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SERIOUS HAZARDS OF TRANSFUSION SHOT

NEWSLETTER

Update from the SHOT Team

The team has been very busy during 2008 not least because of bringing forward the date for the publication of the SHOT Annual Report and the SHOT Symposium. The 2007 Annual Report was published on 7th July 2008 and the Symposium was held at the Royal College of Physicians, London, on the same day. This was 4 months earlier than in recent years and the successful completion of this task is a testament to the hard work and commitment of the authors on the SHOT Writing Group. The report was brought forward not only in order to share new results more quickly with our reporters other stakeholders, but also in order to synchronise reporting with the MHRA. MHRA (the Competent Authority) has a statutory requirement to send haemovigilance data collected through SABRE to the EU Commission by 30th June each year (for the previous calendar year). Meetings were held between key members of the MHRA SABRE team and SHOT in order to reconcile the data before publication of either SHOT data or MHRA data. These meetings were held under the aegis of the Adverse Events Sub-Group of the MHRA's Blood Consultative Committee (Chair, Clare Taylor). The timing of the SHOT report will remain the same for 2009.

The newly created post of SHOT operations manager has been filled by the appointment of David Mold. David has a background as a nurse with experience in accident and emergency, ITU, CCU, cardio-thoracic surgery and haemodialysis. He has also worked as a research analyst, clinical trials data manager, transfusion data manager and transfusion research analyst. His last job was as a Transfusion Practitioner. He not only brings experience of the clinical practice of transfusion medicine in acute settings but also experience of the design and management of clinical trials, studies and audits and the design of data capture tools. He also has experience in the design and management of websites. David's first major project is to oversee the procurement and implementation of a web based database for SHOT.

Recently appointed SHOT Operations Manager, Mr. David Mold.

Another new post within the SHOT team, the Laboratory Incidents Specialist, will be advertised in the near future. It is a Band 7 post for an experienced Biomedical Scientist in Transfusion Medicine. The post holder will work within the SHOT team developing laboratory related initiatives, analysing laboratory data, writing for scientific journals and representing SHOT in driving forward the laboratory based initiatives nationally.

Clare Taylor has now left the Royal Free Hospital and is working solely for SHOT, 3.5 days per week. Her job title has been changed to Medical Director of SHOT. Clare is looking forward to being able to focus solely on haemovigilance through SHOT, MHRA and the EU and aims to develop the role of SHOT within the European Haemovigilance Network for which she is now Secretary.

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Participation in Haemovigilance

This year's data from both SHOT and MHRA showed that there was still no improvement in the overall participation rate in haemovigilance in the two parts of the UK haemovigilance system. Approximately 25% of registered reporters to SABRE have not reported any serious adverse events (SAEs) or serious adverse reactions (SARs) during 2007. There are some reporters who have not reported anything since reporting was instigated in November 2005. Likewise SHOT finds that approximately 30% of possible reporters have not been reporting any cases.

At the MHRA Blood Consultative Committee on 1st July 2008 the inspection team at MHRA indicated that they are 'becoming interested' in the non-reporters to SABRE. The Department of Health is aware that there are a number of hospitals, including major users, who are non-compliant with the legislation in terms of haemovigilance reporting. SHOT is very keen to find out what the obstacles and barriers are to reporting from hospitals and the SHOT office is very pleased to help with any queries or difficulties that reporters are encountering. A new SHOT toolkit is available on the SHOT website which may with help some issues. Reporters should not hesitate to contact the SHOT office to discuss problems.

SHOT data have repeatedly been found to identify trends which then go on to inform policy within the UK Blood Services. This has had measurable impact on patient safety and the rate of reporting of transfusion related adverse events. Examples of these positive benefits of haemovigilance include the high rates of TRALI which were being reported to SHOT until 2003. A decision was then taken by the UK Blood Services, based on SHOT data, to source FFP from only male donors and this resulted in a rapid, significant decrease in the number of cases of TRALI reported. Similarly a decision partly based on SHOT data to divert the first 20mls of blood when donors are being bled, in order to reduce bacterial contamination, has also had a demonstrable effect on the contamination rate of red cells and platelets.

