

Benchmark No. 9 Immunoglobulin Therapy



British Association of Neuroscience Nurses



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History

The Neuroscience Nursing Benchmarking Group (NNBG) was established in the 1990's as a result of increasing concerns over inconsistencies in practices as part of a subsidiary of BANN. The group aims to improve on the quality of care by comparing and sharing practice with each other, and set explicit standards for comparison of current practice against the ideal standard. The group is committed to searching for the best evidence related to specific areas of neuroscience practice. Membership of the group consists of representatives from neuroscience units within the UK and Ireland, together with educational colleagues from both the NHS/HSC and Higher Educational Institutes. The group is further subdivided into regions and this benchmark was developed by the North East group of the NNBG in 2007.

In 2016, the NNBG consolidated back into BANN and further information about NNBG can be found on the BANN website www.BANN.org.uk.

BANN would like to acknowledge the leadership and significant contribution made by the NNBG, and all its contributors, to neuroscience nursing over the years.

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Immunoglobulin Therapy

Key Points

- Immunoglobulins are naturally occurring proteins that are used by the immune system to produce antibodies and other factors that detect, bind and destroy antigens such as a bacteria, viruses, fungi and spores. Immunoglobulin therapy is used for the treatment of a wide range of inflammatory primary and secondary auto-immune conditions that can leave patients susceptible to infections.
- Patients suffering from long-term neurological conditions, for example primary immunodeficiency (PID), multiple sclerosis and chronic Inflammatory polyneuropathies will normally have their Immunoglobulin therapy administered in an out-patient facility or at home. However, this benchmark will focus on intravenous administration (IVIg's), to patients presenting with acute onset conditions such as Guillain Barré syndrome or acute exacerbations of myasthenia Gravis.
- There are several companies that produce Immunoglobulin products and consequently there is wide variation between batches and preparations, products cannot be administered interchangeably.
- Consent to treatment must be obtained from patients; there is a theoretical risk that the blood products could transmit prion disease, Hepatitis B, C or HIV
- A structured training and education programme is available for staff on the administration of immunoglobulin therapy.
- An evidence-based protocol should be available relating to the individual patient's needs.
- The patient information that is given is current and evidence based and in accordance with local policy

FACTOR 1 – Documentation - assessment and implementation of care

	STATEMENT OF BEST PRACTICE	EVIDENCE & REFERENCES	ACHIEVED	NOT ACHIEVED	VARIABLES
1.0	Written guidelines are available for the administration of immunoglobulin products.	Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (2024) Department of Health (2012)			
1.1	Patient documentation reflects the rationale for the decision to use immunoglobulins and is based on clinical need.	NMC (2018) DoH (2012) NHSE (2018)			
1.2	A risk assessment is completed by the patient’s consultant. Clinical information includes: <ul style="list-style-type: none"> • Clinical indications for administration • Theoretical risk of blood borne infections • Prescribing guidelines • Procedure for administration • Signs and symptoms of adverse reactions • Management of adverse reactions • Product range and availability • Awareness of alternative methods of administration i.e. subcutaneous immunoglobulin (SGIG) & the criteria, benefits & contra-indications of domiciliary administration. • Documentation 	Gov.UK (2020) CQC (2023)			

	STATEMENT OF BEST PRACTICE	EVIDENCE & REFERENCES	ACHIEVED	NOT ACHIEVED	VARIABLES
1.3	The patient has an understanding of the treatment intervention and has given informed consent.				
1.4	The batch number is documented in the patient's records in order to track product use in the case of major adverse reactions.				

