

# PREVENTION OF PNEUMONIA: THE PREVENT 2 STUDY

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National Institutes of Health

Yale

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# THE PROBLEM

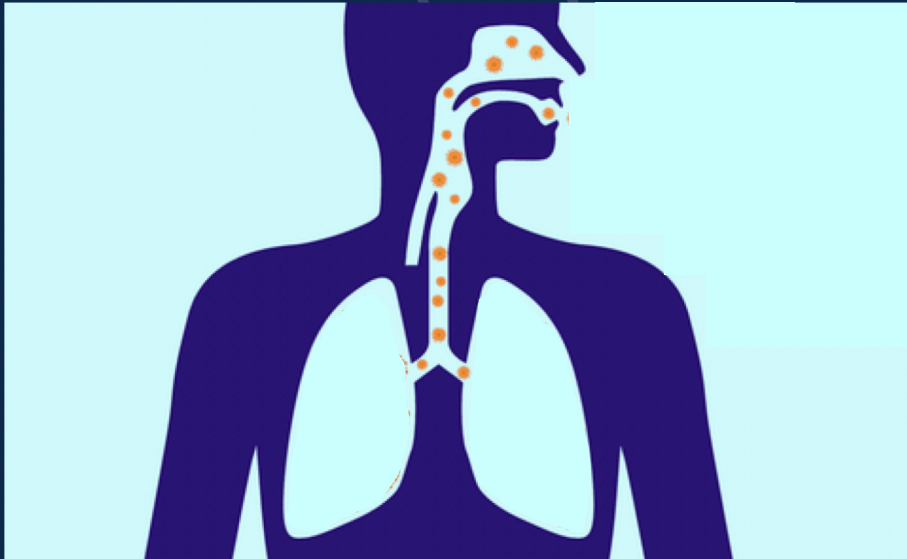


- ▶ Developing infection of the lungs (PNEUMONIA) is a common problem in the hospital, especially in the Intensive Care Unit



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# WHY PNEUMONIA HAPPENS

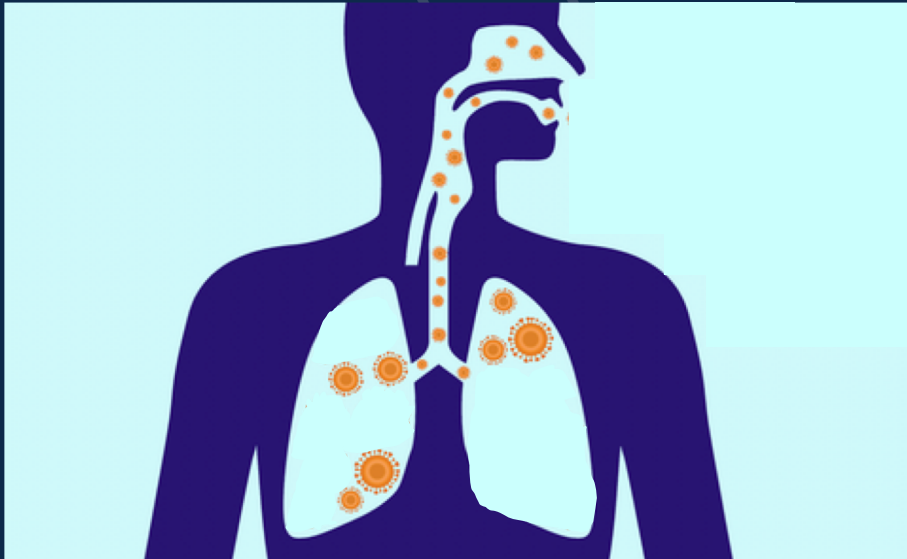


- ▶ When people are sick, bacteria that are not normally present start growing in the mouth and airways



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# HOW PNEUMONIA DEVELOPS



- ▶ These bacteria can make their way down into the lungs



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# WHY PNEUMONIA IS A PROBLEM



- Pneumonia leads to other complications, including more time in the hospital and possibly death



