University of Pittsburgh | School of Health and Rehabilitation Sciences

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INFORMED CONSENT DOCUMENT

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: The Aspirometer: A noninvasive tool to detect swallowing safety and efficiency

PRINCIPAL INVESTIGATORS: Dr. James L. Coyle, Ph.D., CCC-SLP; BCS-S
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SOURCE OF SUPPORT: National Institutes of Health

Why is this research being done?

Swallowing difficulties are common in various medical conditions, including strokes and head injuries. Speech-language pathologists assess swallowing in different ways, including "bedside assessment" and an x-ray called a videofluoroscopy or a VFS.

The aim of this study is to determine whether swallowing difficulties can be detected accurately without an x-ray, using a noninvasive sensor that is placed on the neck during swallowing. We already know that vibrations related to throat movements can be measured, and give us information about swallowing. And we already know that the usual way that hospitals try to identify people with swallowing difficulties, which is watching you drink water at the bedside, often misses detecting people with swallowing difficulties, or it can incorrectly identify a person without swallowing difficulties as having them. We have been developing a tool for several years, that we believe, based on our research, can tell us whether a person has a swallowing disorder without using an x-ray test. Now we want to test whether our tool called the Aspirometer, is as accurate, or more accurate, than a bedside water swallowing screen, at identifying which people have an actual swallowing difficulty and need more testing with an x-ray test. We are particularly interested in developing a technology for detecting aspiration, a problem that occurs when food or liquid enters the airway instead of the tube leading to the stomach. This is a common and troubling occurrence for people with swallowing difficulties, and can lead to pneumonia

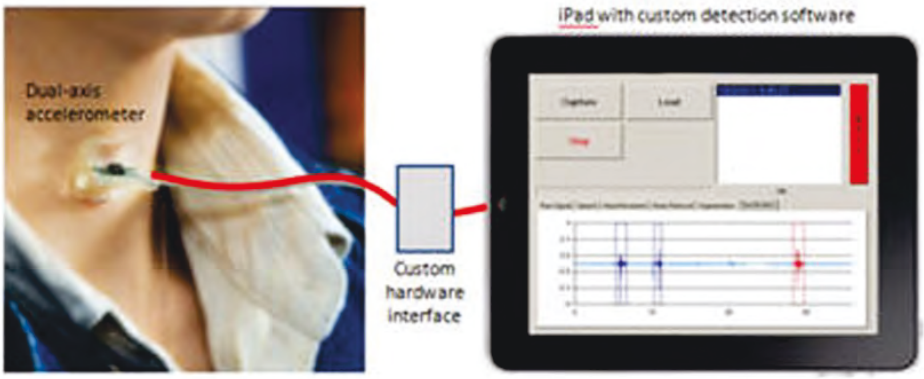
Who is being asked to participate in the study?

You are being invited to participate in this study as you are a person who was hospitalized for a medical condition and who is suspected of having a swallowing problem that could cause a negative outcome like pneumonia. All patients in this hospital who are suspected of having a

swallowing problem are evaluated by a speech-language pathologist (SLP) and if they suspect that you may be swallowing food or liquids into your windpipe/airway, they will refer you for the VFS x-ray test that you are here for. We would like to invite you to participate in this study. If you agree, you will still undergo the videofluoroscopy x-ray test your doctors ordered for you, and some additional testing that is described in the next section.

What procedures will be performed for research purposes?
If you agree to participate in this study, we would like you to wear a small sensor that measure vibrations and sounds on your neck during an x-ray procedure at Presby. You will undergo the experimental procedures listed below.

1. Prior to the x-ray, we will attach two small sensors to the front of your neck using surgical tape as shown below. These sensors send signals from your throat to the computer.



