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EFFECT OF CERTOLIZUMAB PEGOL ON WORKPLACE AND HOUSEHOLD PRODUCTIVITY IN UNITED STATES PATIENTS WITH RHEUMATOID ARTHRITIS WITH OR WITHOUT PRIOR ANTI-TNF EXPOSURE: RESULTS FROM THE PREDICT STUDY

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OBJECTIVES: To investigate the effect of CZP treatment on workplace and household productivity and social participation in US RA pts with and without prior anti-TNF exposure in the PREDICT trial (NCT01255761). **METHODS:** Pts received CZP standard dosing regimen (400mg at Wks 0, 2, 4 [loading dose], then 200mg Q2W). The arthritis-specific Work Productivity Survey (WPS; administered Q4W until Wk24, then Q8W) assessed the impact of CZP on workplace and household productivity, stratified by pts with (A) and without (B) prior anti-TNF exposure. Mean WPS responses (LOCF) are summarized over 52 wks **RESULTS:** 733 pts were randomized; 55.5% were prior anti-TNF failures. At baseline (BL), 38.8% (A) and 49.4% (B) pts were employed outside the home. A high burden of RA on workplace and household productivity and social participation at BL was reported, with on average >6 working days (A: mean 1.8 work days missed, 6.5 days with reduced productivity/month; B: mean 1.1 work days missed, 4.9 days with reduced productivity/month) and >14 days of household work (A: mean 9.6 housework days missed, 7.8 days with reduced productivity/month; B: mean 7.5 housework days missed, 7.4 days with reduced productivity/month) affected per month. By Wk4, pts reported reductions in workplace absenteeism and presenteeism (A: mean 1.2 days missed, 3.0 days with reduced productivity/month; B: mean 0.7 days missed, 1.9 days with reduced productivity/month), and improvements in household productivity (A: mean 6.2 housework days missed, 4.8 days with reduced productivity/month; B: mean 4.4 days missed, 4.0 days with reduced productivity/month). Improvements continued to Wk12 and were maintained to Wk52. Similar improvements in social participation were reported in both groups. **CONCLUSIONS:** In RA pts initiating CZP, there were similar improvements between those with and without prior anti-TNF exposure in workplace, household productivity and social participation. These improvements were observed as early as Wk4 and maintained through Wk52.

MUSCULAR-SKELETAL DISORDERS – Health Care Use & Policy Studies

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GENDER AND RACIAL DISPARITY OF SERUM VITAMIN D INADEQUACY: RESULTS FROM NATIONAL DATA IN THE UNITED STATES

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OBJECTIVES: To describe the level of serum vitamin D (25(OH)D) inadequacy by gender and race among US adults using national level data. **METHODS:** Cross-sectional study was conducted using the National Health and Nutrition Examination Survey (NHANES) from 2001 to 2006, i.e., the latest data including serum 25(OH)D concentration, including all US adults (>=40 years). Predictive factors of serum 25(OH)D inadequacy (i.e., <20 ng/ml) were evaluated using study variables including patient demographic, health and lifestyle factors, health care utilization, insurance coverage, and clinical comorbidities. All analyses were performed with SAS statistical software, version 9.1, at an alpha of 0.05. **RESULTS:** Of 125 million adults, 37.3% had inadequate serum 25(OH)D levels. The inadequacy was higher in female than male participants (40.6% vs 33.6%: p<0.0001, respectively). Among race/ ethnicity groups, the prevalence of serum 25(OH)D inadequacy was significantly higher in non-hispanic black populations (77.6%), hispanic populations (50.5%), and other race (53.2%) than non-hispanic whites (29.7%) (p<.0001). Participants who had no health insurance coverage was associated with the higher prevalence of serum 25(OH)D inadequacy (47.4% vs. 35.9%: p<0.0001). **CONCLUSIONS:** A significant number of US adults maintain inadequate serum 25(OH)D level. The prevalence of the inadequacy was significantly higher in female participants and black populations as compared to their counterparts. Coordinated efforts through comprehensive programmatic approaches or improved collaboration including other health care professionals such as pharmacists and nutritionists can be a key element to improve vitamin D adequacy in US health care system.

