BRITISH SOCIETY FOR IMMUNOLOGY COMPETENCY FRAMEWORK FOR IMMUNOLOGY NURSING

British Society for immunology

British Society for Immunology CIPN Clinical Immunology Professional Network

ABOUT THE BRITISH SOCIETY FOR IMMUNOLOGY

The British Society for Immunology (BSI) is the leading UK charity organisation representing scientists and clinicians who study the immune system in humans or animals. As a membership organisation, we act as a focal hub for the immunology community, supporting and empowering immunologists working in academia, industry and clinical setting to drive forward scientific discovery and application together. We also aim to harness the knowledge generated by our membership and reach out to the wider world – policymakers, public, healthcare professionals – to ensure that society is aware of and can gain from the health benefits that immunology research can deliver.

ABOUT THE BSI CLINICAL IMMUNOLOGY PROFESSIONAL NETWORK (CIPN)

The BSI Clinical Immunology Professional Network fully represents all aspects of clinical immunology practice in the UK. Formed from a merger with the UK Primary Immunodeficiency Network, we aim to deliver increased support for the immunology clinical community to network and engage across many disciplines, building closer links between clinical practitioners and basic scientists. We also work to strengthen the voice of clinical immunology in policy and the public arena to increase the impact of our work in advocating for the care of patients with immunodeficiencies.

This competence framework is endorsed by:

British Society for Immunology
CIPN
Clinical Immunology Professional Network

BRITISH SOCIETY FOR IMMUNOLOGY LEGAL DISCLAIMER

REVIEW

This document was first published in May 2023. A review will take place five years after the date of publication.

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FOREWORD

It is with great pleasure and enthusiasm that I introduce the British Society for Immunology Clinical Immunology Professional Network (BSI-CIPN) competency framework for Immunology nursing.

This framework is a testament to the collective efforts and expertise of a working group of ten Advanced Nurse Practitioners, Nurse Specialists and Nurse Consultants working in Immunology around the UK. Working together as members of the BSI-CIPN, the group have dedicated themselves to advancing patient care and nursing practice.

Immunology nursing plays a vital role in the healthcare system, providing essential support to individuals with immune-related conditions. The complexity and diversity of immunological disorders necessitate specialised knowledge and skills, demanding a highly competent nursing workforce. By combining underlying immunology knowledge with clinical best practices and the latest therapeutic advances, this framework provides a comprehensive roadmap for mastering the skills and knowledge required in Immunology nursing.

These competencies cover the breadth of the Immunology nurse's role, from newly entering into the speciality to undertaking Nurse-led clinics. It outlines the core competencies necessary to deliver safe and effective care for patients across a range of settings and scenarios.

Recognising the rapidly evolving field of immunology, this framework is designed to be flexible and to empower Immunology nurses to stay abreast of advancements and work innovatively to improve standards of care. It also emphasises the importance of multidisciplinary collaboration with healthcare professionals from various disciplines, recognising that optimal patient care is achieved through shared expertise and teamwork.

I extend my sincere gratitude to the dedicated individuals who have contributed their time, knowledge and passion to the development of this competency framework. On behalf of the working group, I would like to personally thank Dr Sorena Kiani (Royal Free London), Dr Tomaz Garcez (Manchester Foundation Trust) and Dr David Lowe (Royal Free London) for the support and feedback they have given to enable the development of these competencies. I also want to express my appreciation to the British Society for Immunology for supporting this initiative and their ongoing commitment to supporting the immunology clinical community in coming together to advance patient care.

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GUIDELINES FOR USING THIS DOCUMENT

The purpose of this document is to provide a framework for practitioners to show their level of competency within Immunology nursing. The competencies should be assessed by an appropriate practitioner with suitable experience within the immunology field of expertise. These competencies cover the breadth of the Immunology nurse's role, from newly entering into the speciality to undertaking Nurse-led clinics.

Modules should be selected based on their relevance to the specific practitioner's role. Practitioners should document self-assessment prior to assessment by their assessor. There is no intended limit to the formative assessments and practitioners must continue to be supervised and re-assessed until they are considered competent. Where there are difficulties with the practitioner achieving a competency, the assessor must give guidance as to where the learning requirements are. If a practitioner is unable to achieve the minimum standard, then the assessor may wish to consider further training.

For the formative and summative assessments, **Pr** refers to the practitioner and **A** to the assessor.

1.	**Competence**	This is a description of the skill or knowledge that you are required to attain.
2.	**Formative Assessment**	These assessments are a developmental tool. They allow the practitioner to be assessed at any point in their development, the aim being for the assessor to guide the practitioner and identify where there is a need for further practice or acquisition of knowledge. As many or as few as necessary formative assessments can be performed.
3.	**Summative Assessment**	This is where the practitioner is expected to meet the required standard for the competence.

THE DERBY ASSESSMENT CRITERIA

STANDARD	CRITERIA
International Influencer (I)	Knowledge gained from new and existing evidence is utilised to inform or create policy
Advanced Expert (A)	Sees gaps in knowledge or care delivery. Devises audit/research to improve standards of care
Expert (E)	Has intuitive grasp of the situation and zeros in on the accurate region of the problem
Proficient (P)	Perceives situations as a whole rather than in terms of aspects
Competent (C)	Begins to understand actions in terms of long-range goals
Beginner (B)	Can note recurrent meaningful situations, components, but not prioritise between them
Novice (N)	Novices have no professional experience

FURTHER READING

Mortimore *et al.* 2021 From expert to advanced clinical practitioner and beyond. *Br J Nurse* **30** 656–659. **doi:10.12968/bjon.2021.30.11.656**

BSI-CIPN NURSES:
UNDERLYING KNOWLEDGE TO SUPPORT NURSING COMPETENCIES

The purpose of this document is to assess the underlying knowledge needed to support the core concepts within the BSI-CIPN nursing competencies.

This knowledge document is supported by the following BSI-CIPN competencies:

- Nurse-led clinics for initial screening and management for patients with immunodeficiency
- Subcutaneous immunoglobulin (SCIG) administration and Intravenous immunoglobulin (IVIG) administration

In the current absence of a national nursing Immunology course, it is recommended that this document is signed by a professional with independent competency, e.g. Consultant or Nurse Consultant, so that reduction in national variability is minimised. It is envisaged this will be a cascade system where signed off competent nurses can sign off other nurses.

To reduce national variability, this document has been benchmarked against the British Society for Immunology and United Kingdom Immunodeficiency Network (UKPIN) consensus guidelines for the management of immunoglobulin replacement therapy (2022).[1]*

In the UK, immunoglobulin replacement is used in the management of patients with both primary and secondary antibody deficiencies, following the NHS England Commissioning criteria (NHS England, 2018), overseen by local and sub-regional immunoglobulin advisory panels (SRIAPs).

At local level, there is a lack of published evidence and therefore BSI-CIPN* provides national guidelines based upon consensus from specialists in the UK. The statements contained within the BSI-CIPN consensus document provide the clinical detail to support the clinicians (to include senior nurses) and the decisions made by SRIAPs. It is expected that the relevant resources and competencies will be read together as this is a good starting point for any nurses joining immunology.

