



NASH/NAFLD Community Screening

A Study of Community Engagement

Life Line Screening (LLS) is the largest direct-to-consumer provider of preventative health screenings in the United States, providing health screenings to evaluate risks for future health and chronic diseases. Over an 8-week period, LLS offered a Healthy Liver Screen (HLS) to all participants at two mobile screening clinics. The goals of this project were to educate participants on NAFLD/NASH risk factors, determine the effectiveness of community-based screening to detect probable NAFLD/NASH, assess co-morbid conditions associated with NAFLD/NASH, and provide participants a baseline screening result for liver health.

On average, LLS screens 725,000 participants at approximately 15,000 mobile events a year. Building on these community-based screenings, LLS developed a successful model to identify older adults at risk for NAFLD and NASH. Education and screening were well received by the LLS population.

LLS's direct-to-consumer health screenings focus on cardiovascular risk assessment. This work shows that participants with concern for cardiovascular health also have underlying risk factors for NAFLD/NASH. Rates of probable disease were established and in-line with predicted prevalence based on correlated risk factors. The study confirmed LLS's community-based screening model as a viable approach to identify individuals at risk for NAFLD and NASH.

Ready to Adapt to Your Trial's Needs

Life Line Screening is the industry leader in delivering strategic patient recruitment and enrollment solutions.

Nimble

Flexible

Innovative

What to Expect

The featured case study is an overview of LLS's community-based screening model and how it served as a viable approach to identify individuals at risk for NAFLD and NASH.

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recruitment@llsa.com
www.lifelinescreening.com

Methods:

Two LLS screening teams performed HLS for eight consecutive weeks in Central Florida and Houston Texas. HLS consisted of Echosens Fibroscan® to determine controlled attenuation parameter (CAP) value, a measure of steatosis, and vibration-controlled transient elastography (VCTE) value, a measure of liver stiffness. Blood tests for alanine transaminase (ALT), aspartate transaminase (AST), hemoglobin A1c (HbA1c), and a lipid profile were determined. ALT, AST, and HbA1c were measured by finger stick blood card assay. Lipid profiles were determined using a point of care analyzer. In addition, blood pressure was measured, and body weight and height assessed to calculate BMI.

Upon arrival at the screening event, all participants were presented with information about NASH and NAFLD. Interested participants were educated about the risk factors and offered a complementary HLS. All participants who opted-in for HLS also consented to share their information with a local research site offering diagnosis of and treatment for NASH. Following the HLS, participants determined to have risk for NAFLD/NASH were introduced to a local research site.

Results:

A total of 3430 patients received HLS with 2,643 (76.9%) considered to have a complete data set. Of these, 1833 (69.4%) had a BMI > 25 kg/m2, 2368 (89.6%) had a HbA1c >5 mmol/L, and 2639 (99.85%) had AST/ALT < 5x Upper Limit of Normal (ULN). 1708 (64.6%) had a CAP score of > 238 dB/m, 307 (8.9%) had a VCTE score >7 kPa, and 243 (7.1%) had both elevated CAP and VCTE scores. Among this group with elevated CAP and VCTE scores, AST/ALT vs VCTE, BMI vs CAP and HbA1c vs CAP showed positive predictive correlation trends for either NAFLD, NASH, or both. No/poor correlation was observed comparing VCTE with BMI, HbA1c, and Lipid profiles CAP also did not correlate with Lipid profiles.

Patients	Results
3430	Received Healthy Living Screening (HLS)
2643	Complete Data Set (100%)
1833	BMI > 25 kg/m2 (69.4%)
2368	HbA1c >5 mmol/L (89.6%)
2639	AST/ALT < 5x ULN (99.85%)
1708	CAP score > 238 dB/m (64.6%)
307	VCTE score >7 kPa (11.6%)
243	CAP and VCTE scores both elevated (9.2%)

*Patients with elevated CAP and VCTE scores, AST/ALT vs VCTE, BMI vs CAP and HbA1c vs CAP showed positive predictive correlation trends for either NAFLD, NASH, or both.

Highlights

- **2** months
- **2** LLS mobile screening clinics
- **3430** patients received Healthy Liver Screening (HLS)
- **69.4%** patients with BMI > 25 kg/m², revealed risk for NAFLD and/or NASH

Our Solution to Your Challenge

Life Line Screening brings clinical research studies to 60,000 participants per month.

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NAFLD & NASH in the Community:

As the Nation's largest community screening provider, LLS has shown that community-based screening is a novel approach to screening older adults at risk for NAFLD/NASH.

LLS sees community based screening as an important tool to help address the major challenges in recruiting for NASH trials. Generally, success in recruiting for NASH trials relates to the capabilities of sites involved in a study. Successful sites are focused on fatty liver and have worked in the field long enough to have a disease education program that expands out into primary care, endocrinologists and gastroenterologists in the community. However, not enough sites offer this depth of experience and specialization. Enrollment then suffers from screening an un-enriched or under-educated population. This translates into the need to screen a large number of potential subjects with possible NASH to enroll clinical trials.

Life Line is a pioneer in disease awareness and pre-screening for NAFLD/NASH in the United States. Participants with identified risk for NAFLD/NASH benefit most when they are properly educated and pre-screened in an accessible community location, and then referred to experts within the industry who bring depth of experience in diagnosis and treatment.

Life Line Screening utilizes community engagement as a pathway to build trust, encourage participation, and educate on the importance of clinical research.

