PATIENT INFORMATION SHEET

Information for parents of babies admitted to neonatal units

ENewborn International Neonatal Research Database

UK National Research Ethics Service reference 26/LO/0444

Summary

This information sheet tells you about eNewborn, an international neonatal research database. In eNewborn we use information from your baby's medical records. This information includes mother's details such as type of delivery and baby details such as diagnoses, care received and outcomes. These data can improve newborn care in many other ways such as helping neonatal units to improve their work and testing new and improved ways to care for babies and support families. We will only use information that we need. We will not use your name or contact details, or your baby's name and no one will be able to identify you or your baby. Everyone involved in eNewborn will keep your data safe and secure. We will also follow all privacy rules.

What is eNewborn?

ENewborn is a collection of information (a database) about babies from neonatal units around the world. All the information on eNewborn is "de-identified"; this means it is impossible to find out about or identify individual babies from the database. The headquarters of eNewborn is in the UK at Imperial College London, one of the top ten universities in the world.

ENewborn is approved by the UK National Research Ethics Service (reference 26/LO/0444) for use under data protection and research legislation to improve newborn care. Imperial College London is the data controller for eNewborn and is responsible for looking after the information in the database and using it properly. Everyone involved at Imperial College will keep your data safe and secure and follow all privacy rules. No one will be able to work out who you or your baby are from any outputs of the database.

How will we use information in eNewborn?

The purpose of eNewborn is to improve patient care. We use eNewborn to check whether neonatal care does what we want it to do (audit), to describe and compare care across many countries and units (evaluation and benchmarking), and to study new and improved ways to care for babies and their families (research). Other individuals and organisations can apply for permission to use eNewborn. If the application is considered in the interests of babies and likely to benefit the care they receive, and if the applicants have obtained all necessary regulatory approvals to ensure that the use of data is in the public interest, and meets ethical standards, the eNewborn International Investigator Group will normally give permission. No individual can be identified in any output.

How do we keep data secure?

The local lead within each hospital or network of hospitals sends data electronically using a secure system to Imperial College London, where eNewborn is located. No patient names are included, nor any information like date of birth or address, that might identify you or your baby. We work with times or dates as either "month and year" or "minutes from birth", not actual dates.

Can I refuse to have my baby's data included in eNewborn

Under General Data Protection Regulations, you are free to refuse to have your baby's data included in eNewborn. This will mean that your baby's data will not contribute to any of the purposes for which eNewborn is used. Data on all babies admitted to his neonatal unit are included routinely in eNewborn unless a parent refuses. Including information on every baby helps maximise benefits by ensuring all audits, evaluations and research studies are properly representative of neonatal care. If you do not wish to have your baby's data included in eNewborn, please inform a member of staff on the neonatal unit where your baby is receiving care. They will make sure your baby's data are not included in eNewborn by contacting Imperial College London.

What are my choices about eNewborn?

You can request a copy of the information on your baby that your neonatal unit sends to eNewborn. Please ask a member of staff on the neonatal unit where your baby is receiving care. You can stop your neonatal unit sending your baby's data to eNewborn at any time, without giving a reason, and without affecting your baby's care. We will retain any information that is already in eNewborn.

Legal basis of eNewborn

Imperial College London is a university and, in this capacity, uses personal information to conduct research to improve health, care and services. As a publicly funded organisation, Imperial College London has to ensure that it is in the public interest when we use personal information. Health and care research should serve the public interest, which means they have to demonstrate that research serves the interests of society as a whole. They do this by following the UK Policy Framework for Health and Social Care Research, and by complying with the law, and the recommendations and guidance from the UK Information Commissioners Office.

International data transfer

We may share eNewborn data outside the UK for research conducted by external investigators. If this happens, we will only share the data that is needed. We will also make sure you cannot be identified from the data that is shared. If your data is shared outside the UK, it will be with researchers conducting research ethics committee approved studies. We will make sure your data are protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some countries your data may be shared with have an adequacy decision in place which means we know their laws offer a similar level of protection to data protection laws in the UK
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing

- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office website: https://ico.org.uk/for-organisations/report-a-breach

What should I do if I wish to make a complaint?

If you wish to make a complaint against Imperial College London on how they have handled personal data, please contact Imperial College London's Data Protection Officer by email at dpo@imperial.ac.uk, by telephone on 020 7594 3502 and/or by post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with the response or believe Imperial College is processing your personal data in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO). The ICO recommends that you try to resolve matters with the data controller (Imperial College London) first before involving them.

Whom should I contact for more information?

We hope you have found this information helpful. If you would like to know more about eNewborn please go to our website https://www.imperial.ac.uk/neonatal-data-analysis-unit/enewborn/, email eNewborn@imperial.ac.uk, ask a member of staff or contact Imperial College London's Data Protection Officer by email at dpo@imperial.ac.uk, by telephone on 020 7594 3502 and/or by post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

Thank you for reading this information,

The eNewborn Investigator Group