UNIVERSITY OF WASHINGTON
CONSENT FOR

Learning from a Distance: A Practical Model for Improving Asthma Care Study

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Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Spirometry is a recommended component of asthma diagnosis and treatment in the primary care setting, yet few providers report routine use of spirometry for their asthmatic patients. This is especially true in pediatrics. Misclassification of asthma severity occurs when assessment is based on symptoms alone. This misclassification can lead to inadequate treatment, increased morbidity, and increased healthcare utilization/cost.

The goal of this study is to evaluate the effectiveness of a distance-learning quality improvement program aimed at improving asthma care for pediatric patients through the appropriate use of office-based spirometry. This program includes:

A) "Spirometry Fundamentals™: A Basic Guide to Lung Function Testing", a computer-based CD-ROM training program that teaches primary care providers and their staff techniques required to perform high-quality spirometry tests, and proper interpretation of spirometric data
B) Virtual asthma learning sessions utilizing WebEx, a computer-based virtual meeting tool. This tool allows providers and their staff to attend asthma quality improvement learning sessions from a distance because meetings are conducted over an Internet connection using WebEx.
C) EasyData, an innovative secure Internet-based audit and feedback reporting system. This tool allows experts to both assess the quality of spirometry curves produced remotely at practice sites and give feedback to providers and their staff via a secure reporting system.

STUDY PROCEDURES

We are asking you to participate in this study because you are a doctor, nurse, medical assistant, or other medical staff person who provides care in a pediatric practice that cares for

children with asthma. If you agree to be part of this study, we will ask you to do several things over a 15 month period.

1) Your practice will be provided with an ndd EasyOne spirometer after you enroll. You will receive standard training as well as ongoing technical support from ndd when your new spirometer is delivered. Any spirometry tests you do during the study will be at your discretion when you determine they are clinically indicated. No spirometry tests will be conducted solely as a study procedure.

We will need you to install a software program on your computer to participate in the study. We will mail you this program which is called EasyData. EasyData allows you to transmit spirometry curves via the internet to a secure central data warehouse for the study. It will only upload spirometry curve data, so any information that identifies who your patients are (names, ages, medical record #s, etc.) will not be transmitted to us. We will provide you with directions and any technical support you need to install the software and send us data.

2) We will ask you to transmit new spirometry curve data on a weekly basis to the central data warehouse for the 15 months of the study. Uploading spirometry curve data from the EasyOne spirometer should take less than 5 minutes to complete.

3) You will be invited to an introductory meeting as part of a larger asthma guidelines update meeting in Albany, NY in October of 2007. Attendance at this meeting is not mandatory for study participation although we will encourage all participants to attend. At this meeting, you will have the opportunity to meet project faculty and research staff and have your questions addressed.

Following this meeting, we would ask you to agree to being randomly assigned to either the intervention or control group for the study. This random assignment will be determined by a computer program. Both the control and intervention groups will send us spirometry curve data weekly for the entire 15 month study period. Both groups will also go through the same distance learning quality improvement (QI) program described below, however, control practices will start the program 5 months after the intervention practices.

4) We will ask you to participate in the distance learning QI program at the times scheduled for your group.

If you are in the intervention group: You will begin to receive the components of **Phase 1** of the training program approximately **5** months after receiving your ndd spirometer. Phase 1 will focus on implementing spirometry into your office practice to aid in the management of your asthma patients.

a) We will mail all participants from your practice their own copy of the Spirometry Fundamentals CD™ to view. Watching the CD should take no more than 1-2 hours of your time and can be done at a time and location that is convenient for you.
b) We will ask you to attend a series of 3 WebEx virtual learning session conference calls which will last 1-2 hours each and occur over a 6 week period (approximately 1 call every 2 weeks during months 5 and 6 of the study).
c) After Phase 1 begins, we will send you monthly feedback reports regarding your practice's spirometry curve quality via a secure internet reporting system.

d) Finally, you will have access to research team experts for short, scheduled "office hours" calls to help trouble-shoot around particular issues you are having related to performing and interpreting spirometry tests. This last part of Phase 1 is optional.