*In 2023, the UK Primary Immunodeficient Network (UKPIN) merged with the British Society for Immunology (BSI), leading to the formation of the BSI Clinical Immunology Professional Network (BSI-CIPN).

THE BSI-CIPN CONSENSUS RECOMMENDATIONS:

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
STARTING IMMUNOGLOBULIN REPLACEMENT THERAPY (IGRT)							
Has an understanding of basic immunity, can discuss the innate and adaptive immune system							
Has a basic understanding of the eight different classifications of primary immune deficiency (PID)[2] based upon what cells or parts of the immune system are affected, e.g. common variable immune deficiency (CVID)							
Can discuss what is meant by the definition 'increased burden of infection'; a useful tool is SPURR: • **S**evere • **P**ersistent • **U**nusual • **R**ecurrent infections • history **R**unning in family							
Is aware of the ten warnings signs of PID to support underpinning knowledge of consensus guidelines							
Has a basic understanding of relevant genetic aspects based on local policy							
Understands CVID[1] • CVID is the commonest immunodeficiency and is a spectrum of diseases with variable degree of T cell and B cell deficiency, hence the name CVID • Patients can present with a spectrum of diseases, all at risk of sinopulmonary infections and variable degrees of immune dysregulation (autoimmunity, inflammation, etc.) in some patients Has a basic understanding that antibody deficiencies can increase the risk of sinopulmonary infections Understands that T cell deficiencies can increase risk of opportunistic infection							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Understands what opportunistic infections are in CVID patients, to include: sinusitis, ear, throat, skin, stomach and intestinal infections; other symptoms can present: enlarged spleen, bleeding or bruising and/or severe anaemia							
Basic knowledge that there are two types of lung disease in CVID: 1. Recurrent infections can cause chronic lung disease, bronchiectasis, which can occur in the small airways, hence the importance of preventing that with IgRT and antibiotics 2. Inflammatory lung disease that occurs in the lung parenchyma (interstitium) is called interstitial lung disease (ILD). In CVID a variation of ILD can be present called granulomatous and lymphocytic interstitial lung disease (GLILD); this is inflammatory and may need immunosuppression							
Basic knowledge of gastrointestinal (GI) disorders in CVID • Symptoms such as prolonged or recurring diarrhoea, bloating, blood in stool, abdominal pain and weight loss							
Has an understanding of X-linked agammaglobulinaemia (XLA)							
Has an understanding of severe combined immunodeficiency (SCID)							
Has an awareness of other treatments for SCID (apart from IgRT) such as bone marrow transplant and genetic therapy							
Has an understanding of other conditions such as hyper IgM syndrome, Good's syndrome							
Understands the reason for requesting certain immunology tests and has an understanding of why results are actioned. This basic knowledge is expanded within the Nurse-led follow-up clinic for patients with immunodeficiency competency							
Has an understanding of the differences between primary immune deficiency (PID) and secondary immune deficiency (SID)							
Has an understanding of the common causes of SID (e.g. certain drugs or treatments such as Rituximab)							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Has read and understood the Department of Health (2018) criteria for IgRT in PID and SID patients[3]							
Has an understanding of disadvantages and advantages of the different routes through which IgRT can be administered (see Table 1)							
Understands the dosing of IgRT[4]							
MONITORING IMMUNOGLOBULIN REPLACEMENT THERAPY (IGRT)[1]							
Has understanding of the optimal IgRT target for specific conditions, including optimal IgG target of 8 g/l							
Has an understanding of the impact of long-term damage of persistent infections, e.g. lungs/bronchiectasis, GI/*Giardia* despite being on IgRT; this may require higher levels of IgRT							
Is aware that patients with PID and SID who continue to have high infection burden will need discussion in multidisciplinary team (MDT) to ensure other treatments are maximised, e.g. antibiotics							
Has a basic awareness that IgRT can be increased or decreased, is aware of the reasons that these changes may need to occur • Suggested evidence: Discuss clinical cases involving dose changes							
ADMINISTRATION, CLINICAL AND BLOOD TEST MONITORING (Supported by the Nurse-led clinics for initial screening and management for patients with immunodeficiency competency)[1]							
Is aware of the responsibility for monitoring the trough levels; at senior level is aware of the importance of infection monitoring							
Has a good understanding of monitoring infection frequency, hospital admissions, microbiological cultures and antibiotic use • Suggested evidence: Individual case studies in MDT							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Knows to advise patients to start treatment promptly if symptoms are suggestive of bacterial infections – is aware of these symptoms, e.g. temperature, change of colour of sputum							
As becomes more experienced, uses the knowledge to monitor all aspects of IgRT, such as number of infections, so they could discuss in MDT							
Is aware of the role of health promotion in chronic conditions in a patient cohort – advice on keeping well and healthy, e.g. smoking, vaccines, etc.							
Has a basic understanding of complications of PID							
Is aware of complications of PID unrelated to infection, such as autoimmunity (Table 2), granulomatous and cancer							
HOME THERAPY							
Has read and understood the UKPIN/BSI (2022) consensus document[1] to support the UKPIN home therapy programme, supported by the subcutaneous immunoglobulin (SCIG) administration nursing competency							
STOPPING IMMUNOGLOBULIN REPLACEMENT THERAPY							
Has an awareness of reviewing a patient's need for IgRT on an annual basis							
Has an understanding of why patients with SID should have a trial off IgRT							
Has full understanding of the reasons for monitoring during trial off IgRT							

This knowledge combined with clinical skills provides the competency expected of an immunology nurse working towards expert practice.

This document assesses the underlying knowledge needed to support the core concepts within the BSI-CIPN nursing competencies. The BSI-CIPN nursing competency group is aware that with increasing nursing roles, there will be a future need for further knowledge of complications of immunodeficiency; however, this is outside the remit of this document.

TABLE 1. Benefits and disadvantages of the main routes of immunoglobulin – subcutaneous (SCIG), facilitated subcutaneous (fSCIG) and intravenous (IVIG).

SCIG	BENEFITS OF SCIG	DISADVANTAGES OF SCIG
	Does not require intravenous access	Frequent (weekly) infusions or injections
	Lower rate of adverse reactions	Local infusion site reactions (can be transient)
	Patient autonomy	
	Fewer days lost to school or work to attend hospital (likely to be home trained)	
	SCIG can be more cost effective than IVIG	
	Past thrombosis Renal failure	
	Past history of aseptic meningitis	
IVIG	**BENEFITS OF IVIG**	**DISADVANTAGES OF IVIG**
	Unable to physically administer SCIG	Requires intravenous access
	Fewer treatments	
	Quicker up-dose	Likely to be in hospital, more days lost to school or work to attend hospital
		Higher chance of severe adverse reactions (meningitis, haemolytic reactions)
fSCIG	**BENEFITS OF FACILITATED (f)SCIG**	**DISADVANTAGES OF FACILITATED (f)SCIG**
	Availability	Known systemic hypersensitivity to hyaluronidase or rHuPH20
	Allows much larger doses to be administered per infusion than SCIG (reduces treatment frequency)	

TABLE 2. What autoimmune diseases are associated with PIDs? The table shows the different 'organ-specific' and 'non-organ specific' autoimmune diseases are associated with PIDs.

