Clinical Audit of Rheumatoid Arthritis Management: Adherence to NICE and EULAR Guidelines.

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ABSTRACT:

Objective: To assess adherence to National Institute for Health and Care Excellence; Guideline number 100 (NICE NG100) and European Alliance of Associations for Rheumatology (EULAR 2022) guidelines across five domains: initiation of Disease-Modifying Antirheumatic Drugs (DMARDs) at an early stage, selection of appropriate first-line therapy, implementation of treat-to-target monitoring, timely escalation to biologics in non-responders, and comprehensive pre-biologic evaluation including infectious disease screening and vaccination.

Methodology: A retrospective audit of 153 recently diagnosed rheumatoid arthritis patients was conducted. Data collected included demographics, diagnostic intervals, DMARD initiation times, first-line therapy choice, DAS28-ESR scores, remission rates, biologic escalation, and pre-biologic screening compliance.

Results: The cohort comprised 121 females (79.1%) and 32 males (20.9%), with diagnostic intervals of 7-24 days. All patients initiated DMARDs within 6 weeks of diagnosis. First-line therapy included methotrexate monotherapy (n=128, 83.7%), methotrexate plus hydroxychloroquine (n=6,3.9%), and sulfasalazine plus hydroxychloroquine (n=19, 12.4%), Remission was achieved in 101(66.0%) patients with first-line conventional synthetic DMARDs within an average of 10 weeks. The remaining (n=52, 34.0%), were escalated to biologics after 12 weeks; mean DAS28-ESR decreased from 4.2±1.1 pre-biologic to 1.8±0.8 post-biologic at 3 months. Pre-biologic infectious disease screening (hepatitis B, hepatitis C, tuberculosis, lipid profile) showed 100% compliance. However, no patients received pneumococcal, influenza, or varicella vaccines before biologic initiation, and COVID-19 vaccination status was undocumented.

Conclusion: This audit demonstrates strong adherence to core guideline recommendations, including: Early DMARD initiation, Methotrexate-based first-line therapy, Implementation of treat-to-target strategies, Timely escalation to biologic therapy in non-responders. Compliance with infectious disease screening was satisfactory. However, a significant gap was identified in pre-biologic vaccination, underscoring the urgent need for standardized vaccination protocols prior to initiating biologic therapy.

Keywords: Rheumatoid arthritis, clinical audit, DMARD therapy, treat-to-target, vaccination compliance.

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Introduction:

Rheumatoid arthritis (RA) is a long-term condition with autoimmune inflammation leading to joint destruction, impaired functioning, and a serious disability if not treated properly. The incidence rate of rheumatoid arthritis is about 5/1000 worldwide.[1] Its pathophysiology involves inflammation of synovial joints mediated by the immune system, leading to degradation of cartilage, erosion of bone, and ultimately causing permanent joint destruction and morbidity.[2] In advanced study of pathogenesis of rheumatoid arthritis, it has been transformed to therapeutic strategies with strong evidence that describes the early detection of the disease and early start of DMARD can prevent or lessen the chances of joint damage up to 90% of patients.[1]

The concept of "window of opportunity" has become a key principle in the treatment of rheumatoid arthritis. It refers to an early stage of disease where management provides long-term relief.[3,4] Studies state that early starting DMARD therapy within weeks to months of the appearance of symptoms is essential to secure better outcomes and prevention from permanent damage.[3,5] According to both the American College of Rheumatology and the European Alliance of Associations for Rheumatology, the DMARD should be started just after diagnosis, ideally within 6 weeks to 3 months of symptom appearance.[5-7] Treat-to-target strategy is another important approach in the management of RA that focuses on regular assessment and follow-ups every 1 to 3 months and early stepping forward in treatment if remission is not achieved.[5,8] The therapeutic goal is achieving clinical remission, defined as a DAS28 score less than 2.6, or alternatively, low disease activity when remission proves unattainable.[1,5,9] Current international guidelines recommend methotrexate as first-line therapy for newly diagnosed patients with rheumatoid ar-

