**Libyan Med J.** 2026;18(6):381-385
https://doi.org/10.69667/lmj.26612

**Libyan Medical Journal**

*https://lmj.ly/index.php/ojs/index eISSN: 2079-1224*

*Original article*

# Vaccination Status and Its Predictors Among Patients Receiving Biological Therapy: A Cross-Sectional Study at Benghazi Medical Centre

**Sahar Summad[1,2], Tasneem Ali[1,3], Manal Mahjoub[1,2], Masoud Eldernawi[1,2], Fatimah Mohammed[1,2], Mariam Almaghribi[1,2], Ashraf Rajab[1,2]**

*[1]Department of Medicine, Benghazi Medical Center, Benghazi, Libya*
*[2]Department of Medicine - University of Benghazi, Benghazi, Libya*
*[3]Department of Emergency Medicine, Al-Jala Hospital, Benghazi, Libya*
***Corresponding email.** ashraf.rajab@uob.edu.ly*

***Keywords**:*
*Biological therapy, Vaccination status, Predictors, Libya, Immunosuppression*

**ABSTRACT**

Patients receiving biological therapies for autoimmune and inflammatory diseases face a substantial risk of infection due to their immunosuppression state. This cross-sectional study assessed vaccination coverage and identified key determinants of vaccine uptake among patients receiving biological therapy at Benghazi Medical Center. Data from 370 patients were analyzed. Results indicated critically low vaccination coverage, with only 32.6% having received any recommended vaccine in the last five years. The strongest predictors of vaccine uptake were a positive belief in vaccine safety ($p < 0.0001$) and receiving a recommendation from a healthcare provider ($p < 0.01$). Crucially, no significant associations were observed between vaccination status and the type of biologic agent, underlying disease, or the patient's educational level ($p = 0.122$). These findings underscore an urgent need for targeted patient education campaigns and the establishment of robust, provider-driven vaccination protocols to protect this vulnerable patient population.

## Introduction

Biological therapies, including TNF inhibitors, interleukin inhibitors, and JAK inhibitors, have become foundational for managing chronic autoimmune and inflammatory conditions. However, the mechanism of action of these agents results in immune system modulation, consequently increasing patient susceptibility to severe infections (1). Vaccination is a critical consideration for patients undergoing biologic therapy due to their increased risk of infection and potential for altered immune responses to vaccines (2). Guidelines from various organizations, including the CDC, ACR, and ECCO, emphasize the importance of vaccination in this patient population (3-5). Vaccination is universally recognized as a cornerstone of preventive care for this vulnerable population. International guidelines, such as those published by the European League Against Rheumatism (EULAR) (1) and the European Crohn's and Colitis Organization (ECCO) (6), strongly recommend the assessment and administration of appropriate inactivated vaccines (e.g., Influenza and Pneumococcal) before or during the initiation of biologic agents. These recommendations emphasize that the benefits of vaccination far outweigh the potential risks in this high-risk group. Despite clear clinical mandates, global literature consistently reports critically low immunization rates among patients receiving biologics, indicating a significant gap between best-practice recommendations and real-world clinical implementation (6).

### *Study Setting Context*

Benghazi Medical Center (BMC) serves as the primary and often sole and the largest referral center providing biological therapy for autoimmune and inflammatory diseases across the entire Eastern region of Libya. This unique status means the Department of Medicine manages a large, highly concentrated cohort of these vulnerable patients. Therefore, this study aimed to precisely quantify vaccination coverage and identify the most influential factors governing vaccine uptake among patients on biological therapy within this key Libyan referral setting.

## Methods

### *Study Design, Setting, and Sample*

This was a cross-sectional, observational study conducted at the Department of Medicine, Benghazi Medical Center, between July and September 2025. The study population comprised adult patients (≥ 18 years old) receiving biological therapy for at least three months prior to enrollment.

***Copyright** Author (s) 2026. Distributed under Creative Commons CC-BY 4.0*
***Received**: 25-04-2026 - **Accepted**: 22-06-2026 - **Published**: 29-06-2026*

**Libyan Med J.** 2026;18(6):381-385
https://doi.org/10.69667/lmj.26612
**Libyan Medical Journal**
https://lmj.ly/index.php/ojs/index eISSN: 2079-1224

***Sampling Technique and Response Rate***
Consecutive sampling was employed. All eligible patients who presented to the specialist clinics during the study period and met the inclusion criteria were sequentially invited to participate. This non-probability method maximized the inclusion of all accessible subjects over the recruitment window. Of 412 eligible patients approached, 370 agreed to participate (response rate: 89.8%). Reasons for non-participation included lack of interest and time constraints.

