(2) 血小板

年	2009							
月	1-2	3-4	5-6	7-8	9-10	11-12	合計	発生率
A) 非溶血性副作用								
重症アレルギー反応	0	0	0	1	0	0	1	0.1%
輸血関連急性肺障害 (TRALI)	0	0	2	0	0	0	2	0.3%
輸血関連循環過負荷 (TACO)	0	0	0	0	0	0	0	0.0%
輸血後移植片対宿主病 (GVHD)	0	0	0	0	0	0	0	0.0%
輸血後紫斑病 (PTP)	0	0	0	0	0	0	0	0.0%
その他	68	120	149	128	145	89	699	99.6%
発生件数	68	120	151	129	145	89	702	100%
B) 溶血性副作用								
急性溶血	0	0	0	0	0	0	0	0.0%
遅発性溶血	0	0	0	0	0		0	0.0%
発生件数	0	0	0	0	0	0	0	0.0%
C) 感染症								
HBV	0	0	0	0	0	0	0	0.0%
HCV	0	0	0	0	0	0	0	0.0%
HIV	0	0	0	0	0	0	0	0.0%
細菌	0	0	0	0	0	0	0	0.0%
その他	0	0	0	0	0	0	0	0.0%
発生件数	0	0	0	0	0	0	0	0.0%
発生総数 A) +B) +C)	68	120	151	129	145	89	702	100%

(3) 血漿

年	2009							
月	1-2	3-4	5-6	7-8	9-10	11-12	合計	発生率
A) 非溶血性副作用								
重症アレルギー反応	0	2	0	0	0	1	3	1.8%
輸血関連急性肺障害 (TRALI)	0	0	0	0	0	0	0	0.0%
輸血関連循環過負荷 (TACO)	1	0	0	0	0	0	1	0.6%
輸血後移植片対宿主病 (GVHD)	0	0	0	0	0	0	0	0.0%
輸血後紫斑病 (PTP)	0	0	0	0	0	0	0	0.0%
その他	35	16	33	25	19	35	163	97.6%
発生件数	36	18	33	25	19	36	167	100%
B) 溶血性副作用								
急性溶血	0	0	0	0	0	0	0	0.0%
遅発性溶血	0	0	0	0	0	0	0	0.0%
発生件数	0	0	0	0	0	0	0	0.0%
C) 感染症								
HBV	0	0	0	0	0	0	0	0.0%
HCV	0	0	0	0	0	0	0	0.0%
HIV	0	0	0	0	0	0	0	0.0%
細菌	0	0	0	0	0	0	0	0.0%
その他	0	0	0	0	0	0	0	0.0%
発生件数	0	0	0	0	0	0	0	0.0%
発生総数 A) +B) +C)	36	18	33	25	19	36	167	100%

分担研究報告書
日本における血液製剤の副作用サーベイランス体制の確立に関する研究
血液製剤サーベイランス体制の構築
(海外における体制について)

分担研究者：岡崎　仁（東京都赤十字血液センター
兼　日本赤十字社血液事業本部中央血液研究所）

研究要旨

【背景・目的】　血液製剤のサーベイランス体制は海外ではヘモビジランス（血液監視体制）と呼ばれているためこの報告書の中では、サーベイランスの替わりにヘモビジランスという用語を使用することとする。昨年の報告では海外におけるヘモビジランスの進捗状況を国際会議における発表や、各国の年報などに基づき分析を行った。採血から輸血までの一連の Transfusion Chain をカバーすることでより安全な輸血医療に貢献することは、ヘモビジランスの基本理念であり、特に欧州を中心とする国々でのヘモビジランスの発展は、欧州以外へも広がりを見せており、それぞれの国情にあった体制でヘモビジランスを構築していくことが今後必要になっていくと考えられる。

【方法】欧州において 1999 年に始まった European Haemovigilance Network による年次のセミナーはすでに今年で 12 回目を迎えている。日本は日本赤十字社が今のところ日本の代表として昨年より Network に加わっているが、すでに 4 年前より日本のヘモビジランス体制についてはすでに海外で紹介を行い、さらに 2 年前より国際的ヘモビジランスのデータベース作りのための STARE (Surveillance of Transfusion-Associated Reactions and Events) と呼ばれるプロジェクトの pilot study にも参加し協力している。今年より名称も International Haemovigilance Network (IHN) と変更され、国際輸血学会、WHO 等とも協力し合いながら、世界各国のヘモビジランスの発展を目指している。

アメリカにおいても国レベルのヘモビジランスの構築を US Biovigilance（輸血のみではなく細胞治療や臓器移植を含めた監視体制）の一部として進めていた。2010 年 2 月に、The Centers for Disease Control and Prevention （CDC）が、まず患者の安全性を中心として輸血の安全性を確保するために輸血に伴う有害事象の監視システムをアメリカの輸血を行っているすべての病院に対して、参加できるようなシステムを開始した。