TISSUE OR ORGAN AFFECTED	EXAMPLE OF THE RESULTING AUTOIMMUNE DISORDER
Blood / bone marrow	May lead to a high risk of cancers of the blood, bone marrow and lymph nodes; example of a common condition: immune thrombocytopenia
Bones, joints, connective tissues	Rheumatoid arthritis, Sjögren's syndrome, dermatomyositis, systemic lupus erythematosus (often referred to as SLE or lupus)
Liver	Liver disease called autoimmune hepatitis
Lungs	Recurrent infections can cause chronic lung disease Inflammatory lung disease that occurs in the lung parenchyma (interstitium) is called interstitial lung disease (ILD). In CVID a variation of ILD can be present which is called granulomatous and lymphocytic interstitial lung disease (GLILD); this is inflammatory and may need immunosuppression[1]
Pancreas	Diabetes, especially Type 1 (insulin dependent) diabetes
Skin	Vitiligo – loss of skin pigment which results in white patches on the skin Alopecia – abnormal loss of hair

REFERENCES AND RESOURCES

1. Grigoriadou *et al.* 2022 British Society for Immunology and United Kingdom Primary Immunodeficiency Network (UKPIN) consensus guideline for the management of immunoglobulin replacement therapy. *Clin Exp Immunol* **210** 1–13 **doi:10.1093/cei/uxac070**
2. Bousfiha *et al.* 2018 The 2017 IUIS phenotypic classification for primary immunodeficiencies. *J Clin Immunol* **38** 129–143 **doi:10.1007/s10875-017-0465-8**
3. NHS England 2018 Updated Commissioning Guidance for the use of therapeutic immunoglobulin (Ig) in immunology, haematology, neurology and infectious diseases in England December 2018. **https://bit.ly/3VeGmle**
4. Jolles 2022 Subcutaneous and intramuscular immune globulin therapy. Available at: **https://bit.ly/40GhtzN**

FURTHER RESOURCES

British Society Immunology (BSI) **www.immunology.org/public-information/bitesized-immunology**

Immunodeficiency UK **www.immunodeficiencyuk.org**

The International Nursing Group for Immunodeficiencies (INGID) **https://ingid.org**

SUBCUTANEOUS IMMUNOGLOBULIN (SCIG) ADMINISTRATION

The decision to commence a patient on home therapy with immunoglobulin should be discussed with the Immunology team and agreed with the patient.

This discussion should include the following considerations:

- Patient motivation and willingness to self-infuse
- Patient preference (IVIG/SCIG/Manual push/facilitated) if options are available
- Dexterity and mental capacity of the patient should be assessed
- The patient (and their infusion partner, if available, should be assessed on a regular basis to verify their knowledge about their condition, their treatment, potential adverse events and infusion technique. The patient's compliance with the therapy should also be checked (at least every 24 months)
- Patient's General Practitioner (GP) should be notified of home therapy treatment.

This document is to be used as a guide only. Individual centres may have their own specific protocols or this guideline can be adapted accordingly.

PRE-INFUSION GUIDANCE/CHECKLIST FOR SUBCUTANEOUS IMMUNOGLOBULIN (SCIG) INFUSION VIA PUMP OR RAPID PUSH OR FACILITATED (f)SCIG

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Understands what immunoglobulin is and the process of manufacturing it							
Able to assess patient's understanding of condition/diagnosis and proposed immunoglobulin treatment							
Able to carry out a patient risk assessment including full explanation of treatment and the associated risks and consideration of administration method							
Can demonstrate an understanding of how to dose immunoglobulin products							
RATIONALE: *Immunoglobulin therapy depends on patient weight, among other parameters. Any significant change in weight may indicate a need for dose increase or (less likely) reduction.*							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Understands the rationale for patient to stay on one product unless clinically necessary to change							

RATIONALE:

It is usual practice not to change the immunoglobulin product that the patient receives unless there is a medical reason. At times, however, it has been necessary to change the product because there have been problems with availability or because of patient choice.

Patients may require a change of immunoglobulin for several medical reasons:

- *Frequent or severe adverse reactions to the product*
- *Anti-IgA antibodies causing adverse reactions in patients with sIgA deficiency*
- *Allergic reactions to the product*
- *Poor venous access*

Patients may require a change of immunoglobulin product for other reasons:

- *To enable the patient to go onto home therapy*
- *Product availability and adherence to the national framework for therapeutic immunoglobulins (1 July 2017)*[1]
- *Change in product by manufacturers*
- *Other hospitals/pharmacies who are not able to allow for product choice*

Understands immunoglobulin therapy, as well as the adverse events that might occur and the implication of it being a blood product							
Able to discuss monitoring blood tests and their relevance							

RATIONALE:

Patients should be tested for exposure to known blood-borne pathogens before starting SCIG therapy. Once immunoglobulin therapy has been started, serologic tests may become positive because of the passively transferred antibodies and not be informative of the patient's infection status. Normally, pre-treatment monitoring bloods include HIV antibodies, immunoglobulin levels, Hepatitis C PCR (first bloods only or according to local policy – by PCR if immune-deficient), Hepatitis B PCR (first bloods only or according to local policy – by PCR if immune-deficient), full blood count, hepatic transaminases, renal function and serum save.

In immunodeficient patients, serologic tests are frequently not informative because patients are not able to form antibodies specific for these pathogens. A negative serologic test in a patient with immune deficiency does not mean that the patient has not been exposed to the pathogens. PCR tests are used to detect active infection with Epstein-Barr virus, CMV and Hepatitis B and C.

RATIONALE:

To monitor the effectiveness of treatment.