In order that SHOT data can continue to have this invaluable impact on patient safety it must be as complete as possible and this requires everybody involved in the transfusion process to be aware of the need to report adverse events and reactions, both large and small, to SHOT for analysis. The purpose of SHOT haemovigilance is to identify patterns and trends in adverse incidents and not in any way to 'name and shame' hospitals in which these events are taking place.

SHOT Symposium July 2008

Held in the Royal College of Physicians, London, this was extremely well attended. Feedback once again, was excellent. The day was introduced by Dr. Adrian Copplestone, Chair of the NBTC and the data from the 2007 SHOT report were presented by Dr. Clare Taylor and Dr. Hannah Cohen. The keynote speaker, Dr. Pierre Robillard, from Quebec, Canada, spoke about the Canadian haemovigilance systems and compared Canadian data with the UK SHOT data. This was a fascinating talk as Canada collects far more adverse events per 100,000 components transfused. One of the areas in which they receive a large number of reports is transfusion associated circulatory overload (TACO). This category is being collected separately by SHOT in 2008 and the team anticipates an increase in the number of cases once reporters start to send them. The middle section of the day consisted of two talks from MHRA. Mr. Chris Robbie went through the SABRE data from 2007 and also gave very helpful advice and hints on how to use the system when reporting to SABRE. Mr. David Churchward then gave a talk about the MHRA inspections and the most commonly occurring deficiencies detected in hospitals. After lunch Mr. John Forsythe, Chair of SaBTO, gave a broad picture of blood safety in the UK giving an added perspective to the SHOT data. Mr. Bill Chaffe updated on the progress of the UK Transfusion Laboratory Collaborative which is now preparing to publish a paper setting minimum standards for hospital transfusion laboratories. Dr. Pat Hewitt updated on transfusion transmitted infections in the UK and Ms. Susan Tuck gave an overview of the guidelines for the use of Anti D in ante-natal care with a robust discussion of the evidence base for the use of Anti D. The day finished with cases and views from the laboratory from Mr. Tony Davies and an amusing and thought provoking presentation from Ms. Sinead McNally bringing the concept of professional responsibility to the fore. Dr. Brenda Gibson, President of the BSH, chaired this last session and gave a summary presentation and final statement.

Presentations are available on the SHOT website.

EU Update

MHRA submitted its first Annual Return to the EU commission in late June this year, and was surprised and pleased to find that the UK was the first member state to submit haemovigilance data under the EU Blood Directive! SHOT continues to work closely with MHRA throughout the year, but in particular for the purpose of reconciliation of numbers of (anonymised) cases reported in the different categories. In the future MHRA plans to engage an additional clinical based member of the SABRE team, as well as an expert panel to consult over classification and interpretation of SARs and SAEs.

The EU commission has a Haemovigilance working party which is a subgroup of the Competent Authorities' (CAs) committee. It consists of members from both regulatory bodies and haemovigilance organisations from member states. Members from the UK are Clare Taylor, Nigel Goulding and Chris Robbie.

The group has done a lot of work on a guidance document for CAs for reporting to the EU, which should allow for standardisation of reports and emergence of some comparative data.

The European Haemovigilance Network is a growing organisation bringing together haemovigilance organisations globally. From February 2009 it will become, as a result of demand, the International Haemovigilance Network. Clare Taylor has recently become Secretary of the group, and one of its current tasks is to set up a database for the analysis of European data.

Near Miss Pilot

Phase 1 of the Near Miss Pilot Study, looking at samples rejected by the first laboratory barrier to error (i.e. the booking in process) was run from 1st April 2008 for a period of one month. Data collection was in the form of a 'tickbox' matrix, and many thanks must go to the laboratories who took part in what was an intensive data-gathering process.

131 hospitals expressed interest in participating in the pilot, and we received data from 121 of those; 92 from England, 15 from Wales, 6 each from Northern Ireland and Scotland, and 2 from the Channel Islands.