今回の報告では主に本年度の IHN での各国の発表をもとにした世界のヘモビジランスの進捗状況、および、最新のアメリカにおけるヘモビジランス体制の開始について、日本におけるヘモビジランスの改善に役立つ情報を報告する。

【結果と考察】

ヨーロッパのみならず、アメリカでも同様のヘモビジランスのシステムが動き出しつつあり、日本でもこの動きに注意を払い、既存のシステムで不備な点がないかを見直して、縦割りの組織の横の連携（データの共有など）を密にすることにより、輸血に関する監視体制をさらに強化しなければならない。

A. 研究目的

サーベイランス体制は海外ではヘモビジランス（血液監視体制）と呼ばれているためこの報告書の中では、サーベイランスの替わりにヘモビジランス

という用語を使用することとする。昨年の報告では海外におけるヘモビジランスの進捗状況を国際会議における発表や、各国の年報などに基づき分析を行った。採血から輸血までの一連の Transfusion Chain をカバーすることでより安全な輸血医療に貢献することは、ヘモビジランスの基本理念であり、特に欧州を中心とする国々でのヘモビジランスの発展は、欧州以外へも広がりを見せており、それぞれの国情にあった体制でヘモビジランスを構築していくことが今後必要になっていくと考えられる。

B. 研究方法

欧州において 1999 年に始まった European Haemovigilance Network による年次のセミナーはすでに今年で 12 回目を迎えている。日本は日本赤十字社が今のところ日本の代表として昨年より Network に加わっているが、すでに 4 年前より日本のヘモビジランス体制についてはすでに海外で紹介を行い、さらに 2 年前より国際的ヘモビジランスのデータベース作りのための STARE (Surveillance of Transfusion-Associated Reactions and Events) と呼ばれるプロジェクトの pilot study にも参加し協力している。今年より名称も International Haemovigilance Network (IHN) と変更され、国際輸血学会、WHO 等とも協力し合いながら、世界各国のヘモビジランスの発展を目指している。今回の報告では主に本年度の IHN での各国の発表をもとに、世界のヘモビジランスの進捗状況、最近のトピックスについて日本におけるヘモビジランスの改善に役立つ情報を収集し、報告する。本年の IHN の会議はクロアチア共和国で行われたが、クロアチアの地域的な問題も討議の対象となったが、この報告では世界的に見て重要であり、今後日本のヘモビジランスにも必要と思われる情報を中心に報告する。

また、2010 年 2 月にアメリカにおいても国レベルのヘモビジランスのシステムが稼働し始めたので、そのことについても若干考察を加えて報告する。

C. D. 研究結果・考察

まず Global Affair (世界的な問題) に関してであるが、ヘモビジランスの国際データベースの構築に関わる STARE pilot study について簡単に紹介する。このプロジェクトの目的は、世界のヘモビジランスのデータや予防対策などを世界的に共有することにより、献血者および患者の安全を高めていくことである。現在、第二段階のパイロット研究が行われており、まだ一般には公開されていないが、現時点で世界の 16 の国と地域から統一した形式でのヘモビジランスのデータが収集されており解析されている。データはすべてエクセルシートに埋め込むようになっており、日本からも日赤のデータを報告している。

項目としては多岐にわたるが、

＊その国/地域の基礎情報

人口、ヘモビジランスでカバーされる項目、ヘモビジランスの体制、製造された製剤のトレーサビリティー等

＊献血者の数、製剤の種類と製造数などの基本的な統計の分母となりうる数の情報

＊製剤の種類と製造本数

＊献血者の採血副作用の種類と重傷度に基づくデータ（全血採血と成分採血に分けて）

＊過誤輸血の数（ABO ミスマッチ、製剤へのミスラベル、サンプリング過誤）

＊患者の輸血副作用（感染性、溶血性、非溶血性等）の製剤ごとの数

＊患者の副作用の重傷度（それぞれの副作用の種類に分けて）

＊患者の副作用の輸血との関連度（それぞれの副作用に分けて）

＊患者の副作用の頻度(それぞれの副作用に分けて)

について報告を行っている。もちろん現在は日赤で収集できている副作用報告に基づくデータであるので、献血者の採血副作用については、精度の高いデータが提供できているが、患者の輸血副作用については重症なものに偏る傾向があるのは否めない。

この STARE pilot study の集計されたデータを見ても、各国、地域でかなりバラバラな印象があり、すでにヘモビジランスが確立されているようなところでも、収集の仕方やシステムが異なっており、精度の高いデータベースの構築には、なおかなりな時

間と労力がかかりそうであり、今後の進展が期待されている。

最近の世界的なヘモビジランスの傾向として、輸血に関わるインシデント・ニアミスなどをヘモビジランスの一環としてデータを収集する方向に向かいつつある。日本では平成13年より現在のPMDA(医薬品医療機器総合機構)が担っていた医療安全対策ネットワーク整備事業(ヒヤリ・ハット事例収集事業)が平成16年に日本医療機能評価機構に移管されて以来、輸血に関する事項も含めてすべての医療安全に関するインシデント・ニアミスを一括して取り扱っているため、輸血という項目はもうけられているものの、特化したものとして区別されてはいない。日本医療機能評価機構の平成20年度の報告では「輸血に関連した医療事故」とのテーマで輸血療法に関連するテーマで医療事故事例が分析され、ヒヤリハット事例の概要と件数が報告されているが、継続的に毎年行っているわけではなさそうである。

