Privacy Notice

Information about how the Evaluating ICON Study processes data from existing datasets and survey of professional organisations

Background

The commonest severe injury in infants is brain trauma, caused by being struck or shaken. This is called abusive head trauma (AHT). Although infrequent, it is a devastating injury, with high rates of death or lifelong disability. AHT is most common around the age when babies cry most, a period known to be stressful for carers. Whilst it is not always possible to reduce how much a baby cries, it is possible to help parents cope. Research suggests that AHT may be preventable with clear education and support messages for families about normal crying, especially if given on several occasions. Using this evidence, a programme called 'ICON' was developed, and has been growing in use. It comprises four simple messages, given to families by healthcare professionals on five occasions in the baby's early life. In the Evaluating ICON study we will investigate whether AHT occurs less often in areas offering the ICON programme than areas that do not, and what factors influence its impact.

To answer these questions, we will measure the number of cases of AHT before and after the introduction of the ICON programme using a range of health record systems. We will contact families and healthcare professionals to ask what they know about ICON, and their views on it, including how to make it available and understood by as many families as possible. By doing this we will find out what helps, or hinders, its rollout to new areas. Using this research, we will make recommendations to policy makers and commissioners on whether ICON is beneficial for families, and if it is, recommend the best way to implement it. By engaging with a wide range of people, including healthcare professionals, policy makers, and the owners of the ICON programme, we will generate reliable and generalisable results.

What datasets will we process for the study?

The quantitative analyses will use existing datasets which collect information on infants who have suffered abusive head trauma between 2016 and 2021. These include Hospital Episode Statistics Admitted Patient Care, Emergency Care and Diagnostic Imaging Datasets, the Trauma and Audit Research Network (TARN) dataset, the National Child Mortality Database (NCMD), and the Paediatric Intensive Care Audit Network (PICANet).

Trauma audit & research network (TARN) – TARN is the National Clinical Audit for Trauma Care which collects data on the acute care pathway of patients with major traumatic injury. It collects data on all children with major trauma from 218 hospitals across England, Wales, Northern Ireland and Ireland. It is used to monitor trauma care and facilitate improvement of trauma services. Submitters note whether abuse is suspected as the injury cause. Using TARN will identify most cases of severe AHT, but identification requires clinicians and/or submitters to recognise potential for abuse, which may lead to some cases being missed. Deaths in the pre-hospital environment are not captured on TARN. The information on the collection and use of TARN data can be found here: https://www.tarn.ac.uk/Content.aspx?ca=2&c=3860

Paediatric intensive care audit network (PICANET) – PICANET is a national registry containing data on admissions to paediatric intensive care units. It is used to monitor clinical practice, facilitate resource planning and study the epidemiology of critical illness in children. We may identify via this route a cohort of children

with severe AHT who would be missed by other means. The information on the collection and use of PICANET data can be found here: https://www.picanet.org.uk/patients-and-families-information/

National child mortality database (NCMD) – The NCMD is an NHS-funded national registry that collects information on all children who die in England. The main purpose of data collection is to capture and disseminate learning from child death reviews, and that actions are taken when necessary. It is maintained and managed by the University of Bristol. Utilising this registry will identify cases who die in the community. The information on the collection and use of NCMD data can be found here: https://www.ncmd.info/privacy-notice/

Hospital episode statistics (HES) – The Hospital Episode Statistics is a data warehouse that contains details of admissions, outpatient consultations and A&E attendances at NHS Hospitals in England. It is used by NHS Trusts for payment for activity undertaken, as well as research and health services planning. We will interrogate this to determine whether it is possible to identify children with less severe AHT based on combinations of diagnostic and outcome codes. For the study, we will be using the following HES datasets:
Admitted Patient Care (APC) – This dataset contains information on all admission in NHS Trusts in England.
Emergency Care Data Set (ECDS) – This dataset contains information on A&E attendances in NHS Hospitals.

The information on the collection and use of HES data can be found here:
https://digital.nhs.uk/about-nhs-digital/our-work/keeping-patient-data-safe/gdpr/gdpr-register/hospital-episode-statistics-gdpr/hospital-episode-statistics-hes-gdpr-information

Diagnostic Imaging Dataset (DID) – The DID contains detailed information about diagnostic imaging tests carried out on NHS patients. We will use this data to determine whether it is possible to identify children with less severe AHT based on requests for fracture imaging in combination with a diagnostic code for suspicion of head injury from HES APC and/or ECDS. Details of the NHS England's Privacy Notice which covers data collection and processing for the DID can be found here: https://www.england.nhs.uk/contact-us/privacy-notice/

Aside from existing patient level datasets, we will also be collecting data from the ICON programme, the ICON Commissioning Tracker. This dataset is kept and maintained by the ICON Programme to track adoption by different organisations, including the level of implementation. This is at the level of the Clinical Commissioning Groups (CCG) and contains no personal data. It will be linked to the patient-level datasets at the CCG level.

