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## Hepatitis B Care and Treatment in Zanzibar, Tanzania: A Demonstration Project Following 2015 WHO Treatment Guidelines, 2017–2021

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### Abstract

Zanzibar, a low-resource semiautonomous region of Tanzania, has an estimated prevalence of hepatitis B virus (HBV) infections of 3.6%. To assess the feasibility of care and treatment, a 5-year hepatitis B demonstration project was implemented in Zanzibar during January 2017–December 2021, following the 2015 WHO HBV care and treatment guidelines. Participants included adults (aged 18 years) who tested positive for HBV surface antigen and tested negative for HIV and hepatitis C antibody. Participants were examined for clinical signs of liver disease and testing was conducted at baseline to assess treatment eligibility and every 6–12 months thereafter. Tenofovir disoproxil fumarate (TDF) was provided at no cost to treatment-eligible participants. Clinical and laboratory data were analysed to assess improvement in proximal disease outcomes. Among 596 participants enrolled, the median age was 32 years (IQR 26–39) and 365 (61%) were male. Of those enrolled, 268 (45%) returned for 1 follow-up visit, with a median of 511 days of follow-up. Overall, 58 patients initiated treatment: 15 met treatment criteria based on liver cirrhosis alone; 13 by APRI > 1.5; among those with HBV DNA results, six met criteria based on HBV DNA levels and ALT activity; 24 met 2 criteria. Significant decreases in ALT activities, APRI scores and HBV DNA levels were observed among those treated. This hepatitis B care and treatment programme was demonstrated to be feasible in a low-resource setting. Despite challenges, testing and linkage to care is critical to decrease the global burden of hepatitis B.

### Keywords

hepatitis B; Tanzania; treatment; Zanzibar

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This article has been contributed to by U.S. Government employees and their work is in the public domain in the USA.

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Sanaa S. Said and Shaun Shadaker contributed equally to this work.

Conflicts of Interest

The authors declare no conflicts of interest.

## 1 | Introduction

In 2019, approximately 296 million persons were living with chronic hepatitis B virus (HBV) infection worldwide and an estimated 820,000 HBV-related deaths occurred, primarily from chronic infection, liver failure and hepatocellular carcinoma (HCC) [1]. According to the World Health Organisation (WHO), 66% of the world's chronic HBV infections occur in the African and Western Pacific regions [1]. Most countries in sub-Saharan Africa have a high prevalence of HBV infection, management of which is complicated by a lack of testing and treatment availability [2]. Zanzibar, with a population of 1.9 million [3], is a low-resource, semiautonomous region of Tanzania with an estimated hepatitis B prevalence of 3.6% on its main island of Unguja [4].

According to the 2015 WHO hepatitis B care and treatment guidelines, not all persons with chronic HBV infection require treatment; indications for treatment include higher HBV DNA levels, fibrosis or high risk of cirrhosis and HCC [5]. Of those with chronic HBV infection, 15%–40% will die prematurely from liver cirrhosis, liver failure or liver cancer [6]. Thus, all persons with HBV infection require routine assessment of liver enzymes, HBV DNA and liver cancer surveillance to monitor disease progression and ascertain treatment viability [5].

To mitigate the global burden of HBV infection, the WHO issued hepatitis B care and treatment guidelines in 2015, which called for the use of simple, noninvasive tests to assess treatment eligibility and prioritisation of patients with advanced liver disease for treatment [5]. Furthermore, in 2016, the World Health Assembly endorsed goals for viral hepatitis elimination, which called for a 90% reduction in incidence and 65% reduction in mortality for both hepatitis B and hepatitis C worldwide by 2030 [5, 7]. Guided by these initiatives and global interests, a 5-year demonstration project for the establishment of hepatitis B care and treatment clinics in the United Republic of Tanzania was launched in December of 2016 at Mnazi Mmoja Hospital in Stone Town, Zanzibar. The goals of the project included establishing a model care and treatment programme and evaluating the feasibility and impact of the care model, while increasing the capacity of health professionals in the country. This analysis reports on the implementation, cascade of care and treatment results of Zanzibar's programme.

## 2 | Materials and Methods

Clinical and laboratory staff at Mnazi Mmoja Hospital received training from CDC Division of Viral Hepatitis subject matter experts on the diagnosis, evaluation and clinical management of persons with chronic HBV infection following 2015 WHO HBV care and treatment guidelines [5].

The programme period was from 1 January 2017 through 31 December 2021. Participants were recruited from inpatient and outpatient clinics, as well as Zanzibar's National Blood Donation Program where donors are systematically screened for HIV, hepatitis C antibody (anti-HCV), syphilis and hepatitis B surface antigen (HBsAg). Additionally, household contacts of persons with chronic HBV infection could be referred to the programme.