システムとして良いか悪いかの話は別として、現在の輸血の副作用の頻度の高さを考えると、副作用(Adverse reaction)の中にインシデント(Incident)事例が含まれて見逃されている可能性もあるという視点も必要なため、相互のデータの共有も今後検討されなければならない。(用語の定義については国際輸血学会の定義〈付表1〉を参照)

患者の輸血副作用の内でも重篤になりうる副作用であるTRALIについてはその取り組みをアメリカ赤十字からの報告をもとに紹介する。

まずTRALIついてアメリカ赤十字での最新のデータについて簡単に紹介する。アメリカ赤十字では、2006年の終わりくらいから血漿製剤を男性由来の血液から製造することを目標として、2007年11月には95%の血液を男性由来のものとした。ただし、AB型の血漿に関してはまだ男性62.1%女性37.9%と女性の比率は高い。その結果、血漿製剤のみの投与でprobable TRALI(TRALIとpossible TRALI)を起こして死亡した症例は6例(2006年)、5例(2007年)、0例(2008年)と確実に減少している。

さらに、今後日本がヘモビジランスの先進国として特にアジアの地域を中心として国際協力していくためにもDeveloping Countryにおけるヘモビジランスの構築や導入の仕方についての知見は非常に重要であり、その例として、Arab Hemovigilance Networkをエジプトの人が中心となって立ち上げ、おそらくそれぞれの国の基幹病院だけに限定されているようなレベルではあるが、少しずつ輪を広げていくという意味においては重要な取り組みであり、今後日本やシンガポール、香港といったヘモビジランスにおける先進諸国がアジアの各国においても少しずつヘモビジランスの考えを浸透させていく必要がある。

アメリカにおいても国レベルのヘモビジランスの構築をUS Biovigilance(輸血のみではなく細胞治療や臓器移植を含めた監視体制)の一部として進めていた。2010年2月に、The Centers for Disease Control and Prevention (CDC)が、まず患者の安全性を中心として輸血の安全性を確保するために輸血に伴う有害事象の監視システムをアメリカの輸血を行っているすべての病院に対して、参加できるようなシステムを開始した。(http://www.cdc.gov/nhsn/bio.html) このシステムはCDCのDivision of Healthcare Quality Promotionにおける National Healthcare Safety Network (NHSN)の一部のBiovigilance Componentの下に位置づけられており、患者の安全やHealthcareに関わる人々の安全を調査している部署が取り扱うことになっている。おそらく日本における日本医療機能評価機構と似たたような仕組みと思われる。日本の厚労省にあたるアメリカのFDAはこれまでもAdverse Event Reporting SystemをMedWatchというシステムで運用してきたが、これは輸血に限られたものではなく、さらに因果関係のはっきりしない事象も報告されている。毎年輸血に関わる死亡例の統計は出されていたが、信頼のおけるデータであるかどうかは、疑わしいものだった。そのため、このNHSNのヘモビジランスが確実に運用されれば、かなり正確なデータの収集が期待される。

今後日本でもこのような海外の動きに注意を払い、既存のシステムで不備な点がないかを見直して、縦割りの組織の横の連携（データの共有など）を密にすることにより、輸血に関する監視体制をさらに強化しなければならない。

E. 研究発表

1）学会、研究会発表

1．Iijima T, Nakazawa H, Okazaki H, Hashimoto S, Ohkawara R, Yatomi Y, Ohnishi H, Takamoto S, Hotta H, Shimizu M: Effect of fresh frozen plasma from male-only donors versus mixed donors on postoperative respiratory function in surgical patients. aaBB annual meeting & TXPO (New Orleans, USA) (Oct/23-29/2009)

2．Okazaki H: Fight against TRALI. XXth Regional Congress Asia ISBT (Nagoya, Japan) (Nov/14-18/2009)

