summary report. Important cases are extracted and shared to enhance awareness, including the preventive and corrective measures generated. If necessary, policy and guidelines would be developed or revised for service and practice improvement. Consequent to this haemovigilance mechanism, the first transfusion guideline across public hospitals territory-wide was developed in year 2004 and reviewed regularly thereafter. Similarly, an informed consent for blood transfusion was implemented in 2005.

In the private sector, there is no formal haemovigilance system established. Transfusion incidents and adverse transfusion reactions are handled by individual hospitals. They are also encouraged to inform the incident or reaction to the HKRCBTS, which can provide assistance in the investigation or implementation of improvement measures, if necessary.

For the donor aspect of the haemovigilance system, information is captured separately under the quality management system of the HKRCBTS.

Regarding optimal use of blood products, both the HKRCBTS and CTC strongly advocate optimal use of blood products. The CTC in conjunction with HTC plays the leading role in the monitoring of the utilization and wastage of blood products in public hospitals. The HKRCBTS also assisted the CTC to implement a benchmarking system in 2001 to compare the patterns of blood component utilization and wastage among hospitals with similar case mix and among the various medical specialties. A formal benchmarking report is provided to CTC and HTCs half-yearly. In addition, individual HTCs are advised to carry out transfusion audits to monitor the appropriateness of blood component utilization in their own hospitals. As an initiative to promote optimal use of blood products, training workshops and educational seminars in transfusion medicine are organized regularly. However, responses of individual hospitals to the advocate have been variable.

Question 2

The CTC made reference to successful examples in other countries and has established the operation of Transfusion Safety Officers (TSO) who are responsible to work outside the context of laboratory areas to improve transfusion safety and promote effective and appropriate use of blood. In Hong Kong, all public hospitals are grouped into seven geographical clusters for management. A cluster-based TSO pilot scheme has recently been put into trial in a few hospital clusters. The major responsibilities of TSO are: monitor hospital performance through surveillance of bedside processes related to blood requests and blood component administration, tracking data on key indicators of the transfusion process, including optimal use of blood products, participating in reporting, screening and follow-up of transfusion-related errors and incidents and educate clinical staff to recognize and report transfusion reactions and disseminate information on transfusion guidelines and the initiatives of judicious blood utilization. There are variations in the operating model of TSO; in one hospital cluster, the duties of TSO are ascribed to nursing staff committed to risk management.

With the objectives of minimizing unnecessary transfusion, conserving blood components and reducing healthcare expenditures, from time to time, small-scale hospital-based blood utilization audits are conducted. They are usually in the form of retrospective audits of utilization of specific types of blood product over a specified period of time and/or transfusion in specific surgical procedures or medical conditions. Criteria for the audits are set based on established international blood utilization standards [1–3] and local transfusion guidelines. Audit results are analysed and discussed at HTC and communicated to the clinical blood users, whenever possible, for any preventive and corrective measures to be adopted to enhance optimal use of blood components. Members of the CTC opined that cases of inappropriate and unnecessary transfusions should be reported as transfusion incidents; however, the policy has not been decided.

In 1996, a local district hospital has implemented the mandatory compliance with transfusion guideline for blood component requests. Briefly, the abridged guidelines and check-boxes are printed on the blood component request form for the requester to follow and check compliance. Any request outside the guideline must be supported by clinical justifications. The system was well accepted by clinicians who considered that the form had actually saved their time, because reference to the full transfusion guidelines is no longer necessary. In actual fact, it was observed that inappropriate transfusion was significantly reduced [4]. In 2007, this concept was further extended into a territory-wide computer system, known as Generic Clinical Request System – Laboratory Request System (GCRS-LRS) for blood requests in public hospitals with variable degrees of success.

C. K. Lin, C. K. Lee & W. C. Tsoi
Hong Kong Red Cross Blood Transfusion Service
15 King's Park Rise
Kowloon, Hong Kong, China
E-mail: cklin@ha.org.hk

References

1 Stehling L, Luban NL, Anderson KC, Sayers MH, Long A, Attar S, Leitman SF, Gould SA, Kruskall MS, Goodnough LT: Guidelines for blood utilization review. *Transfusion* 1994; 34:438–448
2 AABB Scientific Section Coordinating Committee: Guideline for Blood Utilization Review. ??????, AABB Press, 2001

3 UK Blood Transfusion and Tissue Transplantation Services: Better Blood Transfusion Toolkit – Appropriate Use of Blood – The Appropriateness of Blood Transfusion Audit. 2009. http://www.transfusionguidelines.org.uk/docs/pdfs/bbt-01_appropriate-transfusion-guidelines.pdf

4 Cheng G, Wong HF, Chan A, Chui CH: The effects of a self-educating blood component request form and enforcements of transfusion guidelines on FFP and platelet usage. Queen Mary Hospital, Hong Kong. British Committee for Standards in Hematology (BCSH). *Clin Lab Haematol* 1996; 18:83–87

E. Lawlor

Question 1

A haemovigilance system is in place in Ireland since October 1999 to collect serious adverse reactions and events associated with blood transfusion. The National Haemovigilance Office (NHO) in the Irish Blood Transfusion Service (IBTS) collects both clinical errors called Incorrect Blood Component Transfused (IBCT) and errors that are now categorized as Serious Adverse Events under the EU Blood Directive 2002/98/EC. Included in the definition of IBCT are unnecessary transfusions and a number of these mostly involving red cells but also platelets and plasma are reported every year. Figures for 2006 showed that unnecessary transfusions were the highest single error accounting for 33% of all reports in the IBCT/SAE category.

