Title: **Empowering Immigrants in the Greater Boston Area to Connect to HBV Care**

Sponsor Name: **Gilead Sciences, Inc**

PI Name: **Fusco, Dahlene** Protocol #: **2014P000921** Type: **Amendment 8**

Date Received: **April 04, 2017**

Signatures

PI Name: Fusco, Dahlene, N, MD,Ph.D
Authenticated: April 04, 2017

Amendment

Performance Sites

Are you adding or removing a performance site?

○ Yes ⊙ No

Study Staff Amendment

Are you adding or removing study staff? REMINDER: Do not add Non-Partners collaborators unless they are engaged in the conduct of the research at a Partners institution or they plan to rely on the Partners IRB, and not their own IRB.

○ Yes ⊙ No

Central IRB Performance Sites

Is this a NeuroNEXT or STRIDE network protocol?

Note: The Partners IRB is the Central IRB for the NeuroNEXT and Stride networks.

○ Yes ⊙ No

Sponsor Amendment

Is there a sponsor amendment number?

○ Yes ⊙ No

Continuing Review

Indicate if this amendment is part of a continuing review submission.

⊙ Yes ○ No

NOTE: Attach only the study-related documents being revised as part of this amendment in the Attachments section of this submission. All other study-related documents not being revised should be attached in the continuing review submission.

Sponsor / Funding

Is a Sponsor / Funding source being added?

○ Yes ⊙ No

Protocol Title

Is the title of the protocol being changed?

○ Yes ⊙ No

Does your study involve an intervention / interaction with human subjects?

NOTE: Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject (45 CFR 46.102(f)).

⊙ Yes ○ No

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1. Data Forms Updates

Indicate below what forms need to be updated as part of this amendment. After clicking the save button you will be able to open any applicable forms that need to be updated/completed on the Forms page.

- ☐ Ancillary Drug
- ☐ Ancillary Non-hospital Device(s)
- ☐ Clinical Trials Registration
- ☐ Conflicts of Interest
- ☐ Diaries (e.g., Drug Diary)
- ☐ Drugs / Biologics / Dietary Supplements
- ☐ Instruments / Questionaires
- ☐ Informed Consent Form / Process
- ☐ Medical Device

- ☐ Non-Intervention / Non-Interaction Group
- ☐ Nursing Implementation
- ☐ Privacy / Confidentiality
- ☐ Radiation (Ionizing)
- ☐ Radiation (Non-Ionizing)
- ☐ Recruitment
- ☐ Remuneration
- ☐ Study Type / Classification (for example, physiologic, therapeutic, genetic)
- ☑ Study Population (for example, enrollment targets)
- ☐ Study Population - Special Populations

Change in Protocol Status

Do you need to change the overall status of the protocol? For example, Re-Open to Enrollment or indicate that Research Interventions/Assessments Continue after telling the IRB these have ceased.

○ Yes ⊙ No

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2. New/Revised Study Documents (Attachments)

Are you submitting new or revised study-related documents? Note: If you answer 'no' to this question you will not be able to attach documents to this submission.

○ Yes ⊙ No

Are you removing any study-related documents because they are not being used, e.g., you are no longer using advertisements?

○ Yes ⊙ No

Briefly describe the proposed changes:

We recruited 101 subjects but were approved to recruit 100 : we would like to amend the protocol to allow additional 1 subject recruitment.

Provide rationale for the proposed changes:

There was 1 additional subject who expressed interest in attending an outreach session.

Will the proposed change(s) significantly alter the risk to benefit assessment the IRB relied upon to approve the protocol?

○ Yes ⊙ No

Will the proposed change(s) significantly affect the integrity of the protocol?

○ Yes ⊙ No

Study Population

How many subjects do you plan to enroll at Partners' sites?

100

NOTE: Target enrollment at Partners sites is the number of subjects you expect to provide written or verbal consent, or implied consent by voluntary completion of a survey or participation in a focus group.

How many subjects will be enrolled study-wide?

101

What is the age range of eligible subjects who will be enrolled at Partners sites?

Enter 'None' if there is no maximum age.

Minimum age:

18

Maximum age:

none

Will both males and females be enrolled?