3．岡崎　仁：教育講演　TRALI・TACO の病態と診断．第 57 回日本輸血・細胞治療学会（大宮）（平成 21 年 5 月 30 日）

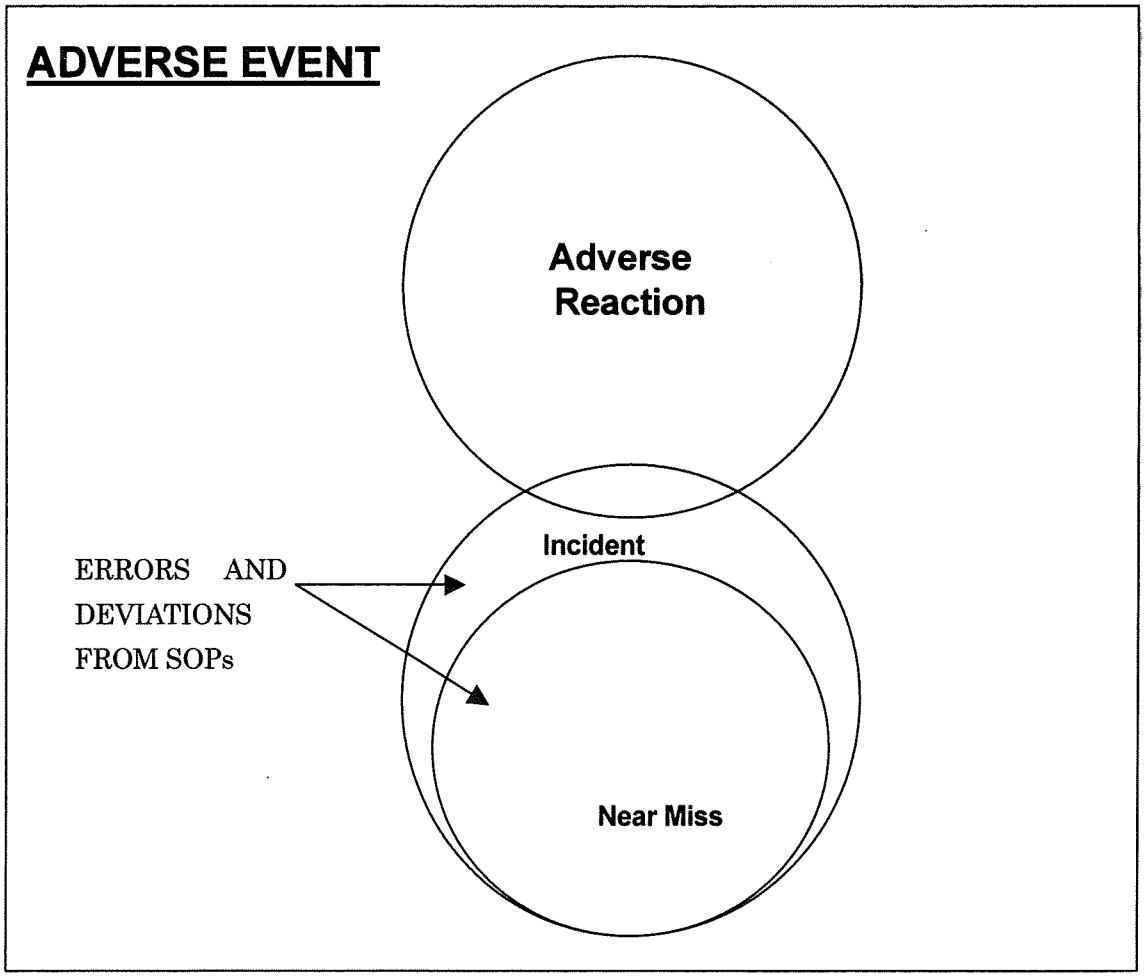
付表 1

・An **adverse event** is an undesirable and unintended occurrence before, during or after transfusion of blood or blood component which may be related to the administration of the blood or component. It may be the result of an error or an incident and it may or not result in a reaction in a recipient.

・An **incident** is a case where the patient is transfused with a blood component which did not meet all the requirements for a suitable transfusion for that patient, or that was intended for another patient. It thus comprises transfusion errors and deviations from standard operating procedures or hospital policies that have lead to mistransfusions. It may or may not lead to an adverse reaction.

・A **near miss** is an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or to a reaction in a recipient.

・An **adverse reaction** is an undesirable response or effect in a patient temporally associated with the administration of blood or blood component. It may be the result of an incident or of interaction between a recipient and blood, a biologically active product.



Adopted from "ISBT Working Party on Haemovigilance"
available from http://www.ihn-org.net/Portal.aspx (>Public library>ISBT documents)

別紙４

研究成果の刊行に関する一覧表レイアウト

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書　籍　名	出版社名	出版地	出版年	ページ

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
H. W. Reesink, S. Panzer, C. A. Gonzalez, et al	Haemobigilance for the optimal use of blood products in hospital.	Vox Sanguinis,			in press 2010.
浜口功	ヘモビジランス（血液安全監視体制）とは.	検査と技術.	37巻9号	864-866	2009.

