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Modeling the Disease Burden and Cost-Effectiveness of Screening and Treatment for Non-Alcoholic Fatty Liver Disease in Type 2 Diabetes Patients

Project Number	Contact PI/Project Leader	Awardee Organization
5R01HS026937-02	ROTHBERG, MICHAEL	CLEVELAND CLINIC FOUNDATION
	Other PIs	

Description

Abstract Text

Project Summary/Abstract In the US, type 2 diabetes (T2D) is a major cause of morbidity and mortality due to microvascular and macrovascular complications. Nonalcoholic fatty liver disease (NAFLD) is another common co-morbidity but its burden in patients with T2D is poorly studied. Although NAFLD affects 50-70% of T2D patients, there is neither a screening guideline nor established treatment for NAFLD. Besides weight loss, pioglitazone – an old diabetes drug – is the only drug recommended by the American Association for the Study of Liver Diseases for treating NASH, the more progressive form of NAFLD, in patients with T2D. In addition, liraglutide (in phase 2 trials) and obeticholic acid (with phase 3 interim data) appear effective for improving NASH and advanced fibrosis. At least 4 other drugs (making a total of 5) are undergoing phase 3 trials and up to 50 drugs are in phase 2 trials. As new drugs become available in the near future, physicians and patients will face difficult tradeoffs among long-term benefits, risks, and costs. Given the widespread nature of NAFLD in patients with T2D, screening to identify those with NASH, who are at high-risk of advance liver disease, for early intervention may help patients live longer with a better quality life. Yet, the lack of comparative effectiveness and cost- effectiveness analyses of screening for NAFLD has resulted in conflicting clinical guidelines. Choosing the best treatment and screening strategy for NAFLD is complicated and can be aided by the use of computer-based models. Unfortunately, existing diabetes models do not include NAFLD, and NAFLD models do not account for diabetes and its complications. The objective of this study is to develop a computer simulation model of NAFLD in T2D to estimate its burden, and evaluate treatment and screening options for NASH. Specific aims are: 1) Develop and validate a microsimulation model of the natural history of NAFLD, including NASH; 2) Estimate and project the burden of NAFLD-associated liver complications in patients with T2D until 2030; 3) Assess the cost-effectiveness of treatments for NASH in patients with T2D; and 4) Evaluate the cost-effectiveness of screening for NASH in patients with T2D. This proposal builds upon our inter-disciplinary team’s strong foundation of constructing decision models to assist clinical decision making and studying the epidemiology of diabetes and NAFLD. Our model will provide a better understanding of a prevalent, important, yet underappreciated diabetes complication, using an innovative approach to diabetes and liver disease modeling.

The study also establishes the groundwork for future evaluation of new treatment regimens and screening modalities for patients with T2D and NAFLD, which will advance the prevention and treatment of both diseases for millions of patients each year.

Public Health Relevance Statement

Project Narrative “Modeling the disease burden and cost-effectiveness of screening and treatment for non-alcoholic fatty liver disease in type 2 diabetes patients” will provide a better understanding of an under-recognized yet common comorbidity of patients with type 2 diabetes (T2D) in the US. As part of this project, we will develop and validate a computer-based model that can be used to estimate and project the burden of non-alcoholic fatty liver disease (NAFLD) in T2D patients. We will then apply the model to identify the most cost-effective medications and the optimal screening strategy for NAFLD, in order to improve the medical care and quality of life for millions of patients suffering from diabetes and NAFLD.

Project Terms

No Project Terms available.



Details

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UNITED STATES (US)

Department Type
Unavailable

Organization Type
Research Institutes

State Code
OH

Congressional District
11

Other Information

FOA PA-18-795	Administering Institutes or Centers AGENCY FOR HEALTHCARE RESEARCH AND QUALITY	Project Start Date	30-September-2020
Study Section Healthcare Effectiveness and Outcomes Research [HEOR]	CFDA Code 226	Project End Date	31-August-2025
Award Notice Date 24-August-2021	DUNS Number 017730458	UEI TDGUJ1WA4U	Budget Start Date 01-September-2021
Fiscal Year 2021	809775336	JB17GKEK	Budget End Date 31-August-2022

Project Funding Information for 2021

Total Funding \$389,092	Direct Costs \$264,127	Indirect Costs \$124,965
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Year	Funding IC	
2021	AGENCY FOR HEALTHCARE RESEARCH AND QUALITY	\$389,092

Sub Projects

No Sub Projects information available for 5R01HS026937-02

Publications

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No Publications available for 5R01HS026937-02

Patents

No Patents information available for 5R01HS026937-02

Outcomes

The Project Outcomes shown here are displayed verbatim as submitted by the Principal Investigator (PI) for this award. Any opinions, findings, and conclusions or recommendations expressed are those of the PI and do not necessarily reflect the views of the National Institutes of Health. NIH has not endorsed the content below.

No Outcomes available for 5R01HS026937-02

Clinical Studies

No Clinical Studies information available for 5R01HS026937-02

News and More

Related News Releases

No news release information available for 5R01HS026937-02

History

No Historical information available for 5R01HS026937-02

Similar Projects

No Similar Projects information available for 5R01HS026937-02

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No