

Exclusive Coverage of the

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ALSO IN THIS ISSUE

Time is Bone: Unchecked Rheumatoid Arthritis Affects More Than Joints

DAVY JAMES

Rheumatoid arthritis carries risks for several comorbidities that can impact organ systems, such as the heart and lungs.

While rheumatoid arthritis (RA) is commonly perceived as a condition that only impacts bone and joint health, realistically, it can elevate the risk for several comorbidities that can lead to death, underscoring the need for consistent monitoring.

During an educational symposium for healthcare professionals at the Asembia Specialty Pharmacy Summit 2017, Kevin Mange, MD, MSCE, head of North America Medical Immunology at Sanofi, gave a comprehensive overview that emphasized RA is more than a disease that just affects the joints.

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Digital Health Plays a Crucial Role in Medication Adherence

LAURIE TOICH

Emerging technologies could tackle the multibillion-dollar problem of medication adherence.

Technology has rapidly advanced over the past several years, disrupting numerous aspects of day-to-day life, including healthcare. The partnership between technology and healthcare can allow patients to speak face-to-face with a physician thousands of miles away, or may come as a simple text-message reminder to take a medication.

Can these groundbreaking advances in technology be leveraged to improve medication adherence? This question was addressed in the session, Can Digital Health Solve the \$100 Billion Medical Adherence Problem? presented at the Asembia Specialty Pharmacy Summit 2017.

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Time is Bone (Continued from page 1)

“RA is disease that affects multiple organ systems,” Dr Mange said during the session. “This relatively new concept has been integrated into the American College of Rheumatology [ACR] guidelines of treating patients with RA to a level of severity.”

RA currently affects approximately 1.5 million adults in the United States, typically in their 40s and 50s, at a female-to-male ratio of approximately 3 to 1.

“If you sit and talk with a patient after they’ve been diagnosed with RA and ask, ‘What were your earliest symptoms you had?’, their symptoms at presentation relate to how stoic that patient is,” Dr Mange said. “It relates to their pain tolerance, or intolerance as the case may be, and also how active that individual is. What they will say consistently is that when they wake up in the morning, they’re stiff. It takes a while for them to get going.”

In describing the early symptoms of RA, Dr Mange described how inflammation of the joint lining causes patients to experience stiffness that progresses to tenderness, which puts stress on the joints. This stress limits motion and causes pain and swelling, ultimately impairing daily activity.

“If we’re talking about a couch potato, they are going to present a bit later,” Mange said. “Why? Because they’re not moving and when they start to move, they have pain. So, it’s kind of a negative reinforcement.”

Mange also noted that a significant minority of patients experience chronic inflammation that manifests in their ankles and feet, which creates a diagnosis challenge for physicians.

Updated ACR Guidelines direct early RA treatment

In their recent guidelines update, the ACR specified that patients with early RA should be addressed with a treat-to-target strategy instead of a nontargeted therapeutic approach. The ACR guidelines recommend the early target treatments should be low disease activity or remission.

“After 2015, the ACR recommended that clinicians providing care to patients with RA need to regularly measure the level of disease activity,” Dr Mange said. “Doing it once a year is no longer adequate. Why? Because there is a state of chronic inflammation.”

For patients with low disease activity who have never taken a disease-modifying anti-rheumatic drug (DMARD), the ACR guidelines recommend DMARD monotherapy versus double or triple DMARD therapy. Meanwhile, for the majority of patients with early, active RA, methotrexate is the preferred initial therapy. For patients on DMARD monotherapy who still show moderate or high disease activity, the ACR guidelines recommend switching to a DMARD combination treatment regimen or a tumor necrosis factor (TNF) inhibitor or non-TNF biologic, with or without methotrexate.

Early diagnosis and treatment can lessen the risk of comorbidities

Active adults are often slow to recognize or receive treatment for their inflammation. In these cases, the risks that accompany RA intensify greatly. Chronic inflammation causes erosion in the bone and leads to narrowing of the joint space, which is a significant determinate of disability. Inflammatory joint symptoms determine disability in the early course of the disease, while the subsequent effect of joint destruction dominates disability late in the disease, Dr Mange noted.