(A) Able to take written/signed patient consent prior to treatment **OR** **(B)** Has awareness that written consent should be obtained prior to commencing treatment							
Is able to assess the patient's general health prior to treatment (e.g. pyrexia, active infection) and the relevance of this							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
RATIONALE: *To establish what is normal for each patient and detect potential infusion-related abnormalities. During an infusion, an alteration of vital signs could indicate an adverse event. If fever is present and/or other signs of an acute infection the infusion may need to be postponed until antibiotic treatment is started and/or fever settles. Infusing when a patient has an acute infection can lead to antigen–antibody reaction by formation of immune complex. This effect is most common on first infusion as the concentration of antigens is highest at that time. It is important not to confound this effect with systemic adverse events, and to educate patients about the difference so that they do not fear future treatment sessions.*							
Can discuss how immunoglobulin products are to be stored as per specific product characteristics (SPC)							
RATIONALE: *Systemic adverse events are very rare in SC administration; however, they are more likely to occur with cold immunoglobulin solutions (fridge temperature), with the first infusion, a fast infusion, a large infusion, a long interval since the prior infusion, a switch to a new product or batch number, or the presence of a current infection. The most common immediate reactions are headache, cold sweat, light dizziness, chills, fever and muscular pain. These are usually mild and occur within an hour of starting an infusion and disappear within six hours. Both pharmacologic and non-pharmacologic interventions (supplying blankets or pillows, heating pads and encouraging the use of relaxation techniques) may be indicated. Although local reactions are very common with SC administration (local itchiness, swelling and redness) they are deemed normal and are not considered worrisome.*							
Is able to check drug chart against local medicines policy							
Can identify all equipment and ancillaries required for subcutaneous and rapid push infusion							
Can demonstrate preparation of immunoglobulin and equipment using ANTT procedure							
Can identify suitable sites for subcutaneous infusion							
Can demonstrate appropriate needle insertion and how to check if in correct position							
Can demonstrate an understanding of how the infusion pump works (if applicable) and is able to explain it to the patient							
Can identify common side effects associated with infusion, i.e. redness and swelling at infusion site							
Can identify other potential adverse events/reactions and how to manage them (see troubleshooting, Appendix 1)							
Can demonstrate safe removal of needles and disposal of sharps/ syringes							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Demonstrates the responsibility of maintaining accurate documentation: • dose of immunoglobulin • batch number • date and time of infusion • any adverse reactions							
Can discuss how immunoglobulin products are stored depending on product							
Is able to check drug chart against local medicines policy							
Able to explain the importance of checking for contamination in vials							
RATIONALE: *The liquid should be clear and transparent; if it is cloudy or has deposits, the product should not be used.* *RATIONALE:* *Although the risk of transmission of blood-borne infections with currently licensed immunoglobulin products is minimal, it is still present. The dose, brand, batch number, expiration date and manufacturer of any immune globulin product infused into any patient should be carefully recorded in patient's medical records, as is done for all blood products. In addition, patients should be trained to keep their own logs of this information, as it is often required by law to have donor-to-recipient traceability. Each Trust may have different ways of recording batch numbers onto the national database for patients on home therapy.*							
Demonstrates the ability to provide reassurance and specialist advice to patients and their carers							
Demonstrates the ability to teach a patient/carer the administration steps of subcutaneous and rapid push infusions with appropriate information given							
Understands accountability in relation to administration of subcutaneous immunoglobulin							

FURTHER READING

International Nursing Group for Immunodeficiencies (INGID) 2017 European Nursing Guidelines for Immunoglobulin Administration. **https://ingid.org/nursing-guidelines-english**

Jolles *et al.* 2015 Current treatment options with immunoglobulin G for the individualization of care in patients with primary immunodeficiency disease. *Clin Exp Immunol* **179** 146–160 **doi:10.1111/cei.12485**

Jolles *et al.* 2011 New frontiers in subcutaneous immunoglobulin treatment. *Biol Ther* **1** 3 **doi:10.1007/s13554-011-0009-3**

Skoda-Smith *et al.* 2010 Subcutaneous immunoglobulin replacement therapy in the treatment of patients with primary immunodeficiency disease. *Ther Clin Risk Manag* **6**, 1–10 **doi:10.1057/rm.2009.17**

Stiehm 2013 Adverse effects of human immunoglobulin therapy. *Transfus Med Rev* **27** 171–178 **doi:10.1016/j.tmrv.2013.05.004**

APPENDIX 1 – TROUBLESHOOTING

To avoid problems during infusion it is very important to inspect carefully the area before needle insertion. Look for nodules in subcutaneous tissue, oedema (SCIG), haematoma, fibrosed veins (IVIG) or irritated skin/rash.

In the following table, the following format is used: 'what to check: how to act'.

In SCIG therapy, most local problems after the first 8–10 infusions are caused by the use of too short needles.

PROBLEM	IVIG	SCIG	fSCIG
Leaky site	• Needle: correct position • Connections: tighten • Fixation: secure dressing/tape/bandage • Check integrity of equipment	• Needle: correct position, length, diameter • Connections: tighten • Fixation: secure dressing/tape/bandage • Volume: decrease per site • Infusion rate: slow down • Check integrity of equipment	• Needle: correct position, length, diameter • Connections: tighten • Fixation: secure dressing/tape/bandage • Volume: decrease per site • Infusion rate: slow down • Check integrity of equipment
Discomfort/pain at infusion site	• Needle: correct position • Fixation: secure dressing/tape/bandage • Extravasation: start over	• Needle: dry needle insertion. Needle too short or too long? Movement of needle? Change type, brand and/or length of needle • Fixation: secure dressing/tape/bandage If you can't resolve the problem, remove needle and start again with a new needle/location	• Needle: dry needle insertion. Needle too short or too long? Movement of needle? Change type, brand and/or length of needle • Fixation: secure dressing/tape/bandage • Volume: decrease per site
Blood at the infusion site or in the line, before starting the infusion	• This is normal, you are in the correct position	• Blood at the site only (none in the line): proceed to infusion • Blood in the line: remove the needle and start again with a new needle in a new location. In case of multi-site lines, you may clamp the site, which has blood in the line, and infuse through the remaining ports if you consider the change of volume per site will not be a problem	• Blood (even small amounts) at puncture site or in the line: remove the needle and start again with a new needle in a new location (there might be a risk of severe haematoma due to the hyaluronidase)
Local reactions (swelling, redness, induration, itching, burning)	• Needle: correct position • Connections: tighten • Fixation: secure dressing/tape/bandage • Check integrity of equipment: replace if necessary • Allergies to any used products: change equipment, antihistamine can be given, inform a doctor	• Infusion site: inform the patient that local reactions are expected after the first 8–10 infusions and usually resolve between 12 and 72 hours • Volume: decrease per site • Infusion rate: slow down	• Infusion site: inform the patient that local reactions are expected and usually resolve between 12 and 72 hours • Volume: decrease per site • Infusion rate: slow down

FURTHER READING

International Nursing Group for Immunodeficiencies (INGID) 2017 European Nursing Guidelines for Immunoglobulin Administration. **https://ingid.org/nursing-guidelines-english**

INTRAVENOUS IMMUNOGLOBULIN (IVIG) ADMINISTRATION

The decision to commence a patient on immunoglobulin should be discussed with the Immunology team and agreed with the patient.

This discussion should include the following considerations:

- Patient motivation and willingness to self-infuse
- Patient preference (IVIG/SCIG/Manual push/facilitated) if options are available
- Dexterity and mental capacity of the patient should be assessed
- The patient (and their infusion partner, if available, should be assessed on a regular basis to verify their knowledge about their condition, their treatment, potential adverse events and infusion technique. The patient's compliance with the therapy should also be checked (at least every 24 months)
- Patient's General Practitioner (GP) should be notified of home therapy treatment.

This document is to be used as a guide only. Individual centres may have their own specific protocols or this guideline can be adapted accordingly.

PRE-INFUSION GUIDANCE/CHECKLIST FOR INTRAVENOUS IMMUNOGLOBULIN (IVIG) ADMINISTRATION

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Understands what immunoglobulin is and the process of manufacturing it							
Able to assess patient's understanding of condition/diagnosis and proposed immunoglobulin treatment							
Able to carry out a patient risk assessment including full explanation of treatment and the associated risks and consideration of administration method							
Can demonstrate an understanding of how to dose immunoglobulin products							

RATIONALE:
Immunoglobulin dosing depends on patient weight, among other parameters. Any significant change in weight may indicate a need for dose increase or reduction. The weight is also important to calculate the infusion rate.

