scamper down the hall, cutting sharply to enter a patient room. Car-

From the COLLEGE

NEWS FROM THE ACR AND THE ARHP

ADVOCATING FOR YOU

ACR on the Hill

“By tomorrow night, there will be so many more people on Capitol Hill who know—and are sensitive to—rheumatology and the issues that im-

pact you and your patients. There is no substitute for what you are doing,” says Martha M. Kendrick, a partner at Patton Boggs, LLP, the ACR’s lobbying firm. This is what she told the physician, health professional, and patient participants of the ACR’s 2008 “Advocates for Arthritis” advocacy event—termed a fly-in—before they took their personal

stories to the lawmakers on Capitol Hill.

Over 150 advocates participated in 225 meetings during the February Washington, D.C., fly-in. However, numbers cannot fully demonstrate the power of constituents speaking with their lawmakers. It is an effort that affects laws and decision-making in ways that extend past the traditional benchmarks of success.

“An association can successfully lobby lawmakers to a certain extent. It is when constituents call, write, and show up that lawmakers really take notice,” says Kristin Wormley, the ACR government affairs director. “The February ‘Advocates for Arthritis’ fly-in was one of those times when lawmakers took notice of the issues affecting the rheumatology community.”



(Left to right) Pamela E. Prete, MD; Rep. Pete Stark; and Steve Lee, DO

The fly-in began with a day of preparation where advocates were trained by Patton Boggs. In addition to the training, participants were briefed on both the Senate and House perspectives of the issues affecting rheumatology by Billy Wynne, counsel on the Senate Finance Committee Health and Welfare Team, and Nick Shipley, legislative director to Rep. Jay Inslee (R-Wash.).

Stephen Katz, MD, PhD, director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and William Rogers, MD, medical officer of the Office of the Director of the Physicians Regulatory Issues Team at the Centers for Medicare & Medicaid Services (CMS), gave participants an overview of the current issues coming out of their institutions.

To give participants an overview of the legislative issues affecting the *entire* medical community, Todd Askew, director of congressional affairs at the American Medical Association, reviewed the Sustainable Growth Rate (SGR), dual energy X-ray absorptiometry, and other important topics with participants.

The advocacy training ended with Rep. Shelley Berkley (D-Nev.) offering her advice for advocates as they head to the Hill. Rep. Berkley immediately won the crowd over by announcing that, at the age of 47, she married a physician. She told a story of her husband asking her to test his new bone density scanner on one

of their first dates. “After five minutes, a technician came in the room and told me I have osteoporosis,” says Rep. Berkley. “I realized shortly after that, he had done that deliberately.” Her husband—Dr. Larry, as she calls him—had suspected that Rep. Berkley had osteoporosis, and used his new bone density scan to “accidentally” stumble on a diagnosis. By the end of her address, it was obvious that Rep. Berkley not only understands the issues affecting rheumatology, but that she is also directly touched both as a patient and a physician’s wife.

On the second day of the fly-in, advocates loaded buses and flooded the steps of Capitol Hill—all wearing “No SGR” stickers to provide a visual aid for their meetings. Advocates representing 34 states met with their lawmakers to ask for their support of the four main issues affecting rheumatologists and their patients:

- > **A long-term solution to the flawed physician reimbursement formula:** Lawmakers were told that physicians should be paid based on increases to the cost of practicing medicine and were asked to base physician payments on the Medical Economic Index and eliminate the SGR formula.
- > **The Medicare Fracture Prevention and Osteoporosis Testing Act of 2007:** Lawmakers were encouraged to sign on in support of this legislation, which restores funding that is vital to preventative service in healthcare.
- > **The Arthritis Prevention, Control, and Cure Act of 2007:** Lawmakers were asked to support this legislation, which would expand efforts to discover and implement new ways of preventing, treating, and caring for patients with arthritis and related rheumatic diseases.
- > **Support for arthritis and rheumatic disease research by increasing NIH funding:** Lawmakers were asked to increase funding to federal programs engaged in vital research to combat arthritis and related diseases, which are essential to continuing the search for innovative treatments that can help millions of Americans live longer, healthier, and more productive lives.

By all accounts, the “Advocates for Arthritis” fly-in was a successful lobbying effort on behalf of the ACR and ARHP. Several lawmakers have taken immediate action in response to the February Hill visits, and participants felt like their message was heard. “Advocacy on the Hill was amazing,” says fly-in participant Barry Waters, MD. “The lectures were fantastic and the experience of lobbying was exhilarating. It was a perfectly assembled program and every ACR member should try to find time to participate in a future event. Sincerely, it was one of the highlights of my career as a rheumatologist.”

Outside of the effect the fly-in had on legislation, this year’s event was a success within the ACR by showing members to be passionate and willing to reach out on behalf of the rheumatology community. “It is certainly difficult to judge the success and impact we have on Congress, as it takes time for legislation to move,” explains ACR Government Affairs Specialist, Aiken Hackett. “More than tripling the event’s attendance in a two-year span is evidence that ACR and ARHP members are willing to get involved in advocacy activities and speak out on issues that affect them and their patients. This is the true success of this year’s fly-in.”

All ACR and ARHP members are encouraged to advocate on behalf of themselves and their patients year-round. The best way to begin your advocacy efforts is by visiting the ACR legislative action center at www.capwiz.com/acr.

For more information about “Advocates for Arthritis” or advocacy issues, contact Aiken Hackett or Kristin Wormley at (404) 633-3777, or ahackett@rheumatology.org and kwormley@rheumatology.org, respectively.

CODING CORNER!

May’s coding challenge:

A 68-year-old male established patient with osteoarthritis of the lumbar region returns to the office for a scheduled paravertebral facet joint injection. The patient is currently on a nonsteroidal anti-inflammatory drug, ranitidine, and glucosamine-chondroitin. He reports pain and stiffness in his lower lumbar area and denies any other complaints. The two facets at L4-5 were each injected with glucocorticoid preparations. Fluoroscopic guidance was done for the supervision of needle placement.

How would you code this? See page 13 for the answer.

REF NEWS

New Investigators Struggle to Find the Path to Independence

While practicing rheumatologists face budgetary cuts in Medicare reimbursement, new investigators are facing a challenge of their own. Federal budget cuts and other vanishing funding sources are making it extremely difficult to support their research activities. “Over the past several years, sources of funding for these individuals have become increasingly restricted, with the Arthritis Foundation’s Arthritis Investigator award no longer available and the mentored Career Development Awards (K08 and K23) from the NIH affected by the federal budgetary constraints,” remarks ACR Research and Education Foundation (REF) President Leslie Crofford, MD.