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thritis having moderate to high disease activity, typically combined with short-term glucocorticoids.[5-7] For patients demonstrating insufficient response to conventional synthetic disease-modifying anti-rheumatic drugs within 3 to 6 months, particularly those with poor prognostic factors including autoantibodies, high disease activity, or early erosions, escalation to biologic disease-modifying anti-rheumatic drugs or targeted synthetic disease-modifying anti-rheumatic drugs is recommended.[5-7]

Screening for infectious diseases prior to initiating biologic therapy is a critical safeguard, as immunosuppressive agents markedly heighten the risk of latent tuberculosis, hepatitis B, and hepatitis C reactivation.[10–12] In addition, vaccination against preventable infections is strongly advised before treatment onset, when immune responses are most effective.[13],[14] The 2019 European Alliance of Associations for Rheumatology recommendations and the 2022 American College of Rheumatology guidelines emphasize that the majority of patients with autoimmune inflammatory rheumatic diseases should receive influenza and pneumococcal vaccines, ideally administered prior to immunosuppression.[13–15] Despite the availability of clear guidelines, substantial variation persists in the application of evidence-based vaccination practices across healthcare settings. Data from the American College of Rheumatology's Rheumatology Informatics System for Effectiveness registry revealed that only 15.5% of patients had documented pre-biologic vaccination status prior to commencing biologic therapy, underscoring a serious safety concern.[16] Similarly, vaccination rates among patients with rheumatoid arthritis remain inadequately documented in many clinical environments, highlighting ongoing deficiencies in preventive care practices.[16]

This study primarily aimed to evaluate adherence to National Institute for Health and Care Excellence; Guideline number 100 (NICE NG100) and European Alliance of Associations for Rheumatology (EULAR 2022) guidelines across five domains: early DMARD initiation, appropriate first-line therapy selection, treat-to-target monitoring, timely biologic escalation in non-responders, and pre-biologic health evaluation, including infectious disease screening and vaccination.

Methodology:

This retrospective clinical audit was conducted over a 12-month period from February 2025 to February 2026 at the rheumatology outpatient departments of Dr Ziauddin Hospital, Karachi, a tertiary care institution. Data were collected from two campuses (North Campus and Clifton Campus) to evaluate the management of recently diagnosed rheumatoid arthritis patients against established international guideline standards.

Ethical Approval: The study was approved from Ziauddin university ethical review committee, before starting data collection. Informed written consent was taken from all participants. The sample size for this study was determined by use of the single-proportion formula for estimating compliance rates in clinical audits.[17] Using data from previous studies, based on an expected compliance rate of 80% with a 95% confidence interval and a margin of error of 6.35%, we calculated that a minimum sample size of 153 patients would be required to estimate compliance. All complete record of patients presenting to rheumatology outpatient department at Ziauddin north and Clifton campus fulfilling the inclusion criteria of study, over the audit period were taken. We utilized a non-probability sampling method to recruit participants into our audit as this type of recruitment strategy has been shown to be acceptable in clinical audit literature as it includes all possible eligible cases seen within a specific time frame thereby reducing selection bias.[17] We included 153 patients with a new diagnosis of rheumatoid arthritis and fulfilling the 2010 American College of Rheumatology / European League Against Rheumatism classification criteria. We used the following inclusion criteria; age > 18yrs, recently diagnosed with rheumatoid arthritis, started any disease modifying antirheumatic drug (DMARD) and followed up for a minimum of 12 weeks to assess outcomes appropriately. We excluded any patients with incomplete medical records or coexisting autoimmune diseases which could potentially complicate assessing active disease.

Comprehensive clinical data were extracted from electronic medical records across both campuses. Demographic data, including age, gender, and baseline clinical characteristics, were recorded. The diagnostic timeline was documented as the interval between the patient's first hospital presentation and confirmed rheumatoid arthritis diagnosis. Treatment initiation was measured as the time from diagnosis to commencement of DMARD therapy. First-line therapy selection was categorized as methotrexate monotherapy, methotrexate-based combination therapy, or alternative conventional synthetic DMARDs (csDMARDs).

Disease activity was monitored using serial Disease Activity Score 28-joint count with Erythrocyte Sedimentation Rate (DAS28-ESR) scores recorded at baseline, at 12 weeks, and at each subsequent follow-up visit. The DAS28 -ESR was calculated using the standard formula incorporating tender joint count (28 joints), swollen joint count (28 joints), erythrocyte sedimentation rate, and patient global assessment of disease activity. Treatment response was defined as achievement of remission (DAS28-ESR 2.6) or low disease activity (DAS28-ESR 2.6 to 3.2) with first-line csDMARDs.