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Understands the rationale for patient to stay on one product unless clinically necessary to change							

RATIONALE:
It is usual practice not to change the immunoglobulin product that the patient receives unless there is a medical reason. At times, however, it has been necessary to change the product because there have been problems with availability or because of patient choice.

Patients may require a change of immunoglobulin for several medical reasons:
- *Frequent or severe adverse reactions to the product (see protocol administration of immunoglobulin)*
- *Anti-IgA antibodies causing adverse reactions in patients with sIgA deficiency*
- *Allergic reactions to the product*
- *Poor venous access*

Patients may require a change of immunoglobulin product for other reasons:
- *To enable the patient to go onto home therapy*
- *Product availability and adherence to the national framework for therapeutic immunoglobulins (1 July 2017)*[1]
- *Change in product by manufacturers*
- *Other hospitals/pharmacies who are not able to allow for product choice*

Understands immunoglobulin therapy, as well as the adverse events that might occur and the implication of it being a blood product							
Able to discuss monitoring blood tests and their relevance							

RATIONALE:
Patients should be tested for exposure to known blood-borne pathogens before starting IVIG therapy. Once immunoglobulin therapy has been started, serologic tests may become positive because of the passively transferred antibodies and not be informative of the patient's infection status. Normally, pre-treatment monitoring bloods include HIV antibodies, immunoglobulin levels, Hepatitis C PCR (first bloods only or according to local policy – by PCR if immune-deficient), Hepatitis B PCR (first bloods only or according to local policy – by PCR if immune-deficient), full blood count, hepatic transaminases, renal function and serum save.

In immunodeficient patients, serologic tests are frequently not informative because patients are not able to form antibodies specific for these pathogens. A negative serologic test in a patient with immune deficiency does not mean that the patient has not been exposed to the pathogens. PCR tests are used to detect active infection with Epstein-Barr virus, CMV and Hepatitis B and C.

RATIONALE:
To monitor the effectiveness of treatment.

(A) Able to take written/signed patient consent prior to treatment **OR** **(B)** Has awareness that written consent should be obtained prior to commencing treatment							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Is able to assess the patient's general health prior to treatment (e.g. pyrexia, active infection) and the relevance of this							
RATIONALE: *To establish what is normal for each patient and detect potential infusion-related abnormalities. During infusion, an alteration of vital signs could indicate an adverse event. If fever is present and/or other signs of an acute infection the infusion may need to be postponed until antibiotic treatment is started and/or fever settles. Infusing when a patient has an acute infection can lead to antigen–antibody reaction by formation of immune complex. This effect is most common on first infusion as the concentration of antigens is highest at that time. It is important not to confound this effect with systemic adverse events, and to educate patients about the difference so that they do not fear future treatment sessions.* *RATIONALE:* *Systemic adverse events are more likely to occur with cold immunoglobulin solutions (fridge temperature), with the first infusion, a fast infusion, a large infusion, a long interval since the prior infusion, a switch to a new product or batch number, or the presence of a current infection. The most common immediate reactions are headache, cold sweat, light dizziness, chills, fever and muscular pain. These are usually mild and occur within an hour of starting an infusion and disappear within six hours. Both pharmacologic and non-pharmacologic interventions (supplying blankets or pillows, heating pads and encouraging the use of relaxation techniques) may be indicated.*							
Can discuss how immunoglobulin products are stored depending on product							
Is able to check drug chart against local medicines policy							
Able to explain the importance of checking for contamination in vials							
RATIONALE: *The liquid should be clear and transparent; if it is cloudy or has deposits, the product should not be used.*							
Able to assess the need for premedication							
RATIONALE: *Premedication is usually only given if there has been a recent systemic adverse event. Many adverse events can be minimised or prevented by oral premedication, for example with antihistamines, corticosteroids or non-steroidal anti-inflammatory agents.*							
Can demonstrate preparation of treatment and equipment (ANTT procedure)							
Is able to carry out venepuncture							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Can safely administer intravenous immunoglobulin (understands the need for titration of dose as appropriate)							
Is able to assess for signs of anaphylaxis and adverse events and act accordingly (as per local guidelines)							
Understands the need to take pre and post observations if required							
Demonstrates the ability to maintain accurate documentation: • dose of immunoglobulin • batch number • date and time of infusion • any adverse reactions							
RATIONALE: *Although the risk of transmission of blood-borne infections with currently licensed IVIG products is minimal, it is still present. The dose, brand, batch number, expiration date and manufacturer of any immune globulin product infused into any patient should be carefully recorded in the medical record, as is done for all blood products. In addition, patients should be trained to keep their own logs of this information, as it is often required by law to have donor-to-recipient traceability.*							
Demonstrates the ability to provide reassurance to patient/family							
Demonstrates the ability to teach a patient/carer the administration of intravenous immunoglobulin (if required)							
Understands accountability in relation to administration of intravenous immunoglobulin							

FURTHER READING

International Nursing Group for Immunodeficiencies (INGID) 2017 European Nursing Guidelines for Immunoglobulin Administration. **https://ingid.org/nursing-guidelines-english**

Gürcan *et al.* 2010 Information for healthcare providers on general features of IGIV with emphasis on differences between commercially available products. *Autoimmun Rev* **9** 553–559 **doi:10.1016/j.autrev.2010.03.003**

Jolles *et al.* 2015 Current treatment options with immunoglobulin G for the individualization of care in patients with primary immunodeficiency disease. *Clin Exp Immunol* **179** 146–160 **doi:10.1111/cei.12485**

Orbach *et al.* 2005 Intravenous immunoglobulin: adverse effects and safe administration. *Clin Rev Allergy Immunol* **29** 173–184 **doi:10.1385/CRIAI:29:3:173**

Stiehm 2013 Adverse effects of human immunoglobulin therapy. *Transfus Med Rev* **27** 171–178 **doi:10.1016/j.tmrv.2013.05.004**

APPENDIX 1 – TROUBLESHOOTING

To avoid problems during infusion it is very important to inspect carefully the area before needle insertion. Look for nodules in subcutaneous tissue, oedema (SCIG), haematoma, fibrosed veins (IVIG) or irritated skin/rash.

In the following table, the following format is used: 'what to check: how to act'.

