NATIONAL
HAEMOVIGILANCE
OFFICE

ANNUAL
REPORT
1999

1 October 1999 – 31 December 1999
FOREWORD

The National Haemovigilance Office was officially launched by the Minister for Health and Children in November 1999 and the publication of this initial report represents a milestone in the development of best transfusion practice for the benefit of all patients requiring transfusions in the Republic of Ireland.

Although covering a very short period of time (1 October, 1999 to 31 December 1999) this represents a sizable number of transfusions of blood products, (in excess of 87,000).

The ultimate goal of this programme, is of course, to provide safe transfusion for all patients. Although this report focuses on adverse events, the office has also been involved in extensive interaction and feedback with the hospitals in the form of visits and educational advice which has been a pro-active and two way process.

The National Haemovigilance Office wishes to express a particular word of thanks to the Consultant Haematologists, Hospital Consultants, Pathologists, Chief Technologists, Transfusion Surveillance Officers and Laboratory Technology staff in the various hospitals throughout the country who have participated in this programme. Their input, experience and continued feedback is the foundation upon which this programme is based and the level of support and enthusiasm they have given has been most heartening. We would also like to thank the Hospital Administrative staff, Chief Executive Officers and Directors of Nursing.

Acknowledgement is also due to a number of people who have been involved in the development of the National Haemovigilance Programme including the Minister for Health and Children and his Department. We would like to acknowledge the support and advice of the Medical Director and staff of the Pharmacovigilance Department of the Irish Medicines Board. A special mention must be made of the National Haemovigilance Steering Committee, the National Blood Users Group and the Chief Executive Officer, the National Medical Director and Staff of the Irish Blood Transfusion Service.

The information collected is analysed and collated and will provide a means for establishing patterns in errors or reactions. It is through this that ultimately improvements in transfusion safety nationally will be achieved.

It is hoped that during the year ahead, a more complete overview of areas of transfusion risk and other difficulties will emerge, thus permitting an informed assessment of means by which patient welfare and care can be improved.

Dr Emer Lawlor
Director National Haemovigilance Office
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1. **Haemovigilance**

The term Haemovigilance can be defined as

“A set of surveillance procedures, from the collection of blood and its components to the follow-up of recipients, to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence”

The National Haemovigilance Scheme is a anonymised system similar to that in place for monitoring drug safety (Pharmacovigilance) and is dedicated to the improvement of practice within the transfusion chain at all stages from donor to recipient. The National Haemovigilance Office (NHO) has been established at the Blood Transfusion Service Board (BTSB) Headquarters in Dublin.

The remit of this office is to:

- Receive, collate and follow up reports from hospitals and general practitioners of adverse reactions to transfusion of blood components and provide feedback information to reporters as appropriate.
- Advise on the follow-up action necessary, particularly with regard to suspected hazards.
- Report adverse reactions to the Irish Medicines Board (IMB) according to an agreed procedure.
- Support the training of hospital-based Transfusion Surveillance Officers (TSO) and as appropriate, the training of medical, nursing and technical staff in haemovigilance.
- Provide medical and scientific analyses of adverse reaction reports.
- Advise on improvements on the safety of transfusion practice based on the data made available by hospitals.
- Advise on clinical guidelines and hospital practice in relation to the use of blood components.
- Advise on the recording of transfusion data by hospital staff.
- Support the audit function of hospitals in relation to transfusion practice.
- Report to the National Blood Users Group on a periodic basis.

The programme functions under the directorship of a Consultant Haematologist. A Clerical Administrator was appointed in November 1998 and two Transfusion Surveillance Officers (TSO) took up their posts in May 1999. A major part of their remit is education/training and support in relation to best transfusion practice at hospital level.
The NHO Staff spent much of the year in preparatory work, developing structures and systems necessary for the establishment and smooth operation of the National Haemovigilance Programme.

A number of general circulars were issued to Hospital/Health Care Managers and senior staff in Nursing and Laboratory areas. Considerable time was invested working with hospitals and their appointed TSOs, explaining the remit of the NHO and the support structures that are available to promote improvements in transfusion practice. With effect from 1 October 1999 the office commenced collecting reports of Adverse Events following transfusion of blood components/products.

2. National Haemovigilance Steering Committee
A multi-disciplinary National Steering Committee was established to oversee and monitor the initial implementation of the scheme. The members of the Committee maintain working relationships with the users of the scheme and takes into account feedback from users on aspects of the programme, thus monitoring progress and initiatives.