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INTERNATIONAL FORUM

Haemovigilance for the optimal use of blood products in the hospital

H. W. Reesink, S. Panzer, C. A. Gonzalez, S. Gimbatti, E. Wood, M. Lambermont, V. Deneys, D. Sondag, T. Alport, D. Towns, D. Devine, P. Turek, M.-K. Auvinen, T. Koski, C. K. Lin, C. K. Lee, W. C. Tsoi, E. Lawlor, G. Grazzini, V. Piccinini, L. Catalano, S. Pupella, H. Kato, S. Takamoto, H. Okazaki, I. Hamaguchi, J. C. Wiersum-Osselton, A. J. W. van Tilborgh, P. Y. Zijlker-Jansen, K. M. Mangundap, M. R. Schipperus, D. Dinesh, P. Flanagan, Ø. Flesland, C. T. Steinsvåg, A. Espinosa, M. Letowska, A. Rosiek, J. Antoniewicz-Papis, E. Lachert, M. B. C. Koh, R. Alcantara, M. Corral Alonso & E. Muñiz-Diaz

Haemovigilance systems (HSs) have been established in many countries (see Vox Sang 2006; 90: 207–241). The main purpose so far has been the registration of all incidents and untoward effects related to blood transfusion. However, the question has arisen whether the optimal use of blood should be included in the HS. For this international forum, information was obtained on the opinion of the relevant authorities concerning this aspect of haemovigilance and how it should be organized. To obtain this information, the following questions were sent to representatives in the various countries.

Question 1

Has a HS been established in your country?

- If so, is the optimal use of blood products in the hospital part of the system?
- If not, do you feel that this aspect of haemovigilance should be included in the system and, if so, do you intend to include it in the future?

Question 2

If the optimal use of blood products in the hospital is part of your HS, or is expected to be so in the future, how will this part of the HS be organized, e.g.

- via a haemovigilance officer in the hospitals;
- audit methods in the hospital to check the use of these products and compliance with guidelines;
- other methods.

We obtained 16 contributions to this forum. A national HS has been established in all but three of the participating countries. In Argentina, although there is no official HS, the creation of hospital haemovigilance committees is promoted, and the blood banks are legally obliged to report all data concerning blood transfusion to the Ministry of Health, but because these data are not properly analysed, it is not considered to be a national HS. In Japan, where there have been local activities since 1993, a national HS is being organized, and in Australia, where there is an HS in some of the states/territories, a national system is on its way.

All HS were initially set up to record all transfusion incidents and adverse reactions and have led to the institution of transfusion committees (TCs) and transfusion officers (TOs) in the hospitals.

The opinion that the optimal use of blood products should be part of the HS, or that at least it should be actively propagated, is almost general. At present, it is already an integral part of the national HS in Belgium, Ireland and the Netherlands. In these countries, there are TCs and TOs in the hospital, and national guidelines for the optimal use of blood are available. In Poland, it will be included in the national HS as soon as possible. In Finland, this aspect of transfusion medicine is a separate project in which the five university hospitals and five other larger hospitals participate. In most of the other countries, where the optimal use of blood products is not (yet) part of the HS, there is much local activity to promote it. In Canada, New Zealand and Australia, the optimal use of blood products is not expected to become part of the HS.

The measures taken, or that are expected to be taken, to control the optimal use of blood products are the creation of TCs and the appointment of TOs in the hospitals, the availability of guidelines in which the proper medications for blood products are outlined and the education and training of clinicians and laboratory personnel and audits. An interesting scheme has been on trial in Hong Kong: an abbreviated form of the guidelines for the use of a blood product is printed on it. Any requests outside the guidelines must be supported by clinical justification. This policy has been successfully applied already, saving blood products.

Many of the answers we obtained are extensive and contain many interesting details, which can only be appreciated by reading the answers.

It can be concluded that there is much interest in including the optimal use of blood products in the national HS, and in some countries, this aspect is already an integral part of the HS, while in others, it is expected to become part of the HS in the near future. Hospital TCs and TOs and the education of clinicians and laboratory personnel play or will play an essential role in controlling this important aspect of transfusion medicine.

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C. A. Gonzalez & S. Gimbatti

Question 1

Our country does not have a haemovigilance national system. The technical and administrative standards in Argentine [1] promote the creation of haemovigilance hospital committee. Based on a tree-monthly standard form, all blood banks are legally obliged to send all data concerning blood transfusion to the Argentine Ministry of Health. Because the data are not fully analysed or reported throughout the country, we do not consider this as a haemovigilance system.

Undoubtedly, any system of haemovigilance should include between its parameters the control of the optimal use of blood products, co-ordinating its activities with the Hospital Transfusion Committee, without overlapping activities.

Question 2

The deficiencies in knowledge of prescription, administration or identification of transfusion recipients may impact on patient safety and, in some cases, result in death. This point was consistently demonstrated by audits of clinical transfusion practices [2]. Another significant contributing factor to this problem may be the limitations of budgets, inadequate facilities and insufficient numbers of experienced trainers make it impossible to meet the training needs.

In many developing countries, the lack of proper testing and understanding effects blood safety still is considered as a major problem in acquiring life-threatening transfusion-transmitted infections [3,4]. Another significant contributing factor to this problem may be the presence of fragmented and hospital-based blood transfusion system.

Buenos Aires city has the more complex health system in Argentina, and there is no doubt that is in great need for highly qualified, skilful, trained healthcare staff members, to provide an up-to-date, high-quality blood transfusions service.

