DGIM Project Summary

Name of Project:
UCSF NASH Among Diabetics in Primary Care (NASH-DPC) Study

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)
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Research question(s):
Aim 1: To assess the needs of Primary Care Providers (PCPs) and the barriers they face in effectively diagnosing and referring patients with NASH.
Aim 2: To evaluate the validity of a tests-based case-finding algorithm to identify patients with NASH in a high-risk population of type 2 diabetes mellitus patients in a primary care practice.
Aim 3: To prompt PCPs to refer patients identified as likely to have NAFLD with high risk of NASH to the specialty hepatology clinic for determination of treatment and/or co-management plans.

Brief Background/Significance:
The prevalence and disease burden of NAFLD and NASH are increasing and are a major cause of rising rates of cirrhosis and liver cancer. NAFLD is present in 20-30% of the US population. Patients with diabetes mellitus, obesity and dyslipidemia are at particularly high risk for NAFLD. Classifying NAFLD patients as having definite NASH requires liver biopsy. The lack of a simple and low-cost diagnostic tool is one reason that the condition is missed by PCPs. Unfortunately, patients then remain unaware of the condition and an important window of opportunity for intervention may be missed. As novel therapies for NASH are advancing, screening for NAFLD may be recommended in the future. Now is the time to develop streamlined methods that real-world clinicians can use to accurately and efficiently find patients with NAFLD and NASH. Clinical prediction rules such as FIB-4 and NAFLD Fibrosis Score (NFS) have demonstrated high levels of accuracy for prediction of advanced fibrosis in patients with NAFLD, with these scores also predicting long-term outcomes. For many primary care patients, the clinical data needed to determine the FIB-4 or NFS already exist and are readily available in the EMR.

Inclusion/exclusion criteria (list)
Inclusion criteria
1. Patients receiving primary care at DGIM (at least 1 in-person visit in past 3 yrs)
2. Age $\geq$ 18
3. DM2 defined by HbA1c $\geq$ 6.5% and/or ICD-9/10 code for DM2 at any time

Exclusion criteria
1. Positive HBsAg and/or ICD 9/10 code for chronic HBV at any time
2. Detectable HCV RNA and/or ICD 9/10 code for chronic HCV at any time
3. ICD 9/10 code for alcohol use disorder at any time

Method of contact/recruitment (be specific)
This study will not have any direct contact with patients. There will be no requests for testing or treatments of any kind from the study team. The patients may have testing

or treatment recommended by their PCP or by hepatologists they may see in the Fatty Liver Clinic, but these would be within routine care.

Benefits/burden for participants (clearly identify potential for harm)
Benefits to patients:
1. Their PCP will receive a non-invasive assessment of their risk of NASH and will have a clear recommendation on whether or not to refer the patient for further evaluation.
2. The patient will gain awareness about fatty liver and will potentially be more motivated to achieve target diabetes control as well as lipid and BMI targets.
3. If they attend a Fatty Liver Clinic visit, they may have a Fibroscan performed and may have nutritional counseling.

Harms to patients:
1. Patients could have anxiety about a new diagnosis and have questions about the workup or long-term risks.

Any benefits or burden to DGIM practitioners?
DGIM practitioners will benefit from:
1. Receiving fast, convenient information about each of their diabetic patients.
2. Learning an approach to determining NAFLD risk for the future.

DGIM practitioners will be burdened by:
1. 1 email requesting he/she completes a brief needs assessment survey online and up to 3 email reminders to complete this survey.
2. 1 telephone encounter within Apex from the study team for each of their patients with diabetes who meets inclusion/exclusion criteria. The message will be concise and will inform the PCP the study team has assessed this patient as to their risk of NASH and will either include a pended order for a referral to Fatty Liver clinic or will include brief recommendations for how to follow the patient for the future. We will aim to spread out the messages to the PCP so that telephone encounters are evenly sent over a few months and not all at once. We will assist PCPs with offering a smart phrase that they can use to relay the information to the patients about their risk of fatty liver disease and if a referral is recommended.

Timeline for recruitment (projected start and stop dates)
Start date: 7/1/20
End date 7/1/22

Funding source
Gilead Sciences

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular)
We would gladly welcome any resident, fellow or student who wishes to be involved.

Do you agree to notify us when recruitment is completed?
Yes

Date form completed:
5/29/20