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PATTERNS OF DISEASE REMISSION AMONG PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH BIOLOGIC THERAPIES IN THE UNITED STATES

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OBJECTIVES: To assess the patterns of disease remission among Rheumatoid Arthritis (RA) patients recently treated with biologic therapies in the United States (US). **METHODS:** A multi-center medical chart-review study of RA patients was conducted among physicians (majority: rheumatologists) in hospitals/private practices to collect de-identified data on patients who are currently on a biologic or recently discontinued a biologic within past 3-months. Physicians were screened for practice-duration and patient-volume and recruited from a large panel to be geographically representative of the US. Patient charts of ~10 successive patients visiting each center/practice during study period were selected. Physicians abstracted patient diagnosis, treatment patterns/dynamics and patient symptomatology/disease status (incl. assessment of 'disease remission', per physician clinical judgment). **RESULTS:** In 4Q2011, 109 physicians abstracted 851 eligible RA patient charts; patient mean-age:51yrs, female:73%; 69% and 24% were on 1st line and 2nd line biologic respectively. Overall, 48% of patients were in remission. Remission-rate differed by biologic lines: 1st-line:51%, 2nd-line:45%, 3rd-line:26%, 4th-line:27%. Among those with lab measures, results differed between those in remission vs. those who were not: mean ESR(mm/h): 18.9vs.37.2, mean CRP(mg/dl): 1.6vs.5.3, Rheumatoid Factor (% positive): 87%-vs-89%, Anti-CCP (% positive): 74%-vs-79% and HLA-B27 (% positive): 7%-vs-9%. Among those with data, recent (mean) disease severity scores differed between those in remission vs. those who were not: Tender Joint Count: 1.6-vs-6.3, Swollen Joint Count: 0.8-vs-4.8, 100mm VAS score: 18.9-vs-39.8, HAQ: 0.6-vs-1.5 and DAS28: 2.2-vs-4.1. **CONCLUSIONS:** More than half of the patients were not in remission in this cohort of RA patients in the US who were treated with a biologic recently; they experienced disproportionate level of disease burden. As the line of treatment increased, proportion of individuals achieving remission decreased. These observed patterns warrant further scrutiny to determine the best practices and improve remission rates, thereby alleviating patient burden.

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WHAT HAPPENS WHEN PERSONALIZED MEDICINE GUIDELINES DON'T AGREE? A SYSTEMATIC REVIEW OF CLINICAL GUIDELINES FOR THIOPURINE METHYLTRANSFERASE TESTING FOR DOSE SELECTION OF THIOPURINES

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OBJECTIVES: A common application of personalized medicine is testing for thiopurine S-methyltransferase (TPMT) status prior to treatment with thiopurine drugs which are used to treat several auto-immune disorders and acute lymphoblastic leukemia (ALL). The objective was to systematically review guidelines that include statements regarding TPMT testing to 1) investigate variations in testing and dosing recommendations and 2) appraise their quality. **METHODS:** Citation databases, websites and online repositories were searched. Guidance documents were compared within therapeutic areas. A quality appraisal was carried out by three appraisers using AGREE-II. Scores were recorded for domains related to Scope and purpose, Stakeholder involvement, Rigor of development, Clarity of presentation, Applicability and Editorial independence. Guidance documents were scored and ranked according to quality. **RESULTS:** A total of 20 guidelines were reviewed, covering inflammatory bowel disease (IBD) (n=8), inflammatory skin disorders (n=3), autoimmune hepatitis (n=3), rheumatic disease (n=2), ALL (n=2) and pharmacogenetics in general (n=2). Six documents focused on paediatric patients. Five specifically recommended genotyping while four recommended phenotyping. The remainder included general statements. Thirteen documents included dosing recommendations based on TPMT status, with the most common recommendation to avoid treatment in patients with extremely low or absent TPMT activity and to reduce thiopurine doses in patients with intermediate TPMT activity. Five documents recommended adjustments of a typical dose for each TPMT genotype or phenotype. Wide variation in quality was observed across all domains. Guidance documents that included dosing recommendations demonstrated higher quality. **CONCLUSIONS:** Variations in TPMT testing recommendations reflect the need for clarity in the clinical validity and utility of alternative TMPT test methods. The variable quality among guidelines illustrated a lack of consistency and rigor in the methods used to develop recommendations. Interdisciplinary collaboration between experts in genetics, pharmacology and clinical disciplines and careful adherence to methods for evidence-based guideline development is warranted.

