

SHOT *Privacy Notice*

Serious Hazards of Transfusion (SHOT) Privacy Notice – Data protection and Confidentiality

Version 2.0, 05/01/2018

What is the SHOT database?

The SHOT database is the haemovigilance database for adverse events and reactions in blood transfusion reported by healthcare organisations that are involved in the transfusion of blood and blood components in the United Kingdom. The information in the database will be used to identify risks and problems, from which SHOT produces recommendations to improve patient safety. The recommendations are published in the Annual SHOT Report which is then circulated to all the relevant organisations including hospitals, the four UK Blood Services, the Departments of Health in England, Wales, Scotland and Northern Ireland and all the relevant professional bodies.

What information does it contain?

SHOT has been collecting data on adverse events and reactions in blood transfusion since 1996 and since 2010 this has been supplied by reporting healthcare organisations via the SHOT database. The information includes restricted details about the patient, such as medical diagnosis and investigations performed, plus treatments given and outcomes of the adverse event. The information importantly also contains the patient date of birth and gender. These details can be essential for assessment of the incident. Transfusion requirements vary at different ages, some of which need to be very precise, so use of age alone may not be sufficiently accurate. . There are also substantial differences between male and female patients in relation to transfusion. The Information Commissioner's Office (ICO) has confirmed that they regard date of birth, gender and a procedure (incident) as sufficiently anonymous to maintain patient confidentiality

To increase security of patient identification, a new policy regarding use of the date of birth was introduced in 2017:

- Only the age, calculated from the supplied date of birth, will be shared with SHOT experts as required for analysis of cases
- The date of birth will remain only accessible to authorised staff via the SHOT database

- Case studies used in the Annual SHOT Report and for educational purposes will no longer include an age of the patient and will be restricted to a decade, e.g. 'in their 70s'.

What is the legal basis for the SHOT database?

SHOT data are provided by healthcare organisations that are involved in the transfusion of blood and blood components under a professional duty of candour and are collected for a "medical purpose", as defined in the 2006 National Health Service Act Section 251, for the provision of care and treatment and the management of health and social care services.

Who manages the SHOT database?

The SHOT database is managed by the SHOT Steering Group (SG), which provides professional ownership and strategic direction, monitors the performance of SHOT and is accountable to the UK Forum (representing the four UK blood services) through the SHOT Medical Director for the use of resources and management of the budget. Membership of the Steering Group will consist of nominated representatives of the Medical Royal Colleges and other professional bodies.

What happens to the data and who can see it?

The data are collected by the hospital staff treating and managing the patient, including doctors, nurses and laboratory staff. Once the records have been loaded to the SHOT Database they can be reviewed by authorised staff at the reporting hospital and by SHOT staff, using an approved user account with a secure password. These data do not include patient names or addresses. All SHOT staff are required to undertake regular mandatory training on information governance.

Hospital staff enter the information directly into a secure Web-based database via the Medicines and Healthcare products Regulatory Agency (MHRA) database known as SABRE. Reporting of serious adverse events and reactions to the MHRA is mandated by law.

When the data have been checked and confirmed by the hospital reporters, the software engineers and data analysts at Dendrite Clinical Systems™ will download the data to a secure server in Dendrite's offices.

The information collected allows SHOT to analyse adverse events and reactions in blood transfusion and learn from these. SHOT produces an annual report with recommendations for improved practice. These annual reports do not contain the details of individual patients. Annual reports are available via the SHOT website www.shotuk.org. No data which could identify somebody will be shared with anyone, or used for purposes other than those required to perform

the analysis. If the current arrangements for running this haemovigilance analysis through SHOT should end, the data will be deleted or securely transferred to a new provider.

SHOT Database Server

The server is hosted on the NHS network (N3) within a data centre in London, by Pikel. This is a tier four data centre which meets the highest levels of building security.

The service delivery and information governance provided complies with ISO 20000 & ISO 9001 accreditation and the security structure is aligned alongside ISO27001. The security arrangements are internally audited approximately every three months and externally audited every six months.

All servers have firewall and anti-virus software installed which is configured to use real-time scanning.

Backup Resilience

The data is securely backed-up each day. All backed up data stored is compressed, de-duplicated and encrypted within a secure off-site vault.

There are two backup vaults, the primary one is hosted locally and is then backed up to a secure secondary off-site vault hosted within a separate datacentre located at Heathrow.

Dendrite Security

Dendrite Clinical Systems™ is assessed against NHS Information Governance standards, which includes both physical and organisational security measures. Dendrite's toolkit assessment score is available on the IG Toolkit website (<https://www.igt.hscic.gov.uk/Home.aspx>).

The computer software program created by Dendrite that holds the SHOT data has been independently tested to ensure that it is not vulnerable to unauthorised access, or internal breaches of security.

Can I ask to see the data that the SHOT registry holds about me?

The anonymity associated with SHOT reporting means it would not be possible to identify data on a particular individual.

Further information

Queries should be directed to SHOT via shot@nhsbt.nhs.uk or 0161 423 4208.