Commentary

Enhancing Patient Safety with Biologic ID-Colored Bracelets for Monoclonal Antibody Users

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The manuscript proposes the implementation of biologic ID-colored bracelets for patients using monoclonal antibodies (mABs) to enhance safety by preventing adverse effects and drug interactions, especially during travel like pilgrimages. Biologics, being complex molecules with variable pharmacokinetics and potential for severe side effects, require stringent monitoring. The suggested color-coded bracelet system provides critical information at a glance, facilitating immediate and accurate medical responses in emergencies. This approach aids in maintaining continuous visibility of treatment specifics and assists healthcare professionals in providing timely and appropriate care, particularly in settings away from usual healthcare facilities. The concept is intended for incorporation into patient safety guidelines and medication packaging.

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Abbreviations

- TNF-α = tumor necrosis factor
- mABs = monoclonal antibodies

Background

A biologic is any virus, therapeutic serum, toxin, antitoxin, vaccine, allergenics, blood and blood components, somatic cells, gene therapy, recombinant therapeutic proteins, allergenic product (or any other analogous product), or any trivalent organic arsenic compound that can be used to treat,

prevent, or cure human disease. Biologics can be living things like cells and tissues, or they can be complicated combinations of carbohydrates, proteins, and nucleic acids. Biologics can be created using advanced technologies and biotechnology techniques, and they can be extracted from a range of natural sources, including humans, animals, and microorganisms. They are different from chemical-origin compounds. Because of the strong binding that can prevent deeper penetration, the tissue distribution of monoclonal antibodies (mAbs) may not be uniform. Small molecules, on the other hand, exhibit less of this pattern since they can passively diffuse through a tissue. In contrast to chemical compounds, which are small molecule medications that are eliminated by renal/biliary excretion or hepatic metabolism, the body as a whole destroys mAbs mostly by intracellular lysosomal proteolytic degradation. The primary means of eliminating IgA-based antibodies is biliary secretion. The pharmacokinetics of over half of the mAbs now on the market are nonlinear. Another difference is that the most popular dosing strategy for adult patients using small-molecule medications is a fixed dose, while biologic products, however, are frequently dosed according to body size. The impact of a patient's body size on the pharmacokinetics (PK), pharmacodynamics (PD), and therapeutic window of a medicine determines whether or not it should be supplied based on body weight (BW) and body surface area (BSA). Reducing inter-patient variability in PK and/or PD and eventually optimizing therapeutic outcomes are hallmarks of a sound dosage strategy [1].

The big concern during the use of biologics, especially mABs, is severe adverse reactions during the injection or long-term side effects like opportunistic infections such as reactivation of latent tuberculosis. Patient safety is a great challenge for scientists, so we think at this point, and writing this novel idea for the first time in the world will support patient safety and help health professionals and specialists in oncology and rheumatology.

Biologics are large complex molecules derived from living organisms—either plant, animal, or human —and are different from small chemical molecules like aspirin. They are expensive. Even though biologics are far more expensive than chemical entities, because they are not chemical compounds, there may be variations in efficacy at different doses. However, most payers and healthcare providers believe that they are worth the expense, provided that the right individuals receive them and experience the intended therapeutic results. Biologics are pharmacological substances that are synthesized or isolated from biological sources, frequently exhibiting intricate structural compositions. They can be roughly classified as replacement/modulators of enzymes, receptor modulators, or monoclonal antibodies. To ensure consistency and quality of the final product, the

manufacturing processes of biologics involve complex processes (e.g., gene isolation, recombinant DNA engineering, protein purification) and living systems (e.g., mammalian cell lines, microbial agents, plants, and fungi). These processes require high technological expertise with precision. [2]

Biologics medications are growing so fast, and now they are key in oncology, as many FDA approvals in the last year. The market for cancer medications is shifting in favor of biologics, and by 2029, the combined market for these medications is expected to rise at a rate of 786 billion. The success of biologics in treating uncommon solid tumors is largely responsible for this amazing development, the report states. There are many types of biologics [3]