Integral to the NHO scheme since its inception is the presence of at least one haemovigilance officer (HVO) with a nursing or laboratory background in each hospital or group of small hospitals who, in addition to adverse event and reaction investigation and reporting, is involved in the development of standard operating procedures and guidelines for blood administration and blood use, staff education and audit of component use.

The HVO generally works within a dedicated haemovigilance team along with a medical scientist, which is generally led by a consultant haematologist.

Question 2

Audit is an important tool, but optimal blood use requires a number of key interventions involving availability of guidelines, education of medical and nursing staff, effective audit tools and evaluation and feedback of findings.

National blood usage guidelines developed by the National Blood Users Group (1999–2007) are in place for surgical blood use [1], massive transfusion [2] and neonatal transfusion [3], and the British Committee for Standards in Haematology and Blood Transfusion (BCSH) guidelines [4] are widely adopted by Irish clinicians and hospitals.

Education of medical staff in optimal blood transfusion is challenging and needs input at undergraduate level followed by targeted education throughout their hospital careers. Induction programmes for first year doctors have been developed and delivered by HVOs together with haematologist input in most hospitals, but ensuring attendance of more senior grades can be problematic. The Scottish National Blood Transfusion Service (SNBTS) e-learning programme (Learn Blood or learnProNHS http://www.learnbloodtransfusion.org.uk), which is made available to Irish hospitals through the IBTS who hold a licence and which is administered by HVOs, is an extremely useful adjunct to the HVO educational tool-kit. Each module of this programme has a competency assessment which staff can take and obtain a certificate valid for 2 years.

The NHO in conjunction with Dublin City University has also run professional development modules aimed at nursing, scientific and haemovigilance professionals, incorporating lectures on optimal blood use from experts in the field of transfusion medicine in Ireland. It also supports the continuing professional development of those working in transfusion practice through an annual national conference workshops and open days and publication of an annual report with recommendations on transfusion practice [5]. The NHO has also given advice and input to development of a number of audit tools (platelet usage, transfusion in iron deficiency) in association with the hospitals and intends to expand this aspect of the NHO activities if resources permit.

HVOs are ideally placed to undertake audit but require the support of senior medical staff and to be of use, audit results must be reviewed by a haematologist and/or by a clinician working in the relevant area, and the key findings discussed by an oversight committee such as the Hospital Transfusion Committee who in turn should report remedial actions if required to the Medical Board and Hospital Management.

The amount of audit undertaken varies from hospital to hospital and is dependent on resources. Figures for 2007 [5] and 2008 (unpublished) show that the numbers of unnecessary transfusions reported are down on 2006 figures. This may reflect improved clinical practice, but the increasing traceability requirements of EU Directive 2005/61/EC and achievement of the ISO 15189 quality standard to which Irish hospital blood banks must adhere may have impacted on the extent of audit, which is being undertaken.

E. Lawlor, FRCPath, FRCPI
National Haemovigilance Office
Irish Blood Transfusion Service
James's Street
Dublin 8
Ireland
Tel.: +353 1 4322887
Fax: +353 1 4322933
E-mail: emer.lawlor@ibts.ie

References

1 National Blood Users Group: A Guideline for Transfusion of Red Blood Cells in Surgical Patients. Dublin, Department of Health, 2001

2 National Blood Users Group: A Guideline for the use of Blood and Blood Components in the Management of Massive Haemorrhage. Dublin, National Blood Users Group, 2002

3 O'Riordan JM *et al*; for National Blood Users Group: Transfusion of blood components to Infants under four months: review and guidelines. *Ir Med J* 2007; 100 S1–S24

4 British Committee for Standards in Haematology: http://www.bcshguidelines.com/ (last accessed 5/11/09)

5 National Haemovigilance Office Annual Reports 2000–2007 http://www.giveblood.ie/Clinical_Services/Haemovigilance/Publications/

G. Grazzini, V. Piccinini, L. Catalano & S. Pupella

Question 1

Until 2007 in Italy, haemovigilance (HV) data had been collected on a voluntary basis by a limited number of Blood Transfusion Centres (BTCs), and comprehensive national information on serious adverse reactions and events (SARE) in the transfusion chain was not available. Following the transposition of Directive 2005/61/EC [1], previous systems for collecting HV information were abolished, and a new mandatory national HV system was implemented that has been actually in place since April 2009. The Italian HV system collects information on SARE potentially affecting quality and safety of blood and blood components, and it also includes the national surveillance of transfusion transmissible infections (TTIs), which is aimed at periodically defining the prevalence and incidence of HBV, HCV, HIV and Treponema infections in blood donors to assess their residual risk to be transmitted by transfusion.