No incentives were offered for enrolment, but clinical services related to the programme including testing and treatment were provided free-of-charge. Participants were invited to enrol in the programme if they were  $\geq 18$  years of age, HBsAg positive and tested negative for both HIV and anti-HCV, with a goal of enrolling 600 adults. Patients testing positive for HIV or anti-HCV were provided counselling and were referred to AIDS treatment or hepatitis clinics for additional care. After providing written consent, enrolled persons had a physical examination for stigmata of liver cirrhosis including spider angioma, palmar erythema, splenomegaly, caput medusa, ascites, jaundice, pruritis, asterixis or encephalopathy and an ultrasound for the diagnosis of liver cirrhosis and liver cancer. Liver function tests and laboratory diagnostics were conducted to determine alanine aminotransferase (ALT) activity, aspartate aminotransferase (AST) activity and blood platelet levels and AST to platelet ratio index (APRI) scores were calculated. In addition to HBsAg, enrolled persons were tested for other HBV markers including antibody to hepatitis B surface antigen (anti-HBs) and occasionally hepatitis B e-antigen (HBeAg). HBV viral load was quantitated using the CAP/CTM 96 Roche machine. As Mnazi Mmoja Hospital lacked resources for HBV DNA testing, specimens were tested at the Central Pathology Laboratory within Muhimbili Hospital in Dar es Salaam, Tanzania. Following WHO 2015 HBV Guidelines, participants were eligible for treatment if they met one or more of three requirements: (1) evidence of liver cirrhosis from ultrasound and/or presence of stigmata; (2) APRI score  $> 1.5$ ; or (3) HBV DNA  $> 20,000$  IU/mL, 2 ALT readings greater than the upper limit of normal (ULN) and age  $> 30$  years. An APRI threshold of 1.5 was chosen over the 2015 WHO criteria of 2.0 to ensure all patients with evidence of liver inflammation and/or scarring could benefit from treatment. ALT ULN was defined as 40 units per litre (U/L). Tenofovir disoproxil fumarate (TDF) (Viread, Gilead Sciences Inc., Foster City, CA, USA) 300 mg once daily was available for treatment-eligible patients free of charge. Renal function tests were conducted to ensure treatment with TDF could be safely administered. A diagnosis of HCC was determined through ultrasound and alpha-fetoprotein (AFP), or triphasic computed tomography (CT) scan when available. All enrolled persons received counselling on treatment, including proper administration and potential side effects. Participants receiving TDF were given a sufficient supply to last until their next scheduled visit. Hepatitis B-related laboratory testing was performed every 12 months for assessment of treatment eligibility among participants who had not been eligible for treatment at baseline evaluations. Patients receiving treatment returned for follow-up visits every 6 months to assess treatment continuation eligibility and received a physical exam and blood tests for liver function and platelets to calculate APRI. Testing for HBV DNA was also conducted when resources were available.

Statistical differences in treatment eligibility by demographic and other characteristics were determined using chi-square test. For analysis of treatment outcomes, participants' most recent laboratory results were compared to their baseline laboratory results using nonparametric Wilcoxon signed rank test for difference in medians, with alpha 0.05. Patients with laboratory results for only one visit were excluded from treatment outcome analysis. All statistical analysis was performed in SAS version 9.4. (Cary, North Carolina, USA).

The research was reviewed and approved by institutional review boards at the United States Centers for Disease Control and Prevention in Atlanta, GA (# 6791), and in Zanzibar (ZAMREC 0002).

### 3 | Results

During 1 January 2017 to 31 December 2021, 613 adults who were HBsAg positive were referred to the programme in Zanzibar. Of those, two (0.3%) were excluded because they were anti-HCV positive; no participants tested HIV positive. Of 611 HBV-mono-infected individuals, 596 (97.6%) enrolled in the programme, median age was 32 years (interquartile range [IQR] 26–39 years) and 365 (61.4%) were male (Table 1). Among the 15 persons who did not enrol in the programme, three (20.0%) refused and the remaining 12 (80.0%) were either lost to follow-up or chose not to participate in the programme, citing distrust of their HBV test results. Of the 596 enrolled, 328 (55.0%) participants attended only the baseline visit, 117 (19.6%) attended a single follow-up visit, 65 (10.9%) attended two follow-ups and 86 (14.4%) attended 3 visits. Those with 1 follow-up visit ( $n = 268$ ) had a median of 511 (IQR 252–823) days of follow-up between their baseline and last visit. Of 596 enrolled, 512 (85.9%) had complete laboratory results (including ALT, AST, APRI score and HBV DNA) reported for at least one visit, 58 (9.7%) were deemed eligible for treatment and 45 of 58 (77.6%) were started on TDF (Figure 1). Among the 45 patients who initiated treatment, 22 (48.9%) attended only the baseline visit, three (6.7%) attended a single follow-up visit, six (13.3%) attended two follow-ups and 14 (31.1%) attended 3 visits. Thirteen treatment-eligible patients did not receive TDF, among whom six had died, six were lost to follow-up and one was no longer eligible for a follow-up visit. No patients were deemed ineligible for treatment due to renal impairment. Among 11 persons tested for HBeAg, seven (63.6%) were positive and 12 patients were tested for anti-HBs, of whom five (41.7%) were positive.