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IMPACT OF DISEASE SEVERITY ON DURATION OF USE OF FIRST BIOLOGIC AMONG PATIENTS WITH RHEUMATOID ARTHRITIS (RA) IN UK, GERMANY, FRANCE, ITALY AND SPAIN (5EU)

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OBJECTIVES: To assess the impact of disease severity on duration of use of first biologic among patients with RA in 5EU. **METHODS:** A multi-country multi-center medical chart-review study of RA patients was conducted between 3Q2011-1Q2012 among physicians (rheumatologists:97%) in hospitals and private practices to collect de-identified data on patients who were recently treated with a biologic as part of usual care. Physicians were screened for duration of practice (3-30 yrs) and patient volume (incl. >2RA biologic-patients/week) and recruited from a large panel to be geographically representative in each country. Medical charts for ~10 successive patients visiting each center/practice during study-screening-period were abstracted to collect patient diagnosis, treatment patterns/dynamics and disease severity/status (per physician-judgment). Kaplan-Meier (KM) analysis was conducted to determine time-to-discontinuation of 1st-biologic by 50% of patients. **RESULTS:** 4367 eligible RA patients were included in the analysis; mean-age:51.7yrs; female:71%(range:63%(Germany)-75%(France)). Geographic distribution of patients were – UK/France/Spain:20% each, Germany:18%, Italy:21%. Percentage patients currently on 1st-line-biologic:74% (range:69%(France)-77%(Italy)), on 2nd-line-biologic:19%(19% in all countries except Spain(21%)), on >=3rd-line-biologic:7%(range:4%(Italy)-12%(France)). Time between diagnosis & 1st-biologic:52mo(range:31mo(Spain)-57mo(UK)). Medications used prior to 1st-biologic were mostly Non-biological-DMARDs and corticosteroids. Disease-severity at diagnosis (mild:moderate:severe): overall-11%:64%:22%, UK-15%:57%:25%, Germany-17%:68%:13%, France-7%:63%:26%, Italy-8%:65%:25%, Spain-9%:70%:18%. Current disease-severity (mild:moderate:severe): overall-50%:41%:8%, UK-55%:30%:14%, Germany-51%:41%:8%, France-41%:48%:10%, Italy-48%:47%:5%, Spain-57%:38%:5%. Per KM-analysis, time-to-discontinuation of 1st-biologic by 50% of patients was (months):53 (UK-53/Germany-47/France-59/Italy-57/Spain-46); KM-analysis stratified by disease-severity at initial RA-diagnosis revealed differences between disease-severity groups (5EU-aggregate): mild-61mo, moderate-56mo, severe-43mo; KM-analysis stratified by disease-severity at 1st-biologic initiation also revealed distinct differences (5EU-aggregate): moderate-61mo, severe-45mo (mild-group had inadequate events (of discontinuation) for evaluation). **CONCLUSIONS:** Among this large cohort of RA patients who received a biologic, disease severity differed within 5EU. Time-to-discontinuation of 1st-biologic by 50% of patients also varied across 5EU, decreasing with increasing patient severity.