In Buenos Aires City, the hospital transfusion committee was created by Resolution 135/SS/02 [5] that contained the first public clinical guidelines. The implementation of this ministerial resolution demanded a highly efficient training programme as one of the most important prerequisites.

The most challenging part was developing training courses for staff members of hospital blood banks aiming to improve technical competence and laboratory practice to check the use of blood products and compliance with guidelines between the most important objectives to learning.

This culture change involves making decisions with the best scientific evidence available in Transfusion Medicine and Immunohematology. This entails a great effort by all members of blood banks team, in the conviction that no permanent change is possible without education.

For these reasons, those courses are necessary, not as a palliative of inadequate training, but as a real tool for transforming the practice of transfusion medicine.

In our experience, those training courses could be the necessary first step before implementing the haemovigilance programme.

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E. Wood

Question 1

Australia is working towards a national haemovigilance system [1]. At the present time, systems exist covering one or more Australian states/territories (jurisdictions) for identifying, reporting, reviewing and responding to transfusion-related patient adverse events and near-misses [2,3]. There is now agreement that these jurisdictional systems will provide validated data periodically for a national report, using an agreed data dictionary and with event classification and imputability assessments based on International Society of Blood Transfusion/International Haemovigilance Network definitions. The Australian Red Cross Blood Service also receives reports of recipient adverse events where special product support or reference testing is required, or where there are product recall or donor management implications, as well as capturing adverse events relating to donors and blood donation [4].

Formal surveillance for optimal use of blood is not part of the current jurisdictional haemovigilance activities or planned national system, although this could be an important area for future consideration. The current systems usually capture contributory factors such as transfusion decisions that did not conform to hospital or national clinical practice guidelines, or where procedures for appropriate transport, storage and handling were not followed.

Question 2

In Australia, the role of the transfusion practitioner is now well established as a key element in hospital transfusion safety. Most transfusion practitioners have a nursing background. This role works in partnership with other members of the transfusion team such as transfusion medicine specialists, haematologists, laboratory scientists and other clinical counterparts. Transfusion practitioners provide education and training (including to promote optimal use of blood), procedural review and implementation, investigation and follow-up of adverse events and near-misses, and clinical audit. Other audits and surveys relevant to optimal use of blood are conducted by transfusion laboratories, the Australian and New Zealand Society of Blood Transfusion, the jurisdictional transfusion practice improvement collaboratives and the Blood Service. Tools and reports of some of these audits are available online [2,5]. Patient blood management initiatives are also being actively developed in Australia at institutional, jurisdictional and national levels. The role of haemovigilance officer is not presently established in Australia separate from the role of transfusion practitioner. The Blood Service also has a transfusion medicine team (including transfusion nurses) whose role includes promotion of optimal use of blood.

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5 http://www.health.sa.gov.au/bloodsafe

M. Lambermont, V. Deneys & D. Sondag

Question 1

A national haemovigilance system has been formally in place since November 2005 (implementation of the European directive 2002, 2005). The haemovigilance network includes a national cell depending on the Federal Agency for Medicines and Health Products (FAMHP) for notifications of adverse reactions and events associated with transfusions and donations. Haemovigilance data are collected by haemovigilance officers in each blood transfusion establishment and hospital.

In April 2002 (Royal Decree), transfusion committees were created in each hospital, in which all actors in the transfusion chain are represented: the medical director, three medical doctors with different specialities, the director of the blood bank, the director of the nursing department, the pharmacist, a representative from the blood transfusion establishment. Among the committee's various missions, optimal use of blood is clearly identified through the criteria of transfusion, the procedures for the whole transfusion process, the notification of adverse events and reactions, the evaluation of the efficacy of the transfusion and the patient's follow-up.

In collaboration with FAMHP, the Superior Health Council dependent on the Federal Ministry of Health elaborated recommendations for the optimal use of red-blood-cells, fresh frozen plasma and platelet concentrates based on international consensus conferences organized in Belgium. It has also published a transfusion manual to help transfusion committees to implement 'good transfusion practices'.

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Question 2

The optimal use of blood products falls under the responsibility of the blood transfusion committee in close collaboration with the medical directors of the blood banks and the blood transfusion establishments.

The best method for evaluation is participation in clinical and benchmarking studies, audits (internal and external) and inspections by national authorities. The comparison of clinical transfusion practices is at the present time limited to a few hospitals.

All tools for implementing and maintaining a haemovigilance system, including optimal use of blood products, are being set up but are not yet optimally used because of a lack of resources.

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T. Alport, D. Towns & D. Devine

Question 1

In Canada, primary responsibility for haemovigilance rests with the Public Health Agency of Canada who have developed the Transfusion Transmitted Injuries Surveillance System (TTISS Program). The mandate of the TTISS Program is:

- 'To establish a national surveillance system for transfusion, transmitted injuries (ie. infectious diseases and non-infectious adverse events); and
- To support target research to provide information for risk assessment to further reduce the risk associated with blood transfusion in Canada' (see http://www.public-health.gc.ca).

