## The establishment of hepatitis B care and treatment clinics in the United Republic of Tanzania: A demonstration project following WHO guidelines

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#### **BACKGROUND**

- 257 million persons with chronic hepatitis B virus (HBV) globally · 887,000 associated annual deaths: liver cirrhosis, liver cancer
- HBV prevalence in African region is 6.1% ■ 5-17% in Tanzania
- Few HRV care and treatment programs in Δfrica
- World Health Organization (WHO) issued HBV care and treatment guidelines in 2015 for low resource countries

#### **OBJECTIVE**

- Demonstration project following WHO guidelines in Tanzania
- Implement a model HBV care and treatment program
- · Evaluate the feasibility and acceptability of the program Evaluate the impact of the program on proximal disease
- outcomes (improvement in liver enzymes and HBV DNA)
- Increase the capacity of healthcare professionals to care for patients with chronic HBV

#### **METHODS**

- Project period: January 2017 December 2021
- Two clinics of excellence established:
  - Muhimbili National Hospital, Dar es Salaam Mnazi Mmoja, Zanzibar
- Partnerships
  - Ministry of Health
    - CDC-Atlanta and CDC-Tanzania
    - Regional WHO office
  - Hospitals/clinics
  - Blood donation program

- Clinical staff to provide HBV care and treatment
- Laboratory staff to perform HBV related laboratories
- Community partners for communication and outreach Recruitment: mono-infected patients with HBV 18 years and older
  - Blood donors, patients from hospitals (inpatient), clinics (outpatient) screened HBsAg+ and HIV-, anti-HCV-negative 18 years and older
- Follow-up: Evaluate patient for antiviral treatment eligibility
  - Treatment eligibility criteria:
    - 1) Liver cirrhosis or
    - 2) APRI > 1.5 or
    - 3) ALT > 80 IU/mL & HBV DNA > 20,000 IU/ml
    - Treatment eligible patients followed every 6 months · Not treatment eligible patients followed every 12 months
    - Tenofovir provided as gift from Gilead Sciences

#### **RECRUITMENT FOLLOW-UP** Patient NOT taking Tenofovir Patient taking Tenofovir Blood donor, inpatient, or outpatient Follow-Up every 6 months Follow-up every 12 months HBsAg+ and 18 Years or older Counsel/Refer to HIV test HIV/AIDS Tx Center 1) Physical Exam 2) Labs: HBV DNA, HBeAg, anti-Hbe, HBsAg, CMP, CBC, PT/INR, APRI, AFP, eGFR Negative Positive Counseling Anti-HCV test 3) Counseling: Education Negative HBeAg-, Anti-HBe+, HBV 1) Physical Exam: Stigmata of cirrhosis, OR Counsel/Refer to DNA not detectable 2) APRI > 1.5. OR **HBV Clinic** & ALT < 45 for 12 months 3) ALT > 80 IU/mL & HBV DNA > 20.000IU/ml HBsAg clearance 1) Physical Exam: Stigmata of cirrhosis, OR 2) APRI > 1.5. OR 3) ALT > 80 IU/mL & HBV DNA > 20.000IU/ml Yes-Treatment Eligible Tenofovir & Consider STOF Tenofovir & Follow-up 12 months Follow-up 12 months Follow-up 6 months Follow-up 6 months

#### PROGRESS AFTER ONE YEAR (2017)

- Muhimbili National Hospital, Dar es Salaam
- · Large public University hospital with Gastroenterology
- · Endoscopy, ultrasound, HBV DNA lab capacity
- Target enrollment 350 / year Trained 10 physicians, 7 field assistance, 3 laboratory technician, 2
- pharmacists, and 1 data manager
- Mnazi Mmoia Hospital, Zanzibar
- Public hospital for Zanzibar; primary care and internal medicine providers 5 200
- Endoscopy, ultrasound; no HBV DNA testing capacity (samples to MNH) · Target enrollment 150 / year
- Trained 2 physicians, 2 nurses, 1 laboratory technician, 1 pharmacist. and 1 data manager
- 115 diagnosed with liver cirrhosis
- · 46 with AFP > 200 IU/mL which may indicate liver cancer

# Care continuum for 606 patients with chronic HBV in Tanzania, 2017



■ Muhimbili ■ Mnazi Mmoia

#### **DISCUSSION**

- Two clinics of excellence established to provide HBV care and treatment following WHO guidelines
- Successful recruitment and enrollment is on-going
- Challenges include:
  - Fluctuating costs of laboratory supplies including reagents for HBV DNA and HBV serology testing
  - Demand for HBV care and treatment is much higher than capacity to care for all the patients with HBV
- Many patients presenting to clinics with advanced disease Liver cirrhosis
  - Possible liver cancer (Hepatocellular carcinoma)
- Continue recruitment and enrollment Continue HBV training and education
- Monitor adherence to and side effects from TDF
- Monitor and evaluate protocol implementation
- Evaluate the feasibility and sustainability of continuing such a program in low resource settings, including cost analysis for Ministry of Health
- Analyze data to evaluate impact of program on improvement in liver function and HBV DNA suppression

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