Even with the NIH’s commitment to create programs to help new investigators obtain independent research funding, the average age of investigators who obtain R01 funding has increased by five to six years, and “the proportion of R01 grants going to new investigators has remained at approximately 6% of the total R01s awarded throughout the doubling of the NIH budget,” according to the NIH Office of Extramural Research.¹

In the midst of this crisis, the REF is launching a new program designed to close the funding gap and provide a complete portfolio of awards to help even the newest scientist make the transition from postdoc to independent researcher.

The new Rheumatology Investigator Award will provide funds for salary support, overhead expenses, and research costs, thus securing the physicians academic research career for the duration of the award. “The early period of a promising academic career is an incredibly vulnerable time,” says Dr. Crofford. “Young faculty typically struggle to balance clinical and research activities. It is imperative that these physician-scientists obtain funding to protect time for research. The REF’s new Rheumatology Investigator Award seeks to redress these problems by funding the most promising young scientists in our field. We believe that this award will stimulate our young physician-scientists to remain in academic settings. There, they will become the next generation of teachers and scientists who will sustain our profession.”

The Rheumatology Investigator Award is a vital addition to the REF’s award portfolio. The REF has long been funding early career physicians with other awards such as the Physician Scientist Development Award (launched in 2003) and the Clinical Investigator Fel-

lowship Award. “These awards put individuals on the career path of rheumatology-related research,” says Steven Echard, CAE, executive director of the REF. “And now the Rheumatology Investigator Award will close the loop—putting these researchers ever closer to becoming independent researchers.”

Ensuring the Future of Rheumatology

The launch of this new award coincides with an enormous increase in the amount of funds the REF will be providing throughout its entire portfolio. In 2008, the REF will fund \$10.5 million to rheumatology research, training, and education programs—a budgeted increase of \$3.5 million over 2007. This money comes from two very important REF grant programs—*Within Our Reach: Finding a Cure for Rheumatoid Arthritis* research grants and the REF

Apply for an REF Award

The REF is now accepting online applications for all awards. A mandatory letter of intent for the Rheumatology Investigator Award is due June 2. Please visit www.rheumatology.org/REF for details and to apply.

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- Web site development using the ACR designed template.

>> For more information on joining the ACR's ASC, visit www.rheumatology.org, or contact Amanye Chung, CCP, CPC at achung@rheumatology.org.

The Affiliate Society Council is a subcommittee of the ACR Committee on Rheumatologic Care and was formed to strengthen the communication between the state and local societies, the ACR and local rheumatologists.

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core portfolio of research and training awards that amounts to \$4.5 million of the \$10.5 million.

One of the REF's primary objectives is to annually increase the amount of money allocated to its core award portfolio so that grants for rheumatology training and early career development will be funded in perpetuity. Of the \$4.5 million, over \$2 million will fund research awards that cultivate new investigators.

The REF's increase in funding should be a significant boon to the specialty by both replacing disappearing funds and also increasing the amount of money available to new investigators so they can begin—or continue—down the path to becoming independent researchers.

Reference

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the exam and enter data simultaneously, demonstrating the EMR as an active tool in their care.

A strong patient–healthcare provider bond should be established prior to EMR data entry and reinforced through an environment conducive to open communication. The physical arrangement of the exam room should always focus on patient contact, not your new EMR. Initially, you may be tempted to walk into an exam room and place your tablet PC on a corner desk and then shift focus to your patient. This arrangement will most likely place you in a position where you must choose between maintaining contact with the patient or turning to the tablet to enter data, leaving your back to the patient. Avoid this issue by planning or staging your exam room ahead of time. If you have individual monitors for each exam room, consider mounting the monitor to the wall with an extendable arm that will move

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PATIENT FACT SHEET

EXERCISE AND ARTHRITIS

Arthritis is consistently used as a reason why people limit exercise. However, physically active individuals with arthritis are healthier, happier, and live longer than those who are inactive and unfit.

Inactivity, in addition to arthritis-related problems, can result in a variety of health risks including type II diabetes, cardiovascular disease, and osteoporosis. Also, with many forms of arthritis, decreased pain tolerance, weak muscles, stiff joints, and poor balance can be made worse by inactivity. For many older people with arthritis, joint and muscle changes due to aging can further complicate the matter. Therefore, for the person with arthritis, appropriate exercise is very important.

So who should exercise? The answer is everyone. Research shows that people with many forms of arthritis can participate safely in appropriate, regular exercise. It is recommended that patients start slowly with

PRACTICE UPDATES

Embracing Techmanity

Will increasing technology in the exam room have a dehumanizing effect on the patient physician relationship? Maybe not.

Mike Magee, MD, a former senior fellow in humanities to the World Medical Association and a recognized leader in healthcare politics, believes that if physicians were to fully embrace and use technology to its fullest capabilities, “our healthcare system would transform and re-center around relationship-based care, cementing the people to the people caring for the people.” This is the concept of techmanity—or the mutual advancement of technology and humanistic values.¹ (*Editor's Note:* “Health Politics with Dr. Mike Magee,” www.healthpolitics.org, is supported by the Pfizer Medical Humanities Initiative.) Techmanity uses technology to produce better care that is uniquely tailored to each patient. A few simple steps can promote techmanity in your own practice and will allow you to embrace both technology and the essential patient–healthcare provider connection.

It is important not to lose sight of your patients' needs and perceptions of quality care in the excitement surrounding electronic medical record (EMR) adoption and implementation, as patients may initially feel that there is an uninvited third party in the exam room. Put your patients at ease by involving them in the implementation process. Take some time at the start of a visit to explain the purpose of the EMR and its benefits to patients, and to answer any questions they may have. An informed and involved patient will more likely be tolerant and understanding if the “go-live” phase slows visits. Using the EMR to print educational material, care plan documentation, and a visit summary can further reinforce the benefits of the EMR to the patient by giving him or her an immediate, physical representation of EMR capabilities at the point of service.