The significance of biologics: These drugs represent a class that has transformed the management of numerous high-burden illnesses, including cancer, autoimmune diseases, and chronic kidney failure. These cutting-edge medications are frequently expensive but very powerful. By focusing on particular chemicals or cells that are involved in disease processes, they provide individualized treatment alternatives. Biologics: What Are They? Large, complex molecules called biologics—such as proteins, antibodies, or nucleic acids—are derived from living things. In contrast to conventional small-molecule medications that are made chemically, biologics are made through techniques related to biotechnology. These consist of growth hormones, cytokines, monoclonal antibodies, and other specialist treatments. Biologics were the majority of FDA-approved for oncology in 2022, and this year, it's noteworthy to note that dermatology is the second approved indication for FDA-approved medications, despite oncology still being the primary indication. [4].

Adverse Reactions of Biologics: Due to their pharmacologic effects, biologics may result in adverse reactions. These could include administration-site events, infusion responses, and immunogenicity—the body's immunological reaction to the medication 1. These adverse reactions may differ according to the particular biologic.

Immunogenicity: Antibodies directed against the biologic medication may develop in certain patients receiving it. This may result in less effectiveness or perhaps negative side effects. For treatment outcomes to be as good as possible, immunogenicity must be closely monitored. Infections: The use of biologics may raise the possibility of infections, particularly serious ones. When using biologics, patients should be alert for any infection symptoms and notify their healthcare provider right away. Traceability: For biologics, pharmacovigilance, or the monitoring of medication safety, is crucial. It is important to interpret the results with caution because there was inconsistent data across the

outcomes, even though several biologics showed a statistically larger connection with some unfavorable outcomes when compared to the control. [5]

Biologics are classified according to the target of therapy into 4 categories: [6]

1. Tumor necrosis factor alpha inhibitors (TNF-α inhibitors)
2. Interleukin inhibitors like IL-1, IL-6, IL-10
3. T cell inhibitors
4. B cell inhibitors

Our perspective

Because the fast growth of biologic medications in recent decades has taken the picture in many specialties like dermatology, cancer, and immune disease, it is always important to be prepared and take precautions, especially when traveling, including carrying necessary medical information and identification. Wearing a biologic ID-colored bracelet specifically for monoclonal antibodies may not be a common practice. Biologic medications like monoclonal antibodies are typically administered in a healthcare setting by trained professionals who are aware of the patient's treatment plan and medication history.

Creating an identity-colored bracelet for patients who are receiving monoclonal antibody therapy is a valuable idea to ensure their health and safety, especially when traveling to different countries or participating in events like the Hajj pilgrimage. This bracelet will provide essential information about the patient's specific medication, the condition being treated, and any important considerations for healthcare providers in case of emergency or need for medical attention while away from their regular healthcare provider, and help healthcare professionals make rapid decisions.

The identity-colored biologic bracelet can include the following information:

1. Patient's name and date of birth
2. Name of the monoclonal antibody medication being used
3. Dosage and frequency of the medication
4. Name and contact information of the prescribing healthcare provider
5. Emergency contact information
6. Any known allergies or adverse reactions to medications

7. Important instructions or precautions related to the medication and risk of infections after medications
8. Date of last dose administered
9. Any other chronic diseases or co-morbidities

Having this information readily available on an identity-colored bracelet can help healthcare providers in other countries understand the patient's medical needs quickly and effectively. It can also assist in preventing potential interactions with other medications or treatments that may be provided during travel or in emergencies.

Patients should be advised to carry this identity-colored bracelet with them at all times, along with their regular identification, passport, or travel documents. Additionally, it is recommended to keep a copy of this card with a trusted family member or friend in case of loss or emergency.

By creating and wearing an identity colored specifically for monoclonal antibody therapy, patients can help ensure their health needs are met, even when far from home.

Using a biologic ID bracelet can be a useful precautionary measure for individuals using biologics to avoid adverse drug reactions or interactions. This is particularly important when traveling, especially in situations similar to a pilgrimage where access to medical facilities may be limited or communication barriers may exist.

The biologic ID-colored bracelet can provide important information about the specific biologic types being used, dosage, and any other relevant medical details. This can be crucial in case of emergencies or if healthcare professionals need to be aware of the medications being taken.