Of the 58 patients who were eligible for treatment, 22 (37.9%) met the criteria for both clinical evidence of liver cirrhosis and APRI  $> 1.5$ , 15 (25.9%) for only clinical liver cirrhosis, 13 (22.4%) met the criteria for only APRI  $> 1.5$  and eight (13.8%) met WHO criteria by HBV DNA and ALT (Figure 2). Those eligible for treatment were more likely to be in older age groups ( $p = < 0.001$ ), with a median age of 36 years (IQR 31–48 years) compared to 31 years (IQR: 26–39 years) among treatment-ineligible enrollees.

Among 23 treated patients with 2 ALT results, ALT values decreased significantly, from a median of 52.0 U/L (IQR: 28–247 U/L) to 24.0 (IQR: 17–44 U/L) ( $p = 0.001$ ), while among 227 treatment ineligible patients with 2 results, ALT activity remained stable with median values ranging from 20 to 25 at each visit (Figure 3). Similarly, APRI scores decreased from a median of 1.8 (IQR: 0.7–2.9) to 0.3 (IQR: 0.2–1.6) ( $p = 0.01$ ) among those treated while scores for untreated patients ranged from 0.2 to 0.3 for each visit. Among 17 treated patients who had more than one HBV DNA result, there was a decrease in median viral DNA levels from a pretreatment level of 159,535 IU/mL (IQR: 580–354,184 IU/mL) on their first test to undetectable (IQR: 0–327 IU/mL) on their second ( $p = 0.001$ ). Untreated patients with more than one HBV DNA test ( $n = 104$ ) had a median value of 419 IU/mL (IQR: 125–1772 IU/mL) for the first and 335 (IQR: 70–1521 IU/mL) for the last test ( $p$

= 0.08). Over the duration of the programme, of 596 enrolled patients, two (0.3%) were diagnosed with hepatocellular carcinoma, both at baseline and 12 (2.0%) patients died due to complications from HBV-associated liver disease or other causes, including six who were treatment eligible but not treated. Of the 23 treated patients with at least one follow-up visit, 1 (4.3%) temporarily discontinued treatment due to intolerance from fatigue but later restarted treatment with no further complications.

## 4 | Discussion

This analysis of the programme in Zanzibar is significant in that it demonstrates the feasibility of implementing a hepatitis B care and treatment programme following the 2015 WHO HBV care and treatment guidance. The programme demonstrated that patients with hepatitis B can be treated in low-resource settings when simplified evaluation and treatment initiation criteria are used. The programme successfully enrolled nearly 600 patients, just under 10% of whom were eligible for treatment with TDF according to the established 2015 WHO guidelines [5]. Among those who initiated treatment, ALT and APRI improved significantly soon after initiating treatment and decreasing HBV DNA levels were observed among those tested pre and postinitiation of TDF. These results were achieved with minimal known adverse events, with only one patient temporarily discontinuing treatment.

The project encountered various challenges, including access to and cost of HBV DNA testing and antiviral treatment. Throughout the project, Zanzibar lacked the equipment to perform HBV DNA testing, so blood samples were sent to a molecular biology laboratory in Dar es Salaam for testing, leading to delays in ascertaining treatment eligibility, consuming a significant portion of the project budget due to high cost (> \$75 per test) and adding additional logistic barriers.

Patient retention was another significant challenge in the study; more than half of patients did not return for a follow-up visit, including those who initiated treatment. A similar study conducted in sub-Saharan Africa observed comparable rates of loss to follow-up [8]. Reasons for this are not entirely clear, but may include concerns over confidentiality, stigmatisation or transportation challenges [9]. For the latter, decentralisation of care could help to improve patient engagement. Since the end of the programme three more clinics have begun offering hepatitis B care and treatment in other areas of Zanzibar, including one in northern Unguja, one in the island of Pemba and the third catering to patients attending an opioid agonist treatment clinic. Loss to follow-up also was likely prohibitive to linkage to treatment due to treatment eligibility criteria of repeatedly elevated ALT activity, which necessitated at least two clinic visits. Clinicians reported that some treatment-ineligible patients were disappointed from being told they would not receive medication and were demotivated to return for further testing. Furthermore, it was reported that others who began treatment may have mistakenly believed the dosage given would cure the disease with no need to return. Counselling was provided to help patients navigate the process and to increase health literacy regarding hepatitis B and the importance of treatment adherence, but peer-support groups could also be considered to improve retention in care [10].

