Title: Pilot Study: Testing the Feasibility of a Simplified Workflow for Lung Cancer Radiation Target Review With Radiology
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Wake Forest®
School of Medicine

Department of Radiation Oncology

Testing the Feasibility of a Simplified Workflow for Lung Cancer Radiation Target Review with Radiology

Informed Consent Form to Participate in Research
Michael Farris, MD. Principal Investigator

SUMMARY

You are invited to participate in a research study because you have a lung cancer that is large and/or has spread to lymph nodes (small lumps of tissue that help fight infection) in your chest. For these types of lung cancers, the radiation mapping process (planning your radiation) is complicated. This is especially true when the cancer and involved lymph nodes are close to other normal organs in your chest. The goal of this research study is to see whether adding an additional doctor (called a radiologist) to the process of designing your radiation plan, will help us increase the accuracy of mapping out your cancer from the surrounding normal organs.

Key Concepts:
A RADIATION ONCOLOGIST is a doctor who delivers radiation treatments to tumors in order to kill cancer cells.
A RADIOLOGIST is a doctor who looks at pictures of the body like (CT scans) and interprets them.

Radiologists can help radiation oncologists understand exactly where the tumor targets are located on scans.

Sometimes, it can be very difficult for a radiation doctor to see the difference between tumor and nearby organs (like the swallowing tube) especially when these are touching one another. If a patient has cancer in the lymph nodes in the middle of the chest, it can also be difficult to deterimine exactly which lymph nodes are involved or not involed with cancer.

The radiation oncologist has to depend on radiology reports to help guide their decisions for what to treat.

We have developed an efficient way to share our radiation plans with the radiology team so that they can review our plans and provide real time feedback before treatment is delivered. We believe that doing this in a formal way for every lung cancer radiation plan will improve patient safety and the quality of cancer treatments.

When a radiation doctor designs your treatment plan, they must identify (1) places where radiation needs to go (like tumors) and (2) places where radiation does not need to go (like organs without cancer). To do this, your radiation doctor will look at your mapping scan () and digitally draw in the computer exactly where they can see tumor on every picture of the scan. They will also draw out the areas that do not have tumor and need to be protected from radiation. Sometimes cancer can involve more than one tumor in the lungs or even lymph nodes in the middle of the chest or the bottom of the neck. This results in a delicate

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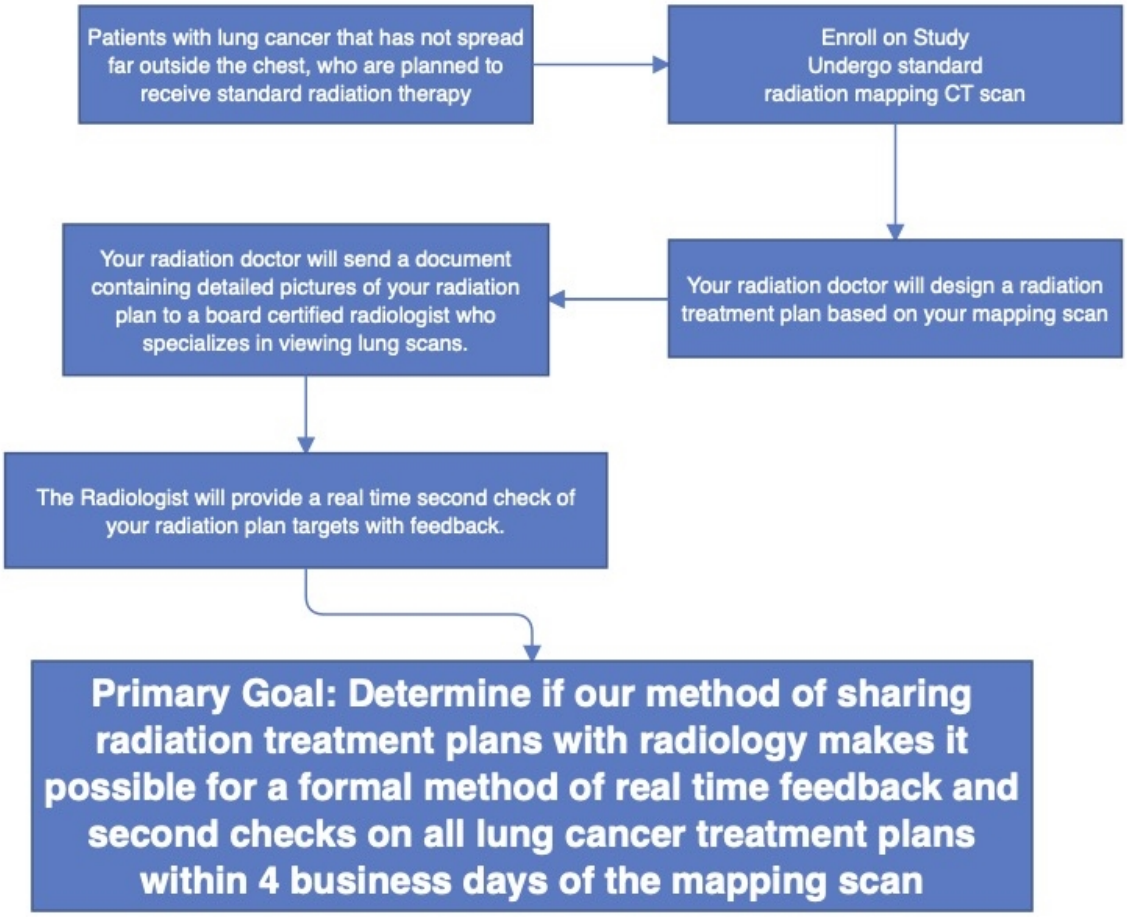
balancing act. Your radiation doctor must treat your cancer completely, but they also must be careful not to put too much radiation in the nearby noncancerous tissues, which would cause side effects. Sometimes, the tumors and noncancerous areas are very difficult to tell apart on a scan. While radiation doctors train extensively on the best ways to give radiation therapy to kill tumors, a different kind of doctor called a radiologist (medical doctor that specializes in diagnosing and treating injuries diseases using medical imaging procedures), trains specifically to interpret scans and distinguish tumors from noncancerous tissue. In complicated cases, the opinion of a radiologist can make a big difference in the final radiation treatment plan.