As patients become accustomed to the presence of the EMR, they will more likely relax during office visits. However, some patients will struggle with this more than others, and many patients will still feel that they are competing with the EMR for the physician's attention—especially during data entry. Initiating discussion through open-ended questions during data entry will show your patients that you are able to conduct

a limited number of exercises at a low intensity to help ensure safety and success with their exercise program. There are four major types of exercise that make up all comprehensive exercise programs, regardless of the level of participation. Each can have a positive effect on reducing arthritis-related pain and disability. The four major types are:

- 1. Flexibility exercises:** Both range-of-motion and stretching exercises help maintain or improve the flexibility in affected joints and surrounding muscles. This contributes to better posture, reduced risk of injuries, and improved function.
- 2. Strengthening exercises:** These more vigorous exercises are designed to work muscles a bit harder. As the muscle becomes stronger, it provides greater joint support and helps reduce impact through the painful joint. Strong muscles, which also contribute to better function, help reduce bone loss associated with inactivity, some forms of inflammatory arthritis, and the use of certain medications such as corticosteroids.
- 3. Aerobic exercises:** Also referred to as car-

diorespiratory conditioning, these exercises include activities that use the large muscles of the body in a repetitive and rhythmic manner. Aerobic exercise improves heart, lung, and muscle function. For people with arthritis, this type of exercise has benefits for weight control, mood, sleep pattern, and general health.

- 4. Body awareness:** Includes activities to improve posture, balance, joint position awareness—or proprioception—coordination, and relaxation. Tai chi and yoga are examples of a recreational exercise that incorporates elements of body awareness.

Having several exercise options and locations keeps patients from becoming bored and provides alternatives on those days when getting out of the house seems impossible.

Starting a regular exercise program can be very challenging. Understanding the benefits and having the support and guidance from their rheumatologists and rheumatology health professionals will help patients feel confident as they begin an exercise routine. Physical and occupational therapists can suggest ex-

ercises that are safe and individualized to a patient's specific needs. They can also teach a patient how to monitor his or her body's response to exercise, and how to modify an exercise routine as needed.

Patient–fact sheet writer Marie Westby, BSc, PT, tells patients to “set realistic short- and long-term goals and reward yourself when you reach them.” She also suggests “exercising with a friend or family member” to keep the routine fun and social. As patients begin their exercise programs, they should discuss any concerns they may have with their rheumatologist and/or other rheumatology health professionals. By communicating directly with patients about their exercise routines, rheumatologists and rheumatology health professionals will help patients build regular physical activity and exercise into their daily routines—allowing them to reap the benefits of an active and healthy lifestyle.

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

CODING CORNER!

Coding Corner answer (question on p. 9):

May's coding answer: 64475, 64475 -50 77033. Diagnosis: 721.3

64475: Injection, anesthetic agent and/or steroid, paravertebral facet joint or facet joint nerve; lumbar or sacral, single level.

64475 -50: Used to bill the injection for the second facet joints between L4-5.

77033: Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural, transforaminal epidural, subarachnoid, paravertebral facet joint, paravertebral facet nerve, or sacroiliac joint), including neurolytic agent destruction.

This was a scheduled visit for the injections and there was no significant, separately identifiable evaluation and management service done. Therefore, an office visit cannot be billed.

Many carriers require fluoroscopic guidance to be done in conjunction with any facet joint injections. The Current Procedural Terminology manual gives clear directions for the use of fluoroscopic guidance and localization for needle replacement and injection in conjunction with 64470-64484.

The ACR is finding that carriers are now performing audits on these codes and reviewing charts as far back as one year. The ACR suggests that practices review their carrier's local coverage determination on facet joint injections and keep in mind that Medicare has the right to review all payments for medical necessity of claims billed.

If you have any questions or concerns on this matter, contact Melesia Tillman, CCP, CPC, at (404) 633-3777, ext. 820, or at mtillman@rheumatology.org.

with you. If you will be using a laptop or tablet PC, look into purchasing a movable cart that can be positioned for maximum effectiveness.

The most important part of introducing your new EMR to your relationships with patients is timing. You should be fully prepared and comfortable with the EMR applications and data entry before involving it in the relationship. The patient does not expect you to be an expert, but they do want to see confidence with the tools being used. If patients see the physician fumbling with the system or displaying any frustration, they are likely to lose confidence in your abilities and grow to resent the intruding EMR.

If implemented properly and used to its fullest capabilities, the EMR will become a natural part of your patient encounter and will recede into the exam room environment. Successful EMR adoption can help you to access information more quickly and easily may allow you more time to build the patient relationships that will

lead to more effective and efficient care.²

For additional information on EMRs and other office technology, contact Itara Barnes, ACR's practice management specialist, at (404) 633-3777, ext. 819, or ibarnes@rheumatology.org.

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Working With Your National Provider Number By Melesia Tillman, CCP, CPC

Beginning May 23, 2008, all practicing physicians who treat Medicare patients must start billing with a working national provider identifier (NPI). Physician and

non-physician providers can make any corrections or changes pertaining to their NPIs by contacting the National Plan and Provider Enumeration System (NPPES) at customerservice@nppenumerator.com, or by visiting the NPPES Web site, <http://nppes.cms.hhs.gov>.

The following changes should be implemented in rheumatology practices by May 23:

- > Report the NPI in Box 17b on the CMS-1500 form (leave Box 17a blank);
- > Leave blank the shaded portion of Box 24j (where providers are currently report the rendering provider's PIN) of the CMS-1500 form; and
- > Verify the NPI for all referring physicians when applicable.

There are steps that a rheumatology practice can take if a physician refers a new patient to the practice after May 23 but does not provide his or her NPI. First, the practice should call the referring physician's office to obtain the NPI. If there is no response to the call, office staff can check the NPI database. In extreme circumstances, CMS gives instruction in Transmittal 235 of the Program Integrity Manual that the rendering provider can use his or her NPI in boxes 17 and 17b if they first take every step necessary to obtain the referring physician's NPI.

Practices that find they cannot bill with their NPIs alone should contact their carriers or NPPES immediately.

For additional questions concerning this matter, contact Melesia Tillman, CCP, CPC, ACR's practice management specialist, at (404) 633-3777, ext. 820, or mtillman@rheumatology.org.

FDA Enforcement Against Injectable Colchicine

The U.S. Food and Drug Administration (FDA) has ordered companies to stop marketing unapproved drug products that contain colchicines in an injectable dosage form.