Participation in the programme is voluntary, but the programme does support the presence of hospital-based Transfusion Safety Officers, and there is good participation of all the provinces and territories.

In addition, Canadian Blood Services and Hema-Quebec, which operates the blood system in Quebec, have their own reporting requirements that are outlined in the Circular of Information (see http://www.blood.ca) and who, in turn, have a regulatory requirement to report significant adverse events to Health Canada. Provinces and hospitals often have their own systems for reporting adverse events and errors that are complimentary to the above.

Optimum use of blood products is not part of the Heath Canada mandate, and there are no current plans to include this as part of the formal haemovigilance programme. Consistent with the focus on consensus-driven practice change in Canadian medicine, it is unlikely that optimal use of blood products would become a mandated activity of a Canadian haemovigilance system. At the present time, the optimal use of blood products with respect to recommendations and guidelines is discussed by various groups including provincially based blood co-ordinating offices, which exist in some Canadian provinces, and the National Advisory Committee on Blood and Blood Products, which is a collaborative group of hospital-based transfusion medicine experts, representatives from Canadian Blood Services, and the government funders of the blood system. This loose system achieves a similar goal to the formal inclusion of optimal use of blood products in the haemovigilance programme.

Question 2

In Canada, utilization management occurs at a number of different levels in the system. As provinces (rather than the Federal Government) have primary responsibility for delivering health care, provinces and hospitals have developed their own systems to ensure optimal utilization of blood products. Some hospitals have transfusion safety officers or equivalent positions to support the appropriate use of blood products. Most provinces have active provincial blood co-ordinating offices with utilization management being a key mandate. The blood operators (Canadian Blood Services and Hema-Quebec) also provide educational information to hospitals and have staff specifically dedicated to working with the hospitals to monitor product use. For example, a formal disposition reporting system has recently been established to provide data on blood product use. The inter-provincial committee responsible for funding of the blood service also has a National Advisory Committee whose mandate includes developing guidelines and programmes to ensure optimal utilization of blood products.

There is collaboration among these groups as well as participation in international efforts to develop clear indications and guidelines for the use of blood products.

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P. Turek

Question 1

Haemovigilance system has been established in the Czech Republic many years ago. In the year 2006, an older system has been modified to be fully compatible with EU Blood Directive. Use of blood components is included in the system only as regards organizational and technical matters (ordering, labelling of samples, mis-transfusions near misses etc.), indications and medical/clinical appropriateness are not included into the system. There is a discussion in the field on how optimal use of blood would be supported and controlled, but there is no intention to include this directly into the obligatory haemovigilance system.

Question 2

The 'optimal use of blood' is not included into our haemovigilance system, but possibilities and needs are discussed. Nowadays, we can hardly conceive it as a task of any specialized officer, self-audits and audits are already organized in some hospitals.

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M.-K. Auvinen & T. Koski

Question 1

The Finnish Red Cross Blood Service (FRCBS) is a financially and operationally independent unit within the Finnish Red Cross. It is a centralized organization providing nationwide blood services in Finland. Its tasks include organizing blood donor sessions and collecting blood as well as testing of donated blood, production of blood components and distribution of blood components to hospitals.

The Blood Safety Office (BSO) operates within the FRCBS and has been appointed by the Ministry of Social Affairs and Health to act as a co-ordinator between the various parties involved in the blood transfusion chain. Reporting serious adverse reactions and adverse events became mandatory at the beginning of 2006. In the same year, BSO was established within the FRCBS. Adverse events have been investigated in the FRCBS for years, but since 2006, all blood safety operations have been centralized in the BSO. BSO forwards reports on serious adverse events to the National Agency for Medicines, which then reports to the EC according to EU Directives. Mild adverse events can be reported to hospital blood centres or directly to BSO. In the case of mild events, sampling is usually unnecessary; a report will suffice. In practice, hospitals generally report mild adverse events on an annual basis to the BSO.

The number of adverse events is annually monitored to detect any noticeable increase in their incidence. Monitoring also helps to detect decreases in the number of adverse events resulting from changes or improvements. All data retrieved are used to improve training and operational instructions in hospitals and at the FRCBS.

The Programme for Optimal Use of Blood (VOK Programme) is a collaborative effort between the FRCBS and major Finnish hospitals to provide commensurate data on blood use in the participating organizations. It is not included in the haemovigilance reporting system and stands as a separate project as there are so many other aspects involved in optimal use of blood than adverse events. However, because both initiatives are run by FRCBS, the close information change and co-operation is possible.

So far, all five university hospitals in Finland and five other major hospital districts have joined the Programme, and the VOK Database now covers about 68% of the consumption of blood components in Finland (year 2007). The VOK Database currently includes data from 2002 to 2007.