⊙ Yes ○ No

Indicate below whether the study population that is being targeted for the research is any of the following groups that require additional protections:

☐ Children (less than 18 years of age)

☐ Economically or Educationally Disadvantaged

☐ Embryos

☐ Employees under the direct supervision of the investigators conducting the research

☐ Employees (physician, nurses, or other healthcare workers) in the course of, or related to, their employment related duties

☐ Individuals with Impaired Decision-Making Capacity

☐ Neonates -age up to 28 days

- ☐ Non-English Speakers
- ☐ Patients from the Medical Practice of the Investigator
- ☐ Pregnant Women / Fetuses
- ☐ Prisoners
- ☐ Students of Harvard Medical School
- ☐ U.S. Military Personnel
- ☑ None of the above

Attachments

Name	Mode
revised protocol summary 4417(Protocol Summary)	Electronic
Revised Detailed Protocol(Detailed Protocol)	Electronic

PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR

Dahlene Fusco

PROTOCOL TITLE

Empowering Immigrants in the Greater Boston Area to Connect to HBV Care

FUNDING

Gilead will provide support for this investigator-sponsored study.

VERSION DATE

2014 5 13

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

Primary Aims:

We hypothesize that a significant proportion of African immigrants to Boston, who are at high risk for chronic HBV infection, are not integrated into appropriate HBV healthcare services. Our current Hepatitis C Community Healthcare Network, located throughout Charlestown, Chelsea, and Revere, now with extension into Everett, is situated in the Boston region most densely populated with recent immigrants [5]. Furthermore, our Community Outreach Network, which extends to African students in Boston and the general Senegalese Community in Boston, is directly situated in a population at high risk for chronic HBV infection. Our primary objective is to identify specific barriers preventing this high-risk population from obtaining adequate HBV screening, diagnosis, surveillance and treatment.

Secondary Aim(s):

Community HBV Outreach Sessions will be designed to provide culturally sensitive education regarding HBV virology, epidemiology, transmission, pathology, and current treatment options. HBV Outreach Sessions will characterize the current HBV knowledge – base of the Boston African Community, and will meet the following secondary objectives: 1) determine whether focused outreach sessions address gaps in this knowledge base adequately, 2) determine whether community outreach leads to increased likelihood of seeking HBV diagnosis, being diagnosed with HBV, and, when appropriate, treatment. Because of the stigma related to seeking care for infectious diseases, initial outreach will focus on outlining and improving the HBV knowledge base of participants.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Although effective vaccines have been available for over 20 years, HBV infection remains an

active global health threat. There are an estimated 350 million people with chronic HBV worldwide, roughly 5% of the population, [1][2], and up to 300,000 people are newly infected every year. Complications of HBV include end stage liver disease, fulminant liver failure and HCC, resulting in an estimated one million deaths per year. Current standard therapy for HBV infection includes oral nucleos(t)ide analogues and interferon IFNa. These agents are highly effective in suppressing HBV replication and can reduce the progression of liver disease and reduce the risk of developing HCC. However, many people infected with HBV are unaware that they are infected and therefore do not access care until the onset of late stage complications. In developed countries, the prevalence of HBV is higher among people who have emigrated from regions with intermediate or high prevalence [3][4], such as East Asia and Sub-Saharan Africa. While multiple outreach programs are being developed to link Asian patients to care, fewer programs are in place to link African immigrants to HBV care. We hypothesize that a major barrier preventing African patients from accessing HBV care is lack of information related to HBV. We further hypothesize that educating African immigrants of risks related to HBV will lead to a significant in the number of patients seeking and obtaining appropriate HBV care.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

Study design: The study will be a prospective cohort pilot study.**101** subjects will be enrolled, study-wide (by Partners researchers).
Eligibility Criteria: Community HBV sessions will be advertised and open to all adults over 18 who are willing to complete the session surveys.
Local site restrictions: n/a

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

Study Procedures:

HBV education sessions will be held every 3-4 mo at each site. The sessions will be structured as follows:
Participants will be provided with refreshments and asked to complete Pre-session HBV knowledge assessment. An interactive education session will then be held, covering HBV virology, pathology, epidemiology, treatment. Following the education session, a Post-session assessment of HBV knowledge base will be completed.
At the closing of each session, participants will be provided with a folder containing 1) an anonymous follow up survey asking whether the participant sought HBV diagnosis, was diagnosed, sought treatment, 2) a stamped / addressed envelope for the survey, 3) a pocket card to empower the participant with focused questions to access HBV care through his /her healthcare provider, 4) contact information for our clinics, 5) a list of HBV providers in the greater Boston area who are currently accepting new patients, with contact information (including providers from MGH Charlestown, Dr. Colvin from MGH Chelsea), Dr. Fusco from MGH Revere) and other HBV providers who are not affiliated with MGH), 6) a schedule for future HBV

education sessions. Participants will be encouraged to return to subsequent sessions, and can complete follow up.