This action was taken because products containing colchicine for intravenous use have been marketed without

[continued on page 23](#)

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Exercise to Improve Outcomes in Knee Osteoarthritis

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An exercise program can improve functionality and quality of life

>> By Marian A. Minor, PT, PhD

clinical trials. Outcomes of exercise include decreased pain and improved function as well as increased strength, range of motion, and cardiovascular health. It appears that moderate exercise does not increase the incidence or speed progression of the disease and there is emerging evidence that regular moderate exercise can reduce effusions and improve the content of glycosaminoglycans in cartilage, an important biochemical indicator of its viscoelastic properties.^{2,3} Aerobic walking, stationary cycling, strengthening, and water exercise are all safe and effective for patients with OA. Whether the exercise is performed at home, in a clinic, or in a group setting, benefits are clear, with generally moderate effect sizes in this diverse population.

Despite the well-documented evidence for the numerous benefits of regular exercise for people with

knee OA, most people with this condition are nevertheless inactive and receive little information or support from physicians on how to be physically active. There are understandable reasons for this inattention to a known, effective intervention. Pain usually prompts the doctor visit and immediate treatment focuses on pharmacologic pain relief. Time and resources to prescribe appropriate exercise and follow-up are limited in most clinical encounters. Furthermore, the general nature of exercise recommendations in medical guidelines, the range of possible activities, and the diversity in this patient population make it difficult for the physician to know what to recommend. Although well-intentioned, the suggestion to “start getting some exercise” is not particularly helpful or often followed.

However, we know that physicians and clinic

staff can influence patients to change beliefs and behaviors in areas such as smoking cessation, diet, and exercise.⁴ With knowledge and planning, it is possible—within the constraints and staffing of the clinic visit—to establish procedures to help patients become more active and exercise successfully. Here is a useful framework for how to: 1) promote awareness of the importance of exercise at the time of the office visit; 2) offer a simple home exercise program; 3) use community-based exercise and self-management resources; and 4) identify patients to refer to physical therapy.

Promote Exercise at the Office Visit

In general, people who receive advice from their physician to exercise are more likely to exercise than people who do not. People with arthritis who

TABLE 1:

Guidelines and Recommendations for Exercise in OA¹

Source	Recommendations
Ottawa Panel: Evidence-based Clinical Practice Guidelines for OA ⁹	<ul style="list-style-type: none"> > Lower-extremity strengthening is effective for improving pain and function. Exercise includes isometric, resistance training of quadriceps and hamstrings, and general lower-extremity exercise including resistance, flexibility, mobility, and coordination training. > Whole body functional exercise, walking, and jogging in water are effective for improving pain and functional status.
MOVE Consensus ¹⁰ for pain	<ul style="list-style-type: none"> > Both strengthening and aerobic exercise can reduce pain and improve function and health status in patients with knee OA. Effect sizes and function were small to moderate (0.22 to 0.76). > To be effective, exercise programs should include advice and education to promote a positive lifestyle change with an increase in physical activity. > Group exercise and home exercise are equally effective, and patient preference should be considered. > Strategies to improve and maintain adherence should be adopted, e.g., long-term monitoring/review, or including spouse/family in exercise.
2002 Exercise and Physical Activity Conference ¹¹	<ol style="list-style-type: none"> 1. Aerobic exercise and physical activity for hip/knee OA: <ul style="list-style-type: none"> > Accumulate 30 minutes moderate-intensity (50–70% maximal heart rate) physical activity or exercise at least three days a week; > Tailor activity type and venue to individual needs; > If overweight, combine activity/exercise with diet; and > Incorporate self-management education into programs. 2. Neuromuscular rehabilitation for people with knee OA: <ul style="list-style-type: none"> > A lower-extremity exercise program should combine strengthening, endurance, coordination/balance, and functional exercise; and > Programs will progress in duration, intensity, and complexity; be individually tailored; move from clinical supervision to self-directed community settings; and be periodically reviewed, revised, and reinforced.

exercise often begin because a physician suggested it and provided information. In a study of rheumatologists and patients with rheumatoid arthritis, only 58% of the physicians discussed exercise with their patients, and most physicians reported that they did not have the time or feel comfortable recommending exercise.⁵ To follow current management guidelines for knee OA, exercise should be discussed at every office visit. It is up to the physician to start the discussion.

Ask every patient at every visit: *What are you doing for exercise now?*

Your response depends upon the patient's answer:

- > If the activity lies within the exercise guidelines for fitness or the physical activity guidelines for general health (see Table 3, below right) reinforce and encourage the activity.
- > If your patient answers that he or she is not doing anything but would like to do something,

or if what the patient is doing is inadequate, refer him or her to a community-based exercise or self-management program (listed on p. 18) or suggest a home program. (Visit www.TheRheumatologist.com and click on the "Download Issues" tab to download a sample home exercise program.)

- > If your patient answers that he or she cannot exercise because of pain, is afraid to try, or exhibits the signs or symptoms listed in Table 2 (left), consider referral to a physical therapist to help him or her overcome barriers and learn how to exercise successfully. Also, suggest a community arthritis-specific exercise program or self-man-

continued on page 18 →

TABLE 2:

Knee OA Impairments and Functional Deficits Improved by Physical Therapy

Impairment or Limitation	Clinical Sign or Symptom	Physical Therapy Intervention	Outcome
Pain	Pain with or following activity Pain at rest	Activity modification Improve ROM Neuromuscular training Transcutaneous electrical neural stimulation Accupuncture Patellar taping	Decreased pain
Joint laxity or misalignment	Knee valgus or varus Giving way Ankle overpronation Uneven shoe wear	Orthotic assessment and fitting (insole, brace)	Improved biomechanics Decreased pain
Fear of activity	Unwilling to attempt exercise Prior bad exercise experience	Individually tailored instruction Supervised activity with feedback	Successful experience Improved adherence
Weakness	Unable to arise from sitting without using arms Poor quad contraction Difficult rising on toes repeatedly, one foot at a time	Neuromuscular training Use of electrical stimulation Balance training	Improved function Decreased pain Improved balance
Deconditioning	Fatigues with less than 10 minutes of slow or moderate-paced walking	Progressive comprehensive aerobic exercise program	Improved endurance Decreased pain
Gait deviation	Noticeable limp or limp worsened with activity	Musculoskeletal evaluation Neuromuscular training Gait training Walking aid	Improved biomechanics Improved energy expenditure
Loss of motion and stiffness	Limited knee flexion Incomplete active knee extension against gravity Stiffness at hips or ankles	Range of motion, flexibility, and strengthening program Manual therapy	Decreased pain Increased motion

TABLE 3:

