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PATIENT OUTCOMES ASSOCIATED WITH BIOLOGIC INFUSION SITE OF CARE FOR THE TREATMENT OF RHEUMATOID ARTHRITIS

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OBJECTIVES: To assess the association of site of care (SOC) for rheumatoid arthritis (RA) related biologic infusion with clinical outcomes, health status, work productivity loss, and healthcare resource use. **METHODS:** In 2009 and 2010, individuals aged ≥ 18 and reporting an RA diagnosis completed a cross-sectional, self-administered, Internet-based questionnaire. SOC was categorized as currently receiving infusions of abatacept, infliximab, rituximab, or tocilizumab: in a physician's office (IOI), a hospital outpatient department (HOPD), or other alternate sites of care (ASOC). Clinical outcomes included the Health Assessment Questionnaire (HAQ) and severity of morning stiffness, fatigue, and pain, measured as 1=none experienced to 10=severe. Health status was assessed using the SF-36, and work productivity loss was assessed using the Work Productivity and Activity Impairment questionnaire. Healthcare resource use in the past six months included emergency room visits, hospitalization, and physician visits. Patient demographics and comorbidities were adjusted using linear regression and negative binomial regression as appropriate. **RESULTS:** Of 273 infusion patients analyzed, 54.6% (n=149) were categorized as IOI, 11.7% (n=32) HOPD, and 33.7% (n=92) ASOC. IOI patients were more likely to be female (80.5%) than HOPD and ASOC patients (50.0% and 65.2% respectively, $p < 0.001$). Other demographics and comorbidities were similar across SOC categories. SOC was not significantly associated with clinical outcomes, health status, work productivity loss, or healthcare resource use with few exceptions. Compared to IOI patients, HOPD patients had poorer SF-36 role emotional scores ($b = -13.54$, $p = 0.022$) and ASOC patients had better vitality scores ($b = 6.67$, $p = 0.006$). Also, ASOC patients had fewer average visits to traditional providers than IOI patients ($p = 0.011$). **CONCLUSIONS:** With few exceptions, clinical outcomes, health status, work productivity loss, and healthcare resource use are similar regardless of SOC for biologic infusion. Therefore, other factors may drive choice of SOC, such as convenience for the patient and cost for the patient and payer.

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INFLIXIMAB INFUSION PATTERNS IN PATIENTS WITH RHEUMATOID ARTHRITIS 'NAÏVE' TO BIOLOGIC THERAPY: AN ANALYSIS OF A NATIONAL HEALTH PLAN

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OBJECTIVES: FDA prescribing information for infliximab (IFX) treatment of patients with rheumatoid arthritis (RA) recommends infusions at weeks 0, 2 and 6 followed by every 8 weeks, with a 4 week option. This study examines infusion intervals in RA patients enrolled in a large United States health plan. **METHODS:** Claims data were obtained from the i3Innovus database for October 2006 through June 2009. Inclusion criteria were ≥ 2 diagnoses for RA (714.xx), absence of a diagnosis for selected anti-inflammatory disorders, age ≥ 18 , ≥ 4 IFX infusions, absence of any biologic claim for 6 months prior to index date, and ≥ 12 months of continuous eligibility post-index. A treatment episode was defined as infusions from index claim to the last IFX claim in the dataset without a claim for other biologics during that episode. Patients with IFX infusions ≥ 180 days were excluded. The sample mean at each infusion was compared to prescribing information. **RESULTS:** Of patients meeting inclusion criteria (N=652), the number of infusions received ranged from 4 to 48 (mean of 11). The mean interval (\pm SD) between the first and second infusion was 20 days (± 17); 76% of the sample received their infusion within three days of the recommended 14 days. The mean interval between the second and third infusion was 33 days (± 12). The mean interval between each of the next 8 maintenance infusions ranged between 50 and 54 days (SDs ranging from 15-16 days), with a mean across all intervals of 51 days (± 7 weeks). **CONCLUSIONS:** Data from this national health plan indicate that induction and maintenance intervals were consistent with the FDA recommended prescribing information. Physicians in this particular health plan appeared to be administering IFX in accordance with the FDA-approved administration schedule for RA.

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ASSOCIATION OF SATISFACTION WITH SUBCUTANEOUS ANTI-TNF THERAPY AND CLINICAL OUTCOMES, HEALTH STATUS, AND LOST WORK PRODUCTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: To assess the association of satisfaction with subcutaneous (SC) anti-TNF therapy and clinical outcomes, health status, and work productivity loss among patients with rheumatoid arthritis (RA). **METHODS:** In 2009 and 2010, individuals aged ≥ 18 and reporting an RA diagnosis completed a cross-sectional, self-administered, Internet-based questionnaire. Satisfaction with current SQ anti-TNF therapy (adalimumab, certolizumab, etanercept, and golimumab) was assessed on a five-point Likert scale. Differences in outcomes were compared between patients who were very satisfied (satisfaction=4 or 5) and not very satisfied (satisfaction=1, 2, or 3). Clinical outcomes included the Health Assessment Questionnaire (HAQ) and severity of morning stiffness, fatigue, and pain, measured as 1=none experienced to 10=severe. Health status was assessed using the SF-36, and work productivity loss was assessed using the Work Productivity and Activity Impairment questionnaire. Patient demographics and comorbidities were adjusted using linear regression for clinical outcomes and health status and negative binomial regres-