According to the HV system's regulation, BTCs are entrusted with the collection of data. This task is easily accomplished, because in Italy, BTCs are by law [2] public hospital-based services, mostly organized in wider multiple-hospital blood departments and regionally co-ordinated. Importantly, the HV system is fully integrated in the new national blood information system (SISTRA – *Sistema Informativo dei Servizi Trasfusionali*), which is a Web-based system managed by the National Blood Centre (NBC) establishing the set of information to be mandatorily provided by BTCs and Regional Blood Coordinating Centres (RBCCs). Serious adverse reactions involving transfused patients and blood donors (grade 3–4 severity and grade 2–3 imputability), serious incidents (SI) that may occur throughout the transfusion chain, as well as information concerning TTI surveillance must be notified by the BTCs to the RBCCs; the latter are entrusted with producing comprehensive periodical regional reports to be notified to the NBC.

The HV system does not directly include data concerning the optimal use of blood products, but essential information about the use of blood components (BCs) will be available from SISTRA and will be easily utilized for HV purposes the HV system being a part of SISTRA itself. Evidence-based scientific support for the optimal use of blood products has been recently provided by the recommendations for the use of BCs and plasma-derived products (PPs) published by the Italian Society of Transfusion Medicine and Immunohaematology (SIMTI) [3–6]; they represent a fundamental reference tool for BTCs and are being adopted as main reference standards by most hospital transfusion committees (HTCs) all over the country.

Question 2

In Italy, HTCs are multidisciplinary teams instituted by law [2] in each hospital or group of associated hospitals to locally promote best practices in BC transfusion, including BC quality and safety issues, and PP utilization. The pivotal role of HTCs consists of the definition and diffusion of local transfusion policies and the dissemination of transfusion guidelines and protocols. Furthermore, they have to perform continuous assessment of appropriateness and safety of transfusion practices by monitoring locally and nationally defined indicators and by carrying out periodical and *ad hoc* audits. Hence, most HV issues are naturally dealt with in HTCs. BTCs' clinical staff play a fundamental role within HTCs both as a provider of transfusion medicine expertise and as a data provider. Importantly, according to a very recent official agreement among the Ministry of Health, in the NBC and the RBCCs, a physician in charge of HV must be in place in each BTC/blood department, and each RBCC must have a HV officer. This HV reference staff will usefully contribute to the mission of HTCs, which is focused on the optimal use of blood products in hospitals.

G. Grazzini, V. Piccinini, L. Catalano & S. Pupella
Italian National Blood Centre
Via Giano della Bella, 27
00162 Roma, Italy
E-mail: direzione.cns@iss.it

References

1 Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events. Official Journal of the European Union, L 256/32-40, 1.10.2005

2 Legge 21 ottobre 2005, n. 219. Nuova disciplina delle attività trasfusionali e della produzione nazionale di emoderivati. Gazzetta Ufficiale della Repubblica Italiana n. 251 del 27 ottobre 2005

3 Liumbruno G, Bennardello F, Lattanzio A, Piccoli P, Rossetti G [as Italian Society of Transfusion Medicine and Immunohaematology (SIMTI) Working Party]: Recommendations for the transfusion of red blood cells. *Blood Transfus* 2009; 7:49–64
4 Liumbruno G, Bennardello F, Lattanzio A, Piccoli P, Rossetti G [as Italian Society of Transfusion Medicine and Immunohaematology (SIMTI) Working Party]: Recommendations for the transfusion of plasma and platelets. *Blood Transfus* 2009; 7:132–150
5 Liumbruno G, Bennardello F, Lattanzio A, Piccoli P, Rossetti G [as Italian Society of Transfusion Medicine and Immunohaematology (SIMTI) Working Party]: Recommendations for the use of albumin and immunoglobulins. *Blood Transfus* 2009;7:216–234
6 Liumbruno G, Bennardello F, Lattanzio A, Piccoli P, Rossetti G [as Italian Society of Transfusion Medicine and Immunohaematology (SIMTI) Working Party]: Recommendations for the use of antithrombin concentrates and prothrombin complex concentrates. *Blood Transfus* 2009; 7: 325–334. DOI: 10.2450/2009.0116-09

H. Kato, S. Takamoto, H. Okazaki & I. Hamaguchi

Question 1

A complete haemovigilance system has not been established yet in Japan, but one is on the way. The Japanese Red Cross (JRC) established a haemovigilance system as early as 1993. However, the system has been utilized by medical doctors mainly for the purpose of examining the cause of adverse reactions. Accordingly, the reports have tended to be limited to moderate to severe cases, and the number of cases has been underestimated. On the other hand, we, the Aichi Medical University group, started to collect data on adverse reactions to blood transfusion from five selected hospitals as well as 214 ordinary hospitals, with a research grant from the Ministry of Health, Labour and Welfare (MHLW) in 2004. In fact, the rate of events per bag in our study is about 50 times higher than that of the JRC system. Thus, we have been trying to establish a haemovigilance system that reflects the actual events across the whole of Japan. The study also aims to standardize items and criteria relating to adverse reactions in Japan. Another project is running to establish an online network system of haemovigilance, also with a grant from the MHLW.