Our primary endpoint is the precise identification of specific barriers preventing high-risk African immigrants to the Greater Boston Area from obtaining adequate HBV care. Barriers to care will be identified for a minimum of **101** high risk individuals. Barriers to care will be assessed using IRB-approved \"Pre-session assessments\" which will be completed prior to HBV education session. Questions will assess whether participants understand their risk for HBV, have access to an HBV provider, feel comfortable asking about HBV testing, and understand that treatment is available, potentially with copay assistance. Barriers to care will be scored for each participant and the number of participants citing each barrier will be calculated to yield the most common barriers to HBV care.

Secondary Endpoints(s):

Secondary objectives will be answered using the following metrics, which will be designed by our team, translated appropriately, and IRB approved:

1. Post-session assessment of HBV knowledge base;

2. Follow up anonymous survey to determine whether patient was 1) tested, 2) sought treatment;

3. Develop a long-term follow-up plan with an HBV provider. *All participants will be provided with a pocket card to increase the likelihood of a successful first encounter with HBV care. This card will outline the reason the participant has sought care (for HBV assessment), tests being requested (HBV SAg, SAb, DNA), and will provide the contact information for our HBV providers as an open access resource for providers.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

n/a

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

We will minimize risks to subjects by empowering them to seek diagnosis / care with physicians practicing HBV management according to standardized guidelines.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

We will not perform any diagnosis or treatment. We have tailored our education session to minimize the potential stress related to hearing about a viral infection and enhance the positive actions that a patient could take if concerned about HBV (speak with physician, provide physician contact info, provide navigator card to facilitate conversation with physician).

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

There are psychosocial risks associated with hearing about the potential exposure to an infectious agent such as HBV. As mentioned above, we have tailored our information session to address the stress and anxiety that can be associated with such a diagnosis, including slides describing how to approach your doctor about HBV, how to address coworker concerns, and how to approach HBV treatment.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

Subjects may benefit through increased awareness of HBV risks and, eventually, HBV diagnosis and treatment.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

No group of adult subjects is excluded from this study. Children are excluded as the content is tailored to a general adult education level.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

n/a

For guidance, refer to the following Partners policy:

Obtaining and Documenting Informed Consent of Subjects who do not Speak English
http://healthcare.partners.org/phsirb/nonengco.htm

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

How: posters (included in this IRB submission)
When: posters with the date of the next information session will be placed several weeks in advance
Where: in the Chelsea, Charlestown, and Revere Community Health Centers, and distributed to the Senegalese Community Group and Suffolk University African Students' Association
By Whom: the study staff

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Refreshments will be provided at each information session, and each participant will be provided with a $10 T pass.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
http://healthcare.partners.org/phsirb/recruit.htm

Guidelines for Advertisements for Recruiting Subjects
http://healthcare.partners.org/phsirb/advert.htm

Remuneration for Research Subjects
http://healthcare.partners.org/phsirb/remun.htm

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

Verbal consent for participation will be obtained for each participant at the beginning of the information session, by a member of the study staff, at the info-session site.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
http://healthcare.partners.org/phsirb/newapp.htm#Newapp

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects
http://healthcare.partners.org/phsirb/infcons.htm

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

The PIs will perform data and safety monitoring on a quarterly basis.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

n/a

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

While this study will not include case report form entries, source documents, or written informed consent, pre- and post-session questionnaires will be completed anonymously by subjects, and collected by the study staff, stored in a locked, secured location (Dr. Fusco's office) and analyzed. The PIs will be responsible for ensuring that data is collected and analyzed from these forms accurately and completely.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
http://healthcare.partners.org/phsirb/guidance.htm#13

Reporting Unanticipated Problems (including Adverse Events)
http://healthcare.partners.org/phsirb/guidance.htm#7

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

All questionnaires will be anonymous, and at each session pre- and post- session questionnaires will be handed out in pairs, paired by number (eg, subject #1 will receive questionnaire 1-pre and 1-post, so that pre versus post results can be compared).

