LCCC 20-3115: Overcoming barriers to the uptake of cascade screening for Lynch Syndrome

Version Date: 05/14/2021

Information Sheet – Patient

Information Sheet: Overcoming Barriers to the Uptake of Cascade Screening for Lynch Syndrome

Concise Summary: The purpose of the study is to test the feasibility of an educational workbook intervention to improve cascade screening in families with Lynch Syndrome. Participants will be involved in the study for approximately 6 weeks. Participants will read the educational workbook and complete the workbook exercises on communicating with relatives about their Lynch Syndrome diagnosis. After using the workbook, participants will complete a survey and interview about their experience using the workbook. Participants may personally benefit from using the workbook by learning more about Lynch Syndrome, how to communicate with family members, and what resources are available for persons with Lynch Syndrome. The main risk in participating is the risk of breach of participant confidentiality.

Who is conducting this research study? Dr. Megan Roberts, Division of Pharmaceutical Outcomes and Policy, UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill

What is this research study about? The purpose of the study is to test the feasibility of an intervention to improve cascade screening in Lynch Syndrome families. Lynch Syndrome is a genetic condition that means you are at a higher risk of developing certain types of cancer, primarily colorectal and uterine cancer. Cascade screening is the process of conducting genetic testing for Lynch Syndrome among the close family members of an individuals diagnosed with Lynch Syndrome. The research team has developed an informational workbook on Lynch Syndrome and the importance of family communication to encourage genetic testing. We would like to understand the practicality of the workbook from the perspective of patients with Lynch Syndrome who are undergoing cascade screening. Eligible participants must (1) live in the United States and speak English, (2) be at least 18 years old, and (3) have been diagnosed with Lynch Syndrome within the last year and receive care at the Ohio State University Comprehensive Cancer Center or UNC Health System.

A description of this clinical trial will be available on 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 website at any time.

What will I be asked to do? You will complete a 15-minute study enrollment interview via telephone and confirm your eligibility. If you are eligible to participate, your genetic counselor will introduce the workbook to you in a 30-minute virtual session and you will be provided a PDF version of the workbook via email for you to complete the remaining activities independently. After approximately one month, the research team will schedule a 60-minute video conference interview with you and send you a 20-minute survey to complete. The virtual interview will be conducted on Zoom and recorded. During the interview, the research team will ask questions to elicit your opinions on the strengths and weaknesses of the workbook content and design.

Participation is voluntary. There is no penalty for refusing to participate in the interview or survey or to answer specific questions. If you decide to participate, you may choose not to answer a question in the interview at any time for any reason and you can end the interview at any time.

What are the risks and benefits of participating? Research is designed to benefit society by gaining new knowledge. You may personally benefit from using workbook by learning more about your Lynch Syndrome diagnosis and how to communicate with your relatives. There are minimal risks to study

participation, and you may decline to participate at any time. The audio and screen-sharing from interviews over Zoom will be recorded, but participants will be instructed to keep their cameras off. The interview recordings will be stored on a secure network drive; the network drive will only be available through a UNC password-protected computer and will only be accessed by the research team. The information from the recordings will be deidentified during the analysis of interview results and participants will not be identified in any report or publication from the study. Survey and enrollment data will be stored in REDCap, a password-protected secure web application for collecting and managing clinical research data. Participants' de-identified data may be used for additional future research without additional consent.

What are the costs of participating? Participants must have internet access and a device able to support using the PDF workbook and completing a virtual Zoom interview.

Will I be compensated for participating? Participants who complete the virtual interview and the electronic survey will receive a $75 Amazon gift card via email.

What is a Certificate of Confidentiality? This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Who can I contact with questions or concerns? Dr. Megan Roberts at megan.roberts@unc.edu.

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu. The IRB number for this study is 20-3115.

Verbal Consent Script – Patient

I am now going to confirm that you meet the requirements to participate in this study. Please answer yes or no to the following questions.

Are you at least 18 years old? [If yes, continue. If no, stop now]

Do you speak English and reside in the United States? [If yes, continue. If no, stop now]

Have you been diagnosed with Lynch Syndrome during the last 12 months? [If yes, continue. If no, stop now]

Are you receiving genetic counseling for Lynch Syndrome at (the Ohio State University Comprehensive Cancer Center)/(UNC Health System)? [If yes, continue. If no, stop now]

Did you receive and read the information sheet about the study testing the feasibility of an educational workbook on cascade screening with Lynch Syndrome patients?

[If no] Ok, we are required to provide this information before we introduce the workbook and collect your feedback. I will be reading from the document, but please stop me if you have any questions. [Read information sheet aloud] Do you have any questions? [Answer questions]

[If yes] Ok, I would like to remind you that all study activities, including completing the workbook exercises and participating in the interview and survey, are voluntary. There are no penalties for refusing to participate. You can stop using the workbook at any point and you may end the interview at any time and refuse to answer any question. The interview will be conducted through Zoom and will be recorded, but your camera will be off. Do you have any questions? [Answer questions]

Ok, I am now going to confirm your verbal consent to participate in this study. Please answer yes or no to the following questions.

Do you agree to participate in this study, including using the workbook and completing a virtual interview and survey? [If yes, continue. If no, stop now]

[If applicable] Do you agree for the interview conducted through Zoom to be recorded? [If yes, may record. If no, end participation because recording is required.]