Data for the VOK Database are collected from hospitals' administrative, laboratory, blood bank and operating theatre registers as well as from the Blood Service's Blood Donor Registry. Patient identifications are encrypted in the Database and cannot be traced back to the individual patient. The Database includes information about diagnoses, procedures, laboratory results and the transfused blood components. The Database allows analysis of differences in blood use and evaluation of clinical practices. The participating hospitals are also able to conduct specific analyses of data pertaining to their own organization. The ultimate aim of the VOK Programme is to improve patient safety and outcomes of patient care.

The reports are designed to compare blood use in participating hospitals and to illustrate changes from previous reports. FRCBS organizes 2–3 benchmarking events annually for clinical professionals involved with blood use in different hospitals. The benchmarking events typically consist of presentation of specific VOK reports and, most importantly, group discussions of differences in practices among hospitals. Lectures are given by the participants as well as invited experts. Experiences from the events are encouraging, and the benchmarking discussions have led to the adoption of best practices in several cases. It may be simple actions such as controlling the practice for blood reservations for operations. After such action, the blood use in orthopaedic interventions has decreased with 27%, whereas the total number of interventions has increased with 14% for the same period 2002–2007. Naturally, there are several other changes happening, and in the same time,

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new techniques as well as medicines have been adopted, but we would like to believe that also the benchmarking activities play a role here.

Question 2

We don't have any national plans for establishing haemovigilance officers at the hospitals. Only a few hospitals have transfusion committees, and most of them are not active. This may reflect the fact that Finland has not had any major public mistrust in blood transfusions in the past compared with some other countries (a very low number of transfusion transmitted HIV, no BSE). Many of the practical issues have been solved between the clinicians and FRCBS directly.

For the follow-up of the transfusion triggers, some blood bank software programs show for the person ordering blood the latest haemoglobin and platelet levels of the patient. However, the possibility for automatic alarm when the laboratory values are above the predefined triggers has not been actively promoted. The alarms might be an inefficient way of guiding transfusions because the person facilitating the blood order at the ward rarely is a member of team transfusing the patients.

The laboratory technologists (and in some hospitals laboratory physicians) contact the clinic whether it is likely that the product or the number of units ordered is incorrect or unusual. The FRCBS requests that the physician consults if rarely used products are ordered (e.g. washed components, HLA-typed or volume reduced platelets).

Formal audits at the hospitals are rare because we don't have national guidelines for blood usage.

Locally, there are some guidelines that are only recommendations. Quality systems are increasingly implemented in the clinical wards, and blood usage and transfusion triggers are monitored at least in some hospitals e.g. in association with stem cell transplantations.

The adverse events of transfusions are reported as described in Q1. There are now an increasing number of hospitals using softwares for collecting and reporting data for severe adverse events and reactions in all fields of medicine. Ideally, the haemovigilance issues would be integrated in the same system. This would probably facilitate and increase the reporting of other haemovigilance issues than transfusion reactions leading to safer transfusions.

In the current economic climate, the cost-savings may be the most important driver for better practices in the transfusions field. This economic excuse may turn out to be beneficial for the patients if the decision to transfuse is made on a strictly medical basis and a decision not to transfuse is seen as an equally valid decision. Transfusion of blood may be a minor action in the whole process of treating a patient, but its economic impact is rather large. Any activities or excuses that attract the interest to evaluate the current practice are justified.

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C. K. Lin, C. K. Lee & W. C. Tsoi

Question 1

In Hong Kong, a haemovigilance system was established in 2001 among all public hospitals, which covered some 95% of health services and accounted for about 90% red cell utilization. The system, including a standardized reporting format, was implemented by the Central Transfusion Committee (CTC) of the Hong Kong Hospital Authority (HA), which is an organization responsible for the management of all public hospitals and outpatient clinics and the Hong Kong Red Cross Blood Transfusion Service (HKRCBTS). The CTC is a formal committee chaired by a senior executive who reports to the Chief Executive of the HA. Membership of the CTC includes all Hospital Transfusion Committee (HTC) Chairpersons and representative from the HKRCBTS. It took the CTC a year to implement the haemovigilance system that enables electronic reporting. Based on the consensus among CTC members and frontline clinicians, it was decided to categorize reporting into two major areas, namely, transfusion incidents and adverse transfusion reactions. The former mandates compulsory reporting of all incidents and near-miss events related to blood transfusion activities in hospitals. The severity of the incident is graded according to a 7-point scale, where 0 is equal to near-miss i.e. incident detected before transfusion took place and six means fatality as a direct consequence of transfusion.

For adverse transfusion reactions, the system encourages voluntary reporting of any adverse reactions happened during and after transfusion and adopts same severity grading scale as incident reporting. HTCs are responsible for the investigation and follow-up of local hospital issues and identify possible imputable relationship between adverse transfusion events and the blood components involved.

At half-yearly intervals, the HKRCBTS assists the CTC to collate and analyse the data that will be presented in a

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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.

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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.

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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.

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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.

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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

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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.

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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.

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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 clinicians find the blood banks involvement in optimal use of blood useful.

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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.

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