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# BREATHING SUPPORT

- ▶ Use of a breathing machine (ventilator) and breathing tubes are risk factors for pneumonia



- ▶ Studies show that more than one in four patients who are on a breathing machine develop pneumonia

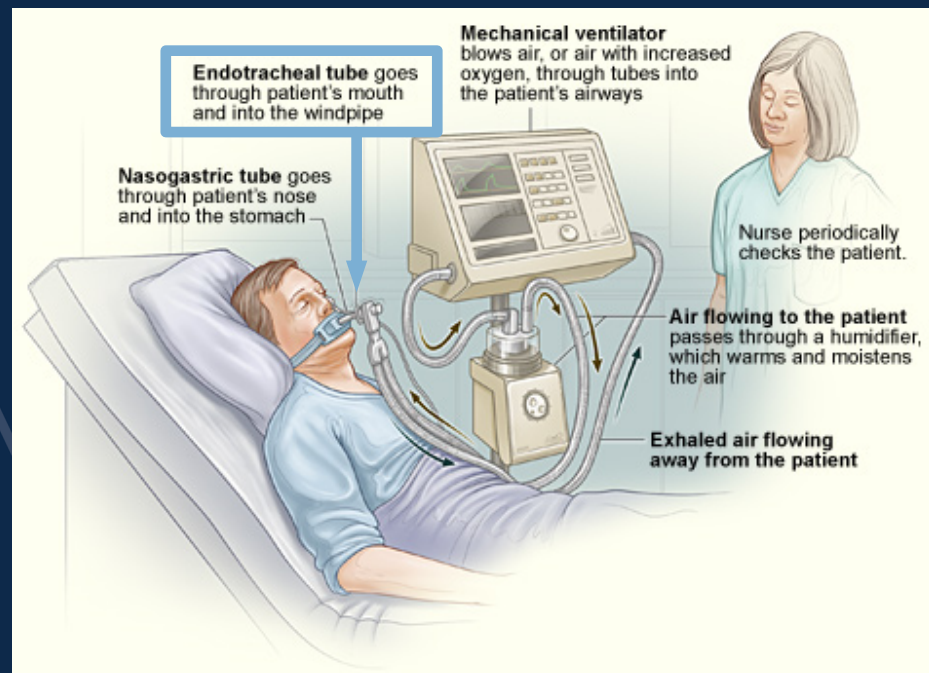


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# VENTILATOR

## Ventilators support breathing

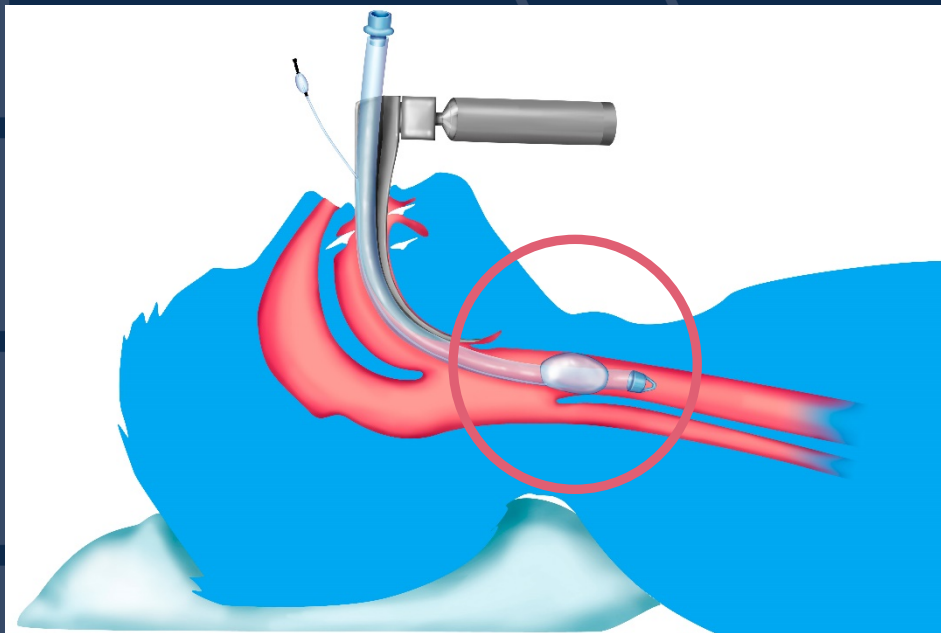
- ▶ Help people breathe easier
- ▶ Breathe for people who have lost all ability to breathe on their own
- ▶ Get oxygen into the lungs