Regarding the optimal use of blood products, the first guideline was published by the MHLW in 1986 and carried out in practice, and it has been revised two times. Therefore, the haemovigilance system does not include the optimal use.

Question 2

A transfusion committee has been established in more than 90% of hospitals in Japan. The members of the committee comprise the hospital director, medical doctors, technologists, nurses and office workers. The committee checks the optimal use of blood products and compliance with guidelines and also analyses reports of adverse events in hospitals. The committee investigates the status of usage and optimal use of blood products, reports of adverse events and the management of transfusion medicine once every 2 months.

H. Kato
Department of Transfusion Medicine
Aichi Medical University, 21, Karimata
Yazako, Nagakute, Aichi 480-1195, Japan
E-mail: hkato@aichi-med-u.ac.jp

S. Takamoto
Department of Transfusion Medicine
Aichi Medical University, 21, Karimata
Yazako, Nagakute, Aichi 480-1195, Japan
E-mail: shigetan@aichi-med-u.ac.jp

H. Okazaki
Central Blood Institute, Blood Service Headquarters
Japanese Red Cross Society
2-1-67, Tatsumi, Koto-ku
Tokyo 133-8521, Japan
E-mail: h-okazaki@jrc.or.jp

I. Hamaguchi
Department of Safety Research on Blood and Biological Products
National Institute of Infectious Diseases
4-7-1, Gakuen, Musashimurayama
Tokyo 208-0011, Japan
E-mail: 130hama@nih.go.jp

J. C. Wiersum-Osselton, A. J. W. van Tilborgh, P. Y. Zijlker-Jansen, K. M. Mangundap & M. R. Schipperus

Question 1

A national haemovigilance system has been in place in the Netherlands since 2003 and is run by an independent foundation, 'Transfusion reactions in patients' (TRIP). TRIP's board is composed of representatives of the professional societies involved in blood transfusion. An annual budget is allocated by the Ministry of Health from the revenue of blood components. TRIP uses a broad definition of haemovigilance, extending it to cover all that may contribute to a safer and more effective use of blood products. By definition, therefore, TRIP regards optimal blood use as part of its remit.

From its inception, TRIP has registered all types of transfusion reactions, both minor and serious. Besides the category of incorrect blood component transfused, TRIP also receives reports on near miss and other incidents. Reporting is voluntary in principle but regarded as the professional standard; reports to the competent authority are sent in parallel to TRIP and the authority, a process that is

facilitated by the TRIP online reporting system. So far, optimal blood use has not been the direct focus of data collection. However, suboptimal blood use is concerned in some of the reports analysed.

Some of the reports highlight suboptimal blood transfusion practice, e.g.

- Unnecessary transfusions (such as transfusion on the basis of erroneous Hb result) are captured and reported on as 'other incident'.
- Traceability failure where actual transfusion of a selected and issued unit is not documented by returned compatibility form or any record in the intended recipient's case notes.
- Transfusion lasting beyond 6 h after removal from controlled temperature storage or after expiry of cross-match validity.

In addition, the analysis of other reports of both incidents and transfusion reactions repeatedly reveals that the transfusion was (most probably) medically unnecessary or inappropriate. Hitherto, TRIP has commented on failings of transfusion practice but refrained from discussing medical judgement or observance of transfusion triggers.

There are several reasons why optimal blood use is likely to become a more formal focus of national data capture and reporting in the future.

(1) In hospitals, 'haemovigilance' already embraces not only the reporting of adverse reactions and incidents but also the optimizing of blood transfusion practice. The prospect of optimizing (i.e. generally reducing) blood use was a major trigger for appointments of haemovigilance assistants (see remarks below).

(2) Haemovigilance is all about safety of patients, safety of blood components, safe blood transfusion practice and avoiding preventable harm. Instant reduction of risks can be obtained by eliminating unnecessary use of blood, providing this is achieved in a controlled manner and evaluated accordingly.

(3) The national transfusion guideline, currently undergoing revision, recommends the use of performance indicators for evaluation of the transfusion chain and of transfusion practice. This is primarily the task of hospitals themselves. However, it is foreseeable that organizations will wish to benchmark their transfusion practice. TRIP is considering the development of performance indicators of hospital transfusion practice and optimal blood use.