The membership is as follows:

Mr. Martin Hynes, (Chairman) Chief Executive Officer, BTSB
Dr. Emer Lawlor Consultant Haematologist BTSB
Dr. Joan O’Riordan Consultant Haematologist BTSB
Mr. Don Mullahy Senior Technical Officer BTSB
Sr. Deirdre Gough Transfusion Surveillance Officer St. James’s Hospital
Mr. Stephen McGrath Senior Medical Laboratory Technologist, Cork University Hospital
Dr. Fred Jackson Consultant Haematologist, Waterford Regional Hospital
Mr. William Moran Regional Manager, Acute Services, Western Health Board
Dr. Siobhan Jennings Specialist in Public Health Medicine, Eastern Health Board

3. Launch
The NHO was officially launched by the Minister for Health and Children, Mr. Brian Cowen, TD on Friday 12 November, 1999 at a Reception held at the Royal College of Surgeons, Dublin. Dr. Lorna Williamson, Director of Serious Hazards of Transfusion (SHOT) UK, gave the keynote address. Approximately 100 people, including representatives from senior medical, laboratory, nursing, hospital and Health Board administrative staff and the Department of Health, together with Senior Officers and Members of the Board of the BTSB were in attendance at this event.
4. **Education, Promotion and Developments**

A number of different means were employed in the promotion and support of improvements in hospital transfusion practices. A vital part of the support structures for the NHO is training and education programmes for nursing, medical and laboratory staff. One particular programme is arranged at Pelican House for newly appointed Hospital based TSOs, and it is proposed to continue this programme until all Hospital appointed TSOs have attended.

Two National Haemovigilance study days have been held. The first in April was a two-day event to introduce the scheme and a second, follow up one-day event, was held in November. Both were well attended by a cross section of disciplines from hospital/healthcare centres. The content of these study days was geared primarily at medical, nursing and laboratory hospital personnel, and had particular relevance for TSOs. The speakers included Consultant Haematologists, Blood Transfusion Technologists, TSOs, Pharmacovigilance experts and Risk Managers with hospital experience. It was suggested that future study days be held on a weekday, perhaps at a Regional venue. This matter will be considered next year.

Presentations have been made for senior Health Board personnel at local based venues in the North Eastern Health Board, the South Eastern Health Board, the Western Health Board and the Mid Western Health Board. A presentation was also given at the Medical Laboratory Technicians Association (MLTA) conference held in Kilkenny in November. Contact was made with General Practitioners at a Symposium held at Cappagh Orthopaedic Hospital. Within the BTSB, in-house information lectures have been arranged for Donor Attendants, Team Leaders and Nursing Staff.

The NHO Staff have also been actively establishing a network of contacts throughout the country by personal visits and regular correspondence. They have taken part in interview panels when requested by hospitals. Upon the appointment of hospital based TSOs, information packs and other correspondence have been supplied to encourage uniformity of practice and a free exchange of information.

Articles on Haemovigilance have been issued to a wide range of publications directed at a variety of disciplines including ‘GP Forum’, ‘Converse’ (Medical Laboratory Technician Journal), and PEI (Medical Supplies distributor). Circular letters were issued to Hospital CEOs and Secretary Managers with copies to senior nursing and laboratory personnel advising that the programme was fully operational.

Information on Haemovigilance can be directly accessed on the IBTS Website @ www.ibts.org.
5. **Reporting Forms**
A complete set of Reporting Forms have been compiled:

1. Initial Report Form
2. Incorrect Blood Component/Blood Product Transfused
3. Acute Haemolytic or Other Severe Acute Transfusion Reaction
4. Delayed Haemolytic Transfusion Reaction
5. Transfusion-Related Acute Lung Injury
6. Severe Acute Anaphylaxis/Anaphylactoid Reactions
7. Transfusion Associated Circulatory Overload
8. Post Transfusion Purpura
9. Transfusion Associated Graft versus Host Disease
10. Transfusion Transmitted Bacterial Infection
11. Transfusion Transmitted Viral Infection
12. Unusual Transfusion Reactions

6. **National Blood Users Group**
The National Blood Users Group, whose expertise includes specialists with a particular interest in blood utilisation, met constantly during the year both at sub-group and national level. Their primary goal is to develop and produce National Guidelines for the optimal use of blood and blood products based on research and practice.