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# BREATHING TUBES

- ▶ The tube allows a ventilator to fill the lungs, and prevents secretions from going into the lungs



The balloon sits in the windpipe (trachea) and seals the airways from the digestive tract



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# LEAKING PROCESS



- ▶ Secretions (blue dye) that are contaminated with bacteria can leak around the breathing tube, and descend into the lungs
- ▶ This can lead to pneumonia

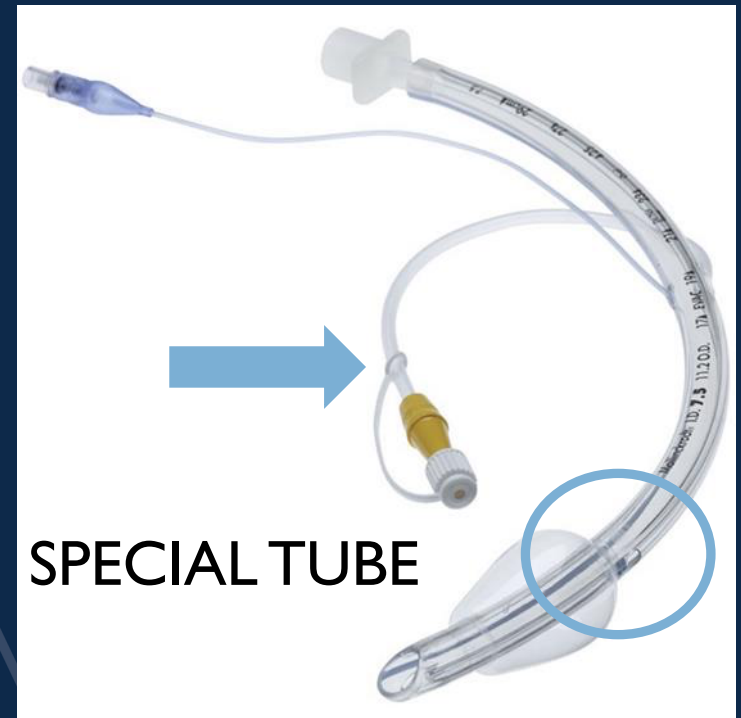


# HOW CAN WE PREVENT THIS?

## Development of a SPECIAL breathing tube

- ▶ Hole above the balloon and additional port allowing secretions pooling above the cuff to be sucked out