Recommendations for Health and Fitness¹**PHYSICAL ACTIVITY FOR GENERAL HEALTH**

Mode: Whole body, repetitive activities

Frequency: Most days of the week

Intensity: Moderate; 55–70% age-predicted maximal heart rate; RPE* 12–13 or 2–4

Duration: 30 minutes accumulation (three 10-minute bouts)

EXERCISE TRAINING FOR CARDIOVASCULAR FITNESS¹²

Mode: Rhythmic, aerobic exercise

Frequency: Three to five days/week

Intensity: 70–85% age-predicted maximal heart rate; RPE* 14–16 or 4–7

Duration: 20–30 minutes continuous

EXERCISE TRAINING FOR MUSCULAR FITNESS (STRENGTH AND ENDURANCE)

Mode: Dynamic, resistance exercise for major muscle groups

Frequency: Two to three days/week on alternate days

Volume: Eight to 10 exercises; resistance adequate to induce fatigue after eight to 12 repetitions; or 10–15 repetitions if over 50–60 years of age or frail

EXERCISE FOR MUSCULOSKELETAL FLEXIBILITY

Mode: Gentle stretching

Frequency: Two to three days/week minimum

Intensity: Stretch to a position of mild tension/discomfort

Duration: Hold position for 10–30 seconds for static

Repetitions: Three to four repetitions for each stretch

*RPE (rating of perceived exertion) is a self-report scale that corresponds with the intensity of exertion. In the original scale of 6–20, the numbers reflect the actual heart rate if you add an additional final "0". That is, 6 corresponds to a heart rate of 60 bpm and 10 corresponds to a heart rate of 100 bpm. The modified scale ranges from .5 (resting) to 10 (maximal exertion). On the modified scale, 4–7 corresponds to moderate exercise intensity.

agement program for continued use and support.

Table 4 (p. 19) outlines the role of the healthcare professional in promoting exercise and the characteristics of a successful exercise program.

Exercise Starts at Home

Many people with mild to moderate knee OA can lessen pain and improve function and endurance with a simple home exercise program. Studies reporting successful home exercise interventions usually include initial instruction and supervision. The Enabling Self-management and Coping with Arthritic Knee Pain through Exercise (ESCAPE) trial also includes self-management training in the initial six-week period.⁶ More information on the patient education materials in the ESCAPE trial can be found at www.kcl.ac.uk/gppc/escape.

Offering specific suggestions of safe and effective activities may help some patients get started. Basic strengthening and flexibility exercises, combined with a progressive program of regular walking or bicycling are a simple, no-cost routine that can be accomplished at home. (Visit www.The-Rheumatologist.com and click on the "Download Issues" tab to download a sample home exercise program.) Combining a beginning home program with referral to a self-management course helps the person learn skills, experience success, and develop self-efficacy for exercise, thereby improving adherence and outcomes.

Evidence-based Community Resources

Learning the self-management skills for self-directed exercise is central to long-term exercise maintenance.⁷ There are a number of community-based opportunities that offer initial instruction, access to a knowledgeable leader, and social support to gain these skills. The Arthritis Foundation and CDC-supported state Arthritis Programs are excellent sources of evidence-based programs. These programs have been shown to improve symptoms, reduce disability, and promote self-efficacy for managing the disease. The self-management programs include exercise information and teach skills that foster self-directed behaviors and success. Learn what is going on in your area, keep course information available in your office, and refer patients to these programs as standard care. The evidence-based programs recommended and supported by the Centers for Disease Control and Prevention (CDC) Arthritis Program are Arthritis Foundation Exercise Programs—Land and Water; Arthritis Self-Management Program; Chronic Disease Self-Management Program; and Enhance Fitness. More information about these exercise and self-management programs may be found at the following sites:

- > **Arthritis Foundation Chapter programs:** www.arthritis.org/programs.php;
- > **CDC State Arthritis Program:** www.cdc.gov/arthritis/state_programs/programs/index.htm;
- > **Enhance Fitness, a senior exercise program developed by the University of Washington:** www.projectenhance.org; and
- > **A list of self-management programs, including chronic disease, offerings in Spanish, and international locations:** <http://patienteducation.stanford.edu>.
Local hospitals, recreation centers, and

fitness facilities offer exercise programs suitable for people with arthritis. Water aerobics, low-impact aerobic dance, cycling, strengthening, and tai chi are safe and helpful. Your own patients are a good source of information on what works, what doesn't, and where to find good instructors and classes. Encourage patients to share experiences with you and your staff. It can be efficient to designate a specific staff member to be the knowledgeable exercise resource and talk with patients and families regularly.

Most people with mild to moderate knee OA can exercise successfully in a community-based program or on their own if the physician initiates discussion of the importance of physical activity, offers positive recommendations and follows up consistently. People who have more severe disease or worse symptoms may initially need more

arthritis-specific instruction and supervision to learn how to exercise without increasing pain or becoming discouraged. People who attribute their activity limitation to arthritis and are currently not engaged in a regular physical activity program often will do better in group classes that address arthritis issues and self-management training. However, people for whom current pain is severe or for whom minimal activity increases pain may benefit from a more individualized therapeutic encounter.

Some Patients Benefit from Physical Therapy

A referral to physical therapy is appropriate if your patient is limited by pain, has a history of unsuccessful exercise attempts, exhibits gait deviations, or exhibits marked weakness or malalignment of the knee (i.e., laxity or varus or

TABLE 4:

Help Patients Succeed with Exercise

ROLE OF THE HEALTHCARE PROVIDER⁴

- > Start the exercise discussion and promise to follow up at each visit;
- > Discuss the importance of adherence;
- > Be positive about benefits and patient's ability to become more active;
- > Refer to community resources for exercise and self-management programs;
- > Offer a specific, simple home program;
- > Be informed about community programs in your area; and
- > Recognize your influence over patient behaviors.

CHARACTERISTICS THAT PROMOTE EXERCISE PROGRAM ADHERENCE

- > Specific, simple, and low cost in time and money;
- > Targeted to specific benefits important to the individual;
- > Initial instruction period for practice and feedback;
- > Knowledgeable instructor for answering questions;
- > Group program with others in similar situations for peer support;
- > Incorporates self-management skills; and
- > Integrated into daily routine.

valgus deformity) or malalignment of the foot/ankle (e.g., ankle/foot pain, uneven shoe wear). A physical therapist can offer evidence-based care and assist the person with knee OA in a number of areas.⁸ Table 2 (p. 17) lists common problems that limit a person's ability to be physically active that can be addressed by a physical therapist.