7. **Hospital Transfusion Committees**
The NHO actively encourages and supports the development of multi-disciplinary Hospital Transfusion Committees. These provide a forum for discussion and exchange of views, thus ensuring local ‘ownership’ of issues that may arise. This is viewed as an essential element in the development of the role of Hospital based TSOs and also to the overall success of the National Haemovigilance Programme.

8. **Definition of Adverse Event/Reaction**

*Adverse Event:*
Definition: An undesirable experience occurring following administration of a blood component/product.

*Adverse Reaction:*
Definition: A reaction which is harmful and unintended and which occurs following transfusion of therapeutic volume of a blood component/product.
Serious Adverse Reaction:
These include adverse reactions, which fall into one or more of the following categories

- Fatal
- Life-threatening
- Require or prolong hospitalisation
- Permanently disabling or requiring treatment to prevent permanent damage or disability
- Potential to cause foetal harm

Reports received by the NHO were monitored for evidence of unexpected frequency of expected adverse events/reactions. No report fell into this category during this reporting period.

These were reports received by the National Haemovigilance Office during the three month period 1 October, 1999 to 31 December, 1999. As this is the early stage of Haemovigilance in the Republic of Ireland and the time period is only three calendar months, the statistical analysis must be viewed with caution.

Denominator: In an effort to put the following data in context, an analysis of the number of units issued in this period was also carried out. Details are as follows:

**Table 1: Platelets, Whole Blood and Fresh Frozen Plasma Units issued by BTSB (October – December 1999)**

<table>
<thead>
<tr>
<th>Month</th>
<th>Total Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 1999</td>
<td>31704</td>
</tr>
<tr>
<td>November 1999</td>
<td>27,706</td>
</tr>
<tr>
<td>December 1999</td>
<td>27,851</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>87,261</strong></td>
</tr>
</tbody>
</table>

A total of twenty-two (22) reports were received, - eighteen (18) of which met the criteria for a Haemovigilance event. Details are set out in Table 2 Event Reported Age/Event
Table 2 Events Reported Age/Event (n=18)

<table>
<thead>
<tr>
<th>Age Category</th>
<th>No. of Events</th>
<th>Event</th>
<th>IBCT</th>
<th>Anaphylaxis/Anaphylactoid</th>
<th>AHOSTR</th>
<th>Circulatory Overload</th>
<th>Unusual</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 yr-15yrs</td>
<td>4</td>
<td></td>
<td>3</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>16yrs-30yrs</td>
<td>2</td>
<td></td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>31yrs-45yrs</td>
<td>1</td>
<td></td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>46yrs-60yrs</td>
<td>5</td>
<td></td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>61yrs–75yrs</td>
<td>5</td>
<td></td>
<td>2</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>76yrs+</td>
<td>1</td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td></td>
<td>8</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

IBCT Incorrect Blood Component Transfused.
AHOSTR Acute Haemolytic or Other Severe Transfusion Reaction

Table 3 Haemovigilance Events Reported Event/Product implicated n=18

<table>
<thead>
<tr>
<th>Product</th>
<th>No. of Events</th>
<th>IBCT</th>
<th>Anaphylaxis/Anaphylactoid</th>
<th>AHOSTR</th>
<th>Circulatory Overload</th>
<th>Unusual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Cells</td>
<td>11</td>
<td>7</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Platelets</td>
<td>5</td>
<td>1</td>
<td>4</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>FFP</td>
<td>2</td>
<td>-</td>
<td>1</td>
<td>-</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>8</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Haemovigilance Incidents Reported Oct-Dec 1999
10. Incorrect Blood Component Transfused

**Definition:** Incorrect component transfused is the transfusion of a blood component which did not meet appropriate requirements and/or was intended for another patient.

This category accounted for 44% of incidents reported (8 of 18).

- No report received of Incorrect Blood Component Transfused involved the transfusion of ABO incompatible units, but referred to errors in labelling, issuing, storage and usage.

- None of these incidents were associated with morbidity or patient adverse events. However, the frequency of reports in this category highlights the need for attention to guidelines and extreme care when issuing blood components/products.

- Interestingly, the number of incidents in this category fits comparably with the number of incidents reported to Serious Hazards of Transfusion SHOT (UK) over the previous number of years.