(4) Currently, the Netherlands are fortunate in that there is no shortage of blood components, nor of voluntary blood donors. The changing demography is likely to lead to an increased use of blood. The Minister of Health's regular review of the state of the blood supply (Ministerieel Plan Bloedvoorziening 2009–2011) refers to the need for appropriate blood use and for appropriate safety measures in the whole transfusion chain. It is in the interests of the national blood supply and of transparency to move towards some form of voluntary monitoring of optimal blood use. Collection of information should not be an end in itself but serve to improve practice.

(5) TRIP annually requests hospitals for minimum data on their blood use (number of units transfused in the main product types). This serves as a denominator for the reported transfusion reactions and incidents. Frequently, hospitals have asked whether they are above or below the national average in reporting adverse reactions and events. For a number of years, TRIP has responded to this and supplied hospitals with graphs showing their own reporting rates in comparison to the national rate. TRIP would be the obvious organization to collect national data and set up benchmarking against the national transfusion guideline.

(6) TRIP conducted a voluntary pilot survey of hospital administrative procedures for traceability of transfusion regarding reporting year 2008.

Question 2

TRIP has a regular contact person in each hospital, the haemovigilance officer who is generally a leading biomedical scientist or haematologist (in the Netherlands, haematology is a primarily clinical medical specialty) without specific time allotted to haemovigilance. Many hospitals have also appointed a ; to perform tasks such as preparing reports to TRIP, running training sessions for nursing staff, revising protocols or drawing up uniform blood order lists for types of surgical procedures. Intermittent or continuous audit of blood use or other relevant aspects of transfusion practice will be designed and generally carried out by the haemovigilance officer and assistant (other names are sometimes used, such as haemovigilance adviser, co-ordinator or consultant) in collaboration with the multidisciplinary hospital blood transfusion committee.

From this, it follows that if data on optimal blood use are to be collected nationally, the usual routes of communication will be used. Materials that are developed will be based on the national transfusion guideline using any available models from hospitals that already have experience of using indicators of optimal blood use. The materials will be evaluated or adjusted in the light of findings and user experience.

Disclaimer

The views expressed in this response are those of the authors and do not necessarily represent those of the TRIP Foundation board.

J. C. Wiersum-Osselton, A. J. W. van Tilborgh, P. Y. Zijlker-Jansen, K. M. Mangundap & M. R. Schipperus
TRIP Dutch National Haemovigilance Office
P.O. Box 40551
4501 LN The Hague, The Netherlands
Tel.: +31 70 3083120
Fax: +31 70 3682626
http://www.tripnet.nl
E-mail: info@tripnet.nl

D. Dinesh & P. Flanagan

Question 1

The New Zealand National Haemovigilance Programme was established in May 2005. Reporting of transfusion-related adverse events to the scheme is voluntary. To date, reports have been received from all (21) District Health Boards. The overall rate of reports received by the National Haemovigilance Programme is approximately 1 in 300 units transfused.

In 2008, 7% reports were classified as 'incorrect blood component transfused' (IBCT). Approximately, half of the errors originated during prescription or administration of the blood product and the other half originated in the laboratory. IBCT includes inappropriate transfusion as well as prescribing/dispensing errors. The haemovigilance notification form includes a section to enter pretransfusion haematology results, i.e. haemoglobin if red cells transfused, platelet count if platelets transfused, INR if plasma transfused and fibrinogen if cryoprecipitate transfused. These pretransfusion values may be used as a surrogate marker for appropriate (or inappropriate) transfusions but alone are not sufficient to assess overall optimal use of blood products, as information on other factors influencing the decision to transfuse may not be provided.

The Haemovigilance Programme therefore does provide an avenue for assessment of optimal (or suboptimal) use of blood products; however, it is unlikely to capture data that could be more comprehensively acquired via an audit process.

Question 2

The New Zealand Blood Service (NZBS) is directly responsible for the provision of hospital transfusion services in the larger hospitals in New Zealand. NZBS manages six major hospital blood banks. Each of these sites has a full-time Transfusion nurse specialist (TNS) whose primary role is to provide staff education and participate in audit initiatives involving hospital blood product usage. In recent years, two non-NZBS hospital blood banks have also appointed a TNS. The TNSs are frequently involved in reporting events to the Haemovigilance Programme. Over 70% of blood products transfused in New Zealand take place within these 6–8 hospitals. Table 1 summarizes the multicentre audits undertaken by the TNSs. Blood product usage is audited to established guidelines produced by ANZSBT (Australia and New Zealand Society of Blood Transfusion), NHMRC (National Health and Medical Research Council of Australia) and AHMAC (Australian Health Ministers Advisory Council).

Table 1 Summary of New Zealand transfusion audits

Audit	Number of centres	Audit period
Overnight transfusion	5	2004
Cryoprecipitate usage	6	2004
Intragam P (IVIG)	8	2004–2005
Irradiated component usage	6	2004 (retrospective)
Platelet usage	7	2005–2006
Fresh frozen plasma usage	6	2007
Red cell usage	7	2008
Rh D immunoglobulin	8	In progress

The final audit reports are sent to the Hospital Transfusion Committees, so that appropriate actions can be undertaken. The audit reports outline specific recommendations based on audit results and conclusions. The reports demonstrate individual hospital data, so that each site can compare their usage to other hospitals. Audit summaries are also published in 'Blood Issues', the Transfusion Medicine Newsletter that is produced and circulated 2–3 times per year by NZBS. This feedback process is crucial in ensuring the optimal use of blood products.