“If that chronic inflammation goes unchecked, then joint damage occurs,” he said. “It’s important to recognize that joint damage is irreparable. It should not be allowed to progress. RA is a disease of the joints, but that’s not the full story. RA, as a disease, affects several other organ systems.”

Mange pointed to data from the Consortium of Rheumatology Researchers of North America (CORRONA) database collected from rheumatologists and patients, beginning in 2002, to illustrate



the risks of multiple comorbidities that may impact patients with RA. These include diabetes, cardiovascular and lung diseases, osteoporosis, certain types of cancer, and greater rates of hospitalization.

“When RA patients have these additional comorbidities, certainly they are more ill,” Dr Mange said. “As a marker, once again, these patients do not do as well as someone in the absence of these comorbidities, perhaps, because that impacts the therapeutic strategy that the physician can do with that patient.”

Because there are limited therapeutic options for these patients’ associated comorbidities, RA can cause multiple conditions to worsen. Dr Mange noted that the inflammatory state caused by RA can be an independent marker or independent risk for the development of cardiovascular disease, events that can present atypically. Silent myocardial infarctions are common, in which patients do not experience chest pain, but the event shows on an electrocardiogram. RA patients also have a greater risk of sudden cardiac death because of their high inflammatory state.

A 2015 study published in *Arthritis & Rheumatology* used data from CORRONA to analyze the correlation between RA disease activity and treatment regimen with cardiovascular risk. The study authors evaluated 24,989 patients with RA for 2.7 years following their baseline visit to the clinician until they were lost to follow-up, experienced an initial cardiovascular event, or died. Of these patients, 61% were administered a nonsteroidal anti-inflammatory drug or a COX-2 inhibitor, 84% were administered methotrexate, and 48% were administered a TNF-antagonist.

As the RA disease activity was lowered, the authors found a significantly lower risk of cardiovascular events. The results showed a 21% reduced cardiovascular event risk for each 10-point drop in the Clinical Disease Activity Index, and a 53% decrease in cardiovascular risk from high disease activity to remission.

The study results further bolster the importance of monitoring and controlling RA disease activity to avoid not only joint pain, but to reduce the mortality risk from cardiovascular events as well.

“Recent data from CORRONA of over 25,000 US patients also confirms that the risk of cardiovascular events in an RA patient increases as their severity of RA increases,” Dr Mange said.

Autopsies show that nearly half patients with RA also experience rheumatologic processes in their lungs, such as inflammation of the chest cavity. Dr Mange noted that between 8% and 15% of RA patients may have interstitial lung disease, a condition that results in an oxygenation problem that may require additional therapy.

Rheumatoid nodules also present a challenge for patients with RA that extends beyond the unsightly appearance. One-third of patients with RA will develop rheumatoid nodules around

“ It’s important to recognize that joint damage is irreparable. It should not be allowed to progress.

their elbows and hands. Dr Mange explained that skin disease in RA is not simply a cosmetic problem. Rheumatoid nodules can interfere with normal muscle function, ulcerate, and become infected, ultimately requiring surgical intervention. They also lead to joint destruction that severely impacts a patient’s functional capacity, especially if a patient’s job requires working with their hands.

“If someone has extra-articular manifestations in another organ system than the joints, you can imagine that the therapeutic strategy to treat that patient’s lung disease or heart disease is very different than someone who has joint-limited disease. Monitoring for that organ system is very different than joint disease,” Dr Mange said.

RA can also lead to peripheral neuropathy; which, while not severe, adds another layer of complexity to the disease, including a greater risk of falls.

