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PROTECT Airways Study

Consultee Information Leaflet

A research study to find out if an alternative airway system is better than standard care for patients connected to a breathing machine

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- This information sheet explains the PROTECT Airways study and what taking part will involve for your relative/friend.
- This study is looking at an alternative airway system, a type of tube that connects critically ill patients to a breathing machine (ventilator), compared to the tube normally used as standard care. The study is looking to find out if the alternative airway system shortens the duration of intensive care unit care and is good value for money.
- We are approaching you because your relative/friend's doctor has decided your relative/friend needs a ventilator and they are unable to decide for themself whether to participate in this research. To help decide if they should join the study, we would like to ask your opinion whether or not they would want to be involved. **Please note: if your relative/friend needed to be put on a ventilator as an emergency procedure we did not have time to approach you and they have already been entered into the study and given either the alternative airways system or standard care**
- It is important that you put aside your own feelings and wishes and consider what the past and present, feelings and wishes of your

relative/friend would have been, had they been able to consent for themselves.

- The alternative airway system being tested is already approved for use in the NHS and available in some hospitals, so we do not anticipate any serious risk to your relative/friend by taking part.
- If you decide that your relative/friend would like to take part, we will ask you to read and sign the consultee declaration.
- We will collect identifiable data from your relative/friend's medical records and national datasets and ask them to complete questionnaires at 2 and 6 months after entering the study to see how they are getting on.
- We will keep you fully informed during the study so you can let us know if you have any concerns.
- If you are unsure about taking on the role of consultee, you may seek independent advice. We will understand if you do not want to take on this responsibility.
- If you decide that your relative/friend would not wish to take part to this study, it will not affect the standard of care in any way.
- When your relative/friend is better, we will provide them with the same information and ask them for consent to carry on in the study.
- The University of Warwick is currently leading several studies looking at how we treat patients in this setting. Your relative/friend may already be in one of those studies. If so, we may share information between these studies to reduce what we need to ask from you/your relative/friend.

Before you decide, please read the information carefully to understand why the research is being done. Talk to others about the study if you wish and please feel free to ask us any questions.

An online and video version of the information leaflet is available on the study website www.warwick.ac.uk/protectairways/public or accessed by scanning the QR code below

There is separate data information which describes how we will use data collected about your relative/friend and can be accessed on the study website, via the QR code or a member of staff can print a copy for you.

Why are we doing this study?

A breathing tube is the pathway through which air flows into the lungs. Intensive care units (ICU) are specialist hospital wards that provide treatment and monitoring for people who are very ill. Close to 184,000 patients annually are admitted to NHS ICUs and 33% require help with a breathing machine known as invasive mechanical ventilation. Treatment involves placing a plastic tube through the mouth into the windpipe and attaching the person to a breathing machine, known as a ventilator. A serious complication of this life-saving treatment is a chest infection or ventilator associated pneumonia (VAP) and affects 20% of people on ventilators. It occurs when infected mucus, a jelly-like liquid that that lines your lungs, throat, mouth, nose, that is infected drips down the back of the throat past the plastic tube into the lungs. Whilst VAP can be treated with antibiotics, some people will die and others will spend much longer on a on a ventilator.

The alternative airway system aims to improve the windpipe seal and reduce the risk of infected mucus passing down into the lung, by maintaining the inflation of the protective cuff. Patient studies suggest this system is safe and effective at removing mucus and preventing lung infection. Some hospitals are using the alternative airway system. However, we do not know if the positive findings seen in a few hospitals would also be seen in the wider NHS, and whether the new tube is good value for money, resulting in benefit to patients. The National Institute for Health and Care Excellence (NICE), the organisation that provides guidance for health and care practitioners to deliver the best care, have therefore recommended a large-scale research study to see if this equipment is needed.

Why are you being approached on behalf of your relative/friend?

Please note: if your relative/friend needed to be put on a ventilator as an emergency procedure we did not have time to approach you, and they have already been entered into the study and given either the alternative airways system or standard care.

We are asking you about your relative/friend taking part in this study because their doctor has decided they need a ventilator and it is not possible to ask them about their views. We would like you to consider their views and interests on whether they would want to be involved based on what you know of their wishes and feelings. Please let us know of any advance decisions your relative/friend may have made about them participating in research studies.

If you think they would like to take part, we will ask you to sign a consultee declaration form. We will give you a copy of this information leaflet and the form to keep. When your relative/friend becomes well enough we will give them the information about the study and discuss their participation with them.

Who is eligible for the study?

Patients who are:

- Adult (aged18 years and older).
- Needing invasive mechanical ventilation.
- Likely to remain ventilated for at least 24 hours following study entry.

In total we will be including 2194 patients from across the UK in this study.

Does your relative/friend have to take part?

No, taking part in this study is completely voluntary. Even if you agree for your relative/friend to be in the study you can change your mind and withdraw your relative/friend at any time just by telling the healthcare team looking after your relative/friend without giving a reason. We will ask permission to keep the data we've already collected about your relative/friend and collect some data. This is important to make sure the study results are valid. They will receive the same standard of care, and this decision will have no influence on their further treatment.

What does this study involve?