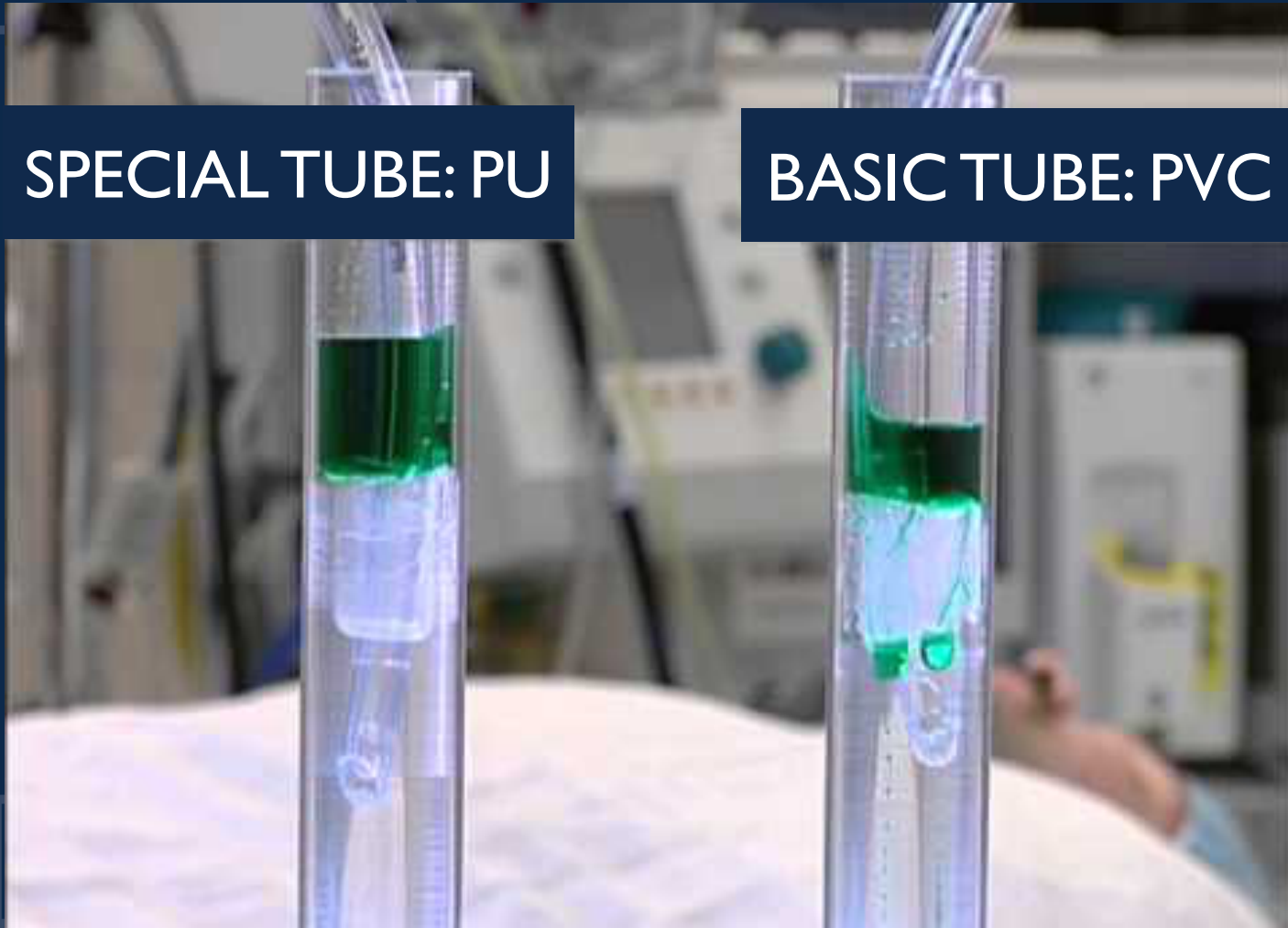
BASIC TUBE



SPECIAL TUBE

# SPECIAL AND BASIC TUBE

- ▶ Balloon of special material (PU instead of PVC)





# WE PLAN TO CONDUCT A STUDY

- ▶ We will test whether a special FDA approved breathing tube can reduce the onset of bacterial pneumonia which typically occurs in 25% of cases involving standard breathing tubes
- ▶ We will compare the special tube with the suctioning port and new cuff material to a basic tube to see if it helps prevent pneumonia



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# PURPOSE OF PREVENT 2 STUDY

- ▶ By preventing pneumonia, the tube should help patients maintain better quality of life and mental ability in the long term
- ▶ A total of 1,074 patients will be enrolled



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# POTENTIAL SUBJECTS

- ▶ This study involves critically ill adult patients that are being cared for at YNHH
- ▶ Patients who require emergency intubation in the Hospital or in the Emergency Room will either receive the basic tube or the special tube
- ▶ This will be random, like the flip of a coin



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# PREVENT 2 STUDY PROCEDURES