Summary

Patients are more likely to follow an exercise program if it is introduced by the physician and reinforced regularly at office visits. If the physician expresses interest, engages in discussion, offers positive suggestions, and promises to fol-

low up on subsequent visits, the patient is more likely to attempt the activity. It is not necessary for the doctor to be an exercise specialist or have all the answers, but it is critical to express interest in what the patient is doing, be positive in your belief in the importance and feasibility of increasing physical activity, and suggest resources and make appropriate referrals. With exercise as a foundation of OA management, outcomes should improve as patients become stronger and more active and their pain and disability diminish.

THE RHEUMATOLOGIST

Dr. Minor is professor and chair of physical therapy at the School of Health Professions at the University of Missouri in Columbia.

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Are You Informed ABOUT INFORMED CONSENT?

As clinical trials migrate from academia to the community, physicians walk a fine line between informed consent and patient trust

>> By Kurt Ullman

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the academic medical center (AMC). In 1991, 80% of industry money for clinical trials went to AMCs.¹ By 2007, the community physician was getting nearly 77% of the spending for clinical investigations.²

In both instances, in the United States, the Institutional Review Board (IRB) takes the lead in approving the outlines of a protocol and making sure these meet the various legal, ethical, and regulatory requirements.

"The IRB serves as an arm of the Office for Human Research Protection [OHRP], of [the Department of Health and Human Services] and is charged with local oversight in institutions involved in human subject research," says Elan Czeisler, di-

rector of the IRB for New York University Medical Center in New York City. "They are charged with both the review and oversight of research and ensure that they comport with safeguards enacted by legislation and regulations in place to protect research subjects."

One major concern for physicians thinking about participating in a clinical trial is in the area of informed consent.

"According to federal statute, informed consent has to be an educational process and not just a form people sign," says Eric Matteson, MD, chair of the division of rheumatology at the Mayo Clinic in Rochester, Minn. "Research subjects have to volun-

tarily decide to participate in research and it is important that they clearly understand everything about the trial, including the very substantial risk that is sometimes involved."

Informed Consent in Clinical Trials Different from Regular Practice

Informed consent in a clinical trial differs greatly from the informed consent obtained before surgery. One of the aspects least understood by both subject and investigator is the focus of the interventions.

"It has to be made unambiguously clear that what they are to receive is not clinical care," says Paul Romain, MD, chief of rheumatology at the Cambridge Health Alliance in Cambridge, Mass. "There is a loss of the physician's ability to make decisions that personalize the intervention. The goal of the research is to produce scientifically valid results and that means adhering to the predetermined research protocol."

In clinical practice, prescribing a drug or suggesting a procedure is done with the assumption that it most likely will benefit the patient. This assumption is not present in clinical trials.

The most meaningless question an investigator can ask is, 'Do you understand?' That isn't really a question, but rather a statement designed to get a yes.

—Eric Matteson, MD

One of the concerns voiced in aftermath of Mohr's death was the issue of the bond between a patient and physician and how it might influence the subject's decision. The normal trust that a patient puts in the doctor may lead to problems with informed consent if the doctor/researcher is not very careful.

"Patients and physicians often have a disproportionate belief in the likelihood that the intervention will benefit the subject-patient," says Dr. Romain. "Data show that subjects in a study often do not appreciate the blinded nature of whether they get placebo or active treatments. They assume the doctor is likely to do what is best for them, not fully understanding that the decisions are being made on what is best for the trial."

This can be especially troublesome if the subjects are not fully aware of how the randomization process may affect their treatment and its impact on disease. For example, giving a placebo in a trial assessing the impact of a medication on rheumatoid arthritis could result in additional damage to the joint.

A similar concern relates to whether subjects know how their care in a trial differs from the standard of care. The trial may require multiple X-rays when usual practice only suggests one. Information on risks that are added because of the study's requirements need to be included.

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Goal Is Not Individualized Care

The goal of a trial is to produce generalizable knowledge, whereas the goal of clinical medicine is to produce individualized care. They are two very different objectives, and the differences need to be thoroughly explained as part of the informed consent process.

Size and complexity of the consent form can be another significant difference. It is not unusual to find consent forms that run to 10 or 15 pages outlining every possible concern in often legalistic language. This was brought out following Mohr's death.

"In the clinic, the consent form largely focuses on things that are common or important," says Arthur Kavanaugh, MD, professor of medicine at the University of California, San Diego. "In clinical trials, they may include a laundry list of things that a reasonable person may not understand. It becomes a balancing act to communicate what are important risks while allowing the potential research subject to see the entire breadth of what the com-

pany's lawyers think needs to be said."

In community settings, the researchers may have little control over the content of the informed consent. The IRB for a particular study gives approval for the form and there is little an individual researcher can do to change it. Thus, one of the important early decisions is whether the researcher is comfortable with the form.

"The informed consent form, in one sense, should be viewed as documenting the important elements of the conversation that you had with the potential subject, reminding the investigator of details that they might have otherwise forgotten and giving the subject a record of those details both before and after they sign," says Dr. Romain.

All of the experts interviewed agreed that informed consent first requires assessment of the potential subject

and their ability to consent. "Informed consent begins with the assessment of the patient's ability to understand before they are even offered the opportunity to become a research participant," says Dr. Kavanaugh. "There must be freedom from coercion, competence, and the ability to understand the ramifications of entering the study."

There must also be equitable access to the study by populations such as the elderly, those who are pregnant, and ethnic minorities.

"One of the more challenging ethical challenges faced by IRBs is to ensure that investigators adhere to the principle of justice, specifically equitable access," says Dr. Czeisler. "The investigator should make every effort to distribute the benefits associated with clinical research in an equitable manner and to not exclude people simply because they are non-English speakers or educationally or economically disadvantaged."

Time may be the best way to assure that informed consent is both fully informed and valid consent. Personal contact—taking the time to explain the terminology and the goals of the study—makes it possible to fulfill the requirements of informed consent. This process is even more important for potential subjects with poor educational achievement.

Regulations require that all forms used in trials be written to a sixth- or eighth-grade reading level. However, that may not be clear enough for patients to comprehend fully, and the researchers should also make sure the subject understands the jargon being used.

"Standard literacy is very different from health literacy," says Dr. Romain. "People do not always know much about how their bodies work and cannot easily appreciate what the implications are of different side effects and interventions."