FACTOR 2 – Protocol

	STATEMENT OF BEST PRACTICE	EVIDENCE & REFERENCES	ACHIEVED	NOT ACHIEVED	VARIABLES
2.0	The patient is informed that immunoglobulins are a blood product and are counselled regarding the theoretical risks of contracting blood borne infections.	DoH (2009) Wiles et al (2002)			
2.1	Prior to commencement of therapy the patient’s biochemical profile is taken including full biochemistry profile, LFT, FBC, Serum IgA, CRP & urinalysis.	Clark (2012)			
2.2	If observations vary from the patient’s normal parameters or if there is evidence of an untreated infection, the medical team is informed before initiating treatment.	Cherin et al 2016 NPSA 2007a			
2.3	Height and weight are recorded prior to administration of the first dose and at each annual review (<i>the dose is usually calculated according to dose determining weight DDW dependant on BMI and local protocols</i>).	DoH (2012) Clark (2012)			
2.4	Baseline observations (temperature, pulse, resps, blood pressure) are recorded: - <ul style="list-style-type: none"> • on commencement of therapy • at least hourly whilst the infusion is in progress. • following any adjustment in rate. 	RCN (2005) ABN (2005) DoH (2012)			
2.5	Pre-infusion medications (e.g., chlorpheniramine, hydrocortisone) are dispensed as prescribed and practitioners understand the rationale for administration.				
2.6	The maximum dosage over 24hr period is checked before administration.				
2.7	A designated peripheral cannula or a butterfly device (21 or 23 gauge) is sited for sole use of immunoglobulin therapy.	Quinn (2008)			

	STATEMENT OF BEST PRACTICE	EVIDENCE & REFERENCES	ACHIEVED	NOT ACHIEVED	VARIABLES
2.8	Immunoglobulins are administered via an infusion pump and the dosage is increased incrementally to avoid adverse effects, (follow protocol outlined in the summary of product characteristics (SPC). Increase rate as per product instructions (Infusion rates used are product-specific).	DoH (2012)			
2.9	Intravenous immunoglobulins are administered through a 15-micron giving set to prevent precipitation of albumin out of solution.				
2.10	The patient is observed for signs of anaphylaxis and other side effects, (headache, nausea, chills, rash, or back pain)	Cherin et al 2016			
2.11	<i>If adverse effects occur, the infusion is stopped until symptoms subside.</i> <ul style="list-style-type: none"> local policy is followed for the management of adverse reactions (completion of Datix). Following consultation with medical staff, the infusion can often be resumed at a rate that the patient tolerates. 	The Royal Marsden NHS Foundation Trust (2020)			
2.12	In the event of an adverse reaction: <ul style="list-style-type: none"> Record batch numbers and timings on the patient's prescription. 	BNF (2022)			
2.13	Manufacturers / Pharmacy instructions are followed for storage, administration and disposal of the product. <ul style="list-style-type: none"> <i>products cannot be regarded as clinically interchangeable.</i> 	BNF (2022) The Royal Marsden NHS Foundation Trust (2020)			
2.14	To facilitate close observation for signs of adverse reactions, IVIG's must be administered during the day (i.e., <i>blood products</i>). Initial/emergency treatments (i.e., overnight) should be recommenced prior to the recommended 24hour interval, to facilitate close observation for signs of adverse reactions (based on patient's clinical condition).	DoH (2012) NICE (2007)			

FACTOR 3 – Education

	STATEMENT OF BEST PRACTICE	EVIDENCE & REFERENCES	ACHIEVED	NOT ACHIEVED	VARIABLES
3.0	<p>A structured evidence-based training and education programme is available for immunoglobulin therapy and includes:</p> <ul style="list-style-type: none"> • Indications for use • Administration procedure • Equipment awareness • Storage and prescribing guidelines • Signs and symptoms of adverse reactions • Management of adverse reactions (including drugs) • Product range and availability • Documentation • Awareness of alternative methods of administration i.e., subcutaneous immunoglobulin (SGIG) and the criteria, benefits, and contra-indications of domiciliary administration. 	<p>NPSA (2007b)</p> <p>Gov.UK. (2020)</p>			
3.1	A formal assessment of competence in practice is completed	NMC (2018)			

FACTOR 4 – Patient Information

	STATEMENT OF BEST PRACTICE	EVIDENCE & REFERENCES	ACHIEVED	NOT ACHIEVED	VARIABLES
4.0	Patient/carers are informed of the procedure and informed consent is obtained.	NMC (2018) DH (2012)			
4.1	Any information verbal /written that is given to the patient & carers is documented in the patient notes. Information given should include the following: <ul style="list-style-type: none"> • Risks and benefits of the treatment • Alternative treatment options • Rational for the treatment • Equipment • Management of the intravenous cannula and any related concerns • Duration of treatment • Explanation of the importance of continuous observations and assessment. • Care of an intravenous cannula (if in-situ) 	NSHLA standards			
4.2	The patient receives instruction on the recognition of adverse reactions so that they can inform and act appropriately according to National and local policy.				

