# **SHOT Privacy Notice**

Version 7.0, 01/07/2021

SHOT is the UK's independent, professionally-led haemovigilance scheme. Since 1996 SHOT has been collecting and analysing anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations that are involved in the transfusion of blood and blood components in the United Kingdom. SHOT is funded by, and accountable to, the 4 UK Blood Services via the UK Transfusion Forum. Where risks and problems are identified, SHOT produces recommendations to improve patient safety. The recommendations are put into its annual report which is then circulated to all the relevant organisations including the four UK Blood Services, the Departments of Health in England, Wales, Scotland and Northern Ireland and all the relevant professional bodies as well as circulating it to all of the reporting hospitals. As haemovigilance is an ongoing exercise, SHOT can also monitor the effect of the implementation of its recommendations.

## **Information Governance**

SHOT is hosted by NHS Blood and Transplant (NHSBT) for information governance purposes, as such the NHSBT is the data controller for the data processed by SHOT. The NHSBT is responsible for ensuring that all practices and processes within SHOT are designed to support people's privacy and data rights and making sure data protection is represented at a board level. All members of the SHOT team are employed by the NHSBT. The NHSBT are the nominated data controllers (NHSBT privacy notice <a href="https://www.nhsbt.nhs.uk/privacy/">https://www.nhsbt.nhs.uk/privacy/</a>).

If you have any questions or concerns about your privacy rights within SHOT, these can be referred to informationgovernanceteam@nhsbt.nhs.uk.

The Data Protection Rights (right to access and control how your data is used) do not apply to the data held by SHOT. SHOT do not hold any personal data.

### 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 is used to identify risks and problems, from which SHOT produces recommendations to improve patient safety.

## What is the legal basis for the SHOT database?

SHOT data is processed according to Article 6 1 (e) and Article 9 2 (h) under the General Data Protection Regulation (GDPR) which means that we can process this health care data for the performance of our official task or in the public interest and for the provision of healthcare

#### What information does SHOT collect?

1. Data relating to serious adverse events and reactions: SHOT has been collecting data on adverse events (SAE) and serious adverse reactions (SAR) 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's date of birth and gender (sex). 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 patients that do, or do not, have childbearing potential, in relation to transfusion. The Information Commissioner's Office (ICO) has confirmed that they regard date of birth, gender (sex) 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'.
- 2. Data relating to compliance with SHOT recommendations: SHOT releases a survey annually in which reporters are encouraged to indicate their compliance with recommendations from the previous year's annual SHOT report. The survey includes the geographical location of the reporter (UK devolved country) but the data collected is anonymous. This data is published on the SHOT website and available for reporting organisations to use to improve transfusion safety at a local level.
- 3. Participation data: participation bench marking reports are generated from the information input to the database by reporters when submitting an SAE or SAR. This information is made available on the

website for organisation to benchmark their participation according to size or geographical location. This information is not anonymous as it includes the name of the reporting organisation, as well as the number of reports and the trends, but this information is only accessible by reporting organisations via a password protected link.

4. Data from ad hoc surveys: SHOT may release surveys to support haemovigilance work, these are not mandatory. SHOT may also collaborate with other organisations to release surveys relating to transfusion safety, compliance with national recommendations, or other aspects of haemovigilance. These surveys do not include any identifiable data and publications released from the survey results are anonymous.

## Who manages the SHOT database and data repository?

The SHOT database is managed by the SHOT Steering Group (SG), which provide professional ownership and strategic direction, monitor 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.

Data collected from surveys is stored on the NHSBT network and is protected under the NHS Blood and Transplant for information governance system.

## What happens to the data and who can see it?

The initial data are collected by hospital staff treating and managing the patient, including doctors, nurses and laboratory staff. Once the records have been uploaded 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. This data does not include patient names or addresses. All SHOT staff are required to undertake regular mandatory annual Information Governance training.

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<sup>™</sup> will download the data to a secure server in Dendrite's offices (see Section on Dendrite security).

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 <a href="https://www.shotuk.org">www.shotuk.org</a>. No data collected by SHOT 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.

Data collected though SHOT activities, other than the SAR and SAE reporting database, is stored securely on the NHSBT network and can only be accessed by the SHOT team.

#### **SHOT Database Server**

The server is hosted on the Health and Social Care Network (HSCN) within a data centre in London, by Piksel. This is a tier four data centre which meets the highest levels of building security.

The service delivery and information security provided complies with ISO 20000 & ISO 9001 accreditation and the security management 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 for the SHOT Database**

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 are compliant with the Data Security and Protection

Toolkit (DSPT). Dendrite's toolkit assessment score is available on the DSPT website

(https://www.dsptoolkit.nhs.uk/OrganisationSearch?searchValue=Dendrite).

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 about an

individual. This means that under the Data Protection rights SHOT would not be able to identify individuals

within the anonymous reports.

**Subscriptions** 

SHOT sends haemovigilance-related email communications to users of the SHOT database. These types of

communication will include information regarding SHOT symposia, webinars and podcasts, free educational

resources, newsletters and surveys. If you do not wish to receive these email communications, then please

email us at <a href="mailto:SHOT.unsubscribe@nhsbt.nhs.uk">SHOT.unsubscribe@nhsbt.nhs.uk</a>.

**Contact for further information** 

Please contact us: <a href="mailto:shot@nhsbt.nhs.uk">shot@nhsbt.nhs.uk</a> or 0161 423 4208.

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