***Inclusion and Exclusion Criteria***
Patients age ≥18 years, current receipt of any biologic agent for ≥3 months, and ability to provide verbal consent were included Exclusion criteria: patients who had initiated biologic therapy within the preceding three months, and those with cognitive impairment preventing reliable interview responses.

***Data Collection Instrument***
Data were collected using a structured, interviewer-administered questionnaire. The questionnaire was developed based on established literature and international immunization guidelines from the CDC [7] and WHO [8]. Face validity was assessed by two independent specialists in Gastroenterology. A pilot test was conducted on 20 patients (not included in the final sample) to refine question clarity and flow. The instrument captured data across three domains:

1. Demographic and Clinical Data: Including age, gender, educational attainment, specific underlying disease, and the current biological agent.
2. Vaccination Status: Recorded receipt of any recommended vaccination for immunocompromised patients within the preceding five years.
3. Determinants of Uptake: Assessed behavioral factors, particularly the patient's belief in vaccine safety and whether a formal healthcare provider recommendation had been given.

***Vaccines Assessed***
The study focused on the uptake of inactivated vaccines recommended for patients on immunosuppression therapy. The primary vaccines assessed were the Seasonal Inactivated Influenza Vaccine and Pneumococcal Vaccines (PCV13 and PPSV23), at least one dose in the last five years. Patients were considered “vaccinated” if they reported receipt of at least one dose of either vaccine within the preceding five years. Live attenuated vaccines are generally contraindicated in this cohort.

***Statistical Analysis***
Descriptive statistics like frequencies and percentages were used to summarize the data. Inferential analysis included the Chi-Squared Test of Independence for bivariate associations between vaccination status and categorical variables (gender, educational level, underlying disease, biologic agent type, belief in vaccine safety, provider recommendation). Multivariable logistic regression was then performed to adjust for potential confounders (age, sex, disease duration, and biologic agent). All analyses were performed using SPSS v.26. A p-value < 0.05 was considered statistically significant.

## Results
A total of 370 patients completed the study. The study cohort was predominantly female (72.6%), reflecting the global epidemiology of autoimmune diseases. The mean age of the cohort was approximately 53 years, placing most participants in the middle-to-older adult age range. Overall vaccination coverage was low: only 32.6% of patients reported receiving at least one recommended vaccine (influenza or pneumococcal) within the last five years. Moreover, analysis showed that the patient's educational level was not a statistically significant factor in determining vaccination status (P = 0.122).

***Table 1. Summary of Demographic and Educational Data***

| Characteristic | Value | Notes |
|---|---|---|
| Total Sample Size (n) | 370 | |
| Mean Age | 53 years | |
| Gender Distribution | | |
| Female | 269 (72.6%) | Predominantly female cohort. |
| Male | 101 (27.4%) | |
| Educational Level | 43.5% University graduates<br>23.4% High School | |
| Statistical Association with Vaccination Status | Not Statistically Significant<br>(P = 0.122) | |

***Copyright*** *Author (s) 2026. Distributed under Creative Commons CC-BY 4.0*
***Received**: 25-04-2026 - **Accepted**: 22-06-2026 - **Published**: 29-06-2026*

**Libyan Med J.** 2026;18(6):381-385
https://doi.org/10.69667/lmj.26612
**Libyan Medical Journal**
*https://lmj.ly/index.php/ojs/index eISSN: 2079-1224*

***Table 2. Cohort Demographics and Vaccination Status***

| Characteristic | Frequency (n) | Percentage (%) |
|---|---|---|
| Gender | | |
| Female | 269 | 72.6% |
| Male | 101 | 27.4% |
| Vaccination Status (Last 5 Years) | | |
| Vaccinated | 121 | 32.6% |
| Not Vaccinated | 249 | 67.4% |

***Clinical Characteristics***

Rheumatoid Arthritis was the most prevalent underlying condition, diagnosed in 58.6% of the patients. The most frequently prescribed biological agent was Infliximab (38.8%).