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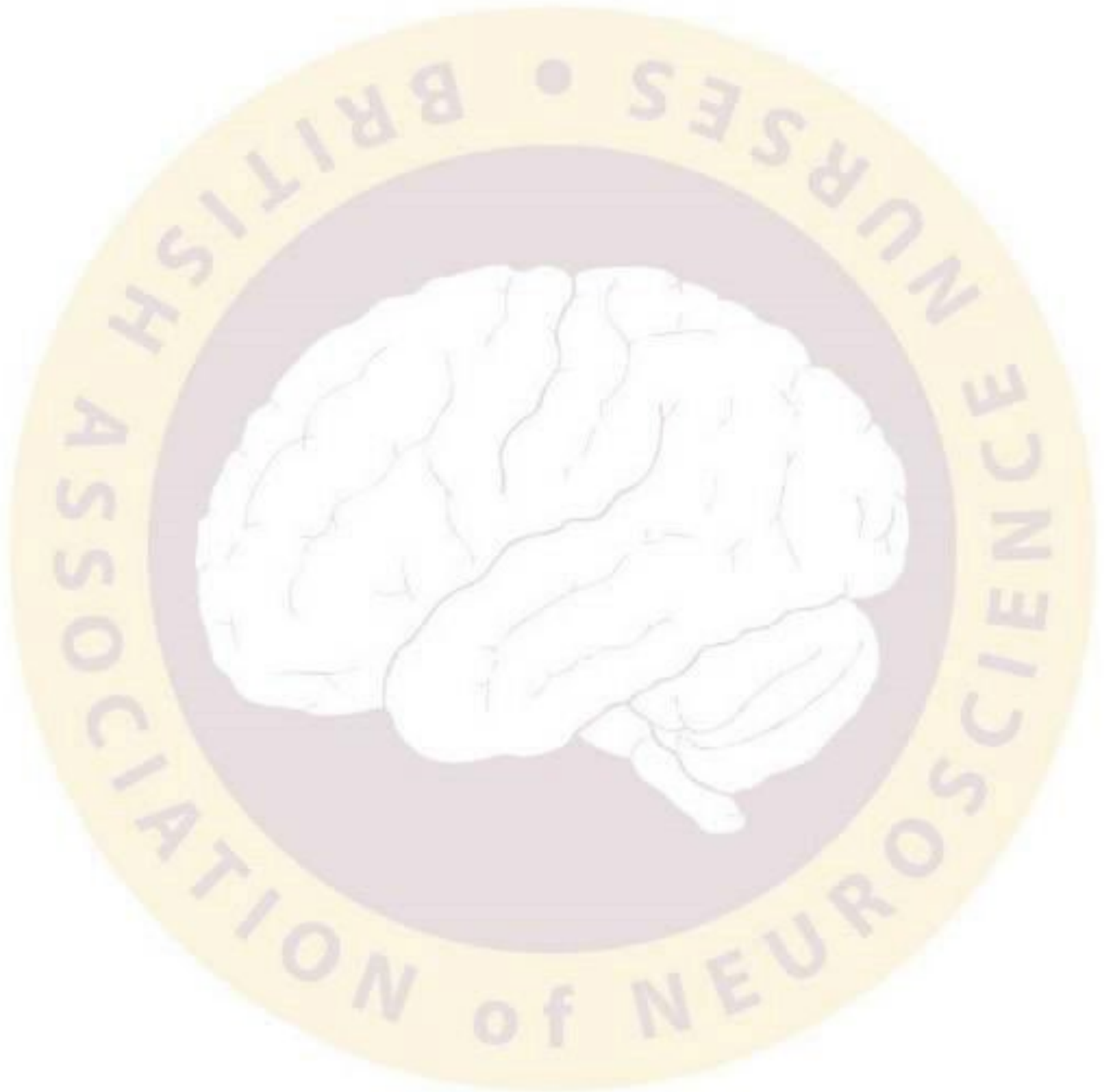
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