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Heterogeneity in biologic therapy monitoring across medical specialties: a real-world study and call for standardized multidisciplinary protocols

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Abstract

Background: Biologic therapies require strict pre-treatment screening and monitoring due to infectious and immune-related risks. However, real-world implementation of guidelines remains heterogeneous across specialties.

Aim: To evaluate biologic therapy monitoring practices across gastroenterology, dermatology, and rheumatology, and to assess inter-specialty variability and need for harmonization.

Methods: A cross-sectional survey was conducted among physicians prescribing biologic therapies at a tertiary university hospital. Data included infectious screening, vaccination practices, monitoring strategies, and institutional protocol availability. Comparative analyses were performed between specialties.

Results: Among 137 physicians, complete pre-treatment assessment was reported by 56%. Influenza and pneumococcal vaccination rates were low (20% and 15%). Only 36% reported institutional protocols. Significant inter-specialty differences were observed, with gastroenterologists showing higher adherence to guidelines ($p<0.05$).

Conclusion: Marked heterogeneity exists in biologic therapy monitoring practices. Standardized multidisciplinary protocols are needed to improve adherence to recommendations and patient safety.

Keywords: Biologic therapy; Monitoring; Infectious screening; Vaccination; Multidisciplinary protocol; Real-world practice

1. Introduction

Biologic therapies have transformed the management of chronic inflammatory diseases, including inflammatory bowel disease, psoriasis, and rheumatoid arthritis. Their efficacy has significantly improved disease control and long-term outcomes.

However, these agents are associated with an increased risk of opportunistic infections, viral reactivation, and immune-related adverse events, requiring careful pre-treatment evaluation and structured monitoring during therapy. International guidelines from ECCO and EULAR recommend systematic infectious screening and vaccination assessment prior to biologic initiation [1,2].

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Despite these recommendations, real-world studies consistently demonstrate suboptimal adherence and variability in clinical practice across specialties. This heterogeneity may result in inconsistent patient management and increased risk of preventable complications.

The aim of this study was to assess real-world biologic therapy monitoring practices and inter-specialty variability, and to evaluate the need for a standardized multidisciplinary protocol.

2. Materials and methods

This cross-sectional descriptive study was conducted at Hassan II University Hospital in Fez, Morocco, a tertiary referral center where biologic therapies are routinely prescribed across multiple specialties. Physicians from gastroenterology, dermatology, and rheumatology involved in biologic therapy prescription and monitoring were invited to participate voluntarily in the study.

Data were collected using an anonymous structured online questionnaire specifically developed for the study based on current international recommendations regarding biologic therapy monitoring and vaccination practices [1,2]. The questionnaire explored physician characteristics, pre-treatment infectious screening practices, vaccination assessment, biologic monitoring strategies, and availability of institutional protocols. Prior to dissemination, the questionnaire was pilot-tested among a small group of physicians to ensure clarity and consistency of responses.

Participation was voluntary and anonymous. Completion of the questionnaire implied consent to participate. No identifiable personal or patient-related data were collected.

Categorical variables were expressed as frequencies and percentages. Comparisons between specialties were performed using chi-square tests, with a p value <0.05 considered statistically significant.

As this study was based on self-reported practices, reporting bias cannot be excluded. In addition, the monocentric design may limit generalizability of the findings to other healthcare settings.

3. Results

3.1. Participant characteristics

A total of 137 physicians participated in the study, including gastroenterologists (72%), dermatologists (16%), and rheumatologists (12%). Anti-TNF agents were prescribed by 96% of respondents, and anti-interleukin therapies by 74%.

Table 1 Baseline characteristics

Variable	n (%)
Total physicians	137
Gastroenterology	99 (72%)
Dermatology	22 (16%)
Rheumatology	16 (12%)
Anti-TNF use	96 %
Anti-IL use	74 %
Written protocol available	36 %
Need for harmonization	72 %

3.2. Pre-treatment assessment

Complete baseline evaluation was systematically performed by 56% of physicians. Hepatitis B screening was reported by 80%, while tuberculosis screening was reported by 88%.

