“We help transfuse”

The ARCBS Transfusion Nurse (TN) role in IVIg management of patients with haematological conditions

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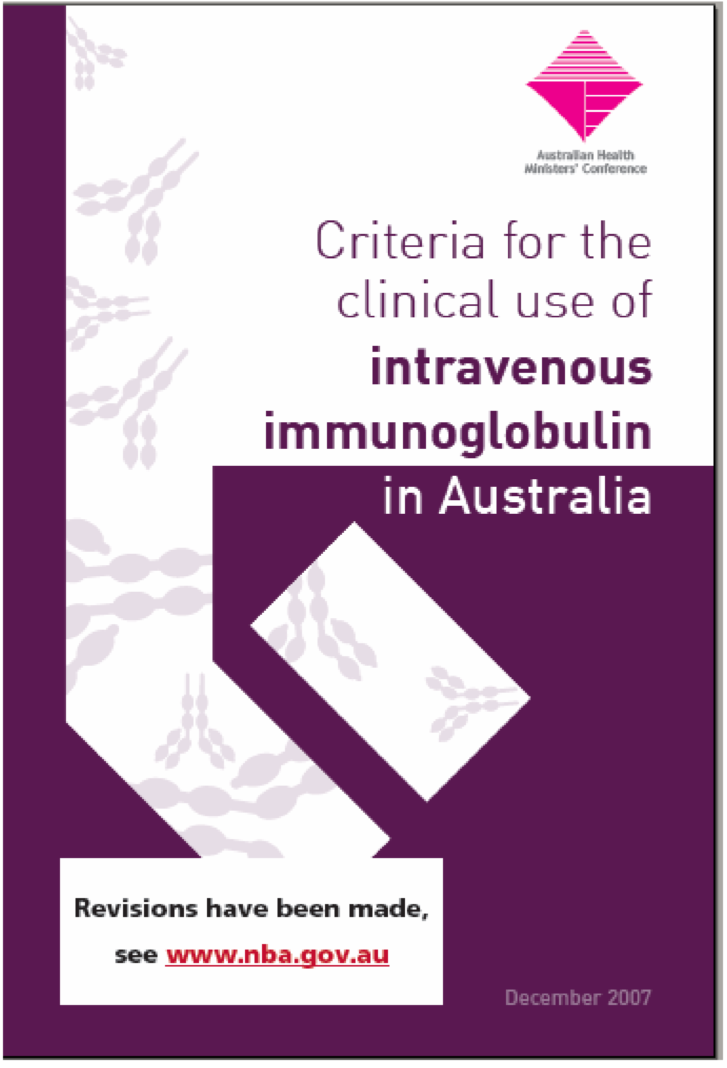
Transfusion Nurse

National Criteria

- Introduced March 2008



http://www.nba.gov.au/ivig/index.html

The Criteria includes:

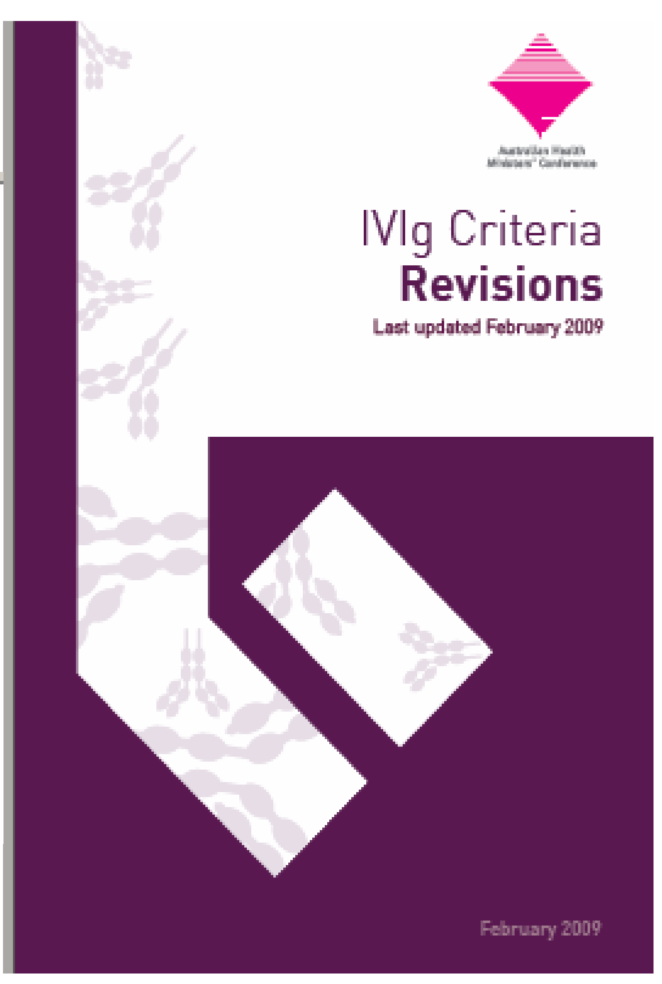
- 12 conditions for which there is an established therapeutic role
- 21 conditions where IVIg has an emerging therapeutic role
- 25 conditions where IVIg may be used in exceptional circumstances due to the availability of effective alternative therapies
- 36 conditions where IVIg is not indicated