In summary, we have effective systems in place to monitor blood product usage in New Zealand. Although the audit and educational activities are vital in ensuring optimal use of blood products, maintaining a high standard of transfusion practice and reducing the occurrence of transfusion related adverse events, our situation demonstrates that they do not need to be included in the haemovigilance system.

D. Dinesh
New Zealand Blood Service
Private Bag 7904
Wellington 6242
New Zealand
E-mail: dorothy.dinesh@nzblood.co.nz

P. Flanagan
New Zealand Blood Service
Private Bag 92-071
Auckland 1142
New Zealand
E-mail: peter.flanagan@nzblood.co.nz

Ø. Flesland, C. T. Steinsvåg & A. Espinosa

Question 1

Yes, a haemovigilance system has been in operation since January 1st 2004. Both transfusion reactions and donor complications have been reported, including 'incorrect blood component transfused'. Since January 1st 2007, near-misses have also been reported [1].

Optimal use of blood in the hospital is not part of the system. In the 'incorrect blood' category, we have had two reports of transfusion with wrong indication. Both were owing to erroneous Haemoglobin reports. We also have a category; lack of effect of transfusion.

Optimal use of blood could be included in the Haemovigilance system or in the National transfusion statistics. All Norwegian patients are registered electronically with diagnosis codes and procedure codes, and it is technically possible to link this to the blood banks information system. Hence, it is possible to determine the use of blood components related to diagnosis and procedures on a local, regional and national level. This could be useful for comparing transfusion practice, but because we do not know what is the correct use of blood, the value of doing this is limited, unless it leads to research. The haemovigilance system could play a role in this, e.g. by supplying data and help with analysis. Hospital transfusion committees are recommended in the Norwegian guidelines in transfusion medicine, and these committees may play an important role in optimal use of blood on the local level, especially if they are supplied with correct data.

In Norway, the drive for correct use comes from clinicians who strive for best practice, and it comes from the hospital blood banks that struggle to supply enough components, and at the same time, find themselves under financial pressure, because most are not paid per component supplied but have a fixed annual budget. Interestingly, we have had a debate on whether the hospital blood banks need to know the indication for use, or if that is a matter solely between the patient and his or her physician. Most blood banks ask for indication for use on the order form, and sometimes the requests are checked against the latest haemoglobin or platelet values from the clinical chemistry laboratory. Our experience is that cliniclans find the blood banks involvement in optimal use of blood useful.

Ø. Flesland, C. T. Steinsvåg & A. Espinosa
The Norwegian Knowledge Centre for the Health Services
PO Box 7004, St Olavs plass
NO-0130 Oslo, Norway
Tel.: +47 46400487
E-mail: Oystein.flesland@kunnskapssenteret.no

Reference

1 http://www.hemovigilans.no

M. Letowska, A. Rosiek, J. Antoniewicz-Papis & E. Lachert

Question 1

In Poland, there is an established national system of haemovigilance as integral part of national supervision over the Polish Health Service implemented by Polish law in 2005, and it covers all adverse events and reactions of the transfusion chain. Hospitals are obliged to immediately report all post-transfusion complications, adverse reactions and near-miss events.

In our country, the optimal use of blood components in hospitals has not yet become part of the system; however, the Institute of Hematology and Transfusion Medicine (IHTM) takes the stand that this aspect of haemovigilance should be included in the overall system as soon as possible. To improve the safety of blood and blood components for clinical use, IHTM is active in international organizations and together with representatives of other European communities participates in developing programmes that may help to resolve challenges to safe blood transfusion practice and optimal blood use. The IHTM:

- is active in the EU Optimal Blood Use Project (EUOPUP) that will result in international recommendations to be implemented in our national haemovigilance system.
- has just completed a series of training courses on Blood Transfusion that were targeted at different professionals dealing with blood and blood components, employed in regional blood centres, blood banks and hospitals. These training sessions were conducted within the framework of the EU Project Transition Facility 2006/018-180.03.05 'Development of institutional control over the safety and quality of human blood and blood components' where one of the goals was the implementation of the EU *acquis* regarding blood and blood components (Directive 2002/98/EC, Commission Directive 2004/33/EC, Commission Directive 2005/61/EC, Commission Directive 2005/62/EC) to improve adequate knowledge on the safety and quality of blood and blood components. Within this programme, we have already trained 100 medical professionals who in turn shall act as trainers for other hospital doctors.
- plans the issue of special recommendations and further training of doctors and other medical personnel in hospitals and Regional Blood Transfusion Centres (RBTCs) (in 2010).
- participates in the Project 'Comprehensive computerization of blood transfusion service in Poland' – PL0067 financed from the resources of Financial Mechanisms EOG.