Phase 2 will focus on improving patient self-management.
a) We will ask you to attend two additional 1 hour WebEx learning session conference calls for this phase of the program. These conference calls will take place over a 4 week period (approximately 1 call every 2 weeks during month 9 of the study).

If you are in the control group: We will ask you to go through the same training program described above. You will begin to receive the components of Phase 1 of the training program approximately **10** months after receiving your ndd spirometer.

a) We will mail all participants from your practice their own copy of the Spirometry Fundamentals CD™ to view. Watching the CD should take no more than 1-2 hours of your time and can be done at a time and location that is convenient for you.
b) We will ask you to attend a series of 3 WebEx virtual learning session conference calls which will last 1-2 hours each and occur over a 6 week period (approximately 1 call every 2 weeks during months 10 and 11 of the study).
c) After Phase 1 begins, we will send you monthly feedback reports regarding your practice's spirometry curve quality via a secure internet reporting system.
d) Finally, you will have access to research team experts for short, scheduled "office hours" calls to help trouble-shoot around particular issues you are having related to performing and interpreting spirometry tests. This last part of Phase 1 is optional.

Phase 2 will focus on improving patient self-management.
a) We will ask you to attend two additional 1 hour WebEx learning session conference calls for this phase of the program. These conference calls will take place over a 4 week period (approximately 1 call every 2 weeks during month 15 of the study.

5) During the last month of the study, we will ask all intervention and control participants to randomly select a sample of 35 medical records of children aged 5 to 18 years who had at least one visit for asthma during the prior 20 months. You will be asked to de-identify and photocopy these records and then send them to the UW research team for abstraction. We will supply you with pre-paid Fed-Ex boxes to mail us the chart copies.

Your participation in the study will be completed after you transmit spirometry curve data to the research team for a 15 month period and after we receive copies of the 35 medical records from your practice.

6) Finally, we would ask you to refrain from participation in any other organized efforts focused on spirometry training during the study period.

RISKS, STRESS, OR DISCOMFORT

You may experience stress related to learning new techniques about performing spirometry tests. We have addressed concerns about the confidentiality of research data in the OTHER INFORMATION section of this consent form. When we publish the results of this study, we will not identify you or this practice.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You could opt to attend alternative training programs focused on learning to use in-office spirometry and/or asthma quality improvement.

BENEFITS OF THE STUDY

Potential benefits to you are primarily educational in nature. Medical providers exposed to Spirometry Fundamentals™, the WebEx learning sessions, and the one-on-one coaching may produce higher quality spirometry curves and provide better processes of asthma care as a result of being exposed to the additional training.

If shown to be effective, more widespread dissemination and use of this distance learning QI program for primary care providers will likely produce higher-quality of care for asthmatic children on a societal level. By producing higher quality spirometry curves, providers will improve their ability to accurately diagnose asthma, resulting in faster, more effective treatment for these patients.

OTHER INFORMATION

Your participation is voluntary. You may refuse to participate or may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

All study data will be stored electronically on password protected computers and registered user only data servers. Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is possible that unauthorized persons might discover that you are in this study, or might obtain information about you. University and government offices sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

Information linking you and your practice's identity to the data you send us will be destroyed 2 years after the study begins. This linkage information will be kept in a locked storage area until it is destroyed.

After all medical record abstractions are completed, the paper record copies you send us will be stored in a locked cabinet in the investigator's research offices for a period of three years and then destroyed.

All results reported in publications resulting from this study will be in aggregate form. No individual practice's spirometry testing results will be identified.

Each participating practice will receive $300 to compensate them for time spent pulling, de-identifying, and copying 35 medical records for the research team. We will require that you provide your institutional tax identification number prior to our issuing this payment

Each participating practice will also receive an EasyOne Diagnostic spirometer, EasyData software, and the Spirometry Fundamentals CD-ROM training course for free.

Printed name of study staff obtaining consent	Signature	Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

Copies to: Researcher
Subject