BSI-CIPN guidance for immunology teams on normal human immunoglobulin product switching

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Background

There are a number of factors to consider after the decision to change an immunoglobulin (Ig) product has been made. These relate to safety of the Ig product itself, the route of administration and the logistics around the switch for both patients and the clinical service.

Historically, patients have been required to attend outpatient clinics for reconsenting, serum save storage, retraining, administration of the new product, and a monitoring period to ensure no significant clinical reaction. Over the past few years, large-scale product changes have provided experience that can guide best practices for future transitions. The practicalities of switching should be individualised, considering the following key factors.

Safety and efficacy of switching immunoglobulin products

Different Ig products are considered to have equivalent efficacy. All Ig products have a license for a common group of indications (across antibody replacement and immunomodulation) that has been obtained following the stringent quality requirements of regulatory agencies.

Published UK data from 30 immunology centres, documented 802 Ig product switches, with only 12 reported reactions[1]. None required hospital admission; one patient was treated with oral corticosteroids, while others only required oral antihistamines or no treatment. Prior to switching, clinical teams should review an individual patient's previous products and any documented reactions.

There have been no confirmed cases of infection transmission in Ig products since the 1990s. While this is reassuring, individual centres may wish to consider storing serum prior to switching to a new product.

Variations in formulation and processing mean that some patients may tolerate certain products better than others. As a result, it is recommended adverse events should be discussed with patients prior to and assessed after switching. For individual cases where continuing on a product not on the framework agreement is deemed necessary, this should be discussed with the local SRIAP (Sub-regional Immunoglobulin Advisory Panel) to facilitate on going accessibility.

Switching intravenous immunoglobulin (IVIg)

The risk of systemic reactions when switching between Ig products is low. However, because the risk is slightly higher for IVIg and collective experience is more limited, the recommendation remains that IVIg product switches should be undertaken in a healthcare setting[2].

Individual IVIg product information should be followed for specific information on infusion rates and administration (www.medicines.org.uk).

Switching subcutaneous immunoglobulin (SCIg)

Whether a subcutaneous product switch can be undertaken at home should be an individualised discussion between the patient and their immunology team, balancing the small risk of local reactions with the benefits of convenience.

The delivery mechanism of the product should be considered individually to determine if new training is required for the patient and/or infusion partner. Changes such as infusion volume variations, pump adjustments, or a switch from pre-filled syringes to vials may necessitate retraining in infusion techniques. These patients may therefore require re-training within the hospital or via video call.

Home-based switches should only be undertaken if the patient:

1. Is stable
2. Has had no previous reactions to immunoglobulin products
3. Has had no previous concerns regarding training/competency
4. Will continue administering SCIg in the same way as before

For some patients/clinicians, a supervised switch in a hospital or clinic setting may be preferable, even if patients meet the above criteria. Patient and clinician confidence should always be factored into the decision.

Regardless of setting, a clear contact pathway should be in place for support in case of any adverse effects, particularly local reactions.

Resources for patients

Immunodeficiency UK offers an online resource to assist patients in understanding the switching process, highlighting the importance of patient involvement in treatment decisions and the need for supervision by immunology teams.

UKPIPS offers patient to patient support through its closed Facebook page.

About BSI-CIPN

The BSI Clinical Immunology Professional Network (BSI-CIPN) is an integrated and impactful professional network for individuals working within clinical immunology. The BSI-CIPN's membership includes over 160 professionals in the clinical immunology space including clinical immunologists, healthcare scientists, allergists, pharmacists and immunology specialist nurses. The network is used to share best practice and guidelines and to foster collaboration, ultimately improving care for patients.

For further information please contact: cipn@immunology.org

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[1] Bethune C, Herriot R. *Switching immunoglobulin products, what are the implications? Result of 2018 census of immunology centres*. Clin Med (Lond). 2019 May;19(3):201-204.

[2] Grigoriadou S, Clubbe R, Garcez T, Huissoon A, Grosse-Kreul D, Jolles S, Henderson K, Edmonds J, Lowe D, Bethune C. *British Society for Immunology and United Kingdom Primary Immunodeficiency Network (UKPIN) consensus guideline for the management of immunoglobulin replacement therapy*. Clin Exp Immunol. 2022 Oct 21;210(1):1-13.