Question 2

The optimal use of blood products in hospitals planned as part of the haemovigilance system in Poland.

The blood transfusion service (BTS) in Poland is a public system, based on 21 RBTCs, one Military Blood Transfusion Center and one Blood Transfusion Center of the Ministry of Internal Affairs. The National Center for Transfusion Medicine in co-operation with the Institute of Hematology and Transfusion Medicine in Warsaw is responsible for the activity of BTS. The Institute of Hematology and Transfusion Medicine is the supervising authority, which, among others, is responsible for the haemovigilance system, because it receives reports of adverse reactions, post-transfusion complications and 'near-miss' events from the RBTCs and from hospitals as well as supervises immunological, viral, bacterial as well as TRALI reactions and supports the RBTCs with the laboratory diagnosis of certain types of adverse reactions.

There are 794 hospitals in our country that perform blood transfusions, and in 315 of them, there are hospital transfusion committees; in smaller hospitals, this activity is supervised by a doctor responsible for blood management. The task of the blood transfusion committee or officer/doctor responsible for blood management is, among others, to review indications for transfusion, to analyse the usage of blood and blood components, to evaluate transfusion methodology, post-transfusion complications, 'near-miss' events and to prepare internal training programmes for doctors and nurses as well as to participate in planning the supply of blood and blood components. The personnel should be periodically trained to perform these tasks in accordance with the constantly modernized methods of transfusion practice.

Our aim is the further strengthening of the Polish haemovigilance system, which should be more developed and elaborated. The number of reports of adverse events and reactions is relatively low, taking into account the number of blood components transfused, which is about 1·5 million per year.

We plan to fulfill this task by implementing a modern IT system to link hospitals with regional centres for automatic data transfer of orders for blood components, confirmations of transfusions completed as well as reports of adverse transfusion events and reactions. Such efficient system will ensure a step by step follow-up of blood donation from the moment of donor registration, through testing, blood collection, processing, distribution to hospitals and patients.

A strong tool of quality system and optimal blood use as part of haemovigilance is internal audits that can help to verify the compliance with all the current legislation and guidelines and to prepare for external audits and national inspections. Internal audits can be carried out by people working in the very institution or by an external organization and are intended for self-improvement purposes. Internal audits must be objective, impartial and independent, as well as focused on the main subjects related to quality and haemovigilance, namely statistic treatment and corrective and preventive measures related to non-conformities, errors and near-misses.

Education and training related to the diagnosis and treatment of all adverse events and reactions should be carried out in all RBTCs and in all hospital wards, and technical material related to these subjects should be distributed among different professionals. This is the first step in a haemovigilance system. One of the crucial aspects is to stress the importance of blood transfusion on every hospital ward, to improve supervision and control as well as to create opportunities for analysing the use of blood and blood components.

To facilitate the relationship between institutions with the aim of strengthening haemovigilance, it is advisable and important to organize and perform regular meetings with professionals from RBTCs, blood banks and hospitals during which clinical practice should be presented to emphasize the significance of 'minimal things' such as errors, near-misses, registers, reports, in the everyday transfusion practice.

M. Letowska, A. Rosiek, J. Antoniewicz-Papis & E. Lachert
Institute of Hematology and Transfusion Medicine
Indira Gandhi 14, 02-776 Warsaw, Poland
E-mails: letowska@ihit.waw.pl;
arosiek@ihit.waw.pl;
jpapis@ihit.waw.pl;
lachert@ihit.waw.pl

M. B. C. Koh & R. Alcantara

Question 1

The Singapore National Haemovigilance Program officially started in 2003 as a voluntary reporting system composed of four hospitals, and by 2004, all hospitals administering blood transfusions participated in the programme. It continues to be run today as a voluntary, non-punitive programme.

Although there are hospital transfusion committees (HTC) in the hospitals, there is no mandatory blood transfusion utilization audit or review required in individual hospitals. Nonetheless, as part of good clinical practice, such audits on blood utilization are carried out. In Singapore, we have a centralized transfusion service, and the requesting doctor is referred to transfusion medicine doctors and consultants to discuss various transfusion indications. There is

also usually input for massive transfusion. This can in some ways be considered as a concurrent review for the optimal use of blood products. Prospective and retrospective audits of different blood component usage are also carried out from the available data. An ongoing study is the inappropriate use of FFP and cryoprecipitate.

Institutions that administer blood transfusions should have procedures and processes in place to monitor and discourage the wastage and inappropriate use of blood products. This is integral to good clinical practice. Transfusion practice should be audited to comply with regulatory and quality standards. Although the decision to transfuse is mostly based on clinical judgment and findings, there is now a vast body of literature on guidelines and thresholds for transfusion of each of the relevant blood components. Inappropriate, unnecessary and non-evidence-based decisions to transfuse may result in more harm than benefit to a patient. Although traditionally not looked upon as a 'classical' transfusion error, this inappropriate usage of blood may actually be the largest source of preventable error that would benefit from further systematic scrutiny.