2. We will ask you to swallow half-filled (3mL) teaspoonfuls of water up to three times, and to drink water from a cup (up to 3 oz.) at your own comfortable pace, while collecting your swallowing vibrations and sounds from your throat.
3. We will then collect your swallowing vibrations and sounds during the swallowing x-ray exam that your speech-language pathologist performs. The exam will include swallows of thin liquid like water, just like the ones you will take in step 2 above, and probably other swallows to help them evaluate your swallowing function.
4. We will also collect the results of your x-ray procedure, but without your name or any other identifying information, in order to compare them to the results of our device.
5. Once your exam is done, we will take the sensors off and your study participation will end.

Dr. Coyle and his staff will also collect your age and sex.

Will I be paid if I take part in this research study?
You will not be paid if you participate in this research study.

Will it cost me anything to participate?
No. There will be no cost to you for participation in the research study. All research study related procedures will be provided at no cost to you or your insurance company. All clinical procedures that were ordered by your doctors will be billed as they would ordinarily be billed, but there is no cost to participate in the sensor-based testing.

What are the risks and benefits?
Participation in this research study is limited to possible irritation from the surgical tape if you have a skin sensitivity, or to coughing if you aspirate (material goes down into your airway) during the testing. Using surgical tape to affix the sensor can cause skin irritation in rare cases. No other known risks are associated with the use of the sensor.

There is a risk that you might become tired or frustrated. If this happens, we will take a break until you are ready to continue. You will not directly benefit from this research. However, we think that you will give us important information that will help us to understand swallowing difficulties in patients with swallowing difficulties. Data collected from you and other patients will help us decide whether our sensor-based screening tool can tell us who has a swallowing problem as well as a nurse or other health care provider observing you swallow.

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator (Dr. Coyle) who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this authorization (consent) form, their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to participation in this research study:

Authorized representatives of the University of Pittsburgh Human Research Protections Office or the National Institutes of Health may review your identifiable research information (which may include identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information related to his/her participation in this research study in response to an order from a court of law.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years and for as long (indefinite) as it may take to complete this research study.

May I have access to my information that results from my participation in this research study?

To protect your privacy, only Dr. Coyle and members of his research team will be aware of your participation in this research study. We will not link your name to any of the information we obtain for this research. This information will be identified by a code or case number, and the information linking these numbers with your identity will be kept separate from the research records. Your identity will not be revealed in any description or publications of this research. Although we will do everything in our power to protect your privacy and the confidentiality of your records, we cannot guarantee the privacy of your research records. If data are shared with other researchers, your identity will not be revealed to those researchers.

Is my participation in this research study voluntary?
Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study with the sensors, you will still continue to have your x-ray swallow study, but we will not perform the water swallowing screen or attach any sensors to your neck. Also, if you decide that you do not want to participate in this study, that will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study. Any information recorded for, or resulting from, your participation in this research study prior to the time and date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Since this research involves only this single visit, if you tell us that you no longer want to participate during the test procedures, we will discontinue signal collection and remove the sensors.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

You may also be withdrawn from the study, if a research team member realizes that you cannot complete the experimental protocol for any reason. We do not expect this to happen because you have already been screened or evaluated by an SLP in your hospital room and have been found to be able to participate in the testing.

As part of this research study, we are asking your permission to use your medical records to confirm your eligibility to participate in the study, and to support other data collected in the study. This permission does not expire. We will collect the following information: your name and date of birth, your primary medical diagnosis, and x-ray images from your swallowing examination.

As part of this study, no research results from testing we do with you (and/or a copy of this consent form) will be placed into your medical records held at UPMC. This medical record information, which includes your name, is available to members of the research team for an indefinite period.
We will protect the confidentiality of your records. This means we will keep your records secure and do all we can to prevent people who have not been given permission to be able to access it. We cannot guarantee the confidentiality of your information from this study including from your medical records once people outside UPMC or the University have viewed it.

You can withdraw your permission to allow the research to team use your information from your medical records. You can do this by sending a request in writing to Dr. Coyle listed on the first page. If you do so, you will be withdrawn from this study since your medical information is a critical part. The research team will continue to use information collected from you or your records up to that point.
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VOLUNTARY CONSENT

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I consent to participate in this research study. A copy of this consent form will be given to me.

_____ _____ _____

Participant's Signature Printed Name of Participant Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date