Structured interventions such as audio-visual presentations or brochures have not been shown to be effective in achieving informed consent. However, most of the experts agreed that questionnaires can find holes in a subject's understanding. Allowing subjects to take the forms home and discuss them with their family and friends is useful as well.

"The most meaningless question an investigator can ask is, 'Do you understand?'" says Dr. Matteson. "That isn't really a question, but rather a statement designed to get a yes. You gauge understanding by having them repeat in their own words the various concepts as you both go through the protocol." THE RHEUMATOLOGIST

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Recommended Reading for Patients

- > American College of Rheumatology Patient Education-Clinical Trials: www.rheumatology.org/public/factsheets/clinical_new.asp
- > Understanding Clinical Trials: www.clinicaltrials.gov/ct2/info/understand
- > National Cancer Institute, Introduction to Clinical Trials: www.cancer.gov/clinicaltrials/learning
- > JAMA Patient Pages, Randomized Controlled Trials: <http://jama.ama-assn.org/cgi/reprint/295/23/2812.pdf>

approval. The FDA is making an effort to ensure that all drugs marketed in the United States have the required FDA approval and are safe, effective, of good quality, and appropriately labeled.

Colchicine is most commonly used for the treatment of gout. Colchicine for injection has been available in the United States since the 1950s and is administered intravenously for the treatment of acute gout attack.

There is an increased likelihood of colchicine toxicity when the drug is administered intravenously. In addition, serious safety concerns associated with the use of intravenous colchicine drugs have caused reports to be made to the FDA.

The FDA states that, "among the commonly reported events were neutropenia (low number of white blood cells), acute renal (kidney) failure, thrombocytopenia (low number of platelets), congestive heart failure, and pancytopenia (low number of all types of blood cells). Many of these adverse events are caused by colchicine toxicity, which can have serious and potentially fatal consequences."

This action by the FDA does not affect colchicine tablets. For additional information, visit the FDA Web site at www.fda.gov or contact Antanya Chung, CCP, CPC, at (404) 633-3777.

one of many degenerative conditions of the lumbar spine, which are typically associated with symptoms that are relieved with flexion of the spine and exacerbated with extension or walking. Therefore, without the proper exercise program, these patients are at higher risk of suffering the consequences of deconditioning.

Iversen believes it is important for health professionals to understand LSS, because chronic low back pain afflicts 20% of people older than 65, limiting their independence and ultimately reducing quality of life.

To sign up for the for the May 21 audioconference, 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. If you are unable to participate, you can purchase a recording on the ARHP Web site. THE RHEUMATOLOGIST



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ARHP NEWS

Nonsurgical Management of Lumbar Spinal Stenosis

Maura D. Iversen, PT, DPT, SD, MPH, of MGH Institute of Health Professions in Boston, will discuss the nonsurgical management of lumbar spinal stenosis (LSS), epidemiology, and common symptoms associated with this condition during the ARHP rheumatology audioconference on Wednesday, May 21, from noon to 1:00 p.m. (EST). Iversen will provide a summary of nonpharmacologic and nonsurgical interventions to manage LSS—including a summary and evaluation of manual therapy techniques and exercise.

Iversen began her career as a physical therapist for inpatient and outpatient physical therapy. She then worked as a clinical specialist in the spine clinic at Brigham and Women's Hospital. This work corresponded with her enrollment in the doctoral program at Harvard University.

Due to Iversen's interest in identifying interventions that are effective, acceptable, and safe for older adults with LSS, she chose this condition as an area of focus for her dissertation. Specifically, Iversen examined the influence of patient expectations of surgery for LSS on self-reported pain and function.

Following the completion of her doctoral studies, Iversen's postdoctoral work focused on the evaluation of an aerobic exercise program for patients with LSS. The genesis for this idea was patients' difficulties with exercise programs and physical activity due to symptoms being exacerbated by walking and relieved by back bending. In her study, Iversen discovered that most patients tended to limit their walking and suffered the consequences of deconditioning as well as weakness, pain, and reduced aerobic capacity, which are a direct consequence of the disease.

Data shows that 40% of older people with low back pain report restrictions in activities of daily living. LSS is

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STOP THE RA CASCADE EARLY

Early arthritis clinics pioneered diagnosis and treatment to prevent disease progression

>> By Sue Pondrom

in early, undifferentiated arthritic patients, and for the advent of new treatments that enhance patient outcomes.

RA patients were first studied in the late 1950s with population-based studies in Bath, U.K., and in the 1960s from cohorts in Middlesex, U.K., and Memphis, Tenn. As a result, research published in the 1980s demonstrated early structural erosion and the long-term consequences of RA. At that time, treatment guidelines for the initial therapy of RA called for nonsteroidal anti-inflammatory drugs, with disease-modifying antirheumatic drugs (DMARDs) prescribed much later, often after early destruction had already occurred.

Although today's EACs vary in their definition of "early" RA (some restrict selection to patients symptomatic for three or less months, while others allow patients with symptoms for up to two years), they have universally adopted improved diagnostic and imaging techniques—and, most importantly, the use of DMARDs earlier in the course of disease.

Beginnings in Birmingham

One of the first EACs was founded in 1983 at Queen Elizabeth Hospital, Birmingham, U.K., by Paul Bacon, MD, at that time the Arthritis Research Campaign (ARC) professor of rheumatology at the University of Birmingham. His goal was to identify factors to predict which patients with early synovitis would go on to develop RA. The Birmingham clinic had ceased operation in the mid 1980s, but then Paul Emery, MD, arrived and restarted it. Dr. Emery is currently the ARC professor of rheumatology at the University of Leeds, U.K., and director of the Leeds EAC, which he formed in 1994.

The goals of the early EACs were important because "one would like to focus therapy on those patients who are going to develop RA while sparing the half of early arthritis patients who get better spontaneously from the risks of therapy," says Karim Raza, MD, the current director of the Birmingham EAC, now located at City Hospital Birmingham. "Much of the work carried out in this early arthritis clinic was done in collaboration with Mike Salmon, PhD, and Dr. Emery, who made important contributions in the field of genetic predictors of disease outcome."

The first Birmingham EAC recruited patients with symptoms up to six months' duration by actively approaching and encouraging primary care physicians to refer appropriate patients. Today's Birmingham EAC has changed its focus to patients with symptom duration of three months or less.

"The great successes of our early arthritic clinics have been that we have been able to identify very specific predictors of the development of RA in patients with early synovitis and have identified, for the first time, that the first few weeks after the onset of symptoms represent a pathologically distinct phase in the development of RA," says Dr. Raza.