Wearing a biologic ID bracelet allows for easy identification of the type of medication being used, which can help prevent potential drug interactions or the administration of contraindicated treatments in emergencies.

According to the color of the biologic ID-colored bracelet, health professionals can easily recognize the types of biologic medications:

For example:

1. Red-colored biologic bracelet: refers to the usage of anti-tumor necrosis factor alpha, and this red color is more commonly associated with reactivation of tuberculosis, as registered in the

black box warning in the package insert. This biologics medication category has potential side effects as created as red.

2. Blue-colored biologics bracelet: refers to the usage of B cell inhibitors like rituximab, which has potential side effects during injection and needs strict observation, as it may cause death because of a suspected severe reaction.
3. Green-colored biologic bracelet: refers to T cell inhibitors.
4. Yellow-colored biologic bracelet: refers to interleukin inhibitors.
5. Black-colored biologic bracelet: refers to any other biologics treatment like insulin, peptides, vaccines.

All these bracelets were inserted with a package insert inside the package of medications for patient safety.

However, it is important to note that wearing a biologic ID-colored bracelet does not guarantee complete protection against adverse reactions or interactions. It should be used in conjunction with other safety measures, such as carrying the medication in its original packaging, carrying a letter from a healthcare provider outlining the prescribed medication, and ensuring access to necessary medical documentation while traveling.

Consulting with a healthcare provider is crucial to determine the most appropriate safety measures to take while using biologics, especially when traveling in situations analogous to a pilgrimage.

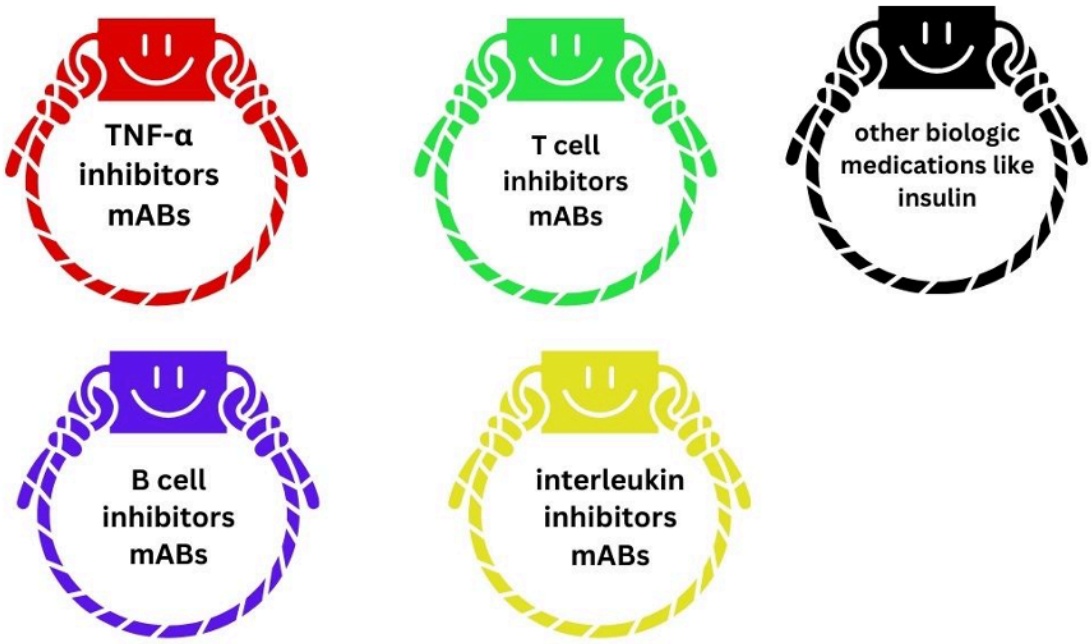

Figure 1. These examples show different types of biologic ID-colored bracelets according to the types and severity of drug adverse effects and drug interactions, and they are suggested to be included in the package insert as guiding patient safety.

Warning

Since the idea is novel and we are the owner of this idea, we control it, and we do not allow anyone or an institution to use or take it without our consent, as this is our concept and we published it for the first time on the Qeios platform.

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Declarations

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