Official Title:	Decreasing antibiotic prescribing in acute respiratory infections through implementation of nurse driven clinical decision support
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Research Subject (Nurse)
Key Information and Verbal Consent

Title of Study:	Decreasing antibiotic prescribing in acute respiratory infections through implementation of nurse driven clinical decision support **S19-01222**
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You are being invited to take part in a research study, which will take place at NYU Langone Health. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

What is the purpose of this study?

This research study is to understand the effects of a novel integrated clinical prediction (iCPR) tool on antibiotic prescription patterns of nurses for acute respiratory infections (ARIs). This research will help NYU Langone and other health systems understand the impact of registered nurses (RNs) using iCPR for ARIs on antibiotic prescribing, diagnostic test-ordering, and resource use patterns.

We are asking you to take part in this research study because you are a nurse that practices at the clinic and are eligible to prescribe antibiotics.

Key Information

This study will last about 5 years, will have three phases, and will involve interview sessions, workflow assessments, and surveys. It is being done to collect your thoughts/reactions/opinions. For the interviews and in-person observations, we will do this through note taking and transcribing your audio-recordings.

If you are involved in phase 1 and 2, you will participate in workflow assessments and near-live usability testing. For workflow assessments, we will interview you regarding your scope of work prior to COVID-19, current workflow as a result of it and conduct in-person observations. As we develop the iCPR tool, we will present the iCPR tool to you and ask you a sequence of questions that allows you to advise us on how to best adapt this tool for your use. During the near-live usability testing session, you will be instructed to follow “think-aloud” protocols while using the tool and tell us all thoughts as you interact with the system.

If you are involved in phase 3, you will participate in in-person workflow observations, live-usability testing of the icpr tool, and completion of survey questionnaires. This phase will start once the clinic you work in begins using the icpr tool to triage and provide care for patients with ARI symptoms.

How long will I be in the study? How many other people will be in the study?

We will interview about 48 nurses for this study. The study will last 5 years and you will be a study participant until the end of the study.

What will I be asked to do in the study?

If you verbally consent to take part in this study, you will be asked to take part in interview sessions, workflow assessments, and surveys.

If you are involved in phase 1 and 2, you will participate in workflow assessments and near-live usability testing. For workflow assessments, we will interview you regarding your scope of work prior to COVID-19, current workflow as a result of it and conduct in-person observations. As we develop the iCPR tool, we will present the iCPR tool to you and ask you a sequence of questions that allows you to advise us on how to best adapt this tool for your use. During the near-live usability testing session, you will be instructed to follow “think-aloud” protocols while using the tool and tell us all thoughts as you interact with the system.

If you are involved in phase 3, you will participate in in-person workflow observations, live-usability testing of the icpr tool, and completion of survey questionnaires. The survey assessments will be conducted at the beginning of the study, at 6 months, and at 12 months. This phase will start once the clinic you work in begins using the icpr tool to triage and provide care for patients with ARI symptoms.

We will audio record the interviews. The study will not collect any identifying information; if inadvertently mentioned during interviews, all identifying information will be removed from transcripts. All recordings will be immediately transcribed and will be destroyed after transcription is completed. All interviews will be given a unique study ID that is not linked to any identifiers.

We will audio record this interview and take detailed notes afterward. We will do so only with your permission. You have the right to review and edit the recording to delete any material you do not want recorded. You may also ask us to turn off the recorder at any point in the conversation.

Your participation in this study will last for 5 years and will involve in-person sessions at the clinic in which you practice, and online survey questionnaires. You may also be asked to interview over a video call as a result of covid-19 precautions.

As an NYU Langone Health Employee, your decision to participate, decline, or withdraw will have no impact on your employment, academic status, salary, performance evaluation, and/or grades respective to the target subject population.

You are free to skip any questions that you prefer not to answer.

Any identifiable private information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

What are the possible risks or discomforts?

There is a possibility that some of these questions may make you uncomfortable or distressed; if so, please let me know. You don't have to answer those questions if you don't want to. You also need to understand that all information that I receive from you, including your name and any other identifying information, will be strictly confidential and will be kept under a lock and key.

What if new information becomes available?

During the course of this study we may find more information that could be important to you.

This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You may not benefit personally from being in this study. However, your participation may improve the future practices of antibiotic prescriptions and care for patients with ARIs. It is also hoped the knowledge gained will be of benefit to others in the future.

What other choices do I have if I do not participate?

If you do not agree to verbally consent to participating in this study, you will continue your regular clinic workflow. Your decision whether or not to take part in this study will have no impact on your employment.

Will I be paid for being in this study?

If you are part of the Phase II Usability session, you will receive a $50 gift electronic card.

If you are part of the Phase III of the study, the randomized control trial, you will be entered to receive a $25 gift electronic card every month based on the number of times you used the triage template.

Will I have to pay for anything?

You will not be expected to pay for taking part in this study.

When is the study over? Can I leave the study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your employment.

How will you protect my confidentiality?

The study will not collect any identifying information; if inadvertently mentioned during interviews, all identifying information will be removed from transcripts. All recordings will be immediately transcribed and will be destroyed after transcription is completed. All interviews will be given a unique study ID that is not linked to any identifiers. If you wish you may have documentation linking your name to your participation in this study, otherwise no record of your name will appear in the study documents.

This study has support from the National Institutes of Health (NIH) and your study information is protected by a Certificate of Confidentiality. This certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we must report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community.

Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. You can also reach out to our project manager, Sumaiya Tasneem at sumaiya.tasneem@nyulangone.org regarding further details about the study. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.