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SERIOUS HAZARDS OF TRANSFUSION SHOT

NEWSLETTER

SHOT in 2008

SHOT is undoubtedly at the forefront of haemovigilance both in Europe and the rest of the world, and continues to be used as a model by countries developing their own systems. However, as a result of the Blood Safety and Quality Regulations 2005, SHOT now finds itself operating in a very different arena, in which reporting of certain types of adverse events is mandatory, and where significant resource is being made available across Europe so that member states can develop haemovigilance systems to fulfill the legislative requirements. In order to maintain its world class operation, SHOT needs to evolve and encompass all the required strands of haemovigilance.

There is a clearly an absolute requirement for a proactive, professionally led haemovigilance system which informs policy, guidelines, standards and clinical research. At the same time there is now a legal requirement for certain data on adverse incidents directly related to component quality and safety to be collected and forwarded annually to the EU Commission for trend analysis and international comparison. This role is formally undertaken in the UK by MHRA. This is no longer as an 'interim' measure, but permanently as the proposed overarching competent authority, RATE, will not now be formed.

Discussions are currently taking place in Europe about the exact breadth of data required under the regulations. It is quite clear that the interpretation of the directive is fairly narrow, excluding all clinically related adverse incidents, and donor related ones, unless they relate to the quality and safety of the component.

A decade of SHOT has had a great impact on clinical transfusion practice with an all time low in ABO incompatible transfusions as well as a dramatic impact on morbidity and mortality from TRALI and new measures to reduce bacterial contamination, through changes to blood services policies. SHOT will continue and extend its activities, adding new areas in order to continue to enhance patient safety and transfusion practice in the UK and beyond.

New for 2008:

- Separate Anti D chapter in Annual Report
- Separate analysis of inappropriate and unnecessary transfusion
- New questionnaire for collections of cases of Transfusion Associated Circulatory Overload (TACO)
- Near Miss pilot (see page 3)
- Cell salvage pilot (see page 3)
- Further development of National Transfusion Laboratory Collaborative

Participation in UK Haemovigilance

Although the number of adverse event reports being sent to SABRE and copied through to SHOT continues to increase overall year by year, the number of reports classifiable into SHOT categories has fallen in 2006 and 2007. This is largely attributable to fewer reports being sent in the IBCT (Incorrect Blood Component Transfused) category. At SHOT there is concern that because it is not mandatory to report clinically based adverse incidents to the EU via MHRA, they may sometimes not be reported at all. Clinical adverse events are mandatory to report under the Clinical Governance Framework and for CPA accreditation. But more important than these imperatives is the professional and moral responsibility to gather these data and continually to learn and improve practice. SHOT continues to collect reports in all its categories, and is indeed extending some of its clinical data e.g. inappropriate transfusion. Over 70% of SHOT reports are clinical, and not analysed by MHRA—please keep sending them.

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The SHOT office team

Tony Davies started with SHOT in May 2007. Prior to this he was a Blood Bank Manager and then a Transfusion Practitioner, and now is split between SHOT and Hospital Liaison as Transfusion Liaison Practitioner.

Vicky Dickson started as an Information Officer with SHOT in October 2007. She has rapidly been learning about the SABRE system and dealing with daily enquiries as well as organising meetings.

Dr Clare Taylor has been National Medical Co-ordinator since July 2007 and has worked closely with MHRA and the EU over the new legislation. She is a consultant at Royal Free Hospital

Meet the SHOT team! It is a great pleasure to introduce three new permanent members of staff who all joined SHOT during 2007. You will find their pictures, together with the existing staff , on this page. Vicky Dickson and Tony Davies are based in the Manchester office, where they join founder member, Hilary Jones, the Scheme Manager, and stalwart temp, Kathryn Gradwell. Dr Clare Taylor , the new National Medical Co-ordinator, works out of Colindale, and spends considerable time on joint projects with MHRA and SABRE as well as participating in the Haemovigilance working party at the EU Commission. She has recently agreed to become secretary of the European Haemovigilance Network. This role commenced in March 2008.