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

n/a

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

n/a

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

n/a

Protocol Title:

Empowering Immigrants in the Greater Boston Area to Connect to HBV Care

Objectives :	**We hypothesize that a significant proportion of African immigrants to Boston, who are at high risk for chronic HBV infection, are not integrated into appropriate HBV healthcare services. Our current Hepatitis C Community Healthcare Network, located throughout Charlestown, Chelsea, and Revere, now with extension into Everett, is situated in the Boston region most densely populated with recent immigrants [5]. Furthermore, our Community Outreach Network, which extends to African students in Boston and the general Senegalese Community in Boston, is directly situated in a population at high risk for chronic HBV infection. Our primary objective is to identify specific barriers preventing this high-risk population from obtaining adequate HBV screening, diagnosis, surveillance and treatment.**

Primary Endpoint:	**Our primary endpoint is the precise identification of specific barriers preventing high-risk African immigrants to the Greater Boston Area from obtaining adequate HBV care. Barriers to care will be identified for a minimum of 101 high risk individuals.** **Barriers to care will be assessed using IRB-approved \"Pre-session assessments\" which will be completed prior to HBV education session. Questions will assess whether participants understand their risk for HBV, have access to an HBV provider, feel comfortable asking about HBV testing, and understand that treatment is available, potentially with copay assistance.** **Barriers to care will be scored for each participant and the number of participants citing each barrier will be calculated to yield the most common barriers to HBV care.**

Scientific Rationale :	**Many people infected with HBV are unaware that they are infected and therefore do not access care until the onset of late stage complications. In developed countries, the prevalence of HBV is higher among people who have emigrated from regions with intermediate or high prevalence, such as East Asia and Subsaharan Africa. While multiple outreach programs are being developed to link Asian patients to care, fewer programs are in place to link African immigrants to HBV care. We hypothesize that a major barrier preventing African patients from accessing HBV care is lack of information related to HBV. We further hypothesize that educating African immigrants of risks related to HBV will lead to a significant in the number of patients who seek diagnosis and, when relevant, treatment of HBV.**

Primary Investigator	
Name / Site :	**Fusco, Dahlene/James Morrill**
Address :	MGH Community Health Associates **300 Ocean Avenue 5th Floor**
City, State, Zip :	**Revere, MA 02151**
Country :	**USA**

Number of Patients :	**101**	Number of Sites :	**5**	Study Duration :	**2 years**

Program Type :	**Non-Interventional**	Program Sub Type :	
Protocol Type :	**Investigator Sponsored**	Program Indication :	
Special Apps/DW :		Sponsor Name :	

Study Details	
Scientific Rationale	Although effective vaccines have been available for over 20 years, HBV infection remains an active global health threat. There are an estimated 350 million people with chronic HBV worldwide, roughly 5% of the population, [1][2], and up to 300,000 people are newly infected every year. Complications of HBV include end stage liver disease, fulminant liver failure and HCC, resulting in an estimated one million deaths per year. Current standard therapy for HBV infection includes oral nucleos(t)ide analogues and interferon IFNa. These agents are highly effective in suppressing HBV replication and can reduce the progression of liver disease and reduce the risk of developing HCC. However, many people infected with HBV are unaware that they are infected and therefore do not access care until the onset of late stage complications. In developed countries, the prevalence of HBV is higher among people who have emigrated from regions with intermediate or high prevalence [3][4], such as East Asia and Sub-Saharan Africa. While multiple outreach programs are being developed to link Asian patients to care, fewer programs are in place to link African immigrants to HBV care. We hypothesize that a major barrier preventing African patients from accessing HBV care is lack of information related to HBV. We further hypothesize that educating African immigrants of risks related to HBV will lead to a significant in the number of patients seeking and obtaining appropriate HBV care.
Objectives	**Primary Objective:** We hypothesize that a significant proportion of African immigrants to Boston, who are at high risk for chronic HBV infection, are not integrated into appropriate HBV healthcare services. Our current Hepatitis C Community Healthcare Network, located throughout Charlestown, Chelsea, and Revere, now with extension into Everett, is situated in the Boston region most densely populated with recent immigrants [5]. Furthermore, our Community Outreach Network, which extends to African students in Boston and the general Senegalese Community in Boston, is directly situated in a population at high risk for chronic HBV infection. Our primary objective is to identify specific barriers preventing this high-risk population from obtaining adequate HBV screening, diagnosis, surveillance and treatment. **Secondary Objective(s):** Community HBV Outreach Sessions will be designed to provide culturally sensitive education regarding HBV virology, epidemiology, transmission, pathology, and current treatment options. HBV Outreach Sessions will characterize the current HBV knowledge – base of the Boston African Community, and will meet the following secondary objectives: 1) determine whether focused outreach sessions address gaps in this knowledge base adequately, 2) determine whether community outreach leads to increased likelihood of seeking HBV diagnosis, being diagnosed with HBV, and, when appropriate, treatment. Because of the stigma related to seeking care for infectious diseases, initial outreach will focus on outlining and improving the HBV knowledge base of participants.