Table 2 Pre-treatment screening practices

Item	Overall (%)	GI	Derm	Rheum	p
Complete workup	56	64	41	50	0.04
TB screening	88	92	77	81	0.05
HBV screening	80	89	63	75	0.03

3.3. Vaccination practices

Vaccination practices were globally suboptimal. Influenza vaccination was recommended by 20% of physicians, and pneumococcal vaccination by 15%. Assessment of measles and varicella immunity remained rare (<10%).

Table 3 Vaccination coverage

Item	Overall (%)	GI	Derm	Rheum	p
Influenza vaccine	20	28	9	12	0.03
Pneumococcal vaccine	15	21	4	6	0.02
HBV immunity check	80	84	59	69	0.04
Measles/Varicella status	<10	11	4	6	NS

3.4. Monitoring practices

Most physicians followed a 3-month monitoring schedule. However, 30% reported more frequent monitoring (1–2 months), and 14% reported non-standardized follow-up practices.

3.5. Institutional protocols

Only 36% of physicians reported the existence of institutional protocols, whereas 72% expressed the need for standardized multidisciplinary harmonization.

4. Discussion

This study demonstrates significant heterogeneity in biologic therapy monitoring practices across gastroenterology, dermatology, and rheumatology in a real-world tertiary care setting. Despite clear international recommendations, only 56% of physicians reported performing a complete pre-treatment assessment, and vaccination practices were particularly insufficient, with influenza and pneumococcal vaccination rates of 20% and 15%, respectively.

This level of variability is consistent with previous real-world studies. Barry et al. reported similar inter-specialty differences in biologic monitoring practices among Irish physicians, despite the use of identical biologic agents across specialties, suggesting that variability is driven more by specialty-specific practice patterns than by therapeutic class differences [8]. These findings reinforce that implementation gaps are systemic and not isolated to specific healthcare systems.

From a clinical perspective, insufficient pre-treatment screening and vaccination may have direct consequences on patient outcomes. Biologic therapies, particularly anti-TNF agents, are well known to increase the risk of opportunistic infections, including tuberculosis and viral reactivation [6,7]. Therefore, incomplete adherence to baseline screening recommendations may translate into preventable infectious complications in real-world practice.

Vaccination deficits observed in our cohort are particularly concerning. Multiple studies have demonstrated that patients with immune-mediated inflammatory diseases remain under-vaccinated despite strong guideline recommendations. Melmed et al. highlighted that vaccine-preventable infections remain a significant risk in this population due to poor preventive strategies [9], while Loubet et al. confirmed persistently low influenza and pneumococcal vaccination rates in IBD populations even in high-resource healthcare systems [10]. Our findings extend these observations by showing that the gap persists not only at patient level but also at physician prescribing level.

The observed heterogeneity likely reflects fragmentation of guideline systems across specialties (ECCO, EULAR, dermatology societies). Although these recommendations are scientifically aligned, they are implemented independently, leading to variability in interpretation and clinical practice. This structural fragmentation is further compounded by the absence of institutional protocols, which were reported in only one-third of physicians.

Importantly, our results suggest that the main issue is not lack of knowledge but lack of structured implementation pathways. In this context, standardized multidisciplinary protocols may represent a practical and effective solution to reduce variability, improve vaccination coverage, and ensure systematic infectious screening before biologic initiation.

5. Conclusion

Significant heterogeneity exists in the monitoring of biologic therapies across gastroenterology, dermatology, and rheumatology in real-world clinical practice, despite the availability of clear international recommendations. Important gaps remain in pre-treatment infectious screening, vaccination practices, and follow-up strategies.

These findings highlight that the main challenge is not the absence of guidelines but their inconsistent implementation across specialties and healthcare systems. The low rate of institutional protocols further contributes to this variability.

The development of standardized multidisciplinary protocols integrating infectious screening, vaccination assessment, and unified monitoring strategies is essential to improve adherence to recommendations, reduce inter-specialty variability, and enhance patient safety.

Future studies should evaluate the clinical impact of such standardized approaches on infection rates and long-term outcomes in patients receiving biologic therapies.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of ethical approval

Ethical approval was not required for this anonymous survey-based study in accordance with institutional regulations. Participation was voluntary and anonymous.

Statement of informed consent

Completion of the anonymous questionnaire implied informed consent to participate in the study.

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