For the 52 patients who did not achieve remission after 12 weeks of csDMARD therapy, biologic escalation data were collected, including pre-biologic DAS28-ESR, choice of biologic DMARD, and post-biologic DAS28-ESR at 3 months. Pre-biologic screening practices were assessed for this subset, including lipid profile, hepatitis B surface antigen testing, hepatitis C antibody testing, tuberculosis screening via interferon-gamma release assay (IGRA), and vaccination status documentation for pneumococcal, influenza, varicella, and COVID-19 vaccines.

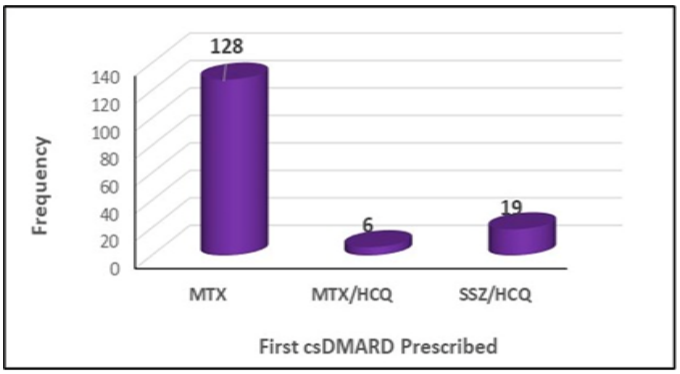
Data were analyzed using SPSS version 26.0. The Shapiro –Wilk test was applied to assess the normality of continuous variables. Age was normally distributed, whereas time duration did not follow a normal distribution. Descriptive statistics were used to summarize patient demographics and audit outcomes. Continuous variables such as age were reported as mean ±SD, while time duration was expressed as median with interquartile range (IQR). Categorical variables were presented as frequencies and percentages. Compliance rates for each audit standard were calculated and compared against predefined targets.

Results:

A total of 153 patients with recently diagnosed rheumatoid arthritis were included in the study. Of these, 121 were women (79.1%) and 32 were men (20.9%). This reflects the typical epidemiological pattern of disease. This cohort has overall mean age of 48.52 ±13.72 years. The median time period between the first hospital visits and the diagnosis was 15.5 days. It shows that there was minimal delay in diagnosis. DMARD was initiated for all 153 patients within

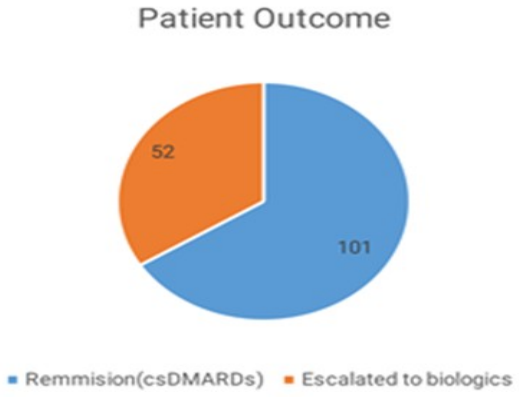
6 weeks as recommended by the window of opportunity. It shows good adherence to the NICE and EULAR guidelines, highlighting prompt treatment start-up. Starting first line DMARD showed very good compliance with guidelines that recommend regimens based on methotrexate:

Figure.1: First csDMARD Prescribe



Disease activity was monitored consistently in all patients by using DAS28-ESR scores. It allows objective evaluation of therapy results and compliance with treat-to-target approaches. Out of 153, 101 patients (66%) achieved remission with first-line csDMARD. Median time to remission was 10 weeks. Among these 153 patients, 52 patients (34%) didn't achieve remission even after 12 weeks of DMARD. DMARD therapy gave 66% remission, which is better than early published research stating remission rates as 40% - 50% in Methotrexate based 1st line treatment regime.

Figure.2: Patient outcome after starting 1st csDMARD.