He further noted that RA patients with extra-articular manifestations, which make up 40% of the RA population, are at a greater risk of mortality than RA patients without extra-articular manifestations. Dr Mange said these patients should be managed broadly in a very different way than someone who has joint-limited disease. Because unchecked joint damage is irreparable and patients with RA are at a high risk of extra articular manifestations, ACR guidelines emphasize the importance of a therapeutic strategy for disease activity measurement after 3 months. At that point, if the patient is not in a state of low disease activity or remission, clinicians need to decide whether to escalate or intensify immune suppression efforts or change therapies within the same drug class.

“If you let that person continue to go unchecked with that level of inflammation, it’s going to put them at a greater risk for joint disease and extra-articular manifestations,” Mange said.

It’s important to consider the additional costs comorbidities add in treating RA

Because of the widespread impact of RA on the patient’s body and the subsequent danger to other organ systems, the cost of the disease on the healthcare system is significant. In 2010, the incremental, annual direct cost attributed to RA in the United States was \$11.4 billion, with another estimated \$14.8 billion in indirect costs.

A 2012 study in *Arthritis Care & Research* examined a sample of respondents from the Medical Expenditure Panel Survey conducted in 2008 to compare a cohort of patients with RA and a control cohort without RA.

The adjusted average annual total expenditure in the cohort of patients with RA in 2008 US dollars (USD) was \$13,012 compared with \$4950 in the control cohort. Furthermore, the annual pharmacy expenditure in the RA cohort was \$5825, which was \$1380 higher than the control group. The study authors found a total incremental expenditure in the United States among all RA patients of \$22.3 billion in 2008 USD.

“RA as a disease garners a lot of attention; not just simply because it’s an intellectual curiosity, but in part because it’s an expensive disease,” Dr Mange said, adding that the higher the disease activity in RA, the higher the use of healthcare utilization and healthcare resources.

Act now: Use the ACR Guidelines to help prevent additional damage caused by RA

Ultimately, with the significant risks that unchecked RA poses to other organ systems, the irreparable damage to joint systems, and the high costs incurred from RA and related conditions, the importance of following ACR guidelines is magnified. The more time that passes without taking prompt action in the treatment of RA equates to damage that cannot be repaired long-term.

“Time is bone; it’s irreparable. If you continue with unchecked inflammation, you’re going to have other organ systems involved,” Dr Mange concluded. “Make a decision, that’s what the ACR guidelines are really emphasizing.” ●

Digital Health (Continued from page 1)

With the number of individuals who have chronic diseases growing each day, ensuring that these patients remain adherent to therapy is vital, not only to their health, but also to the financial stability of the country. Technology has presented a novel option for supporting adherence. The population, from baby boomers to millennials, is “absolutely and utterly willing to engage in digital healthcare,” Nick van Terheyden, MD, chief medical officer of NTT Data, Inc, said during the session.

While we have the technology to further engage in telehealth and other platforms, thus far, Americans have not participated fully; however, Dr van Terheyden predicts that will change very soon. He believes that telehealth combined with drone-delivery technology will create a healthcare environment that will no longer require sick patients to leave home to receive an exam or a prescription.

“We’re never going to be offline and it’s going to change the way we interact with medicine and the healthcare system,” he said.

Medication adherence is a \$300 billion problem, according to estimates by the World Health Organization, which causes thousands of avoidable deaths per year. With a reimbursement system that is changing to include ratings and outcomes, medication adherence has become highly prioritized by stakeholders.

The shift in payment models coupled with growing technology places a greater importance on patients adhering to their treatment, according to the session. Because a majority of Americans own smartphones, companies have harnessed the platform to launch applications for medication adherence.

Harry Travis, president and CEO of EtectRx, discussed how medication adherence technology can come in many different forms, including smartphone applications, therapeutic regulated applications, smart pill bottles, in-home dispensing, smart injectors, digital pills, smart injectors/inhalers, and packaging solutions. These technological advances are aimed at improving medication adherence among patients.

““ The more data that can be shared with providers will likely lead to increased adherence.

“There’s a lot of money going into this space,” Travis reported.