PROBLEM	IVIG	SCIG	fSCIG
Leaky site	• Needle: correct position • Connections: tighten • Fixation: secure dressing/tape/bandage • Check integrity of equipment	• Needle: correct position, length, diameter • Connections: tighten • Fixation: secure dressing/tape/bandage • Volume: decrease per site • Infusion rate: slow down • Check integrity of equipment	• Needle: correct position, length, diameter • Connections: tighten • Fixation: secure dressing/tape/bandage • Volume: decrease per site • Infusion rate: slow down • Check integrity of equipment
Discomfort/pain at infusion site	• Needle: correct position • Fixation: secure dressing/tape/bandage • Extravasation: start over	• Needle: dry needle insertion. Needle too short or too long? Movement of needle? Change type, brand and/or length of needle • Fixation: secure dressing/tape/bandage If you can't resolve the problem, remove needle and start again with a new needle/location	• Needle: dry needle insertion. Needle too short or too long? Movement of needle? Change type, brand and/or length of needle • Fixation: secure dressing/tape/bandage • Volume: decrease per site
Blood at the infusion site or in the line, before starting the infusion	• This is normal, you are in the correct position	• Blood at the site only (none in the line): proceed to infusion • Blood in the line: remove the needle and start again with a new needle in a new location. In case of multi-site lines, you may clamp the site, which has blood in the line, and infuse through the remaining ports if you consider the change of volume per site will not be a problem	• Blood (even small amounts) at puncture site or in the line: remove the needle and start again with a new needle in a new location (there might be a risk of severe haematoma due to the hyaluronidase)
Local reactions (swelling, redness, induration, itching, burning)	• Needle: correct position • Connections: tighten • Fixation: secure dressing/tape/bandage • Check integrity of equipment: replace if necessary • Allergies to any used products: change equipment, antihistamine can be given, inform a doctor	• Infusion site: inform the patient that local reactions are expected after the first 8–10 infusions and usually resolve between 12 and 72 hours • Volume: decrease per site • Infusion rate: slow down	• Infusion site: inform the patient that local reactions are expected and usually resolve between 12 and 72 hours • Volume: decrease per site • Infusion rate: slow down

FURTHER READING

International Nursing Group for Immunodeficiencies (INGID) 2017 European Nursing Guidelines for Immunoglobulin Administration. **https://ingid.org/nursing-guidelines-english**

NURSE-LED CLINICS FOR INITIAL SCREENING AND MANAGEMENT FOR PATIENTS WITH IMMUNODEFICIENCY

This document refers to nurses working specifically seeing new patients triaged by the Consultant in Clinic, telephone or virtually.

Prior to commencing Nurse-led clinics, you will need to have the support and approval from your team and your managers; this may require you to submit your own Advanced Nurse Guidelines and protocols to your Trust for approval.

Requirements: Advanced Assessment Course and ideally independent/supplementary prescribing course and to complete the radiation safety course (if appropriate); it is desirable to have a Master's degree in a relevant/appropriate subject.

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Has understanding and knowledge of responsibilities and the role of the 'Advanced Nurse Practitioner'							
Able to recognise and acknowledge own limitations of practice							
Can assess patient's understanding of why they are attending clinic							
Has knowledge of primary and secondary immunodeficiencies, why and when regular reviews are important							
Understands strategic developments and plans for department and Trust							
Has ability to organise own clinics							
Has knowledge of basic different clinical presentations, e.g. sinus infections, mycobacteria infections and what investigations would be performed for the different presentations							
Can demonstrate awareness of criteria for national and international criteria of primary/secondary immunodeficiencies							
Understands and is up to date with the Department of Health & Social Care (DHSC) – NHS England – or other relevant body (if outside England) criteria for the initiation of immunoglobulin replacement therapy							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Able to perform and record systematically, a full medical history including demographics, general health, baseline observations, medical, social and family history							
Able to record an accurate list of medications (relevant past and present)							
Able to review medications and potentially change if required or suggest review via GP/other speciality							
Review appropriateness and suitability of prophylactic antibiotics and change if required – considering antibiotic resistance							
Knows where to access own Trust's antibiotic therapy guidelines and any specific guidance for patients with immunodeficiencies to provide for GPs and patients, and can discuss importance of these with the patient (where these exists)							
Can demonstrate ability to identify 'red flags' through questioning and examination							
Can perform full physical examination and present findings, able to recognise respiratory/cardiac/abdominal and any other relevant abnormalities							
Has ability to present patients at MDT meetings and to liaise with other specialities as required							
Can explain rationale for blood monitoring, including why tests are required and frequency and any potential implications/ interpretations							
Able to request appropriate blood tests and any other samples required for initial diagnosis and follow-up							
Can arrange additional diagnostic investigations such as prescribing vaccines as part of immunodeficiency work up							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Understands and explains why patients require regular investigations such as lung function tests/scans (CT/ultrasound) as part of their ongoing management of immunodeficiency							
Ability to request investigations as required, such as lung function, X-rays and CT scans							
Able to discuss potential treatments in detail							
Can identify if patients may require additional support such as psychology, vulnerable patients or home assistance and make referrals as required							
Can explain importance of documenting infection frequency and courses of antibiotics, including type and any sputum cultures received							
For patients receiving treatment, has the ability to elicit relevant information to confirm patients are taking medications correctly							
Has an awareness of all up-to-date and relevant research, treatments and patient support charities to convey to patient							
Knowledge of patient support charities/groups, to be able to sign post patients to appropriate organisations							
Ability to review and interpret results from specimens and investigations and prescribe appropriate medications, request further investigations or make referrals, in consultation with immunology Consultant as required							
Promotes healthy living and wellbeing							
Ability to produce comprehensive clinic letters for patients, GP and including other relevant specialties							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Ability to audit clinics							
Able to produce and review guidelines/protocols for clinics, updating as required							
To be up to date with current changes in the diagnosis and management of patients with immunodeficiencies							
Ability to show and demonstrate compassion and empathy to patients and their families/friends							

NURSE-LED FOLLOW-UP CLINIC FOR PATIENTS WITH IMMUNODEFICIENCY

This document refers to nurses working specifically seeing patients alongside Consultants in Clinic, telephone or virtually.

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Understands indication for regular weight checks when seeing patients face to face							
Can explain reasons for blood monitoring including which tests are required and frequency							
Understands why some patients need investigations (lung function tests, CT scan, etc.) as part of their ongoing management of immunodeficiency							
Can explain importance of assessing infection frequency and courses of antibiotics, including type and any microbiology/ virology results received							
Can elicit relevant information to confirm patient is infusing immunoglobulin, including looking at infusion records							
Has an awareness of all up-to-date and relevant patient support charities to convey to patient							
Able to list all the risks and benefits of immunoglobulin replacement therapy and understands importance of verbally confirming consent annually to continue with treatment							
Understands reasons and frequency of infusion assessments for patients self-infusing at home							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Knows where to access own Trust's antibiotic therapy guidelines and any specific guidance for patients with immunodeficiencies to provide for GPs and patients, and can discuss importance of these with the patient (where these exists)							
Aware of national commissioning of Ig and how this links to required clinical data to record, including no. of infections, no. of courses of antibiotics and days in hospital for infection							
Knowledge and awareness of the complications linked to some types of immunodeficiency (lung, gastro, malignancy) and knowledge of relevant questions to ask and when to escalate any patient or other health provider reported symptoms or updates to Consultant (f/u and/or MDT)							
Has working knowledge of the MDSAS app if adopted locally							
Records clinical data where required to local and national databases, including research projects and adding blood trough levels/review of ongoing treatment on MDSAS database							
Depending on scope of practice, able to take written consent or confirm consent and/or can demonstrate awareness of the need to have consent for immunoglobulin replacement therapy, including self-administration							

VACCINATIONS IN CLINIC

This document refers to nurses working specifically delivering vaccinations in an immunodeficiency clinic, e.g. pneumonia, meningitis vaccines.