In total, we processed data on 8535 rejected samples out of 224,829 samples received in laboratories over the month. The number of samples received per hospital varied enormously, from as little as 82 to as many as 6155. 73% of samples rejected arrived during core hours.

The average rate of rejection of samples across the UK was 3.8%, with 76% of the samples being rejected for missing or incorrect patient identifiers, 13% rejected as insufficient or inappropriate and 6% labelled with addressographs.

32% rejected samples were taken by medical staff, 11% by nurses, 14% by midwives, 1% by Healthcare Assistants, and 4% by phlebotomists. In 38% of cases, it was not known who took the samples, and an interesting observation is that many hospitals allowed re-labelling of samples when they recorded that they did not know who had taken them!

These data provide a background to phase two of the pilot, running from 1st September for six months, where we are looking for sample errors detected within the laboratory.

Cell Salvage Pilot

Joan Jones, Manager, BBT Team, Welsh Blood Service, Catherine Howell, Head of Hospital Liaison (Acting), NHSBT and Clare Taylor, SHOT Medical Director, have instigated a pilot study of intraoperative and postoperative cell salvage incidents. Invitations to participate in this study, which is running for 6 months from 1st June to 30th November 2008, were distributed as widely as possible and to date 60 hospitals have agreed to take part.

The incidents covered are:

- *Abandoned procedures due to operator error (incorrect assembly, non IV solutions, incorrect anticoagulant, collection time exceeded)*
- *Abandoned procedures due to machine failure (clotted lines/reservoirs)*
- *Adverse clinical events (PE, coagulopathy etc)*

At the end of the pilot participants will be asked to provide some denominator data (total number of intraoperative and postoperative cell salvage procedures undertaken). The results of the study will be distributed as soon as possible after the pilot has ended and will be available for download on the SHOT website.

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Diary Dates

Joint Meeting of UK NEQAS (BTLP) & BBTS Blood Bank Technology SIG. 18th Nov 2008, Heriot Watt, Edinburgh.

Transfusion Medicine Today, Royal College of Pathologists, November 26th and 27th 2008.

EHN Haemovigilance Seminar, Rome, February 25th– February 27th 2009.

ISBT (International Society of Blood Transfusion) meeting in Cairo 21st March - 25th March 2009.

BGS Reading 2009. University of Reading 2nd - 5th April 2009

Patient Safety Congress 2009. The ICC Birmingham. April 30th to May 1st 2009.

SHOT symposium with 2008 data at RSM, London. 30th June 2009.

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Dr Hannah Cohen (Chair, SHOT Steering Group)

Prof David Cox (NHS Confederation)

Mr Tony Davies (Transfusion Liaison Practitioner, SHOT)

Dr Roger Eglin (NHS Blood & Transplant)

Mr John Getty (Royal College of Surgeons)

Dr Brenda Gibson (Royal College of Paediatrics and Child Health)

Dr Patricia Hewitt (Consultant Specialist in Transfusion Microbiology. NHS Blood & Transplant)

Mrs Hilary Jones (Research Analyst, SHOT)

Ms Joan Jones (Institute of Biomedical Science)

Dr Sue Knowles (British Blood Transfusion Society),

Prof John Lumley (Founder Member)

Mr John Marriott (Lay Member)

Dr Brian McClelland (UK Transfusion Services)

Mr David Mold, (Operations Manager, SHOT)

Dr Kieran Morris (Royal College of Pathologists)

Dr Andrew Mortimer (Royal College of Anaesthetists)

Dr Tim Nokes (British Society for Haematology)

Mr Derek Norfolk (British Committee for Standards in Haematology)

Dr Jonathan Potter (Royal College of Physicians)

Dr Daghni Rajasingam (Royal College of Obstetricians & Gynaecologists)

Ms Joan Russell (NPSA)

Dr Dorothy Stainsby (Past SHOT National Medical Co-ordinator)

Dr Clare Taylor (Medical Director of SHOT)

Ms Tracey Ward (Royal College of Nursing)

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