If after reading the information leaflet you feel your relative/friend would want to take part, we will ask you to sign a declaration form. We will give you a copy of this information leaflet and the form to keep.

Your relative/friend will be placed into one of two groups by chance:

1. Alternative airway system: This is similar to the standard care tube, and in addition has a system to ensure the seal to the patient is maintained and has multiple ports to remove secretions (fluids).
2. Standard care: The tube usually used by your hospital will be used.

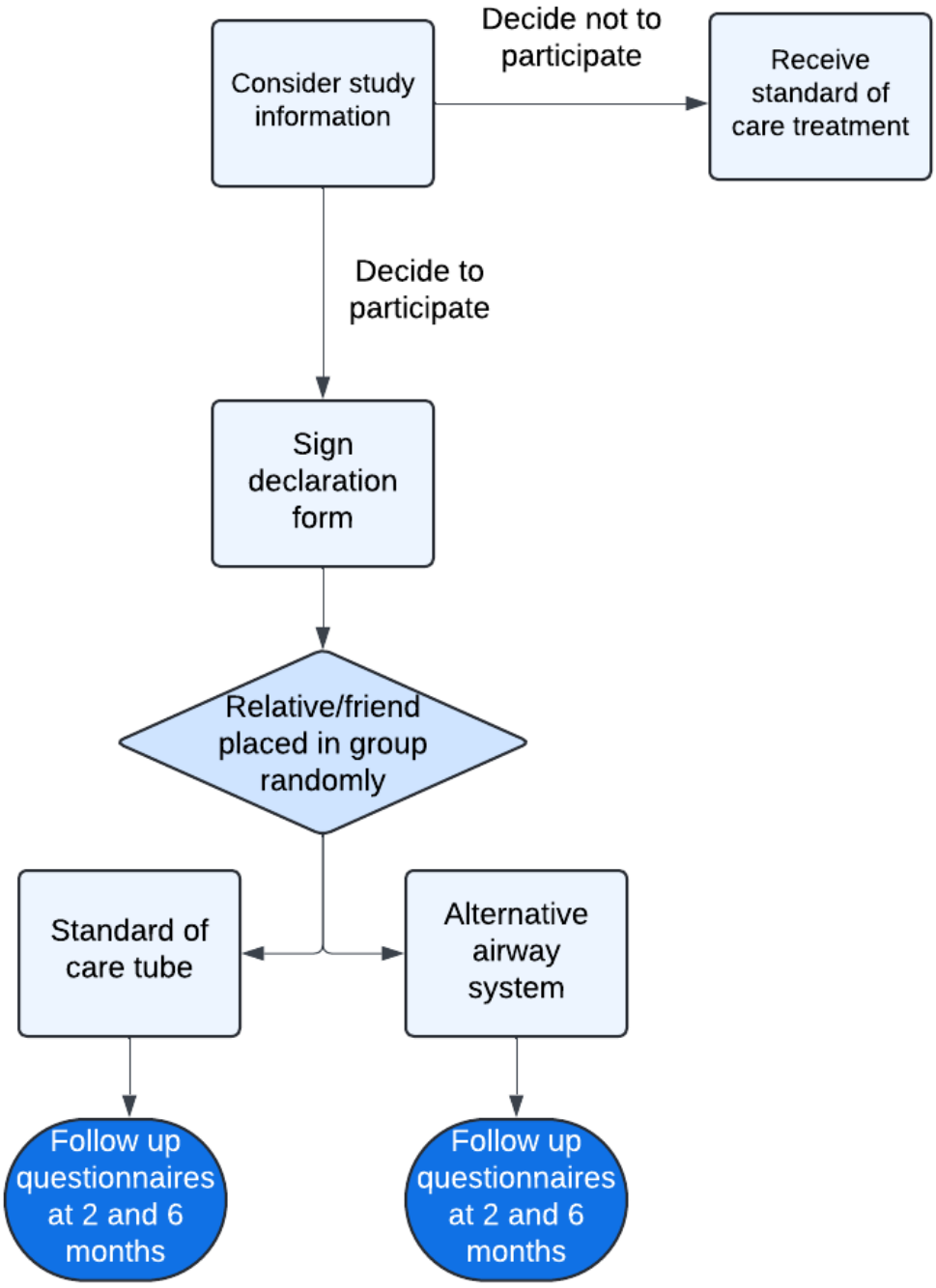
There will be no other changes to care given to patients in both alternative airway system and standard care group.

You, or the hospital team will not be able to choose which group your relative/friend is placed in. This is decided by a computer at random (known as randomisation). This process ensures there is an equal chance of being placed in either group and is the best way to ensure that there is a fair comparison between both tubes.

The research team will collect information about the care your relative/friend receives while in hospital including how the ventilator is used, how long they need the ventilator, and how long they stay in hospital. The research team will collect your relative/friend's personal information such as age, ethnicity, sex and past medical conditions before coming to critical care as this helps us to understand the effect of the breathing tube on different groups of people. Your relative/friend will be sent a questionnaire two and six months after entering the study asking about their overall wellbeing and any healthcare they have used. Each questionnaire will take approximately five to ten minutes to complete. If needed, someone can complete them on your relative/friend's behalf. We will share your relative/friend's name, email

address, and phone number with a third-party company to send them the questionnaires by text message or email.