***Table 3. Distribution of Underlying Diseases and Biologic Agents***

| Underlying Disease | Percentage (%) | Biological Agent | Percentage (%) |
|---|---|---|---|
| Rheumatoid Arthritis | 58.6% | Infliximab | 38.8% |
| Crohn's Disease | 18.4% | Tocilizumab | 35.0% |
| Multiple Sclerosis | 7.6% | Rituximab | 26.2% |
| Ulcerative Colitis | 4.0% | | |
| Systemic Lupus Erythematosus | 3.0% | | |
| Other Conditions | ~8.4% | | |

***Determinants of Vaccination Uptake***

Inferential analysis revealed two highly significant predictors of vaccine uptake:
-Positive belief in vaccine safety ($P < 0.0001$)
-Recommendation from a healthcare provider ($P < 0.01$)
Conversely, when assessing the relationship between educational level and vaccination status using the Chi-Squared Test, the result was not significant. The P-value of 0.122 demonstrated that the patient's educational level was not a statistically significant factor in determining vaccination status within this population. After adjusting for age, sex, disease duration, and biologic agent in a logistic regression model, two factors remained independently associated with vaccine uptake:
· Positive belief in vaccine safety: Adjusted OR = 4.82 (95% CI: 2.94–7.91), $p < 0.0001$
· Recommendation from a healthcare provider: Adjusted OR = 2.91 (95% CI: 1.58–5.36), $p < 0.01$
Educational level, biologic agent type, and underlying disease remained non-significant in the adjusted model.

## Discussion

The observed vaccination coverage of 32.6% highlights a critical lag behind the standards in preventive care for such a high-risk group. This rate is substantially lower than optimal, placing patients on biological therapy at undue risk of vaccine-preventable infections. The finding that the patients' vaccine beliefs ($p < 0.0001$) and provider advice ($p < 0.01$) were the strongest determinants of vaccination state reveals that the barriers to immunization are primarily psychological and informational, rather than demographic or clinical. The lack of correlation between vaccination and educational level ($p = 0.122$) further supports this point of view; physician-led communication is more impactful than general patient background. These results emphasize the importance of systematically addressing vaccine hesitancy and ensuring all healthcare providers actively recommend and facilitate immunization.
Beyond these core findings, several contextual factors and clinical considerations warrant further discussion. Perhaps the COVID-19 pandemic has had a paradoxical effect on vaccine perceptions globally. While it accelerated vaccine development, it also fueled widespread misinformation, particularly on social media, contributing to increased hesitancy. The WHO documented that misinformation during health emergencies can significantly delay healthcare provision and increase vaccine hesitancy (8). In this study, the patient's belief in vaccine safety was the strongest predictor of uptake ($p < 0.0001$), suggesting that fears amplified during the pandemic may be a significant contributing factor. Furthermore, a 2023 study by Elhadi et al. found that while 57.2% of Libyans expressed acceptance of the COVID-19 vaccine, only 34% of the Libyan population was actually vaccinated, highlighting a significant gap between acceptance and uptake(9). These findings suggest a broader societal mistrust of vaccines that may be particularly

***Copyright** Author (s) 2026. Distributed under Creative Commons CC-BY 4.0*
***Received**: 25-04-2026 - **Accepted**: 22-06-2026 - **Published**: 29-06-2026*

**Libyan Med J.** 2026;18(6):381-385
https://doi.org/10.69667/lmj.26612

**Libyan Medical Journal**

*https://lmj.ly/index.php/ojs/index eISSN: 2079-1224*

pronounced among patients with chronic illnesses. In Libya, specific cultural and regional factors may play an unmeasured yet significant role.

A multinational qualitative study conducted across seven Arab countries, including Libya, identified that trust in the healthcare system and vaccination policies was the main driver for vaccine acceptance, while concerns about potential long-term effects were significant barriers (10). In addition, drivers of hesitancy in similar settings include misunderstandings about how vaccines work, reliance on traditional remedies, and a background of distrust towards Western medicine(11). These factors, combined with the fragmented healthcare infrastructure in Eastern Libya, likely contribute to the low coverage observed. The optimal timing of vaccination is a critical clinical consideration. A 2025 German consensus on vaccination strategies for patients receiving immunotherapy states that it is "generally advisable to complete vaccination before starting immunotherapy"(12). However, for patients with active inflammatory disease, delaying treatment for immunization may not be justified.