Regardless of where the technology is headed, the question remains as to how healthcare providers currently address medication adherence. These new digital pills and various platforms are only useful if providers understand them and patients engage with them. At Humana, panelist Nick Walter, director of Digital Business and Marketing Strategy, reported that the pharmacy benefit manager is focused on how they can provide cost transparency tools that help patients manage their adherence. For Humana, it all starts with enrollment and data, according to Walter.

“One rule we live by is: data given to us is data saved, is data shared,” Walter said.

Within the enrollment process, a member will give data about medications. Humana then provides the member with recommendations about how to save money, whether through filling prescriptions at a different pharmacy or switching to a generic, according to Walter. The patient can then present these options to their provider to determine if the solutions would be beneficial.

Additionally, digitizing prescription lists—rather than paper lists—would also increase the amount of data to evaluate and increase adherence. The more data that can be shared with providers will likely lead to increased adherence. To take these data full circle, they need to be shared with caregivers and providers to ensure that patients are, in fact, adhering to their medications and gaining the most benefits possible, according to the session.

“As we’ve seen here through the tools, it’s really about the data and using the data, making sure we have that data and providing the appropriate filters so that consumers—the member, the caregiver, or the provider—can make sense of that,” Walter concluded. ●

21st Century Cures Act May Bring Significant Changes to Healthcare

LAURIE TOICH

The 21st Century Cures Act could have far-reaching implications for specialty pharmacy.

The 21st Century Cures Act was one of the last bills signed into law by former President Barack Obama. The legislation increased funding for medical research, revised the federal policy on mental healthcare, and changed the drug approval process, among other significant actions.

The bill's overwhelmingly positive reception in both the House and Senate highlights the importance of the legislation for the United States. Since it was enacted in December 2016, there have been significant and encouraging results, according to the session "21st Century Cures Act – Implications on Specialty Pharmacy," presented at the Asembia Specialty Pharmacy Summit 2017.

Specifically, Section 3037 broadened the amount of healthcare economic information shared with payers. This section expanded the audience and those who can benefit from the data, according to the panel. Additionally, Section 3037 clarified the definition of healthcare economic information, which gained support from the Academy of Managed Care Pharmacy.

The 21st Century Cures Act mainly focuses on discovery, development, and delivery of novel therapeutics and processes.

As a part of the bill, the Precision Medicine Initiative was created, highlighting the importance of personalized medicine. The law also provides funding for the Cancer Moonshot initiative, which was developed by former Vice President Joe Biden. Further funding has been allocated to research Alzheimer's disease and other conditions.

The legislation streamlines FDA processes to stress the patient's importance in the regulatory review process. It also increases the flexibility of the FDA, allowing the agency to adopt new standards, according to the panel. The 21st Century Cures Act also seeks to speed access to new curative drugs and increases the utilization of electronic health records.

"Even with the 21st Century Cures Act, there will still be challenges for the private sector to address going forward," said speaker Dan Leonard, president, National Pharmaceutical Council.

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Beyond Dispensing: Specialty Pharmacies and a Holistic Treatment Approach

LAURIE TOICH

Specialty pharmacies must be focused on better communication with patients.

From the first interaction to the last, patients must feel that their healthcare provider is invested in their well-being and committed to treating them effectively. Although skilled specialty pharmacies provide optimal care for patients, pharmacists can always make improvements in treating their patients holistically.

During the session, Consider the Patient's Perspective in Building the Future of Specialty Pharmacy at the Asembia Specialty Pharmacy Summit 2017, speaker Kelly Ratliff, president, US Bioservices, shared the unique perspectives of patients treated with specialty drugs. Prior to the session, multiple patients were interviewed to determine how specialty pharmacies excel and where there is room for improvement.

"Their testimonials are a reminder that we are in an important and privileged space to truly make a difference and enhance the value we bring to people and their families, something far beyond just dispensing a specialty pharmacy medication," Ratliff said during the session.