During 2008, thanks to new funding from the UK Transfusion Forum, SHOT hopes that the new Operations Manager, will be in post by July or August 2008, and plans to appoint two more permanent staff including a Laboratory Incidents Specialist and a Clinical Incidents Specialist. With these staff, SHOT will be able to offer comprehensive support to the Writing Group, especially regarding data analysis for the Annual Report. It will also be in a position to take the lead on new studies of specific areas of clinical or laboratory practice where adverse incidents have a documented impact. A capital sum for a new IT system has also been agreed by the UK forum, and option appraisals will be under way in 2008.

The strategic direction and ownership of SHOT, which is affiliated to the Royal College of Pathologists, comes from the SHOT Steering Group which has wide representation from Royal Colleges and professional bodies, while the SHOT Standing Working group focuses on operational aspects.

Steering Group

Chair: Dr Hannah Cohen

Dr Clare Taylor, Ms Hilary Jones, Mr Bill Chaffe, Ms Lisa Brant, Dr Dorothy Stainsby, Mr Tony Davies, Dr Sue Knowles, Dr Derek Norfolk, Dr Tim Nokes, Dr Andrew Mortimer, Prof John Barbara, Dr Brenda Gibson, Dr Brian McClelland, Ms Carol Blears, Dr Roger Eglin, Mr John Marriott, Ms Joan Jones, Mrs Joan Russell (co-opted), Mr Jonathan Potter, Prof. John Lumley, Dr Kieran Morris, Dr Mary Ramsay, Mr Mike Hayward, Ms Pat Edkins, Dr Lorna Williamson, Dr Tracey Johnston, Dr Pat Hewitt

Standing Working Group

Chair: Dr Clare Taylor

Dr Hannah Cohen, Ms Hilary Jones, Mr Tony Davies, Mr Bill Chaffe, Ms Lisa Brant, Dr Catherine Chapman, Ms Clare Milkins, Ms Debbie Asher, Dr Derek Norfolk, Dr Sue Knowles, Dr Hazel Tinegate, Ms Sandra Gray, Ms Liz Still.

SHOT launch November 2007

Held in Birmingham Motorcycle Museum, this was a very successful day. It was co-hosted by NEQAS and had an emphasis on laboratory based adverse incidents. Over 300 delegates attended, and feedback was universally good or excellent. The day opened with a detailed presentation of the 2006 SHOT data by Dr Hannah Cohen, drawing attention to the all time low in ABO incompatible transfusions and proven cases of TRALI. A talk by Prof. Charles Vincent of the Clinical Safety Research Unit at Imperial College entitled “Understanding errors and improving patient safety“ was very thought provoking about the broader issues involved in error. Bill Chaffe (IBMS) gave an update on the National Transfusion Laboratory Collaborative, and proposed a set of standards for hospital laboratory staffing, training and workload which was agreed by the delegates. This is due to be ratified in the near future. There was a talk about the relationship between SHOT, MHRA and SABRE by Dr Clare Taylor and a series of lab based cases chaired by Clare Milkins of NEQAS. All the powerpoint presentations are available to view on the SHOT website.

SaBTO update

The newly established advisory committee on Safety of Blood Tissues and Organs has replaced the previous advisory committee MSBTO (Microbiological Safety of Blood Tissues and Organs). SaBTO is an advisory, non-Departmental Public Body and will advise ministers of the UK Government and the Devolved Administrations as well as the UK Health Departments on the most appropriate way to ensure the safety of blood cells, tissues and organs for transfusion and transplantation. SaBTO will advise across the broader area of safety. Its inaugural meeting, under its Chairman Mr John Forsythe (also a non-executive director of NHSBT) took place in January 2008. SHOT has a nominated contact person (Dr Clare Taylor) who will attend the Committee (or arrange an alternate) whenever the agenda contains items of relevance, or when the Secretariat of SaBTO requests SHOT to attend. The Committee itself consists of 12 individuals who went through an appointments process and who were chosen for their personal experience and expertise. SHOT, and other bodies such as NPSA, MHRA, SEAC and NBTC are in attendance as observers.

Dr Hannah Cohen, Chair of the SHOT Steering Group since its inception in 1995, is a Consultant haematologist at University College London Hospitals.