Challenges

- Limited lead time for development of implementation tools
- Six month transition time frame
- Increased resources required
- Extensive clinician communication which still continues
- Difficulties encountered contacting clinicians to clarify diagnosis
- Supporting clinicians with additional workload
- Time required for additional laboratory tests
- Managing anxiety from some clinicians and patients

Criteria Revisions - Feb 09

- Primary immunodeficiency diseases with antibody deficiency
- Myasthenia Gravis
- Secondary hypogammaglobulinaemia(including iatrogenic immunodeficiency)
- Specific Anitibody Deficiency
- Myocarditis in children
- Paraneoplastic neurological syndromes
- Potassium channel antibody-associated encephalopathy



National IVIg Issued: Total Grams as Percentage Jan 2007- Dec 2008

Percent of Total Grams

45%
40%
35%
30%
25%
20%
15%
10%
5%
0%

Haematology
Immunology
Neurology

Immunology Subcat
Immunomodulation
Immune Replacement

Top 15 Disease Groups: Jul – Dec 2008

	Disease Group	% of IVIG used
1	**Acquired hypogammaglobulinaemia secondary to haematological malignancy**	**19.7**
2	Chronic inflammatory demyelinating polyneuropathy	19.6
3	Primary immunodeficiency diseases	16.8
4	**Idiopathic Thrombocytopenia Purpura (ITP) in adults**	**6.6**
5	Specific antibody deficiency	5.7
6	Multifocal motor neuropathy	5.6
7	Myasthenia gravis	5.1
8	Inflammatory myopathies	3.9
9	Guillain-Barre syndrome	3.9
10	Secondary hypogammaglobulinaemia	2.3
11	Kidney transplantation	1.9
12	**HSCT (for prevention of GVHD in high risk allogeneic HSCT)**	**1.3**
13	**Feto-maternal / neonatal alloimmune thrombocytopenia**	**0.9**
14	Stiff person syndrome	0.6
15	**Autoimmune haemolytic anaemia**	**0.5**

ARCBS TN Role

Diverse role

- Major focus – Liaison between blood service and clinical users of blood and blood products
- Education and support for appropriate use, administration and other aspects of transfusion – in service presentations, tutorials, telephone support, etc

Two key aspects of the role

- Special directed platelet support
- Management of IVIg

ARCBS TN Role in IVIg Management

- Integral role to support optimal patient care by:
  - Assisting clinicians with
    - Decision to transfuse – eligibility criteria
    - Education about the Criteria
    - Appropriate management of product – dosage – product issued
    - Trouble shooting & support
  - Data collection – national ARCBS Supply Tracking Analysis Recording System (STARS) database
  - Monitoring response as outlined in criteria
  - Reporting around IVIg use to local IVIg user groups, Health Departments and the National Blood Authority

ARCBS TN Resources – IVIg Management (Snap shot of Victorian & Tasmanian data only)

- 750 clarification letters sent to clinicians in a 6 month period
- Initial majority focussed on patients receiving replacement therapy
- Review of clinical diagnosis, laboratory results and clinical outcomes
  - e.g. IgG subclass review -117 patients
    - 47 (40%) reclassified
    - 25 (21%) ceased IVIg
  - e.g. secondary hypogammaglobulinaemia – 40 patients
    - 3 (7.5%) reclassified
    - 9 (22.5%) ceased IVIg
- Average of 260 telephone calls/ month
  - Average 4 minutes / call

ARCBS TN Role in IVIg Management e.g. Idiopathic Thrombocytopenic Purpura (ITP)

- Receive request & review for qualifying criteria (plt count, bleeding history, corticosteroid use or contraindication or planned surgery)
- Check STARS database

→ Contact MO if further information or different dose approved

Can require multiple calls to access information

→ Process order – Inventory & Distribution dispense IVIg

→ Enter data on STARS database

→ Follow up call (~48hours)

→ Enter review data on STARS database

ITP: Indications for IVIG use

Medical condition	Idiopathic (autoimmune) thrombocytopenic purpura (ITP) – adult
Indications for IVIg use	1. **Refractory ITP**: Patients with severe thrombocytopenia (platelets <30x10⁹/L) who have not responded to corticosteroid therapy. 2. **ITP with life-threatening haemorrhage**: Patients with severe thrombocytopenia (<30x10⁹/L) with clinical evidence of a haemostatic defect (e.g. mucous membrane haemorrhage) or active bleeding. 3. **ITP in pregnancy**: a. Platelets <30x10⁹/L. b. Impending delivery. 4. **Specific circumstances**: a. Planned surgery. b. Severe ITP (platelets <30x10⁹/L) where corticosteroids and immunosuppression are contraindicated. c. Chronic refractory ITP. 5. **HIV – associated ITP**: Patients with severe ITP associated with HIV infection.