This category can be further sub-divided into the following:

**Table 4 Incorrect Blood component Transfused (Breakdown of incidents)**

<table>
<thead>
<tr>
<th>Details of Incident</th>
<th>No of Events</th>
<th>Sequelae for Patient(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrectly labelled as Red Cell Concentrate rather than whole blood</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Emergency O Negative blood removed from storage site, crossmatched blood was available</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Antibody misidentification at laboratory</td>
<td>1</td>
<td>None</td>
</tr>
<tr>
<td>Incorrect pack issued by laboratory</td>
<td>3</td>
<td>None</td>
</tr>
<tr>
<td>Incorrect storage temperature in transit to Hospital</td>
<td>2</td>
<td>None</td>
</tr>
</tbody>
</table>
11. **Severe Acute Anaphylaxis/Anaphylactoid Reaction**

*Definition:* These reactions include those varying from urticaria and gastrointestinal discomfort to stridor, wheeze, bronchospasm, laryngeal oedema, hypotension and collapse. In their severest form, anaphylaxis reactions can be life threatening.²

This category accounted for 33% of incidents reported (i.e. 6 of 18). In all cases, patients recovered with no ill effects.

### 11.1 Events associated with transfusion of platelets: (4)

*Case 1* Urticaria, hypotension and restlessness developed during transfusion of seventh unit of single donor platelets leucodepleted using bedside filter.

*Case 2* Patient transfusion dependent and had multiple previous uneventful transfusion episodes. Transfused four days earlier and complained of urticarial reaction. Towards end of the transfusion via bedside leucodepleting filter, patient had symptoms of hypotension, urticaria, tachycardia, falling oxygen saturations and feeling unwell. Transfusion abandoned and piriton administered with effect.

- Due to the possible development of cytokines in platelets on storage, the introduction of pre-storage leucodepletion by the BTSB since November 1999 may impact positively on these reactions. However, of the four anaphylaxis/anaphylactoid reactions to platelets, two events occurred to pre-storage leucodepleted products. The NHO will continue to monitor any increased frequency of anaphylaxis/anaphylactoid reactions.

*Case 3* Symptoms of hypotension, substernal discomfort, dyspnoea, restlessness and urticaria occurred within first 100mls of transfusion of CMV negative irradiated leucodepleted platelets.

*Case 4* Symptoms of urticaria facial swelling, bronchospasm and dyspnoea developed at early stage of transfusion of pooled leucodepleted platelets.

- Where no existing policies on transfusion practice exist, Hospital Transfusion Committees are now developing local policies as a result of identifying these incidents.

- Where hospital policy on patient observation during transfusion was not adhered to, attempts are being made by hospital TSOs to reinforce guidelines to all members of staff. TSOs at the NHO are providing literature support with these efforts.
11.2 Event associated with transfusion of Fresh Frozen Plasma (FFP) (1)

Case 1 During transfusion of third unit of FFP, symptoms of severe urticaria occurred. Transfusion was abandoned and antihistamine given with effect.

- Education programmes outlining the benefits and complication of blood component therapy can achieve a reduction in both amounts of FFP to be transfused and the number of patients transfused for inappropriate reasons.3

11.3 Event associated with transfusion of Red Cell Concentrate (RCC) (1)

Case 1 During first 10 mls of first unit of leucodepleted prestorage RCC, this patient developed hypotension, gastrointestinal symptoms and generally feeling unwell. Patient IgA levels were checked and reported as normal. This patient will be subsequently managed with washed cellular components.
12 **ACUTE HAEMOLYTIC AND OTHER SEVERE ACUTE TRANSFUSION REACTION**

*Definition: Acute Haemolytic Transfusion Reactions are those occurring within twenty four hours of transfusion and leading to increased destruction of red blood cells in the recipient due to immunologic incompatibility between donor and recipient.* Acute Haemolytic Transfusion Reactions occurring due to incorrect blood component transfused are excluded as they are captured in a previous section.

For the purpose of this report, Severe Acute Non-Haemolytic Reactions are included here, however, Anaphylaxis/Anaphylactoid transfusion reactions are reported separately.

This category accounted for 6% of incidents reported (i.e. 1 of 18) Following this incident the patient rapidly recovered with no sequelae.

Group A positive patient received two units of Group O positive platelets since no Group A positive platelets were available. Immediately following platelet transfusion, the first of two units of RCC was transfused uneventfully. On commencing the second unit, fever, tachypnoea and hypotension developed. Transfusion was then abandoned and patient recovered uneventfully. As there was a clinical decision to administer non-group specific platelets due to product shortages, this event did not fall into the category of Incorrect Blood Component Transfused.