Endpoints	**Primary Endpoint:** Our primary endpoint is the precise identification of specific barriers preventing high-risk African immigrants to the Greater Boston Area from obtaining adequate HBV care. Barriers to care will be identified for a minimum of **101** high risk individuals. Barriers to care will be assessed using IRB-approved \"Pre-session assessments\" which will be completed prior to HBV education session. Questions will assess whether participants understand their risk for HBV, have access to an HBV provider, feel comfortable asking about HBV testing, and understand that treatment is available, potentially with copay assistance. Barriers to care will be scored for each participant and the number of participants citing each barrier will be calculated to yield the most common barriers to HBV care. **Secondary Endpoints(s):** Secondary objectives will be answered using the following metrics, which will be designed by our team, translated appropriately, and IRB approved: 1.Post-session assessment of HBV knowledge base; 2. Follow up anonymous survey to determine whether patient was 1) tested, 2) sought treatment; 3. Develop a long-term follow-up plan with an HBV provider. *All participants will be provided with a pocket card to increase the likelihood of a successful first encounter with HBV care. This card will outline the reason the participant has sought care (for HBV assessment), tests being requested (HBV SAg, SAb, DNA), and will provide the contact information for our HBV providers
Study Design	The study will be a prospective cohort pilot study.
No. of Subjects	**101**
No. of Sites* (if additional sites, please specify)	5
Participating Countries*	United States
Estimated FPFV Date*	08/01/2013
Estimated LPLV Date*	07/31/2015
Duration of Enrollment*	2 Years
Duration of Treatment*	2 Years
Eligibility Criteria* (Inclusion/Exclusion)	Community HBV sessions will be advertised and open to all adults over 18 who are willing to complete the session surveys.
Study Duration)	2 years
Regimens* (Include dose and mode of administration)	**Product:** n/a **Dose:**

	n/a **Frequency:** n/a
Study Procedure / Frequency Table (if applicable, attach additional details)	HBV education sessions will be held every 3-4 mo at each site. The sessions will be structured as follows: Participants will be provided with refreshments and asked to complete Pre-session HBV knowledge assessment. An interactive education session will then be held, covering HBV virology, pathology, epidemiology, treatment. Following the education session, a Post-session assessment of HBV knowledge base will be completed. At the closing of each session, participants will be provided with a folder containing 1) an anonymous follow up survey asking whether the participant sought HBV diagnosis, was diagnosed, sought treatment, 2) a stamped / addressed envelope for the survey, 3) a pocket card to empower the participant with focused questions to access HBV care through his /her healthcare provider, 4) contact information for our clinics, 5) a list of HBV providers in the greater Boston area who are currently accepting new patients, with contact information (including providers from MGH Charlestown, Dr. Colvin from MGH Chelsea), Dr. Fusco from MGH Revere) and other HBV providers **who are not affiliated with MGH**), 6) a schedule for future HBV education sessions. Participants will be encouraged to return to subsequent sessions, and can complete follow up.
Duration of Enrollment*	2 Years
Other Evaluations (e.g. Pharmacokinetics)	n/a
Statistical Methods	An MGH Clinical Trials Statistician will be consulted for further assistance. In this pilot study of **101** participants, a list of potential barriers to care will be rated numerically by each participant. Highest ranking barriers will be given a score of 10, lowest a score of 1. The mean and standard deviation score for each barrier will be calculated for each community site and for the entire cohort. Addressing barriers to care with the highest scores will become the focus of subsequent sessions. In addition, pre-session and post-session HBV knowledge base will be compared for each participant. The mean difference in knowledge base score will be assessed for each session, each site, and for the entire cohort.

References	References: 1. Lok, A.S., E.J. Heathcote, and J.H. Hoofnagle, Gastroenterology, 2001. 120(7): p. 1828-53. 2. Lavanchy, D., J Viral Hepat, 2004. 11(2): p. 97-107. 3. Lavanchy D. J Viral Hepatology 2004; 11(2): 97-107. 4. Mast EE, Margolis HS, Fiore AE, et al. MMWR Recomm Rep 2005; 54 (RR-16):1-31. 5. Massachusetts Immigrants by the Numbers: Demographic Characteristics and Economic Footprint. Alan Clayton-Mathews, Faye Karp, John W. McCormack, Paul Watanabe. The Immigrant Learning Center, Malden, MA.