An important step to achieve this is the establishment of national or regional evidence-based clinical guidelines for blood transfusion. This is currently in the process of being published in Singapore, and the multi-disciplinary panel consists of haematologists, transfusion medicine consultants and end users such as surgeons, interventional radiologists and gynaecologists.

Question 2

One of our immediate short-term goals is to discuss with the HTC on implementing a blood transfusion utilization review or audit with a designated staff (haemovigilance officer or clinical nurse practitioner) assigned in each hospital. A summary of the audit findings and other pertinent findings will be forwarded to the Singapore National Haemovigilance Program for collation and analysis.

The other advantage of a centrally organized system such as in Singapore is the ability to review national usage and across individual hospitals. This is already currently being performed. In addition, for certain blood products such as platelets and cryoprecipitate, prior approval is required from one of the transfusion medicine doctors. Therefore, usage data and clinical conditions for the usage are also available.

M. B. C. Koh & R. Alcantara
Blood Services Group
Health Sciences Authority
11 Outram Road
Singapore 169078
Singapore
E-mail: mickey_koh@hsa.gov.sg

M. Corral Alonso & E. Muñiz-Diaz

Question 1

Officially, Spain has had a state haemovigilance system since 2004. This state system has been made possible following the creation of 17 haemovigilance systems for each of the 17 autonomous communities that, from the administrative point of view, comprise the Spanish state. Central government has transferred the competences for health to the respective governments of these autonomous regions, which are responsible for managing all health-related matters, including blood transfusion and, therefore, haemovigilance. The Spanish Ministry of Health continues its role as the highest competent authority, produces an annual report that includes the notifications provided by the autonomous communities and passes on such information to the European Commission as the latter requests from it.

The optimal use of blood components is not incorporated into the haemovigilance system of the autonomous communities. Nevertheless, some hospitals in Spain are already working on this matter, especially the hospital services with the greatest activity in the field of transfusion. Daily vigilance of adequate use is the responsibility of the professional who heads the hospital transfusion service, and the transfusion committee usually regularly assesses this activity to analyse possible deviations and to implement the appropriate corrective measures.

The Spanish example demonstrates that it is not essential to incorporate the matter of optimum use into the haemovigilance system. Once again, the professionals in charge of transfusion within the hospital have begun to address the matter of optimal use before putting in train any initiative for including optimal use in the haemovigilance system or, simply, of co-ordinating this personal effort through a programme with similar characteristics to that of haemovigilance. To date, no official initiative has been instigated in this sense, but should this come about, it will be necessary once again to rely on the opinion and good will of the different autonomic regions.

Given that the European Haemovigilance Network (EHN), now called the International Haemovigilance Network (IHN), during its tenth meeting, in Frankfurt (Germany), adopted optimal use as a new objective for discussion at its annual meetings, with the aim of encouraging the development of this subject in the member countries, in the hope that many of these countries will follow the example and finally adopt the same strategy. In more than 15 years that have passed since the creation of the first haemovigilance system, all the countries of the European Community have their own system of haemovigilance, albeit at different stages of development. With respect to this, the incorporation of optimal use into the haemovigilance

system represents a coherent decision that is aligned with the objective of improving the quality and security of blood transfusion.

Question 2

Because there is currently no official initiative for incorporating optimal use in the haemovigilance system, the answer to this question represents the opinion solely of the undersigned. The management of optimal use of the haemovigilance system could and should benefit from the structure of the system itself, from its circuits and especially from its mode of function. Thus, it is fundamental to begin working on the basis of a 'Common Guide to the Optimal Use of Blood Components', with some agreed quality indicators that will enable an objective analysis of the situation. It will probably be necessary to draw up some notification forms on which participants can periodically fill in the data relating to optimal use. These forms will be the object of an overall assessment for the production of an annual report on optimal use in each country, which will necessarily be accompanied by the recommendations or corrective measures that are advisable given the data. A regular audit would help to corroborate whether the information provided by the participants accords with the indications compiled in the guides. Without doubt, the figure of the 'haemovigilance officer' could ensure the rapid incorporation of the subject in all transfusion centres and the high level of commitment that this matter demands and deserves. In the case of Spain, few transfusion centres have such a member of staff, and it is foreseeable that the task will continue to be the responsibility of the person in charge of the hospital transfusion service.

In summary, the strategy of incorporating optimal use into the haemovigilance system could promote advances in a matter that demands consensus, common criteria, analysis and corrective measures whose efficiency needs to be periodically evaluated.

M. Corral Alonso
Blood Transfusion Service
Hospital Universitario de Salamanca
Salamanca, Spain

E. Muñiz-Diaz
Immunohaematology Department
Banc de Sang i Teixits
Barcelona, Spain
European delegate representing the Spanish
Ministry of Health for haemovigilance issues
E-mail: emuniz@bstcat.net