The incident was almost certainly caused by passive Anti-A1 reacting with the second Group A red cell unit. Since the patient was subgroup A2, he would not absorb the Anti-A1 from the platelet plasma, thus leaving it to react with the A1 unit transfused later. The transfusion of Group O platelets to Group A patients, although undesirable, is a fairly common practice when no Group A platelets are available.

This interesting case highlights to need to avoid, where possible, giving Group O plasma products to patients other than Group O. However, failure to give platelets may have been life threatening in this situation and clinical judgement must always take account of the balance of risk involved.
13. **Transfusion Associated Circulatory Overload**

*Definition:* In the elderly, the very small or the patient with cardiac compromise in the non-bleeding situation, rapid transfusion of blood or blood components can quickly lead to circulatory overload with congestive cardiac failure. There is a rise in blood pressure and in severe cases, left ventricular failure may develop.

This category accounted for 6% of incidents reported (i.e. 1 of 18)

This case involved the rapid transfusion of plasma for the reversal of warfarin overdose to a small elderly patient. During the fifth of six units of FFP, symptoms of circulatory overload developed. Patient did not receive diuretic cover with transfusion although on regular oral frusemide. The patient subsequently died of underlying disease, but it is likely that circulatory overload contributed to mortality.

This event reinforces the need to adjust amounts infused to small and/or elderly patients. A Haemovigilance document containing updated information on FFP usage is currently being compiled by the NHO to heighten awareness.
14. **Unusual Transfusion Reactions**

*Definition: These transfusion reactions include those that did not fit criteria for any other category, but which were serious and of significance to the Haemovigilance programme.*

This category accounted for 11% of incidents reported, (i.e. 2 of 18) but involved the same patient with IgA deficiency and IgA antibodies.

Symptoms of back pain and anxiety occurred during first 20-30 minutes of transfusion on two consecutive days. Subsequent investigation revealed no incompatibility, but deficient IgA and the presence of IgA antibodies. Future transfusion should be avoided but if essential would require use of extensively washed products or products from IgA deficient donors and under the supervision of the Consultant Haematologist.

Patients with anti-IgA antibodies often have anaphylactoid reactions following transfusion, but in this case the presentation was more like an acute haemolytic reaction. This event emphasises the need to check Anti IgA levels in patients with atypical reactions.
15. CONCLUSIONS & RECOMMENDATIONS

15.1 The frequency of reports received of Incorrect Blood Component Transfused highlights the need for extreme care when issuing blood components/products and for adherence to guidelines at all times. (Ref Section 10)

15.2 As the risks of circulatory overload and anaphylaxis are significant, the use of plasma should be carefully adjusted to the patients’ clinical condition in accordance with recommended guidelines and dosage/rates of transfusion. The NHO are currently devising updated information on the use of FFP to reverse warfarin, which will be circulated early next year. (Ref Section 13)

15.3 The single case of Acute Transfusion Reaction highlighted the ongoing need for adequate supplies of sufficient compatible blood. It also emphasises that the continued support of the blood donor is essential in the maintenance of a safe and sufficient blood supply. (Ref Section 12)

15.4 In view of the unexpected number of reports received in the Anaphylaxis/Anaphylactoid category, the NHO proposes to develop a protocol in the interest of patient care for these cases.

15.5 Patients with atypical or unexplained reactions should be reported and may need to be investigated further. (Ref Section 14)

15.6 Professional Health Care Workers who are involved in blood transfusion are expected to report all serious unexpected transfusion associated reactions.

15.7 A multi-disciplinary Hospital Transfusion Committee should review in detail all reported incidents or ‘near misses’, and provide a source of clear and co-ordinated guidelines regarding blood component/product availability, storage, use and administration. (Ref Sections 7 and 10)

15.8 It is recommended that an education and training programme be developed in hospitals and maintained to include all members of staff involved in the transfusion chain. The TSOs at the NHO will provide literature support and assistance in this area. (Ref Section 11)

15.9 Currently in Irish practice we are adhering to British Committee for Standards in Haematology (BCSH) guidelines. The National Blood Users Group, set up by the Minister for Health and Children, are developing guidelines in best transfusion practice, which are due to be published by the end of 2000. (Ref Section 6)
16. References


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