It is advisable that, in addition to completing this document, the nurse has completed local Trust vaccination training (i.e. one offered for COVID vaccines).

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Can explain the indications for vaccination							
Has an awareness of conditions vaccine responsiveness diagnose							
Understands the indications for assessing vaccine response							
Can identify the types of vaccines used and their correct storage as per specification							
Has an awareness of differences between vaccines (i.e. specifically between polysaccharide and protein-based/conjugated vaccines)							
Has knowledge of timing of vaccinations and pre and post vaccination measurements and rationale							
Able to list interfering factors for vaccinations							
Can assess patient's level of understanding of the reason for vaccination and provide information regarding indication							
Able to explain possible side effects to gain verbal consent after providing information							
Demonstrates the ability to check validity of current prescription; correct product, dose, expiry date and route of administration (S/C, IM) as per the local medicine policy							
Can maintain accurate documentation: • vaccine given • batch number • date and time of vaccine • any adverse reactions							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Can assess for signs of anaphylaxis and adverse events and act accordingly							
Understands how to make arrangements for patient for further vaccination or blood tests							
Follows local vaccination policy documentation							
Awareness of interpretation of results							

NURSE-LED CLINICS FOR INITIAL SCREENING AND MANAGEMENT FOR PATIENTS WITH HEREDITARY ANGIOEDEMA (HAE)

This document refers to nurses working specifically seeing patients for initial nurse consultation alongside Consultants in Clinic, telephone or virtually.

This BSI-CIPN competency should be read in parallel with the BSI-CIPN competencies on 'Nurse-led follow-up clinic for patients with hereditary angioedema (HAE)' and 'Medications used in HAE'.

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Prior knowledge of different types of angioedema							
Able to distinguish the differences between histamine-mediated and bradykinin-mediated angioedema in terms of its signs and symptoms, kinetics and response to treatment							
Able to assess symptoms: date of onset, frequency, course, location, and duration of swelling/attack							
Able to demonstrate complete documentation of symptoms in the form of diary and photographic evidence if appropriate/where possible (refer to local Trust guidelines)							
Able to identify precipitating factors and prodromal symptoms							
Able to perform medical history, including family history of angioedema and deaths of unknown cause							
Able to perform a full drug history including response to other treatments							
Able to identify medications that are contraindicated or should be avoided if with recurrent angioedema							
Able to request appropriate blood tests and any other samples required for initial diagnosis and follow-up							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Able to arrange additional investigations and diagnostic test including genetic testing							
Knowledge of all available prophylactic and acute treatments; able to discuss mechanism of action and adverse effects of each drug (refer to Medications used in hereditary angioedema (HAE) competency)							
Introduces and provides information about patient support group: HAE UK							
Demonstrates awareness of the importance of having: • letter outlining patient's acute attack management plan – copied to GP, local A&E and patient to carry this at all times; patient may also wish to wear a Medic Alert bracelet • supply of at least 1–2 doses of acute medication for the patient to keep at home in case of emergency (refer to local policy if clinically indicated)							
Able to perform patient counselling on: • treatment management and self-administration training or home therapy if possible • avoidance of precipitating factors • explaining the role of trauma, infection and invasive diagnostic procedures and surgeries including dental procedures • importance of early treatment							
Can demonstrate awareness of all up-to-date and relevant research and treatment							
Knowledge of the NHS England commissioning criteria for long-term prophylaxis							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Awareness of the use of patient reported outcome monitoring tools: • diary • HAE MDSAS app (if available) Validated QOL for angioedema: AECT, AAS, AEQOL (refer to local guidelines)							
Can assess the patient's need for support and encourage independence based on individual needs							

NURSE-LED FOLLOW-UP CLINIC FOR PATIENTS WITH HEREDITARY ANGIOEDEMA (HAE)

This document refers to nurses working specifically seeing patients for follow-up nurse consultation alongside Consultants in Clinic, telephone or virtually.

This BSI-CIPN competency should be read in parallel with the BSI-CIPN competencies on 'Nurse-led follow-up clinic for patients with hereditary angioedema (HAE)' and 'Medications used in HAE'.

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Demonstrates awareness of the medications to treat acute attacks of HAE and how they are administered							
Demonstrates understanding of the commissioning guidelines for prophylactic treatments							
Aware of the medications used for prophylaxis to prevent attacks of HAE and how they are administered							
Understands that patients would have an individual management plan which is regularly reviewed to manage symptoms							
Ensures patient has access to treatment							
Assesses eligibility for home therapy and self-administration training where possible							
Can explain how medications are stored at home for the patients and what arrangements are needed for travel							
Knows that the patient needs a management plan for planned surgery/procedures							
Understands the importance of avoidance of precipitating factors such as NSAIDS, oestrogen and ACE inhibitors							
Performs routine monitoring bloods and diagnostics: liver function test and annual liver scan is checked for patients on AA							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Awareness of additional support for patients, i.e. HAE UK, in addition to support from Immunology service							
Reviews patient treatment response with the use of patient reported outcome measures (PROM), i.e. • HAE validated questionnaires: AECT, AEQOL, AAS • Attack and treatment diary • HAE app (if available)							
Refers for genetic counselling before pregnancy or at the first opportunity after HAE diagnosis (refer to local Trust guidelines)							
Awareness of limited treatment option during pregnancy: • oral prophylaxis – berotralstat, AA and progesterone should be stopped • icatibant is not licensed in pregnancy							
Up to date with current European Academy of Allergy and Clinical Immunology (EACCI) / World Allergy Organization (WAO) HAE guidelines[1]							
Aware of mechanism of action, side effects and monitoring requirements of all HAE therapies in line with national and international guidelines (refer to Medications used in HAE competency)							
Able to perform attack history assessment including factors that trigger the attack, frequency, severity, location, time to administration of treatment, time to complete resolution and medications used to treat acute attacks							
Able to rule out other possible causes of gastrointestinal symptoms and perform investigation such as *H. pylori* testing or stool culture and signpost patients to GP or other specialities for further investigation as necessary							

REFERENCE

1. Maurer *et al.* 2022 The international WAO/EAACI guideline for the management of hereditary angioedema – The 2021 revision and update, *World Allergy Organ J* **15**:100627. **https://doi.org/10.1016/j.waojou.2022.100627**

MEDICATIONS USED IN HEREDITARY ANGIOEDEMA (HAE)

This document is to be used as a guide only. Individual centres may have their own specific protocols, or this guidance can be adjusted accordingly. This list is not exhaustive and is up to date at the time this document was created. New treatments may become available.

This BSI-CIPN competency should be read in parallel with the BSI-CIPN competencies on 'Nurse-led clinics for initial screening and management for patients with hereditary angioedema (HAE)' and 'Nurse-led follow-up clinic for patients with hereditary angioedema (HAE)'.

