



The Non-Invasive Ventilation Outcomes (NIVO) Study
Data processing statement, privacy and fair processing Notice

Issued 22nd April 2020 (updated 22nd June 2020).

The NIVO study is being run by Northumbria Healthcare NHS Foundation Trust. Contact details for the Trust can be found on www.Northumbria.nhs.uk We respect that the privacy of your personal information is important to you and have therefore created this privacy notice to let you know about the types of personal information we may collect from you, how it is maintained and how it will be used.

Study background and aims

In the UK around one in eight patients admitted to hospital have a flare up, or exacerbation, of Chronic Obstructive Lung Disease (COPD). These patients can often have a condition called 'respiratory failure', where their oxygen levels are low and their carbon dioxide levels are too high. There is strong evidence from research trials that treatment with a mask ventilator (called NIV) can be lifesaving. However, we don't currently know which patients are most and least likely to benefit from this treatment.

The aim of the NIVO study is to examine a large group of patients admitted with a flare-up of COPD plus respiratory failure, and who were treated with NIV, in order to try and calculate which patients benefit most from this. This will allow clinicians to provide patients and colleagues with accurate information about their patients, and will hopefully improve communication between clinicians' and their patients. This is an 'observational' study, so there were no changes to medical care while the study was performed.

What is personal information?

Personal information is any item of information which relates to a person who either is, or can be, identified from that information. Examples of personal information are name, address, telephone number, date of birth, email address, or other similar information.

When was the NIVO study running?

The NIVO study was running from October 2016 to February 2018. During this time patients with an exacerbation of COPD and who received treatment with a ventilator in a hospital doing the study were included in NIVO.

The NHS trusts which were participating in the NIVO study were:

- Northumbria NHS Foundation Trust
- Gateshead Health NHS Foundation Trust
- South Tyneside NHS Foundation Trust
- Leeds University Hospitals NHS Trust
- Nottingham University Hospitals NHS Trust
- Oxford University Hospitals NHS Trust
- Guys and St Thomas' NHS Foundation trust

- Taunton and Somerset NHS Trust
- Plymouth University Hospitals NHS Foundation Trust
- Prince Philip Hospital, Llanelli

These organisations along with NHS Digital are the source of the information we process as part of the NIVO study.

Northumbria Healthcare NHS Foundation Trust is running the NIVO study. They are called the 'sponsor site', as they are running the research, and also act as the lead 'data controller' for it (this means they are responsible for the data which is collected). The lead researcher for this study (called the chief investigator) is Professor Stephen C. Bourke. Individual NHS Trusts participating in the Study also remain as Data Controllers for their own information.

What data will be used and how is it collected and used (purpose)?

The NIVO study collected data when patients were admitted to hospital as described above. This included personal information such as patient's name and date of birth, as well as other information about the hospital admission (such as the presence of other medical conditions, blood tests results, and duration of ventilation). Data was collected from both GP and hospital records.

The data collected will be used to allow the conduct of the NIVO study as laid out in the pre-published study protocol (<http://www.isrctn.com/ISRCTN22921168>).

We have not and will not use automated decision making tools, including profiling, during the course of the study.

How is this data stored?

Data collected during the NIVO study was entered onto a password protected, secure electronic database on the NHS secure network (called the N3 network). This can only be accessed from NHS property. The information entered to this database is downloaded to a secure, encrypted and limited access server at Northumbria Healthcare NHS Foundation Trust. This is only accessed by the staff in Northumbria Healthcare's research team. Personal Data is not accessible to other participating sites where they have not submitted the data themselves.

Sharing and collecting data from NHS Digital

Data will also be collected from NHS Digital. This is an NHS organisation which holds data about hospital admissions and deaths around the country. It collects this data as a matter of routine.

To identify patients with NHS Digital we will share personal information with them such as a patient's NHS number, date of birth and unique NIVO study number. NHS Digital will link the personal information we provide to them with their own records. NHS Digital will then return pseudonymised data to us, using the unique NIVO study number alone (with personal information deleted). This will only be used for the purpose of conducting the NIVO study.

The data returned by NHS Digital will allow us to study how many hospitalisations patients had in the year following their admission. It will also allow us to see if and when patients died, including the cause(s) of death, and examine measures of deprivation.

How is pseudonymised data joined together?

When NHS digital return pseudonymised data to us each patient record will be associated with the patients' unique NIVO study number. The NIVO study team at Northumbria Healthcare will then merge this data with the NIVO database that already exists. This will produce one complete database.

How is data protected?

The NIVO study adheres to the Data Security & Protection Toolkit through Northumbria Healthcare NHS Foundation Trusts submission and data is handled in accordance with GDPR. In addition, and as outlined above, the NIVO study data is encrypted with password protection and files stored on restricted access servers to ensure protection.

How long will personal data be kept?

Personal information will be deleted 12 months after final publication of the study. The remaining data from the NIVO study will be stored for 15 years after final publication of the study.

Who have given approvals for this research?

This study has been reviewed by an NHS ethics committee and approval has been provided (Reference: 16/NE/2013). The NHS Health Research Authority approved the project on 27/07/2016.