Regardless of the condition or background, all patients interviewed said they want to discover their new normal. Among

“ The largest impact of chronic disease faced by patients is the emotional burden.

patients diagnosed with a specialty condition, their new normal can be dramatically different compared with life prior to the onset of their disease, which also has a significant impact on their family and loved ones.

Specialty pharmacies are versed in lifting financial barriers, coordinating care, and designing convenient therapies; however, the largest impact of chronic disease faced by patients is the emotional burden. These factors make it more difficult for pharmacies to balance finances, scale, and reach of services with patient attention, according to Ratliff. One of the interviews presented during the session was a patient named Don, a US Army veteran who loved hiking. He was diagnosed with chronic inflammatory demyelinating polyneuropathy, which made walking difficult. Emotionally, Don was dealing with

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Lessons Learned from Outcomes-Based Contracting in Specialty Pharmacy

LAURIE TOICH

Implementing outcomes-based contracting has proven challenging for stakeholders.

Many healthcare stakeholders have been pressured to implement alternative contracts rather than standard fee-for-service reimbursement.

According to the session Value-Based to Outcomes-Based Contracting: Is it Possible? presented at Asembia Specialty Pharmacy Summit 2017, moving away from traditional models and toward outcomes-based contracting would provide significant benefits for patients. These innovative contracts require collaboration between manufacturers and payers.

A common question regarding the contracts is how will this be beneficial? Before pursuing an outcomes-based contract, manufacturers should examine if their product is first to market and evaluate patient response, class of drug, and what competitors are doing. Manufacturers first must determine if they have a product that would make a good candidate for an alternative contract, according to the session.

Panelist Brian Solow, MD, chief medical officer at Optum Life Sciences, said most stakeholders do not understand the

decision-making process for pharmaceutical and therapeutics, which can cause a disconnect. Individuals drafting the contracts must understand that process in addition to what happens when it moves to the trade side of the business. Since these contracts are not the norm, many more stakeholders must be involved, including those involved in health plans, data collection, and legal concerns.

Flexibility is also key to implementing outcomes-based contracts because the ideal agreement for a particular product may differ between the involved parties, according to the panel. A payer will likely not be willing to sign an agreement that does not benefit them.

An additional consideration should be the timing of the contract. While it may seem that post-product launch would be the optimal time, it may be much sooner, according to the panelists. The sooner the discussion can happen, the more time there will be to discuss potential issues that arise.

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Treating Rare Diseases Comes With Different Set of Challenges

LAUREN SANTYE

The high cost of treatment causes some payers to question coverage for these conditions.

About 7000 rare diseases affect approximately 350 million patients worldwide. Despite a relatively small patient population, treating rare diseases comes with significant challenges, including the high cost of drugs and the lack of a sufficient amount of patients to participate in clinical trials, according to a panel discussion at the Asembia Specialty Pharmacy Summit 2017 in Las Vegas.

In 2016, the average annual cost of an orphan drug treatment regimen was \$140,443, compared with \$27,756 for non-orphan drugs. From a payer perspective, the cost of treatment is too high, which creates a demand for clear measurements of improved survival, along with addressing the budget impact to offset the disease and therapy costs, according to the panelists.

From the perspective of pharmaceutical manufacturers, best practices for rare disease therapy include early involvement of the FDA, consultants, payers, prescribers, patients, advocacy groups, financial assistance, hub services, and specialty pharmacies. However, the high pricing of treatments causes payers to question

“If a drug costs too much out of pocket, then a patient is likely to attempt to prolong use of the treatment.**”**

why they should have to cover these significant costs, resulting in arguments between payers and manufacturers.

“But the piece a lot of us miss is the end person, the patient, and no one really asks them the questions,” panelist Mala Crossley, PharmD, said during the session.

Diagnosing a rare disease currently takes an extended amount of time because it can be difficult to find physicians able to accurately determine what is affecting the patient. This often leads to psychological issues, such as depression; furthermore, economic issues and compliance issues also arise.