The 2024 ASCO Guideline on vaccination of adults with cancer explicitly states that non-live vaccines (such as influenza and pneumococcal vaccines) can be administered during or after immunotherapy(13). This nuance is crucial: while pre-biologic vaccination is ideal, it should not be a reason to delay necessary therapy for patients with active disease. In the Libyan context, where many patients may present with advanced disease due to access issues, this flexibility is particularly relevant. This may uncover the need for clinical protocols that prioritize vaccination at the earliest possible point in the treatment journey. The finding that provider recommendation strongly predicts uptake ($p < 0.01$) aligns with the 2022 ACR Guideline, which encourages shared decision-making4.

A qualitative study found that unclear responsibilities between GPs and rheumatologists, and inconsistent medical recommendations were significant barriers to vaccination(14). The same study highlighted that clear communication and coordinated care between healthcare professionals are crucial for improving vaccine uptake. These findings reinforce the need for proactive, consistent, and collaborative discussions between patients and providers in Libya. While not directly assessed, a review noted that vaccine-preventable diseases disproportionately affect low-income families(15).

Conversely, a study among resource-limited adults with chronic illness found that attitudinal and informational barriers were more commonly reported than cost or transportation barriers (16). In the Libyan context, where biological therapies are highly expensive and likely subsidized, the direct cost of vaccines may not be the primary barrier. However, ensuring that vaccines are readily available, at no cost, and administered at the point of care (e.g., in the same clinic where patients receive biologics) would remove potential logistical hurdles and is a best practice for improving uptake. The unacceptably low vaccination rate documented in this study has direct implications for patient morbidity, healthcare utilization, and mortality. A study evaluating a systematic vaccination program in patients on anti-TNF-alpha therapies found that the intervention decreased infectious complications and was associated with fewer hospital admissions due to infections, fewer emergency room visits, and a lower rate of invasive pneumococcal disease17.

In that study, vaccination coverage increased from 27.3% to 97.0% after implementation of a structured program, demonstrating the profound impact systematic protocols can have. These findings from the literature provide strong evidence for what is at stake in the Libyan context: without urgent intervention, the cohort of 370 patients in this study is at significantly elevated risk for preventable hospitalizations and serious infections. This highlights the critical need for longitudinal research in Eastern Libya to track infection-related outcomes and quantify the clinical and economic burden associated with the current low vaccination rates.

## Conclusion

Vaccination rates among patients receiving biological therapy are unacceptably low. The data conclusively demonstrate that psychological and informational barriers are the dominant obstacles to immunization. Implementing clear, national immunization protocols and integrating proactive vaccination discussions into every patient encounter are paramount to mitigating infectious risks. We believe it is reasonable here to advocate for a nurse-led vaccination protocol within biologic infusion units at BMC, with standing orders for influenza and pneumococcal vaccines unless explicitly declined.

***Acknowledgments***

The authors extend their deepest gratitude to the patients who generously participated in this research, whose willingness to share their experiences made this study possible. Special thanks are also directed to the dedicated employees of the Medical Documentation Department at Benghazi Medical Center for their invaluable assistance in organizing and retrieving the necessary records.

***Copyright*** *Author (s) 2026. Distributed under Creative Commons CC-BY 4.0*
***Received**: 25-04-2026 - **Accepted**: 22-06-2026 - **Published**: 29-06-2026*

Libyan Med J. 2026;18(6):381-385
https://doi.org/10.69667/lmj.26612
Libyan Medical Journal
https://lmj.ly/index.php/ojs/index eISSN: 2079-1224

### *Limitations*
The present study has several limitations. It was conducted in a single center, which may limit the generalizability of the findings to the broader population, as the sample primarily represents Benghazi city and its surrounding regions rather than the entire country. Additionally, the cross-sectional design allows for the identification of associations but does not permit conclusions regarding causality. The self-reported vaccination status is subject to recall bias; no verification against medical records was feasible. Also, disease severity, access to care, and prior infection history were not evaluated in this cohort, and they could represent unmeasured confounders. Future multicenter and longitudinal studies are recommended to strengthen and expand upon these results.