In addition, the transfer of personal information between Northumbria Healthcare and NHS Digital has been reviewed and approved by the NHS Confidentiality Advisory Group (Reference: 19CAG0072) and has gone through NHS Digital's own checks and balances.

Northumbria Healthcare Caldicott guardian approval was granted for both the whole NIVO study (Ref: C3104), and separately for the transfer of data between Northumbria Healthcare and NHS Digital (Ref: RPI-1065).

What are the NIVO study's notification procedures?

In the event of an incident or breach of your personal information having been accessed, lost, or stolen by an unauthorised third party, we will exercise reasonable efforts to notify you and disclose the personal information that was accessed/disclosed using contact information we hold for you.

What is the legal basis for this data to be used?

We are a publicly funded NHS body and we the legal basis for the study under the General Data Protection Regulations (GDPR) is:

Article 6 (1) (e) – Processing is necessary for the performance of a task carried out in the public interest; and

Article 9 (2) (j) – Processing is necessary for archiving purposes in the public interest, scientific or historical research purposed or statistical purposes.

The NIVO study also has *National Health Service Act 2006, Section 251 'control of patient information'* approval for the transfer of personal information to NHS Digital. We ensure that it is in the public interest when we use personally-identifiable information in our research. Health and care research should serve the public interest, which means that before we are able to access the personal identifiable information we have to demonstrate that our research serves the interests of society as a whole. Northumbria Healthcare is registered with the information commissioner's office; registration number Z691260X.

What if I don't want my data used?

If you would like to opt out please contact the NIVO study team (details below).

What other information is available to me?

NHS Digital's privacy statement can be found at

- <https://digital.nhs.uk/about-nhs-digital/privacy-and-cookies>

Northumbria Healthcare's generic privacy statements can be found at

- <https://www.northumbria.nhs.uk/about-us/privacy-policy/>

How is the NIVO study funded?

Funding for the NIVO study was from competitive, charitable grants which were applied for by the study team. The funding bodies are: Philips Respironics, Pfizer OpenAir, The ResMed Foundation and Bright Northumbria. The funders have had/will have no input into the study design, development, conduct, analysis or decisions to publish results.

The ResMed Foundation provides charitable grants for clinician-initiated research into ventilation. These grants are awarded independently of ResMed Corporation. ResMed Corporation and Philips Respironics produce medical devices including non-invasive ventilators. Whilst indirect, if the conclusion of this research recommends a change in the increased provision of ventilation this could have an indirect benefit (likewise, if the study recommends the opposite, it may be of financial detriment to these organisations).

What are your rights?

All applicable data subject rights will be available during the 12-month period that data is classed as pseudonymised (identifiable). Once the data has been anonymised data subject rights will no longer be applicable as the data will not be personally identifiable. Your rights however will remain in place with the NHS Trust or organisation who supplied the data.

Under Data Protection laws, you have rights which allow you to find out what information is held about you, on computer and in certain manual records. This is known as "right of subject access".

If you want to see or receive a copy of your records speak to a member of our staff who will be able to help you. In certain circumstances access to your records may be limited, for example, if it is felt to be in your best interest or for the protection of others.

Under the law, you may also have additional rights in relation to your information. For example:

- The right to request any decisions taken by automated decision making with regards to your information;
- The right to rectification of your information is found to be inaccurate (in line with NHS Guidelines);
- The right to restrict processing;
- The right to data portability;
- The right to erasure of your personal information held by us, in certain circumstances;
- The right to withdraw consent at any time, where consent has been given.

What if I want to complain?

Individuals that we hold data about have a right to complain. If you would like to raise a complaint about how we have used your data you can contact the NIVO research team or the Northumbria Healthcare Data Protection Officer or information governance team, who will investigate this matter further. Contact details are listed at the end of this document.

If you are still not satisfied with the responses, or believe we are processing data in a way which is not lawful you can contact the information commissioners (<http://ico.org.uk>) office by post or telephone.

Address: Information Commissioner’s Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF
 Phone: 0303 123 1113

Who can I contact with further questions or for more information?

If you have any further questions about the study you can contact the NIVO research team at Northumbria Healthcare by post, email or telephone.

CONTACT DETAILS

The NIVO Study team	Northumbria Healthcare Information Governance Team	Northumbria Healthcare Data Protection Officer
Address: The NIVO study, c/o Professor SCBourke Department of Respiratory Medicine North Tyneside General Hospital Rake Lane North Shields NE29 8NH Telephone: 0191 293 4160	Address: Information Governance Digital Services 3 rd Floor Cobalt Business Exchange & Conference Centre Cobalt Park Way Newcastle upon Tyne NE28 9NZ Telephone :0191 607 3601	Address: Tracey Best Digital Services 3 rd Floor Cobalt Business Exchange & Conference Centre Cobalt Park Way Newcastle upon Tyne NE28 9NZ Email:

Email: nivo@nhs.net	Email: igofficer@northumbria-healthcare.nhs.uk	Tracey.best@northumbria-healthcare.nhs.uk
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