For example, the Birmingham group noted that

a combination of anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor in patients with three months' or less symptom duration has a high specificity for development of persistent RA.¹ These findings were later validated by the Austrian group led by Josef S. Smolen, MD, chair of the division of rheumatology at the Medical University of Vienna in Austria and chair of the second department of medicine at the Center for Rheumatic Diseases at Hietzing Hospital in Vienna. The Birmingham researchers later demonstrated that early RA is characterized by a distinct and transient synovial fluid cytokine profile.² Dr. Raza notes that these observations need to be reproduced in additional cohorts before being incorporated into predictive algorithms.

While the Birmingham EAC flourished, additional clinics began to emerge in other countries. In 1993, the department of rheumatology of the Leiden University Medical Center in The Netherlands established the Leiden EAC, "because we wanted to study the natural course of arthritis and identify prognostic markers for disease by well-organized follow-up schemes of all patients," says Tom Huizinga, MD, professor of rheumatology at Leiden University Medical Center and director of the Leiden EAC.

The Leiden EAC's earliest challenge was to contact all general practitioners in the area for referrals of patients with symptom duration of less than two years. Now, with a centralized database of over 2,000 patients, Dr. Huizinga says his group has demonstrated that patient outcome can be improved by rapid treatment initiation. Additionally, "an enormous amount of data have been gathered to better understand the pathogenesis and thereby establish better treatment schedules."

While some of the earliest EACs were confined to clinical research units, in the 1990s EACs began to emerge as part of general rheumatology services worldwide, according to research by Mark A. Quinn, MBChB, MRCP, and Dr. Emery.³

Much of the movement towards EACs in the 1990s is credited to work by Dr. Emery early in that decade. He was a founder of the Early Rheumatoid Arthritis Study in 1986, and later the Leeds Early Arthritis Project and Yorkshire Early Arthritis Register. His goal has been the prevention of damage by changing the course of RA. He says the most difficult aspect of that early work was patient recruitment and uncertainty about whether patients would get better in the short term. Happily, their short-term improvement has carried into the long term as well.

The Leeds EAC defines "early" RA patients as those with symptom duration of less than one year, but "ideally three months," Dr. Emery says. Patients are seen within two weeks of referral.

The Challenge: Getting Primary Care Referrals

Because there were initial difficulties in getting the cooperation of local general practitioners to refer early suspected cases of RA, the Leeds EAC team contacted local physicians to re-educate them to the importance of early treatment.

Dr. Emery, along with colleagues from The Netherlands, France, Germany, Austria, and the United States, authored a review article that discussed evidence-based development of a clinical guide for early referral recommendations.⁴ The article advises rapid referral to a rheumatologist if the patient has three or more swollen joints, metatarsophalangeal/metacarpophalangeal involvement, and morning stiffness lasting 30 minutes or more.

The Austrian rheumatologist contributing to that review was Dr. Smolen, who, along with his associate, Klaus Machold, MD, associate professor in rheumatology at the University of Vienna, started Vienna's Früharthritis-Ambulanzen EAC in 1996 to provide early treatment and to establish guidelines for fast decision making regarding DMARDs. "This meant we had to reduce the time lag from first telephone contact with the clinic to the actual appointment with the

rheumatologists in our clinics," says Dr. Smolen. "It also meant we needed to reduce the delay in which patients went to a physician because of their joint problems."

To accomplish this, the doctors devised an information campaign for both physicians and the lay public. "We spoke to representatives of the social security organizations and the president of the chamber of physicians, who liked and supported our initiative," he says. "We held press conferences for the mass media in order to reach the public. We wrote a series of educational articles on RA and the importance to recognize it early, and these were published in the journal of the chamber of physicians."

To be eligible for the Früharthritis-Ambulanzen, patient symptoms should not exceed three months, "since this time frame appears to constitute a window of opportunity," he says. "Obviously we also see patients with longer-term early arthritis, but these go the more regular path."

Another challenge, adds Dr. Smolen, "is the lack of diagnostic or classification criteria" for early RA, a topic he and coauthors addressed in an *Arthritis & Rheumatism* article, in which they discussed the need for and controversy surrounding criteria for early RA.⁵

At the 2006 ACR Annual Scientific Meeting, the Leiden EAC group presented their suggested criteria, which they prefer to call "a prediction rule." Based on their study of 1,700 RA patients with recent-onset disease, they say the prediction rule for persistent RA should include nine clinical variables: gender, age, localization of symptoms, morning stiffness, tender and swollen joint count, C-reactive protein, rheumatoid factor, and anti-CCP antibodies.

Future Options

During the past 10 years, the Austrian group has learned that about 10% of patients with less than three months' symptom duration already have erosions, "indicating that there may be a period of asymptomatic but already aggressive pre-arthritis," says Dr. Smolen. Studies by his group have shown significant differences in all aspects of improvement with earlier treatment, but early DMARD therapy alone "is not sufficient in most patients to halt progression of the disease," he says.

Among the newest medications in the RA treatment armamentarium, the biologic response modifiers can reduce inflammation and structural damage. Three of these drugs work by blocking the activity of tumor necrosis factor (TNF)-alpha molecules, while another works by blocking interleukin-1. However, since more than 40% of RA patients fare well on traditional DMARDs, in Europe biologics are not used until there has been an inadequate response to at least two conventional DMARDs.

On the other hand, the Behandel Strategieë (BeSt study)—including 508 Dutch patients with early RA and led by investigators from Leiden University—demonstrated that individuals treated very early with the DMARD metotrexate plus the biologic infliximab experienced disease remission.⁶ Results of this study have also been published in *Arthritis & Rheumatism*⁷ and *Annals of Internal Medicine*.⁸

"It is likely that there will be a subgroup of patients with very early RA who will turn out to benefit from the very rapid introduction of anti-TNF therapy," says Dr. Raza.

Dr. Smolen notes that, "if patients are still active after three months of tradition-

al DMARD therapy plus steroids, we should consider adding a biological agent."

Whatever the future may hold for diagnosis and treatment, EACs have been instrumental, especially over the past 20 years, in providing better outcomes for rheumatoid arthritis patients. Patient studies have provided data to investigate RA from inception to later stages, resulting in valuable information leading to improved treatment for early RA patients. | THE RHEUMATOLOGIST |

Sue Pondrom is a medical journalist based in San Diego.

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