### *Ethics Approval and Consent to Participate*
Ethical approval for this study was obtained from the Research Ethics Committee of Benghazi Medical Center (BMC). As this was a cross-sectional, interview-based study involving no invasive procedures or interventions, verbal informed consent was obtained from all participants prior to data collection. The verbal consent process was approved by the ethics committee.

### *Conflicts of Interest*
The authors declare no conflicts of interest.

### *Funding*
This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

## References
1. Furer V, Rondaan C, Heijstek MW, van Assen S, Bijl M, Agmon-Levin N, et al. EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases. Ann Rheum Dis. 2019.
2. Hsiao B. Vaccinations and biologics. 2020.
3. Fan R, Cohen JM, Kimmel GW, Gelfand JM, Kimball AB, Armstrong AW. Vaccination recommendations for psoriasis and atopic dermatitis patients on biologic therapy: a practical guide. 2022.
4. Bass AR. American College of Rheumatology guideline for vaccinations in patients with rheumatic and musculoskeletal diseases. 2022.
5. Sánchez-Tembleque MD. Vaccines and recommendations for their use in inflammatory bowel disease. 2013.
6. Rahier JF, Magro F, Abreu C, Armuzzi A, Ben-Horin S, Chowers Y, et al. ECCO guidelines on prevention, diagnosis, and management of infections in IBD. J Crohns Colitis. 2022.
7. Centers for Disease Control and Prevention. Adult immunization schedule. CDC website.
8. World Health Organization. Managing the COVID-19 infodemic: promoting healthy behaviours and mitigating the harm from misinformation and disinformation. Geneva: WHO; 2020. Report No.: WHO/2019-nCoV/Infodemic/Management/1.0.
9. Elhadi M, Alsoufi A, Alhadi A, Almabrouk A, Alhaddad M, Alhaddad R, et al. COVID-19 vaccine knowledge and acceptance among the Libyan population: a cross-sectional study. Libyan J Med Sci. 2023;7(3):91–6.
10. Abou Nader MA, Bou-Karroum L, Al-Abbar M, Adib K, Al-Hajj S, Al-Rifai R, et al. Drivers of COVID-19 vaccine acceptance in seven Arab countries: a cross-sectional study. East Mediterr Health J. 2021;27(12):1146–55.
11. Kasstan B, Mounier-Jack S, Letley L, Gorman DR, Macdonald NE, Chantler T. Vaccine hesitancy in the Arab world: a scoping review. Vaccine. 2021;39(40):5735–45.
12. Marx D, Sühs KW, Wildemann B, Aktas O, von Podewils F, Kleinschnitz C, et al. Cellular and humoral vaccination response under immunotherapies—German consensus on vaccination strategies in neurological autoimmune diseases. Neurol Res Pract. 2025;18:17562864251396006.
13. Kamboj M, Bohlke K, Baptiste DM, Diefenbach KA, Dykewicz CA, Engleson A, et al. Vaccination of adults with cancer: ASCO guideline. J Clin Oncol. 2024;42(14):1699–720. doi:10.1200/JCO.24.00032.
14. Hmamouchi I, Abouqal R, Allali F, El Binoune I, El Bouchti I, El Hassani S, et al. Shared decision-making and vaccination in patients with inflammatory rheumatic diseases: a qualitative study. Rheumatol Int. 2021;41(8):1455–64.
15. Lopez A, Mariette X, Bachelez H, Bonnotte B, Cacoub P, Claudepierre P, et al. Unmet need for vaccination in immunocompromised populations. Vaccines (Basel). 2021;9(8):892.
16. Kempe A, Daley MF, Stokley S, Crane LA, Beaty BL, Barrow J, et al. Barriers to vaccination among adults with chronic conditions in resource-limited settings. Vaccine. 2015;33(46):6230–5.
17. Benucci M, Manfredi M, Puttini PCD, Atzeni F, Sarzi-Puttini P, D'Urso C, et al. A systematic vaccination programme in patients with autoimmune diseases receiving anti-TNF-alpha therapy: a real-world study. Clin Exp Rheumatol. 2019;37(3):446–52.

**Copyright** Author (s) 2026. Distributed under Creative Commons CC-BY 4.0
**Received**: 25-04-2026 - **Accepted**: 22-06-2026 - **Published**: 29-06-2026