The research team will

- ▶ Review hospital reports to identify patients
- ▶ Collect data during the hospital stay to see if patients who receive the special tube have less pneumonia than those with the basic tube
- ▶ Check for any safety issues after the breathing tube is removed
- ▶ Contact patients after six months to see if quality of life and thinking abilities, or any problems that might be related to the breathing tubes, are different



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# PARTICIPATING IN A RESEARCH STUDY

- ▶ To participate in most research studies, patients or their families need to sign a consent form



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# WAIVER OF CONSENT FOR EMERGENCY MEDICINE RESEARCH

The federal government allows emergency studies to be done with a waiver of informed consent if

- ▶ The patient is in a life-threatening situation and cannot provide consent
- ▶ Family members are not immediately available to provide consent
- ▶ Treatment may benefit the patient with reasonable risks
- ▶ The study could not be done without the waiver
- ▶ The community agrees to participate



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# WAIVER OF CONSENT FOR THIS STUDY

- ▶ This emergency medicine study meets the strict criteria for a waiver of consent
- ▶ Because the window to perform an emergency intubation is so small, most participants will be enrolled in this study without first obtaining informed consent





# THERAPEUTIC WINDOW

- ▶ The window of time for emergency endotracheal intubation is very short. It may be seconds to minutes. It is unlikely a patient would be able to make health care type decisions during this time.
- ▶ If possible, we will make efforts to contact the patient's legally authorized representative to ask if they want to opt-out of this research.



# OPTING OUT OF THE STUDY

- ▶ Before intubation, there may be signs that a patient does not wish to participate in a study
  - ▶ A LAR or family member communicates the patient's unwillingness to be in research
  - ▶ Evidence of the patient's unwillingness to participate in research studies in their electronic health record
- ▶ If we learn of opposition to participating in research before intubation, then the patient will not be included and will instead receive a non-study basic tube
- ▶ Emergency intubation will not be delayed in order to wait to obtain consent for this study



# CONSENT PROCESS

- ▶ The research team will make attempts to approach the participant or their LAR to inform them about the study and to obtain consent for participation
- ▶ Attempts to obtain consent will happen at the earliest possible opportunity after the placement of the tube, up until hospital discharge



# INFORMATION IN CONSENT PROCESS

## STUDY RISKS

- ▶ Because a breathing tube was required for clinical care, we expect a participant will be exposed to the same clinical risks if they were not in this study. These are clinical risks and not a result of participation in this research study
- ▶ There are no known increased medical risks between the two tubes being studied
- ▶ There may be some risks that the investigators do not yet know about



# INFORMATION IN CONSENT PROCESS

## POTENTIAL BENEFITS

- ▶ Both tubes are FDA-cleared for tracheal intubation and used in many hospitals
- ▶ There is some evidence that the special tube may help prevent pneumonia. It is not possible to know now if the study tube will prevent pneumonia compared to the usual breathing tube
- ▶ The FDA may inspect subject records



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# OPT OUT OPTION

A community member can express his/her desire not to participate in this study by opting out.

Contact the study team

- ▶ Call: 1-888-202-5977
- ▶ Email: [yarn@yale.edu](mailto:yarn@yale.edu)

To opt out of research at Yale

- ▶ Email: [optout@yale.edu](mailto:optout@yale.edu)
- ▶ Call: 1-877-978-8343, option #3



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# COMMUNITY INVOLVEMENT

Before the study begins, the research team will discuss the study with the community to obtain feedback and understand any concerns

- ▶ Virtual town halls
- ▶ Online survey
- ▶ Flyers
- ▶ MD, RN, & RT education



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# REGULATORY OVERSIGHT

- ▶ Yale University Institutional Review Board
- ▶ Food & Drug Administration
- ▶ National Institutes of Health
- ▶ Data Safety and Monitoring Board



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# RESEARCH TEAM CONTACTS

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- ▶ **Website: [medicine.yale.edu/prevent2](http://medicine.yale.edu/prevent2)**  
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# THANK YOU

## QUESTIONS ??

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