Usually, radiologists will provide detailed reports that describe what they see on a patient's scan. The radiation doctor must rely heavily on reading these reports to make sure they are covering all the cancerous areas with radiation. While these reports are helpful, for the more complex cases the safest approach is for both radiation and radiology doctors to review the treatment plan together as a second check. This ensures that all of the cancerous tissue is well treated, and that noncancerous tissue gets minimal radiation dose. While it would be ideal if every radiation plan could be reviewed by both teams of doctors, there are a lot of challenges that prevent this.

Access to the radiation planning software is heavily restricted for safety reasons. This avoids any accidental tampering with physics calculations or radiation beam (high energy x-rays) arrangements. Because the radiology team does not have access to the treatment planning software, they cannot easily see what the radiation oncology team is planning to treat. Once the targets have been outlined by the radiation doctor, the radiation plan is sent out to other members of the radiation team like a physicist (a scientist who specializes in the field of physics) for calculations. Late changes to a radiation plan after it is sent to these team members would result in possible treatment delays. This means that any feedback from the radiology team needs to be done early in the radiation planning process. Finally, while it would be ideal if every radiation plan could be reviewed by both teams of doctors, there are a lot of challenges that prevent this. This makes it difficult to set aside extra time for second checks.

We have created a unique way of quickly sharing detailed pictures of the entire radiation plan with the radiology team so that they do not need direct access to any planning software. We believe this system of sharing the information for review will make interactions easy for both teams. This will provide the basis of a system at Wake Forest that allows radiation oncology and radiology to work together formally on all complex lung cancer treatment plans moving forward. We also believe that this system will improve the overall quality of our radiation plans and patient safety.



The radiation will be delivered in the standard fashion that would be offered regardless of your involvement on this study. However, on this study your treatment plan will be formally reviewed with a radiologist before you start radiation treatment. This will allow the radiology team to provide a second check to ensure that all suspicious areas of cancer are targeted and that noncancerous areas receive minimal radiation dose. We believe that this formal "extra" check on your radiation plan will help us create the best possible plan for you.

The radiation planning session will be the same as if you were not on the study. Once your radiation oncologist has determined the areas they wish to target with radiation, they will securely share a file containing all views of the planned radiation targets with a board-certified radiologist who specializes in lung cancer. The radiologist will then review the target areas with your radiation oncologist and ensure that these are as accurate as possible. Following this approval of the final targets, the radiation plan will move forward with the planning process as normal to ensure a safe and effective radiation treatment for you.

Our goal with this study is to ensure that starting this "extra" review process is easy to do for both the radiation oncologist and the radiologist, and that it does not cause major delays in getting started with treatments. We hope that this "extra" check by radiology will make mapping out the areas involved with cancer more accurate than the current standard process. However, in this study we may find that radiology does not have any feedback, and that the current standard way of designing plans without a formal radiology review is sufficient. We may also find that changes to plans cause treatment delays if feedback is not provided quickly.

There is the possibility that you may benefit from participation in this study. Your participation in this study is voluntary. You do not have to participate in this study if you do not want to.