All 52 patients who failed to achieve remission even after 12 weeks of DMARD were shifted to biologic therapy. It shows good adherence with the treat-to-target principle and early increase in treatment. Outcomes after biologic treatment:

Table No 1: Treatment response before and after starting biologic therapy measured using DAS28-ESR.

Pre-biologic mean DAS28-ESR SCORE	Post-biologic mean DAS28-ESR SCORE	p value
4.2 ±1.1	1.8±0.8	0.03

Mean decrease in DAS28-ESR score was 2.48±1.3 points, showing significant difference($p<0.05$). It shows that the biologic therapy was effective and gave a better response as post biologic mean DAS28-ESR score is 1.8±0.8 indicating remission. Pre-Biologic Safety Screening including Lipid Profile, Hepatitis B, Hepatitis C, IGRA (TB screening) was performed in all 52 patients (100%). Assessment of pre-biologic vaccination showed a notable gap in preventive care: Pneumococcal vaccination: 0 patients (0%), Influenza vaccination: 0 patients (0%), Varicella vaccination: 0 patients (0%), COVID-19 vaccination: Documentation not available. Before initiation of biologic treatment, there is no pneumococcal, influenza, or varicella vaccination. This shows a total deviation from international guidelines and a big concern for patients' safety.

Discussion:

The findings from this audit indicate that all patients commenced csDMARD therapy within six (6) weeks of being diagnosed with rheumatoid arthritis (RA). This rate of early initiation represents an excellent outcome and is markedly superior to the previous U.K. National Benchmark for early treatment, where only thirty-eight percent (38%) of patients received csDMARDs within six weeks of diagnosis. The high proportion of patients treated promptly reflects effective utilization of the "window of opportunity" concept by rheumatologists. Evidence from multiple clinical trials has consistently demonstrated that initiating csDMARD therapy early—within three (3) months of disease onset—yields highly favorable long-term outcomes, including reduced structural damage and improved functional capacity.[3-5] It is imperative that patients receive early treatment since inflammation related to RA can be most easily controlled during its earliest stages prior to entering into a self-sustaining chronic inflammatory state. There are multiple research-based clinical trial reports demonstrating that those patients initiating therapy earlier have achieved significantly greater remission rates and experienced significantly less joint damage compared to those initiating therapy later.[1,3]

Regarding first-line therapy selection, 87% of patients received methotrexate-based regimens, consistent with both EULAR and ACR recommendations that methotrexate should serve as the anchor drug in newly diagnosed rheumatoid arthritis unless contraindicated.[5-7] The minority of patients (12.4%) who initiated therapy with sulfasalazine or hydroxychloroquine had documented contraindications to methotrexate, most notably reproductive planning and desire to conceive. This represents an appropriate clinical decision and remains fully aligned with established guideline recommendations.[5,6]

Regular monitoring of disease activity using DAS28-ESR scoring was performed for all patients, demonstrating effective implementation of the treat-to-target strategy, which consists of tight disease activity control with regular follow-up every 1 to 3 months and prompt treatment escalation if remission is not attained.[5,8,9] The remission rate of 66% achieved with first-line csDMARD therapy in this audit compares favorably with published literature; a JAMA review reported that methotrexate achieves remission or low disease activity in approximately 40% to 50% of patients[1] while a model-based meta-analysis confirmed that methotrexate monotherapy often fails to achieve remission in a substantial proportion of patients. The higher remission rate observed in this audit likely reflects the combined effect of timely diagnosis, early treatment initiation within the window of opportunity, and systematic disease activity monitoring.[3,4]

All 52 patients (100%) who failed to achieve an adequate response to csDMARD therapy after 12 weeks were esca-

lated to biologic therapy, reflecting complete adherence to the treat-to-target strategy. The 2025 EULAR update recommends that in cases of insufficient response after 3 to 6 months, a bDMARD should be introduced.[18,19] Following biologic initiation in this cohort, the mean DAS28-ESR decreased from 4.28 to 1.80, representing a reduction of 2.48 points; well above the threshold of 1.2 considered clinically meaningful. Moreover, a post-biologic DAS28-ESR of 1.80 lies below the remission cut-off of 2.6, signifying achievement of complete disease remission in this subgroup.[9]

Pre-biologic infectious disease screening was performed with 100% compliance for hepatitis B, hepatitis C, tuberculosis, and lipid profile assessment, which substantially exceeds national benchmarks. Proper screening before biologic escalation is critically important, as immunosuppressive therapies may reactivate latent infections; TNF inhibitors in particular carry the greatest risk of tuberculosis reactivation among bDMARDs and tsDMARDs.[10] Similarly, hepatitis B reactivation has been documented in approximately 12.3% of patients with positive hepatitis B surface antigen who receive anti-rheumatic therapy without appropriate pre-biologic screening.[11,12] The exemplary screening compliance in this audit ensures that all safety assessments are completed before biologic prescription.

