Increased adherence rates deliver improved outcomes for patients
Rheumatoid arthritis (RA) is a chronic, systemic inflammatory disease that affects some 1.3 million adults in the United States. While it primarily attacks joints, causing joint pain, swelling, and stiffness, it can also affect other organs in the body. As the disease progresses and joint damage occurs, patients experience greater disability and decreasing quality of life. RA is associated with significant levels of morbidity and mortality and has a significant impact on total health care costs.

Many patients with moderate to severe RA benefit from the use of injectable, biological, disease-modifying, anti-rheumatic drugs (DMARDS). These medications have been shown to reduce RA activity and retard progression in patients, while improving physical function and quality of life.

The full benefit of biological DMARDS, however, can be achieved only if patients adhere to their prescribed medication regimen. And therein lies the challenge. Many patients fear the self-injection required of DMARDS, others complain of injection-site reactions, side effects, or the drugs’ high costs. Any or all of these factors can cause some patients to abandon treatment – an action that can have significant impact on health outcomes and health care costs.

Although research has shown self-management programs that focus on patient empowerment and education have positive effects on outcomes for RA patients, medication management was not the main focus of these studies. There is limited research evaluating whether RA disease management programs that contain a comprehensive Medication Therapy Management component result in improved adherence.

To study the possible impact of such a program upon RA adherence levels and outcomes, Prescription Solutions implemented an RA Disease Therapy Management (DTM) program in 2007 as an enhanced offering to members who were receiving specialty pharmacy services.
THE PRIMARY GOALS FOR THE PROGRAM INCLUDED:

• Maximize therapeutic outcomes by promoting medication adherence
• Enhance physical functioning and health-related quality of life by empowering patients and increasing their knowledge of RA

Prior to implementation of the DTM program, RA patients who were using injectable medications received routine specialty pharmacy management services from Prescription Solutions mail service pharmacy. These services included mail service delivery of medication; refill reminders from Patient Care Coordinators; access to a licensed pharmacist 24 hours a day/7 days a week; and a patient welcome brochure that described ordering, storing and monitoring medication, and proper disposal of ancillary supplies.

The RA DTM program used a patient-centric model to provide an enhanced level of coordinated health care interventions and communications to patients. Patients were eligible for the DTM program if they had a diagnosis of RA and a pharmacy claim for an injectable RA medication through the Prescription Solutions specialty pharmacy.

Eligible patients were identified on a weekly basis and sent a DTM welcome packet. Patients who returned a Patient Availability Form indicating a preferred date/time for a phone consultation were assigned a clinician – either a licensed pharmacist or a registered nurse – who would remain their main point of contact throughout the entire program.

During the initial telephone conversation, the clinician educated the patient about RA and treatment options, and promoted medication adherence and persistence as a means of achieving the best health outcome. To ensure consistency across consultations, each clinician was required to ask standardized assessment questions and cover specific educational topics. However, the clinician could also provide additional consultation on other topics as well.

Both a regular intensity and a high intensity program were developed for this study. Patients in the regular intensity program received four consultations – at enrollment (month 0), month 1, month 4, and month 6. Patients in the high intensity program received seven consultations – at enrollment (month 0), and monthly through month 6.

The initial consultation typically lasted 40-60 minutes; follow-up consultations were 20-30 minutes.
Based on the initial consultation, the clinician developed a personalized care program for the patient that summarized the phone consultation and contained information relevant to the patient’s needs, such as information about RA and RA symptoms, medications and adverse drug reactions, healthy living, provider/patient communication, home safety, and resources. Both the patient and the prescriber of the injectable RA medication received a copy of the care plan.

During each subsequent consultation, the clinician assessed patient knowledge and health concerns, and provided education on core topics, such as:

- Pathophysiology of rheumatoid arthritis
- Laboratory values pertaining to rheumatoid arthritis or medication therapy
- Optimization of medication therapy including medication adherence
- Symptom management
- Pain management
- Stress management
- Importance of a balanced diet
- Importance of exercise
- Importance of patient-provider communication
- Appropriate use of assistive devices
- Home safety
- Additional resources, including financial

To encourage medication adherence, the program was designed to address the five dimensions of adherence identified by the World Health Organization:

- Health-system/health care team factors
- Therapy-related factors
- Condition-related factors
- Patient-related factors
- Social and economic factors
Health-system factors, such as poor quality of provider/patient relationship and communication, were addressed by encouraging patients to find a provider with whom they were comfortable and could speak openly about their issues. Patients were also advised to keep a journal or write down questions that arose between appointments. Therapy-related adherence barriers were addressed by providing education on adverse drug reactions (including injection site reactions and how to manage them) and the consequences of missed doses. Patients were educated on the damaging effects of RA and the increased damage that may occur as a result of not adhering to the medication regimen.