MHRA and SABRE

The SABRE team at MHRA has sent out annual summary forms to all reporters to confirm data from 2007. This process proved complicated and time consuming last year, but it is hoped familiarity will make it less onerous this time. The data need to be checked and returned with the usage figures and returns will be double checked against the compliance forms due in at the end of April. A process of reconciliation with SHOT data will take place, where categories are congruent, through the Adverse Events sub committee (BCC-AE) of the MHRA Blood Consultative Committee (BCC), chaired by Dr Taylor. This valuable link will continue, although for confidentiality reasons Dr Taylor will no longer be the official haematology advisor for MHRA and SABRE. An expert panel is to be set up to take over this role. More information about reporting, meeting minutes and the compliance form are on the MHRA website. Please keep reporting through SABRE to MHRA and SHOT - some hospitals have still not sent any reports!

Hilary Jones, SHOT Scheme Manager since 1999, undertakes data analysis and provides expert advice on SABRE reporting and haemovigilance issues to reporters

Near Miss pilot

Phase 1 of the SHOT Near Miss pilot is just underway (from 1st April 2008). It is focusing exclusively on the pre-testing phase, in which an erroneous request/sample may be rejected, cancelled or amended prior to testing in the hospital blood bank. Invitations to participate in the pilot have been sent to Hospital Transfusion Teams, together with a form to register for the pilot, instructions and a simple paper based data collection template. The initial phase is running for one month (April) and looking at sample errors and the barriers in place for preventing them. This will provide a useful baseline for Phase 2 of the pilot which will look at errors in the laboratory based testing phase.

Cell Salvage pilot

The UK Cell Salvage Action Group is helping drive the widespread implementation of both intra-operative and post-operative cell salvage. The group, which reports to the Appropriate Use of Blood Group in England, and the equivalent group in devolved countries, is now working with SHOT to develop an adverse events reporting system. Hospitals will receive invitations to join a pilot phase of reporting in the near future. Hospital Transfusion Teams will need to liaise with the lead for cell salvage in their Hospital or Trust to arrange data collection using the special form provided. This paper based data will then need to be submitted to SHOT, where it will be entered into a database and analysed. The pilot is due to commence in June 2008 and is planned to run for 6 months.

Kathryn Gradwell, temporary Information Officer with SHOT since 2006, looks after the day to day running of the office.

SERIOUS HAZARDS OF TRANSFUSION SHOT

SHOT office:
Manchester Blood Centre,
Plymouth Grove,
Manchester,
M13 9LL

Telephone: +44(0)161 251 4208
Fax: +44(0)161 251 4395
Email: SHOT@nbs.nhs.uk

Steering Group Chair:
Dr. Hannah Cohen
hannah.cohen@uclh.nhs.uk

National Medical Co-ordinator:
Dr. Clare Taylor
Clare.taylor@nhsbt.nhs.uk

Scheme Manager:
Ms. Hilary Jones
hilary.jones@nhsbt.nhs.uk

HPA Infections co-ordinator:
Ms. Lisa Brant
Lisa.brant@hpa.org.uk

Diary Dates

BBTS HoT SIG, 15th May Birmingham

ISBT (International Society of Blood Transfusion) meeting in Macau, June 2008

SHOT symposium with 2007 data, Royal College of Physicians, London, July 7th 2008

BBTS ASM 11th—13th Sept, Llandudno

MHRA Www.MHRA.GOV.UK

WEBSITE

Website and Resources

WWW.SHOT-UK.ORG

The SHOT website is fully accessible to all, and contains a great deal of relevant material which can be down loaded and used by individuals for teaching and self study. There is also a direct link to the MHRA and SABRE website. The following contents may be of particular interest:

- User guidelines for SABRE, with FAQs
- All previous SHOT reports and Summaries
- Presentations from SHOT launch meetings
- Standards for investigation of adverse reactions
- SHOT definitions
- SHOT in obstetrics
- SHOT for children
- Lessons for clinical and laboratory staff
- Educational material under development

The MHRA website contains an explanation of SABRE, downloadable copies of the Directives and BSQR, and minutes of BCC meetings.

Please be sure to download and complete your laboratory annual compliance form by April 2008.

Emails from SHOT and SABRE

A number of reporting Trusts and Hospitals have set up specific email boxes for receiving mails for both SHOT and SABRE. These are separate mail boxes with a password shared between a group of people such as the Hospital Transfusion Team. Unfortunately mails sent to these addresses frequently go unanswered for weeks or months as the mail box is not regularly visited. PLEASE make sure this problem is rectified—either by ensuring someone takes on the responsibility to look at mails regularly, or by converting to a group email, so that all mails sent to the group address are delivered to every person's mail box.