sion for lost work productivity. **RESULTS:** Of 474 patients currently using SQ anti-TNFs, 68.1% (n=323) were very satisfied. After adjustment, greater satisfaction was associated with less functional disability (HAQ: regression coefficient $b = -0.21$, $p < 0.001$); less severity of morning stiffness ($b = -1.09$, $p < 0.001$), less fatigue ($b = -1.06$, $p < 0.001$), and less pain ($b = -1.00$, $p < 0.001$); and better health status (SF-36 physical component summary: $b = 3.60$, $p < 0.001$ and mental component summary: $b = 2.98$, $p = 0.005$). Among the employed, greater satisfaction was associated with less absenteeism ($p = 0.059$), less presenteeism ($p = 0.007$), and lower overall work impairment ($p = 0.020$). **CONCLUSIONS:** Greater patient satisfaction with SQ anti-TNF therapy is associated with better clinical outcomes and health status and increased work productivity. However, due to the cross-sectional nature of the study, the direction of these associations cannot be determined. Treatment attributes that improve patient satisfaction may have additional benefits. Further research is needed to investigate the potential impact of treatment attributes on patient satisfaction and outcomes.

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SATISFACTION, PREFERENCE AND REASONS FOR BIOLOGIC TREATMENT DISCONTINUATION IN PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: To assess current patient unmet needs in rheumatoid arthritis (RA) treatment by exploring patient experiences with biologics, including satisfaction, preference, and reasons for non-adherence and discontinuation. **METHODS:** In August 2009, 2,118 patients aged ≥ 18 and self-reporting an RA diagnosis completed a cross-sectional, self-administered, Internet-based questionnaire. Patients provided information about current and past use of biologic medication, treatment satisfaction (satisfied defined as 4 or 5 on a 5-point scale from 1=not at all satisfied to 5=extremely satisfied), preference for dosing frequency (less frequent dosing = every month or less often and more frequent dosing = two or more doses per month), adherence and reasons for non-adherence, and reasons for discontinuation of biologic agents in the twelve months preceding the study. **RESULTS:** 571 (27%) patients had experience with biologic therapy. Of these, 45% were currently using their first biologic, 29% had switched biologics and 27% used biologic therapy anytime in the past, but since discontinued. Among current biologic users, 63% were satisfied with their current therapy; however, among those who previously switched or discontinued, only 56% and 50%, respectively, were satisfied with current therapy. Of current biologic users, 72% preferred less frequent dosing of biologic medication and 28% preferred more frequent dosing. Among patients who stopped using a subcutaneous biologic in the year preceding the study (n=62), whether switching to another biologic or discontinuing altogether, reasons for stopping included, doctors advice (42%), lack of efficacy (37%), side effects or infection (37%), medication cost (18%), and discomfort with administering (15%). **CONCLUSIONS:** From the patient perspective, there are remaining unmet needs related to efficacy and tolerability with biologic therapy. Furthermore, most patients showed preference for longer dosing intervals. Newer treatment options may address some of these unmet needs. The patient perspective should be considered when making access decisions about newer biologic therapies.

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PATIENT EXPERIENCE WITH SUBCUTANEOUS ANTI-TNF THERAPY AMONG RHEUMATOID ARTHRITIS PATIENTS

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OBJECTIVES: To describe the experience of RA patients with subcutaneous (SC) anti-TNF therapy from the patient perspective. **METHODS:** Patients aged ≥ 18 and self-reporting an RA diagnosis completed a cross-sectional, self-administered, Internet-based questionnaire in August 2009. Biologic therapies included in the questionnaire were abatacept, adalimumab, certolizumab, etanercept, golimumab, infliximab and rituximab. This analysis focused on patients who reported current or past use of adalimumab (ADA) or etanercept (ETA), the most commonly prescribed SC anti-TNF agents. Certolizumab and golimumab were not included in the analyses due to the limited time they were available at the time of the study and their very small sample sizes. Patients provided information about their experiences with self-injection and how these experiences have affected self-reported discontinuation of therapy. **RESULTS:** A total of 263 patients were using SC anti-TNF therapy (129 ADA and 134 ETA) at the time of the survey. More than half of SC anti-TNF users (57%) experienced burning during or after injection. Of these, 15% rated the burning as very or extremely intense and 56% rated the burning as somewhat intense. Among SC users who reported that they did not take their medication as directed all the time (n=41), 12% cited discomfort in administering medication as often or very often a reason for treatment discontinuation. Of a small group of patients reported discontinuing in the year preceding the study (n=62), lack of efficacy, side effects, cost of drugs, and discomfort in administering medication were cited as major reasons for discontinuation. **CONCLUSIONS:** More than half of SC anti-TNF users experience burning during or after injection, and this discomfort may adversely affect treatment discontinuation. The results suggest that the patient experience should be considered when making treatment decisions. Further research is needed to examine the relationship between injection site reaction and patient outcomes including observed medication discontinuation.