However, the complete absence of pneumococcal, influenza, and varicella vaccination before biologic initiation represents a serious safety concern and indicates a systematic gap in vaccination protocols rather than isolated oversight. The 2022 ACR guideline for vaccinations in patients with rheumatic and musculoskeletal diseases strongly recommends pneumococcal vaccination for all patients taking immunosuppressive medication and conditionally recommends high-dose or adjuvanted influenza vaccination.[14,15] Similarly, EULAR recommends that influenza and pneumococcal vaccination should be strongly considered for patients with autoimmune inflammatory rheumatic diseases, with vaccination preferably administered before immunosuppression initiation when immune responses remain optimal.[13] Recombinant zoster vaccination is also recommended for rheumatic disease patients over 18 years of age taking immunosuppressive medication, given the increased herpes zoster risk associated with both the underlying disease and immunosuppressive therapies.[14,20] The justification for administering vaccines prior to biologic therapy lies in both the heightened susceptibility to infection and the potential attenuation of vaccine immunogenicity once immunosuppression has begun. Vaccine responses may be diminished under certain therapies, particularly rituximab and methotrexate, making pre-immunosuppression vaccination the optimal strategy.[13,21]

Measures to Address the Vaccination Gap includes:

- Standardized Safety Checklist: Develop a pre-biologic checklist that integrates infectious disease screening with vaccination protocols to ensure consistency across clinical settings.
- Electronic Health Record Integration: Modify EHR systems to mandate documentation of completed vaccination protocols before biologic prescriptions can be authorized.
- Clinician and Patient Education: Provide targeted education highlighting the importance of pre-biologic vaccination, emphasizing safety and long-term outcomes.
- Nurse-Led Vaccination Clinics: Establish dedicated clinics within rheumatology services to facilitate timely vaccination completion during routine visits.

Study Limitations:

This audit has several limitations. First, as a retrospective study, vaccination data for RA patients who may have previously received immunizations was not documented in the medical records and therefore could not be included. Notably, no vaccination records were identified for any patient, which suggests that none had undergone vaccination and supports the validity of the audit findings. Second, the audit was conducted in a single clinical setting (Ziauddin Hospital), and results may not be generalizable to other institutions with different patient volumes or healthcare practices. Finally, long-term outcomes such as radiographic progression, functional status, and quality of life were not assessed, limiting the ability to evaluate broader disease impact beyond short-term treatment responses.

Conclusion:

This report confirms that the Treat-to-Target (T2T) model, as proposed by NICE (NG100) and endorsed by EULAR (2022), is a highly effective strategy for managing rheumatoid arthritis (RA), provided it is consistently implemented. Universal early csDMARD initiation, methotrexate-first prescribing, systematic disease activity monitoring, and timely biologic escalation collectively resulted in a 66% first-line remission rate, with further substantial improvements following biologic therapy. These findings reinforce the principle that adherence to RA guidelines translates into superior clinical outcomes.

However, the absence of pre-biologic vaccination in all patients, despite comprehensive infectious disease screening, highlights a critical weakness in the current T2T framework: evidence-based treatment recommendations are being implemented, while evidence-based preventive safety measures are overlooked. Thus, while the T2T approach is highly effective in controlling RA, it requires formal integration of vaccination protocols as a mandatory pre-biologic measure. Regular re-auditing is essential to close this gap and ensure that patient safety is addressed as comprehensively as disease control.

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Soman Rasool	Study design, Introduction, Data collection,
Ashar Ekhlaq Ahmed	Conception, Draft, Revision
Saqib Saleem	Introduction, Discussion
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Yusra Ashar Ahmed	Data collection,
Ammad Hussain	Results, Data analysis, Discussion