We may send them the questionnaires via post or collect answers to the questionnaire via telephone. We may also get in touch with your relative/friend by phone, text message or email if we have any queries about their questionnaires or if we have any updates related to the study.



How long does the study last?

Your relative/friend will remain in the study for six months after entering the study to complete the questionnaires about their overall wellbeing and any healthcare they have used.

What are the benefits of taking part?

As this is a research study, your relative/friend may or may not experience a direct benefit. However, the findings of the study may help people needing a ventilator in critical care in the future.

There is no payment for taking part in this study. However, to thank your relative/friend for their time in completing the follow-up questionnaires at two-months and six-months, we will provide a gift voucher.

The University of Warwick is currently leading several studies looking at how we treat patients with respiratory (lung) failure. This group of studies is called the 'Confederation of Respiratory Critical Care Trials' or 'CoReCCT'. If your relative/friend are taking part in other studies within CoReCCT, they will not need to complete questionnaires for each study. They will only be asked to complete the questionnaires once and will receive one voucher with each questionnaire.

What are the risks of taking part?

The alternative airway system is approved for use in the NHS and already used as part of standard care in some ICUs. Therefore, we do not anticipate any serious risk to your relative/friend specific to being in the alternative airway system group. However, all patients who are very sick and need a ventilator are at risk of complications such as damage to the lungs or needing the tube to be put back in after it is removed due to ongoing problems with breathing. Some very sick patients may even die.

As part of care in the trial, we may need to change the breathing tube. This is a common procedure in intensive care. Like all procedures, it has some risks. These include a temporary drop in oxygen levels, minor injuries to the lips, teeth or throat, and infection. The intensive care team will carefully assess your relative/friend prior to changing the tube and, in some cases, may decide that it would be unsafe to do so. As such, more serious problems are very rare.

What if new information becomes available?

Sometimes during a research study, new information becomes available about the study treatment(s). If this information changes your relative/friend's involvement in the study, the study treatment may be stopped, and they will continue to receive the usual standard of care.

How will we keep their data confidential?

The University of Warwick is the study sponsor and data controller. This means that they are responsible for looking after your relative/friend's information and using it properly. In this research study we will use information from your relative/friend, their GP, their medical records, and healthcare databases such as NHS England. We will only use information that we need for the research study. We will let very few people know your relative/friend's name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your relative/friend's data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who your relative/friend is from the reports we write. For more details on how your relative/friend's data will be used and kept safe, please take a look at the data information by visiting www.warwick.ac.uk/protectairways/public or scanning the QR code at the end of this leaflet. Alternatively please ask a member of staff to print a copy for you.

Who is organising and paying for the study?

This study is sponsored by the University of Warwick and is being coordinated by the Warwick Clinical Trials Unit. The study is funded by the National Institute for Health and Care Research, Health Technology Assessment (NIHR156500).

Who has reviewed this study?

People with personal experience of having respiratory (lung) failure and other members of the public have helped design and set up this study.

Research in the NHS that involves patients is reviewed by an independent group of people called a Research Ethics Committee (REC). This committee is there to protect your relative/friend's interests. This study has been reviewed and been approved by the Wales REC2 and Scotland A REC.

What happens if something goes wrong?

It is very unlikely that anything will go wrong as a result of taking part in this research. However, if you feel that your relative/friend has been harmed during their treatment there are no special compensation arrangements. The University of Warwick will provide indemnity for this study. If your relative/friend is harmed due to someone's negligence, depending upon the

problem, you may have grounds for legal action but you may have to pay for it.

Depending upon the problem NHS bodies are legally liable for the negligent acts and omissions of their employees. If your relative/friend is harmed whilst taking part in a study as a result of negligence on the part of a member of the study team, this liability cover may apply.

Non-negligent harm by NHS staff is not covered by the NHS indemnity scheme. The University of Warwick, therefore, cannot agree in advance to pay compensation in these circumstances.

If you have any concern about any element of this study, you can contact the researchers at your hospital: **[insert PI contact details]**

You can also seek independent advice via **[insert local PALS details or equivalent]**

The study is covered by the NHS and University of Warwick's insurance and indemnity cover. Any complaint about the way you or your relative/friend has been dealt with during the study or any possible harm they might have suffered will be addressed.

If you remain unhappy, please send your complaint to the person below, who is a Senior University of Warwick Official, entirely independent of this study:

Head of Research Governance, Research & Impact Services
University House, University of Warwick
Coventry, CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 02476 575733

Contact for further information:

If you have any questions about the study, either now or in the future, you may contact your local research team at <<local research contact details>>

You may also wish to seek the advice of an independent contact who has knowledge of the study but is not directly involved with the study <<independent contact details>>

Alternatively please contact Warwick Clinical Trials Unit.
Email: protectairways@warwick.ac.uk

An online and video version of the information leaflet is available on the study website www.warwick.ac.uk/protectairways/public or accessed by scanning the QR code below

Thank you for taking the time to read this information and for considering if your relative/friend should take part in this study.

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