You will not lose any services, benefits, or rights you would normally have if you choose not to participate. The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study.

The person in charge of this study is Michael Farris MD, PI. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted] (clinic & after-hours).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at 3[redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have locally advanced lung cancer. Mapping out all of the suspicious areas in the chest and not over treating areas that do not actually have cancer can be challenging. Your participation is voluntary. Please take your time in making your decision as to whether you wish to participate or not. Ask your study doctor or

the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to see if adding an "extra" check by formal radiology review is possible without disrupting the normal processes that take place to develop and prepare a safe radiation treatment plan for patients. Radiation Oncologists are very knowledgeable in the care of patients with cancer and understand how radiation can be used effectively to fight cancer. While they do become very good at reading and understanding images used for mapping, they do not formally undergo training in radiology. When there are challenging cancers in the chest, a radiologist is often consulted informally to help mark out the final target for radiation. The way this is currently discussed informally is difficult to coordinate and is not possible for most treatment plans.

We are proposing a process to enable all patients with locally advanced lung cancer to have this "extra" check by a radiologist who specializes in the anatomy of the chest or thorax. This review process may ensure that all areas that are suspicious for cancer are indeed being targeted with radiation and that any areas that are more likely to be normal tissues are minimally treated with radiation. This could potentially lead to improved control of the cancer and decreased side effects from the treatment.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There will be 37 people enrolled altogether by Wake Forest University Baptist Health at different sites including Wake Forest Baptist Medical Center, High Point Regional, Lexington Medical Center, and Iredell Health System that will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will be enrolled into this study where all patients will receive the extra review by radiology. Nothing that you experience as the patient in the radiation treatment planning process will change. Essentially the only changes that occur as part of being in this study will be "behind the scenes". From a patient perspective, we anticipate that you should not notice any changes outside of the standard process for planning radiation. In general, radiation plans take 8-12 business days to plan without formal radiology review. We are hopeful that the review process we have created will be streamlined and will not impact this time window at all. If there is the potential for treatment delays because a plan has not been reviewed on time, ultimately your radiation oncologist can decide to proceed without waiting for or using the feedback from the radiology team if they feel it is in your best interest.

In this study, after you complete the treatment planning session, you will return home as you normally would if you were not on study. Over the next 8-12 business days the radiation oncologist and their staff will develop your treatment plan as is typical. The only difference in the development of the treatment plan by being in this study will be that once the treating radiation oncologist maps out the targets which includes the areas involved by cancer, they will share the images of the target with a thoracic radiologist immediately for feedback and a second check. They will discuss the areas that are drawn out and will decide if any changes could be recommended to better target the cancer and minimize radiation to normal tissues. If there are recommended changes that are agreed upon by both the radiologist and the radiation

oncologist, then the target may be modified in the treatment plan. If there are no recommended changes, then the treatment plan will continue through the plan development process by the staff in the radiation oncology department. Ultimately, your radiation oncologist will make the final decision regarding the design of treatment targets.

HOW LONG WILL I BE IN THE STUDY?

You will be in this study during the course of radiation therapy and up to the one month post-treatment visit. This study will not require any extra visits to the hospital or extra imaging outside of your routine standard of care treatment and follow up.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study poses some risk to you. There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict.

You should discuss the risk of being in this study with the study staff.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have.

WHAT ARE THE COSTS?

Research study costs, including any imaging review directly tied to the study will be paid for by the study. However, tests and procedures that are done as part of your routine cancer care, which would be done regardless of your participation in this study, will be the responsibility of you or your insurance company. For this study in particular, we will extract data and results from the following routine-care procedures: CT scans, PET scans, and pathology reports.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified. Participant information may be provided to Federal and other regulatory agencies as required.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Wake Forest institutional funding with the Thoracic Multidisciplinary Tumor Committee, and it utilizes support of cancer center personnel in the departments of statistics and protocol editing. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Michael Farris, M.D. at [redacted] or [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: History and physicals, pathology, labs, imaging and lung function tests.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3) Representatives from government agencies such as the Food and Drug Administration (FDA), NCI (National Cancer Institute), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information

not already in your medical record will either be destroyed, or it will be deidentified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Farris that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Michael Farris M.D.
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The

investigators also have the right to stop your participation in the study at any time. This could be because it is felt by the treating physician to be in your best medical interest, your condition worsened, new information becomes available, or you had an unexpected reaction. Additionally, this could occur because you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Michael Farris M.D. at [redacted] (clinic & after-hours) or [redacted] (office).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted]

You will be given a copy of this signed consent form.

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Version Valid Until: 5/10/2022

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

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