



EMORY

WINSHIP
CANCER
INSTITUTE

National Cancer Institute-Designated
Comprehensive Cancer Center



cholangiocarcinoma
FOUNDATION

ciitizen

Dear Valued Member of the Cholangiocarcinoma Foundation,

We are writing to request your participation in a research study. The study is being conducted through the Winship Cancer Institute at Emory University in collaboration with the Cholangiocarcinoma Foundation and Ciitizen. We are contacting you because you are involved with the Cholangiocarcinoma Foundation and we would like your help!

The goal of our research study is to better understand quality of life among patients with cholangiocarcinoma. We hope this will allow us to identify areas for improvement in patient care as it relates to physical, emotional, and psychological well-being. Thus, it is extremely important that we hear from you!

If you choose to take part in our research study, you will be asked to complete a questionnaire at three different timepoints: at study enrollment (now), 6 months from now, and 12 months from now. The questionnaire should take 10-15 minutes to complete. If you have already signed up with Ciitizen, we also request access to your healthcare information, which will allow us to draw meaningful connections between your ongoing clinical care and the answers you provide to the questionnaire.

Please read the enclosed information leaflet carefully. If you do not wish to take part in the study, please disregard this email. However, if you are interested in taking part in the study, please click the link below to complete the first questionnaire. The information you provide is confidential and will be stored on a password-secured server. If you have any questions about the study or would like additional information, please contact me or Dr. Jessica Keilson directly.

<https://is.gd/EmoryCholangiocarcinomaStudy>

Thank you for your help!

Sincerely,

Shishir K. Maithel, MD FACS
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Scientific Director, Emory Liver and Pancreas Center
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PARTICIPANT INFORMATION LEAFLET

Study Title: Assessment of quality of life and cost burden related to cholangiocarcinoma treatment

Primary Investigator: Shishir K. Maithel, MD

Winship Cancer Institute, Division of Surgical Oncology, Emory University School of Medicine

We invite you to take part in our research study. Before you decide, we would like to provide you with additional information about the study and help you better understand why the research is being done and what it would involve for you. Please take time to read the enclosed information carefully. If you have any additional questions or would like to request additional information, you may contact our study team. Thank you for taking the time to read this.

Purpose of the study

The purpose of this study is to assess health-related quality of life in patients with cholangiocarcinoma. We will evaluate the effect of medical and surgical therapies on self-reported quality of life metrics, as well as assess the cost burden related to treatment and follow-up. The effects of a cancer diagnosis and its related treatments are vast, and not only include physical but also emotional and psychological strains. Additionally, the financial burden of cancer and related treatment is an often-overlooked facet of disease. Gaining a better understanding of the overall patient experience of disease will allow us to identify areas for improvement in patient care.

All members of the Cholangiocarcinoma Foundation will be invited to participate. We will ask you to complete a questionnaire at three time points during your participation in this study. We also request your permission to access your healthcare information if you have registered with Ciitizen.

What we would like you to do

If you would like to participate in the study, you will follow the link included in the patient letter. This will take you to a password-encrypted platform where you will be asked to complete the questionnaire. This should take approximately 10-15 minutes. We would like you to complete this questionnaire at the enrollment time, along with two additional times (in 6 months and in 12 months). You will receive email communication at those time points with the link to your personal password-encrypted questionnaire. If you have enrolled with Ciitizen, we also request permission to access your healthcare information.

Why have I been chosen?

Our research group is focused on studying gastrointestinal malignancies, specifically cholangiocarcinoma. Our current research focuses on clinical and translational work, and we

have developed this study design to better understand the sociobehavioral influences of this disease on patients. Patients with cholangiocarcinoma, much like other cancers, suffer from a variety of symptoms related to the disease itself and the different treatment modalities. The effects of disease and related treatments are vast, and not only include physical strains but emotional and psychological strains that have not been studied.

Members of the Cholangiocarcinoma Foundation are being invited to participate in our study. To be enrolled in our study, you must be able to complete the study questionnaire at each time point listed above. If you have enrolled with Ciitizen, we request permissions to access your healthcare records.

Do I have to take part in the study?

It is up to you to decide whether or not you would like to take part. If you agree to participate in the study, we request permission to access your healthcare information through the Ciitizen platform if you have signed up with them. We will ask you to complete a questionnaire at three time points over the course of a year.

Participation in this study is entirely voluntary. You may refuse to take part in the study and you may withdraw from the study at any time without having to give a reason and without this affecting your membership with Ciitizen or the Cholangiocarcinoma Foundation.

Participants who are currently enrolled with Ciitizen and agree to share their healthcare information or become new members and agree to share their healthcare information will receive a \$25 gift card.

Confidentiality

All protected medical information will be maintained in an encrypted database and stored on a password-secured virtual desktop environment. All personal identifiers will be de-identified in accordance with our Institutional Review Board and Health Insurance Portability and Accountability Act (HIPAA).

What will happen to the results of the research study?

The overall findings of the study may be published in a scientific journal, but will not contain any personal identifying information. If you would like to receive information about the study findings, please contact our group and we will share this information with you at the conclusion of the study.

Who has designed and reviewed the study?

The study has been designed by a group of researchers from the Winship Cancer Institute at Emory University, in collaboration with the Cholangiocarcinoma Foundation and Ciitizen. The study has been reviewed by our Institutional Review Board. The purpose of this review is to safeguard and promote the health and welfare of human research subjects by ensuring that

their rights, safety, and well-being are protected. Their role is to ensure that our research upholds the ethical principles set forth by the governing body and that participants who take part are adequately protected.

To obtain further information:

If you have any questions about this study, please contact Dr. Keilson or Dr. Maithel who will be happy to discuss the study further or answer any questions you may have.

Thank you for taking the time to read this information sheet and considering taking part in our study!