Reference: Commonwealth of Australia 2007 'Criteria for the clinical use of intravenous immunoglobulin in Australia'. pg 76

ITP: Review Criteria

Review criteria for ITP in Adults:

- “Resolution of bleeding.
- Increment in platelet count.
- In chronic refractory ITP, 6-month review assessing evidence of clinical benefit.”

Review criteria for ITP in Children:

- “Platelet count at 48 hours.
- Control or resolution of bleeding.
- Duration of effect.
- Progression to chronic ITP.”

Reference: Commonwealth of Australia 2007. ‘Criteria for the clinical use of intravenous immunoglobulin in Australia’. pg 80

Total Grams of IVIg Issued for ITP: Jul – Dec 2008

Total Grams Issued

25000
20000
15000
10000
5000
0

Immunology Subcat
Immunomodulation

ACT NSW QLD WA
ITP associated with HIV

ACT NSW NT QLD SA TAS VIC WA
ITP in children

NSW QLD SA TAS VIC WA
ITP in pregnancy

ACT NSW NT QLD SA TAS VIC WA
ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)

ACT NSW NT QLD SA TAS VIC WA
ITP refractory

NSW QLD SA VIC WA
ITP with life-threatening haemorrhage

Haematology

Victorian ITP Patients 1 Dec 2008 - 31 Mar 2009 (n=102)

Category	Number of Patients
Associated HIV	1
In Children	13
In specific circumstances	27
Refractory	55
Life threatening haemorrhage	3
In pregnancy	3

Number of Victorian Patients who Received Multiple IVIg doses. 1 Dec - 31 Mar 2009

60
50
40
30
20
10
0

55
27
22
13
12
1
0
2
3
2
3
2

Associated HIV
In Children
In specific circumstances
Refractory
Life threatening haemorrhage
In pregnancy

No. of Patients
No. of patients who received multiple doses

Average Weight & Average IVIg Dose (g) per Victorian Patient

Weight (kg)/ Dose (g)

90
80
70
60
50
40
30
20
10
0

	Associated HIV	In children	In pregnancy	In specific circumstances	Refractory	Life threatening haemorrhage
Average wt/ pt	69	22	65	83	75	77
Average IVIg dose/ pt	70	23	51	64	60	76

Average Victorian IVIg dose /kg

Grams/kg

1.2
1
0.8
0.6
0.4
0.2
0

Associated HIV
In children
In pregnancy
In specific circumstances
Refractory
Life threatening haemorrhage

Average dose /kg

ITP review: Victorian results
1 Dec 2008 - 31 Mar 2009

Total number of patients receiving IVIg for ITP (Vic) = 102

- Follow-up platelet counts were available for 76% of these patients – (78)
  - Varying time frames of counts - 24hours post IVIg to 14 days
  - 70 patients demonstrated response (89.7%)
  - 8 patients showed no response (10.2%)

Average Platelet (plt) counts – Victorian Pre and Post IVIg

Plt count x 10^9/L	**Average plt count *Pre IVIg***	**Plt range *Pre IVIg* (min - max)**	**Average plt count – *Post IVIg* (1-7days)**	**Plt range *Post IVIg* (min - max) (1-7days)**
ITP in children n= 13	17	(1 - 51)	103 n= 11	(30 -185)
ITP in specific circumstances n= 27	31	(0 - 88)	74 n= 19	(12 – 186)
Refractory ITP n= 55	13	(1 – 76)	81 n= 43	(4 - 245)

IVIg Review: Resources – Vic / Tas

1 Dec 2008 – 31 Mar 2009

- 995 telephone calls by TN to clarify eligibility (all diagnoses) including ITP review
  - Average time per call (excluding ITP review) = 4 min
- 122 follow-up telephone calls to collect ITP review data (12.2% of all telephone follow-up calls)
  - Average time per ITP review call = 3½ minutes

Resources

- TN role covers both Victoria & Tasmania
- 1.5 FTE: ARCBS funded to cover IVIg management and special platelet support
- + 0.5 FTE: additional Vic Department of Human Services funding for IVIg Criteria implementation (6 + 6 month targeted funding)

Conclusions

- ARCBS Transfusion Nurses have a key role in IVIg management
- Communication integral component of *patient and product management*
- Management and review requires substantial resources and input
  - Determining eligibility
  - Review letters
  - Review telephone calls
- Victorian experience demonstrates doses between 0.8-1.0g/kg effective in ITP
- Information may help inform clinical practice and criteria review

Acknowledgements

- Plasma Donors
- Hospital scientific, medical and nursing staff caring for patients receiving IVIg
- ARCBS Transfusion Medicine Teams – medical, nursing, administrative staff, and ARCBS inventory and distribution in each operational unit

"We help transfuse"