Because injectable RA medications are not always taken daily, patients may forget to take their medications. To overcome this patient-related barrier, a medication chart or calendar was provided to improve adherence and prevent double dosing. Finally, socioeconomic barriers to adherence were improved by including resources to national foundations and medication manufacturers with medication financial assistance programs.

All participants, regardless of whether they were in the regular-intensity or high-intensity program, received general, non-individualized monthly mailings that included information on life with RA, RA medications, exercises, nutrition, preventive medicine, psychological issues, and pain management.

**Program comparison included three study groups**

Data was obtained and analyzed for patients participating in the Medicare Advantage Prescription Drug Plan (MAPD), the Prescription Drug Plan (PDP), or commercial health plans that use Prescription Solutions specialty pharmacy. Identified patients were separated into three mutually-exclusive study groups:

1) **DTM** – patients who filled a prescription for an injectable RA medication through Prescription Solutions specialty pharmacy and enrolled in the DTM program.

2) **Specialty Pharmacy** – patients who filled a prescription for an injectable RA medication through Prescription Solutions specialty pharmacy but did not enroll in the DTM program.

3) **Community Pharmacy** – patients who filled a prescription for an injectable RA medication at a community pharmacy and did not have any injectable RA medications filled through Prescription Solutions specialty pharmacy. These patients were included to provide a comparison group which had no contact with the specialty pharmacy or DTM program.
DTM program delivers favorable outcomes for RA patients

Analysis showed that this telephone-based DTM program improved clinical outcomes for RA patients. Patients enrolled in the seven-month program showed significantly higher adherence to their injectable RA medications compared with a control group of patients who received the same medications through community pharmacies but did not participate in the DTM program. The average adherence rate for patients in the DTM program was 83 percent; the average adherence rate for patients in the control group was 60 percent.

Patients who completed the program had improvements in physical functioning as measured by the SF-12, a survey instrument that measures mental and physical quality of life. They also experienced improved HAQ-DI scores (Health Assessment Questionnaire-Disability Index), which measures function and quality of life, as well as the patient’s ability to perform everyday tasks.

With the mean age of 61 years and an average duration of disease of 12.7 years, patients in this study would not be expected to have large improvements in HAQ-DI because HAQ-DI generally increases with age and disease duration. Nevertheless, the DTM program delivered significant improvements in HAQ-DI scores.

The DTM program was rated by 98.1% of participants as “very helpful” or “somewhat helpful” in enabling them to better manage their health. Additionally, 91.1% of the participants rated the program as “very good” or “excellent.”

While the study did not demonstrate improvements to SF-12 mental scores or work productivity, these results are not surprising. Previous research has shown that, when measuring quality of life in a disease with physical implications, such as RA, medical treatment has greater impact on assessment of pain and physical health than on assessment of mental status. With regard to work productivity, the small sample size of employed participants – just 18.6% – made it difficult to accurately interpret the results.
As would be expected, participants in the DTM program incurred increased pharmacy costs due to improved adherence and persistence to their RA medication therapy. Preliminary results suggest that those increased pharmacy costs were partially offset by smaller medical costs for the DTM participants when compared with the specialty or community participants. Because total health care costs could only be evaluated for the subgroup of patients with medical claims data, this information may not accurately reflect the entire population. In addition, sample sizes of patients with medical claims data were too small to detect differences among groups. Further research is necessary to compare short- and long-term total health care costs for RA patients who participate in DTM programs versus those who don’t.

Regardless, this program clearly demonstrates the benefits of incorporating a Disease Therapy Management program in the treatment of Rheumatoid Arthritis. By helping patients who are receiving injectable medication therapy increase adherence rates, the program translates into better physical health and quality of life for patients battling this debilitating, chronic disease.

References:
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