Information Sheet – Providers

Information Sheet: Overcoming Barriers to the Uptake of Cascade Screening for Lynch Syndrome

Concise Summary: The purpose of the study is to test the feasibility of an educational workbook intervention to improve cascade screening in families with Lynch Syndrome. Participants will be involved in the study for approximately 6 weeks. Participants will identify Lynch Syndrome patients and introduce the study opportunity to them. For each Lynch Syndrome patients who enroll in the study, participants will conduct a genetic counseling session to explain the educational workbook and complete the first workbook exercise. After introducing the workbook to all enrolled patients, participants will complete a survey and interview about their experience using the workbook with patients. Participants may personally benefit from having an additional resource to use in conducting cascade screening with Lynch Syndrome patients. The main risk in participating is the risk of breach of participant confidentiality.

Who is conducting this research study? Dr. Megan Roberts, Division of Pharmaceutical Outcomes and Policy, UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill

What is this research study about? The purpose of the study is to test the feasibility of an intervention to improve cascade screening in Lynch Syndrome families. Lynch Syndrome is a genetic condition causing increased risks of certain types of cancer, primarily colorectal and uterine cancer. Cascade screening is the process of conducting genetic testing for Lynch Syndrome among the close family members of an individuals diagnosed with Lynch Syndrome. The research team has developed an informational workbook on Lynch Syndrome and the importance of family communication to encourage genetic testing. We would like to understand the practicality of the workbook in aiding cascade screening from the perspective of Lynch Syndrome patients and their genetic counselors. Eligible genetic counselors must (1) speak English and be at least 18 years old, and (2) provide Lynch Syndrome counseling at the Ohio State University Comprehensive Cancer Center or UNC Health System.

A description of this clinical trial will be available on 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 website at any time.

What will I be asked to do? You will complete a 15-minute study enrollment interview via telephone. You will introduce the study opportunity to eligible Lynch Syndrome patients and with their permission, provide their contact information to the UNC research team who will complete study enrollment. We aim to recruit 15 Lynch Syndrome patients total. For patients who enroll in the study, you will introduce the workbook and complete the first exercise with them in a 30-minute virtual session. After you have introduced the workbook to all your enrolled patients, the research team will schedule a 60-minute videoconference interview with you and send you a 10-minute survey to complete. The virtual interview will be conducted on Zoom and recorded. During the interview, the research team will ask questions to elicit your opinions on the strengths and weaknesses of the workbook content and design.

Participation is voluntary. There is no penalty for refusing to participate in the interview or survey or to answer specific questions. If you decide to participate, you may choose not to answer a question in the interview at any time for any reason and you can end the interview at any time.

What are the risks and benefits of participating? Research is designed to benefit society by gaining new knowledge. You may personally benefit from having an additional resource to use in conducting cascade

screening with your Lynch Syndrome patients enrolled in the study. There are minimal risks to study participation, and you may decline to participate at any time. The audio and screen-sharing from interviews over Zoom will be recorded, but participants will be instructed to keep their cameras off. The interview recordings will be stored on a secure network drive; the network drive will only be available through a UNC password-protected computer and will only be accessed by the research team. The information from the recordings will be deidentified during the analysis of interview results and participants will not be identified in any report or publication from the study. Survey and enrollment data will be stored in REDCap, a password-protected secure web application for collecting and managing clinical research data. Participants' de-identified data may be used for additional future research without additional consent.

What are the costs of participating? Participants must have internet access and a device able to support using the PDF workbook and completing a virtual Zoom interview.

Will I be compensated for participating? Participants who complete the virtual interview and the electronic survey will receive a $50 Amazon gift card via email.

What is a Certificate of Confidentiality? This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Who can I contact with questions or concerns? Dr. Megan Roberts at megan.roberts@unc.edu.

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu. The IRB number for this study is 20-3115.

Verbal Consent Script – Providers

I am now going to confirm that you meet the requirements to participate in this study. Please answer yes or no to the following questions.

Are you at least 18 years old? [If yes, continue. If no, stop now]

Do you speak English? [If yes, continue. If no, stop now]

Do you provide genetic counseling for Lynch Syndrome patients at (the Ohio State University Comprehensive Cancer Center)/(UNC Health System)? [If yes, continue. If no, stop now]

Did you receive and read the information sheet about the study testing the feasibility of an educational workbook on cascade screening with Lynch Syndrome patients?

[If no] Ok, we are required to provide this information before we introduce the workbook for use with your patients and collect your feedback. I will be reading from the document, but please stop me if you have any questions. [Read information sheet aloud] Do you have any questions? [Answer questions]

[If yes] Ok, I would like to remind you that all study activities, including using the workbook with your enrolled patients and participating in the interview and electronic survey, are voluntary. There are no penalties for refusing to participate. You may end your participation at any time and refuse to answer any question in the interview or survey. The interview will be conducted through Zoom and will be recorded, but your camera will be off. Do you have any questions? [Answer questions]

Ok, I am now going to confirm your verbal consent to participate in this study. Please answer yes or no to the following questions.

Do you agree to participate in this study, including testing the workbook with your enrolled patients and completing a virtual interview and electronic survey? [If yes, continue. If no, stop now]

[If applicable] Do you agree for the interview conducted through Zoom to be recorded? [If yes, may record. If no, end participation because recording is required.]