C1-ESTERASE INHIBITOR

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Knowledge of the indication of different treatments for HAE and guidelines, e.g. European Academy of Allergy and Clinical Immunology (EACCI)/World Allergy Organization (WAO) HAE guidelines[1]							
Identifies when to infuse C1-esterase inhibitor							
Knowledge of the different products, storage and doses of C1-esterase inhibitor							
Understands the difference between Ruconest and plasma-derived C1-esterase inhibitor products							
Explains the risks involved with blood products and when a serum save should be taken							
Checks for patient consent to treatment (verbal or written)							
Assesses patient's general health prior to infusion							
Demonstrates correct preparation of equipment and medication (ANTT)							
Can carry out cannulation/venepuncture							
Demonstrates safe infusion of C1-esterase inhibitor							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Can assess for and identify allergic reactions and/or adverse events							
Can teach the patient and/or carer how to infuse C1-esterase inhibitor							
Completes documentation and records batch numbers							
Understands the eligibility criteria for prophylactic C1-inhibitor							

ICATIBANT

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Identifies when to use icatibant							
Knowledge of the dose and storage of icatibant							
Checks for patient consent to treatment (verbal or written)							
Assesses patient's general health prior to injection							
Demonstrates correct preparation of equipment and medication (ANTT)							
Safely administers injection subcutaneously							
Can assess for and identify allergic reactions and/or adverse events							
Knowledge of the common side effects and contraindications of icatibant, including in pregnancy and breast-feeding							
Can teach the patient and/or carer how to inject icatibant							
Completes documentation and records batch numbers							

LANADELUMAB

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Understands the eligibility criteria for lanadelumab							
Knowledge of how to switch from prophylactic C1-inhibitor to lanadelumab							
Knowledge of the dose and appropriate storage of lanadelumab							
Checks for patient consent to treatment (verbal or written)							
Assesses patient's general health prior to injection							
Demonstrates correct preparation of equipment and medication (ANTT)							
Safely administers injection subcutaneously							
Can assess for and identify allergic reactions and/or adverse events							
Knowledge of the common side effects and contraindications of lanadelumab, including in pregnancy and breast-feeding							
Can teach the patient and/or carer how to inject lanadelumab							
Completes documentation and records batch numbers							

ORAL MEDICATIONS – ATTENUATED ANDROGENS, TRANEXAMIC ACID AND BEROTRALSTAT

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Can discuss when and why oral medications are used for HAE							
Knowledge of types of medication and doses							
Understands the eligibility criteria for berotralstat							
Can explain the contraindications for use of oral medications in HAE, including in pregnancy and breast-feeding							
Knowledge of the common side effects of oral medications used in HAE							

REFERENCE

1. Maurer *et al.* 2022 The international WAO/EAACI guideline for the management of hereditary angioedema – The 2021 revision and update, *World Allergy Organ J* **15**:100627. **https://doi.org/10.1016/j.waojou.2022.100627**

NURSE-LED CLINIC FOR PATIENTS WITH CHRONIC SPONTANEOUS URTICARIA (CSU)

This document refers to nurses working specifically seeing patients alongside Consultants in Clinic, telephone or virtually.

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Understands the need to rule out allergies based on history before diagnosis and knowledge of the different types of allergic reaction							
Awareness of the need to perform allergy testing, desensitisation to rule out nature of urticaria							
Understands that chronic spontaneous urticaria (CSU) is defined as urticaria, histaminergic angioedema or both for a period of six weeks or longer							
Understands that CSU may spontaneously remit and relapse and it may last for months or years							
Up to date with the current European Academy of Allergy and Clinical Immunology (EACCI)/British Society for Allergy & Clinical Immunology (BSACI) guidelines and local policy in managing CSU							
Demonstrates understanding on the avoidance of possible contributory co-factors, including alcohol and certain medications							
Demonstrates understanding that the management of CSU begins with an explanation to the patient that allergy is not the cause							
Assesses and shows evidence that the patient has trialled standard and escalated dose of antihistamine for a significant amount of time without adequate response before considering referral to specialist centre for further management							
Has an awareness of the antihistamine recommended treatment pathway, including acute treatment pathway using prednisolone (refer to local guidelines)							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	**PR**	**A**	**SIGN & DATE**	**PR**	**A**	**SIGN & DATE**	
Understands importance of documenting itch and hives/swelling attacks and what features of the attacks should be recorded							
Understands the importance of using patient reported outcome measures to review treatment response (refer to local guidelines): • UAS7 scoring system for wheals • activity scoring (AS) system for angioedema • urticaria QOL – for quality-of-life measures							
Ensures that the patient has an appointment for follow-up and a point of contact for any queries							
THE COMPETENCIES BELOW ARE ONLY RELEVANT IN CENTRES PROVIDING OMALIZUMAB THERAPY							
Understands that omalizumab is the standard option in secondary care following treatment failure with licensed-dose and high-dose antihistamines							
Familiar with the BLUETEQ eligibility or commissioning guidelines on the use of omalizumab for CSU, including having an urticaria activity score of 28 or more							
Able to provide patient counselling prior to start of therapy to monitor for possible treatment side effects and reviewing treatment response; if no clinical benefit is observed after four doses, omalizumab should be discontinued							
Aware that omalizumab is an add-on therapy; advise patient not to discontinue regular medication without medical advice							
Able to perform routine blood monitoring, including serum total IgE before the first dose, only if omalizumab is being considered as treatment							
Ensures female patients are aware of the need for effective contraception if omalizumab is being considered as treatment							

COMPETENCE	FORMATIVE ASSESSMENT			SUMMATIVE ASSESSMENT			COMMENTS
KNOWLEDGE AND UNDERSTANDING	PR	A	SIGN & DATE	PR	A	SIGN & DATE	
Demonstrates awareness that if giving omalizumab, dose should be limited to 150mg per injection per site; rotate sites where possible							
Demonstrates understanding on the importance of safety monitoring following omalizumab administration (refer to local policy)							
Aware that omalizumab treatment can be restarted if the patient relapses following a successful treatment course							
Able to assess patient suitability for omalizumab self-administration and home therapy (refer to local policy if service is available)							

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INTRAVENOUS IMMUNOGLOBULIN (IVIG) ADMINISTRATION
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NURSE-LED FOLLOW-UP CLINIC FOR PATIENTS WITH IMMUNODEFICIENCY
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NURSE-LED CLINICS FOR INITIAL SCREENING AND MANAGEMENT FOR PATIENTS WITH HEREDITARY ANGIOEDEMA (HAE)
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Lorena Lorenzo, Lead Immunology Clinical Nurse Specialist, Barts Health NHS Trust

MEDICATIONS USED IN HEREDITARY ANGIOEDEMA (HAE)
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More information on this competency framework and an online version can be found on the British Society for Immunology website. Visit **www.immunology.org/cipn** for more information. For further information, please email the BSI-CIPN at **cipn@immunology.org**.

THE BRITISH SOCIETY FOR IMMUNOLOGY IS COMMITTED TO SUPPORTING OUR IMMUNOLOGY COMMUNITY IN DRIVING SCIENTIFIC DISCOVERY AND MAKING A POSITIVE IMPACT ON HEALTH.

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