ELATE Study Patient Information Leaflet

Background – what is the ELATE study?

The ELATE study is a project based at the London School of Hygiene & Tropical Medicine (London, UK). We brought together a team who are experts at investigating large amounts of health information, including surgeons and patients. As a team, we are carrying out a research study, called ELATE, that aims to improve patient outcomes and costs to the National Health Service (NHS) for a particular type of surgery.

When a blood vessel bursts in the abdomen, there is a real risk of death. A blood vessel is part of our system of veins and arteries that carry the blood to and from our heart. The abdomen is the belly area of the body and lies between the chest and the pelvis. When an abdominal blood vessel bursts, surgeons must repair the blood vessel to stop the severe bleeding. Even when surgery succeeds, between 30-40% of patients die within 1-year.

We are carrying out a research study to learn more about treating the burst blood vessel in the abdomen. The ELATE study will look at two repair techniques surgeons now use. One technique means the patient is put to sleep during surgery (general anaesthetic) and the other has the patient stay awake (local anaesthetic). We will compare the two techniques by closely examining what has happened to people managed with either type of surgery between 1 January 2014 to 31 December 2024.

We do not know enough as to whether surgeons should use one technique over the other. Things like a person's age, health state, sex, and ethnicity, could matter. We already know that women who experience a burst abdominal blood vessel do less well than men.

The NHS also needs to know about the cost of these techniques. We will find out and compare the actual cost for each. If the study finds out that the 2 techniques are just as efficient at treating the patient, the NHS can then confidently ask surgeons and patients to use the technique that costs less, helping the NHS as a whole.

How will we find out what has happened up to now to compare these 2 treatments?

The NHS collects and stores patients' health information whenever they use the NHS. This is often called patient data. The patient data is stored in computers, in patient data libraries called Registries. Before these data are used for research, the personal identifiable information about any one person, such as their name or NHS number, is separated from the health information. In other words, their stored health information, is

no longer personal – it is de-identified. It means researchers can examine what happened before, during, and after treatment, for many tens of thousands of patients, without knowing who those patients were.

Using patient data for research, even when it's de-identified, normally requires each patient's permission (in other words, informed consent). However, for the ELATE study, we are comparing 2 treatment strategies used during an emergency, when someone has a burst abdominal blood vessel. They are already very ill, and surgeons must operate as soon as they can. There is no time to explain which anaesthetic approach will be used and why, and if the patient would like to share their de-identified health information for research.

The information about them is, nonetheless, collected and stored in the National Vascular Registry with approval from the Secretary of State for Health under Section 251 of the NHS Act 2006 (reference number: CAG 5-07(f)/2013). If someone thinks they have been included in the National Vascular Registry and would like to opt-out, they can do this at any time through the National Data Opt-Out.

The ELATE study team has been given ethics approval to do this research from the NHS East Midlands – Leicester South Research Ethics Committee. The Confidentiality Advisory Group (CAG) has given advice to the Health Research Authority under section 251 of the NHS Act 2006 to support this research. These committees meet to consider whether studies like ours can use personal health information without the consent of each individual patient. These committees have decided our study can go ahead, because we have a strong health care reason for the study, and because we proved that we would make very safe and secure use of the patient data.

Specifically, the ELATE study were given approval to use patient information from the following sources:

- The National Vascular Registry
- Hospital Episode Statistics
- Office of National Statistics death data

These sources together contain enough information for the ELATE study team to compare the 2 treatment strategies for a burst abdominal blood vessel. This information includes details about treatment provided during surgery, other health conditions and treatments, whether the person is male or female, age, ethnicity, and whether the patient died.

Analysing patient data and keeping this data safe

Analysing very large amounts of patient information presents many difficulties. For example, have the codes the NHS used to record the patient health information been used properly? We will use advanced statistical techniques to address these difficulties to make sure that what we find out is reliable. We will build a correct account of what has happened to patients who are treated for a burst blood vessel in the abdomen as part of emergency patient care in the NHS.

The ELATE study will take 2 years to do its work. Our funding comes from the government and was approved by the National Institute of Health and Care Research funding committee. They have checked that what we say we want to do, and how we will do it, is technically possible as well as worthwhile for the NHS. The funding information and technical summary of the project are available here.

The information needed from both the National Vascular Registry and the NHS will be brought together by National Vascular Registry and NHS England employees who are trained in data protection and security. Trained staff at the National Vascular Registry and NHS England will use confidential patient information to link the National Vascular Registry audit data with hospital and death data.

The ELATE study data which are sent to the London School of Hygiene & Tropical Medicine will NOT include identifiable information (including names, NHS numbers, postcodes, dates of birth) except for date of death for those people who have already died. The date of death will be deleted from the dataset by the ELATE study team within 6 months of receiving these data.

The ELATE study data will be stored on the London School of Hygiene & Tropical Medicine secure server which is highly secure and only accessible to London School of Hygiene & Tropical Medicine employees. The ELATE study data will be stored on this secure server and will only be accessible to those London School of Hygiene & Tropical Medicine employees on the ELATE research team. The ELATE study data will never be shared with people outside of the research team.

Opting-out of the ELATE study

Our study will not include anyone who has opted-out of their personal health information being used for research via the National Data Opt-Out. Trained staff at the National Vascular Registry will ensure that anyone who has opted-out of their data being used for research are not included in the de-identified patient information which is securely shared with the ELATE study team at the London School of Hygiene & Tropical Medicine.

If you had an emergency surgery to repair a ruptured abdominal aortic aneurysm between 1 January 2014 to 31 December 2024 and you do not want to opt-out via the National Data

Opt-Out, but you do want to opt-out of the ELATE study in particular, please contact the National Vascular Registry who can manage this request.

Involving patients and the public in our study

We held 2 meetings with patients who had experienced this surgery or were familiar with using patient information records for health research. Patients in the meetings were clear that the current uncertainty as to which treatment is better is unacceptable. They reassured us that our plans to understand the differences in the 2 treatment approaches was the right thing to do. They were clear that using routinely collected patient information brought together from different NHS records was essential to improve our understanding of which treatment is best.

We will invite patients and members of the public to workshops to help us decide what benefits are most important to patients who have abdominal blood vessel surgery. They will contribute to how we should understand what we find out. They will guide us on how to share our new findings with NHS surgeons and their associations, the government bodies that decide how to fund the NHS, and the general public.

How will we share the results of the ELATE study?

The ELATE study results will be shared through scientific publications and presentations to scientific and patient and public panels. Our patient and public representatives will help us to make these presentations and reports understandable to the general public.

Outside experts will check our methods and results before we are allowed to publish them in scientific journals. We will never publish or describe information on a single patient in the ELATE study – only groups of people. This helps to protect patient privacy.

Further information

If you would like further information about the ELATE study, please see the ELATE study website: https://www.lshtm.ac.uk/research/centres-projects-groups/elate-project

You can also contact the study co-Principal Investigators and project administrator:

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