We will also be conducting the ICON Programme Implementation Survey, which is a survey of health professional organisations in England. This will help us determine the number of units that have incorporated ICON in training and operational protocols, the number of touchpoints, the number of hospitals implementing the ICON programme, and percentage of parents given advice by the health professionals. This is at the level of the Clinical Commissioning Groups (CCG) and contains no personal data. It will be linked to the patient-level datasets at the CCG level.

What personal information will we be processing?

For the study, we need to use personal data including NHS Number, date of birth, post code, age and ethnicity. We will also be processing health data related to the traumatic head injury such as details of diagnosis, clinical investigations, hospital admissions and death information (if applicable).

How will the data be processed?

Holders of the datasets will be asked to identify and extract cases of abusive head trauma between January 2016 and December 2021. The dataset controllers will send the resulting datasets to NHS Digital as trusted third party for data linkage. NHS Digital will link the datasets together using identifiers such as NHS Number, date of birth and post code. They will then remove the identifiers from the resulting dataset (de-identification) and replace these with a pseudonymised ID. A link key will be held by NHS Digital and destroyed at the end of the study.

The de-identified linked data will be provided to the study team. It will be securely transferred to an encrypted SafeHaven storage space in the University of Bristol, using a secure file transfer protocol. It will only be accessed by members of the study team undertaking statistical analyses of clinical and cost effectiveness.

What is the purpose of data processing?

We are processing data to address the research questions on the effectiveness of the ICON programme in reducing incidence of abusive head trauma (AHT) in young infants.

The research questions being addressed in this study are:
1. In infants, has implementation of the ICON programme, compared to standard newborn advice, resulted in a reduction in the incidence of abusive head trauma?
2. Amongst families and healthcare professionals, what factors determine the reach of the ICON programme, and what are the key enablers and obstacles for its adoption, implementation, and maintenance?
3. Is the ICON programme cost-effective compared to normal care?

What is the legal basis for processing the data?

All research data will be handled according to the principles of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018. We are processing the data for a public interest task, with the lawful legal basis defined in Article 6 (1) (e) of GDPR. We are also processing data on ethnicity and health, which are classes as sensitive data, under the additional legal basis provided by Article 9 (2) of the GDPR. This underpins processing as necessary for reasons of public interest in public health, and for archiving, research and statistical purposes.

How do we keep the data safe?

The Chief Investigator and the research team will preserve the confidentiality of participants in accordance with the Data Protection Act 2018. All data will be de-identified and stored in a secure and encrypted SafeHaven folder located in the University of Bristol, and appropriately backed up.

How long will we store the data for the purpose of the study?

Sensitive personal data held by NHS digital for the purposes of linking datasets and the link key will be deleted on completion of the study which is [end date here].

In accordance with the University of Bristol's 'Guidance on the Retention of Research Records and Data For studies involving human participants, their tissue and/or human data', the de-identified data will be retained for ten years. It will then be destroyed in accordance with the University of Bristol's Records Management and Retention Policy (IGP-03,https://www.bristol.ac.uk/media-library/sites/secretary/documents/information-governance/records-management-and-retention- policy.pdf).

What are your rights?

The data is held solely for research purposes. As an individual you have a right to be informed about the study, its use of the data, and how long we will hold the data for. You have a right to dissent the use of your data in the study.

You can request for your data to be erased at any point during the study through the National Data Opt-Out. This instructs NHS Digital not to include your data for research or planning purposes. You can do this by:

(i) Clicking on this link: How to manage your choice online - Choose if data from your health records is shared for research and planning (service.nhs.uk)

(ii) phone: 0300 303 5678

(iii) email: enquiries@nhsdigital.nhs.uk

You can find more information about the National Data Opt-Out here: National data opt-out - NHS Digital

Study Contact Information

If you are concerned about how the study might process any of your personal data, please contact the Principal Investigator and Information Guardian for the study:

Dr. Mark Lyttle
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You may also contact the University of Bristol Data Protection Officer:

Henry Stuart
Information Governance Manager & Data Protection Officer
University Secretary's Office
University of Bristol
Email: henry.stuart@bristol.ac.uk
Phone: 0117 455 6325

The University of Bristol has information on individual rights and privacy at the following link:
http://www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/