If a drug costs too much out of pocket, then a patient is likely to attempt to prolong the use of the treatment, meaning poor

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21st Century Cures Act (Continued from page 11)

While there may be increased access to groundbreaking medications, there also comes the issue of alignment of cost with value. For example, an upcoming drug may cure a rare disease that causes blindness in children, but how does value play a part in the price of the treatment? Similar issues were previously seen with the approval of hepatitis C virus drugs.

Under the law, the FDA may decide to use real-world evidence to make regulatory decisions that would require the agency to analyze data to find high-quality results. This, in turn, would require increased data and analytic capabilities that the FDA would have to develop. The potential program would be created to green-light supplemental indications for approved treatments through real-world data findings, according to the panel. The

FDA is also looking to use real-world data for the approval of medical devices.

Additionally, with broader information exchange, it is critical for stakeholders to understand which treatments work best for which patients, according to the panel. Going forward, the growth of information exchange must be leveraged to assess the target population across health plans, while also increasing the conversation about efficacy studies prior to implementation, according to the panel. Also, developing parameters for cost-effectiveness models and discussing pricing and benefit design is needed. The greater dialogue will also likely increase the speed of enacting value-based contracting, since specialty pharmacies, health plans, manufacturers, and researchers can work together to integrate data, the panel concluded. ●

Beyond Dispensing (Continued from page 11)

the fact that his condition is incurable, forcing him to adjust to a new way of life.

As patients search for their new normal, specialty pharmacies are tasked with discovering ways to advance patient care. To develop the proper balance, Ratliff encourages specialty pharmacies to consider the patient perspective in every step of their treatment journey and remain focused on improving patient-provider communication. New technologies, including translation services, allow patients to stay in better contact with their specialty pharmacies, according to the session.

This focus on communication is vital to improving the understanding between patients and their providers. With complex therapies, communication is integral for pharmacists to monitor therapy, work with providers to adjust therapy, and respond to patient needs, Ratliff noted. Communication is

also vital to ensure that patients understand their insurance coverage. In other interviews discussed during the session, the patients stressed how empathy and compassion were valuable assets for a pharmacy.

“Effective listening and compassion are the bedrock for building trust with our patients. That leads to better patient engagement, adherence, and outcomes,” Ratliff said.

For specialty pharmacies to remain successful, they must have the patient at the forefront of the conversation and remain willing to go beyond just dispensing a drug.

“Along with the amazing progress we have made, along with the advancements ahead, we must remain focused on our core responsibility,” Ratliff concluded. “That core responsibility is to improve the lives of patients, their families, and those we serve every day. Our patients are depending on each of us every day to make good decisions on their behalf.” ●

Lessons Learned (Continued from page 12)

In discussing other lessons learned, panelist Raymond Risman, vice president of Optum Life Sciences, suggested that contracts should not be based on findings from clinical trials. A successful contract must be widely applicable and something a payer would be interested in, he added.

“When a company has these trials, you should consider it more of a starting point for the development of value-based contracting,” Risman said. “Put it in the hands of researchers who know how to use data to translate the requirements of a clinical trial using claims data to make it applicable to the product population.”

A successful value-based contract is reliant on good quality data. Data for any drug lives in tables that frequently do not interact with each other. There may be a table of data for reimbursement, mortality, and co-payments that do not intersect.

Translating claims data into clinical metrics is essential for innovative contracting, according to the panel.

These contracts are generally only explored by payers at the moment, but involving providers could lead to the inclusion of innovative care programs in the contract itself. Provider involvement would also result in more data being gathered and the ability to track results in real-time, while also addressing gaps in claims data.

A key piece of information is understanding the product and its metrics. For example, a 1-year value-based contract would not effectively measure an adverse event that happens every 3 years. These contracts are not simple and can vary from payer to payer, and even among products within the same payer, according to the panel.

By incorporating these key points, stakeholders may surpass hurdles that have been previously faced by payers, the panel concluded. ●

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