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Although supplies of TDF were donated by Gilead Sciences for the duration of the project, cost and availability of the drug are a challenge for the sustainability of the programme and must be considered where resources are limited. It is worth noting that the price of TDF has fallen dramatically in sub-Saharan Africa to about \$25 per year. Despite this, after the end of the project period, patients who remained engaged in the project were still receiving clinical care at Mnazi Mmoja Hospital in Zanzibar, and those who received TDF through the programme continued to be treated. Further expansion of the programme to other areas in Zanzibar may require innovative strategies to overcome these barriers. Alternative funding sources such as sustained funding by the Ministry of Health could be considered.

In addition to diagnostics and treatment, prevention measures are essential to reducing the burden of hepatitis B. Future sustainability planning for the programme should address the prevention of mother-to-child transmission of HBV, including universal HBV testing of pregnant women using a finger stick test for HBsAg (at a cost of approximately \$1 USD) ideally at the same time HIV testing is done to save costs and implementation of hepatitis B birth dose vaccination [11, 12]. Among pregnant women who are HBsAg positive and who are unlikely to deliver in a health facility, a supply of TDF could be given to last through pregnancy and for 6 months after delivery. Further, universal testing and vaccination can provide protection for health care workers from HBV infection [13] and awareness campaigns can be considered to reduce transmission of infection through unsafe medical practices [14].

After the conclusion of the programme in Tanzania, WHO published new guidelines for HBV, which include treating all persons with HBV DNA  $> 2000$  IU/mL and elevated ALT activity, and persons with evidence of moderate or greater fibrosis via noninvasive testing [9]. The new guidelines also include the use of point-of-care testing for HBV DNA given the wide availability of these platforms globally. Adoption of these revised guidelines would have affected the programme in several ways. First, not all patients in this study received HBV DNA testing due to the aforementioned challenges. Point-of-care testing would have significantly alleviated these logistical barriers. Further, given the median age of 32 years for patients enrolled in the programme, removing the age restriction coupled with a tenfold reduction in the HBV DNA threshold would have led to increased rates of treatment eligibility. Additionally, although only 10% were treatment eligible at the time of the study, nearly a quarter had a baseline APRI score  $> 0.5$  which is the revised cut-off for evidence of moderate or greater fibrosis, and so would have been eligible especially if coupled with an HBV DNA level  $> 2000$ . The updated WHO guidelines also call for a single elevated ALT result, which would have streamlined patient assessment and may have increased treatment rates in the current study. Finally, nearly a third of those who initiated treatment attended  $> 3$  clinic visits, which was double the proportion of the overall cohort. This supports findings that lack of treatment is associated with loss to follow-up [10] and suggests the new guidelines could also have improved patient retention.

This demonstration programme was subject to several limitations. As previously described, HBV DNA testing capacity and the cost of testing were a challenge, which hindered analysis. This can be overcome if desktop diagnostic equipment already present in most larger hospitals in Africa in the HIV programmes could be utilised for HBV testing. The

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number of patients eligible for treatment may have been underestimated by a lack of HBV DNA testing, or the criteria of repeatedly elevated ALT activity, as described above. Monitoring of treatment adherence is difficult, so there cannot be complete certainty that treatment outcomes were only measured among those who sustained treatment. Loss to follow-up is always an issue in such programmes which limits the programme effectiveness, and the subsequent loss of data hinders analytical implications. Finally, there was not sufficient patient retention over the course of the programme to measure adverse events and disease outcomes such as liver failure or hepatocellular carcinoma, limiting our ability to evaluate the effectiveness of the programme. Implementing hepatitis B care and treatment at additional methadone clinics in similar settings could be considered to improve treatment adherence and reduce loss to follow-up.

Despite challenges, this 5-year programme in Zanzibar demonstrated that hepatitis B care and treatment are feasible in low-resource settings when testing and treatment are available. Another recent hepatitis B treatment programme in Ethiopia also showed treatment with TDF to be safe and effective in sub-Saharan Africa, noting the need for increased access to diagnostics and treatment in the region [15]. Testing for HBsAg and linkage to care for those positive is critical to decrease the global burden of hepatitis B, and similar programmes can be considered to reduce that burden and help move towards WHO HBV elimination goals [1]. Integrated testing for HBsAg at sites where HIV and syphilis testing is performed for all pregnant women and providing TDF during the rest of pregnancy and hepatitis B birth dose vaccine to newborns would accelerate the elimination of mother-to-child transmission of HBV [12]. In addition, allowing existing desktop diagnostic platforms originally obtained for HIV testing to be used for HBV DNA testing can yield rapid results and significantly reduce the costs of HBV DNA monitoring; when ALT levels are also available, a rapid point of care decision on whether to prescribe antiviral therapy could be made at the same visit.

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## Data Availability Statement

Research data are not shared.

### Abbreviations:

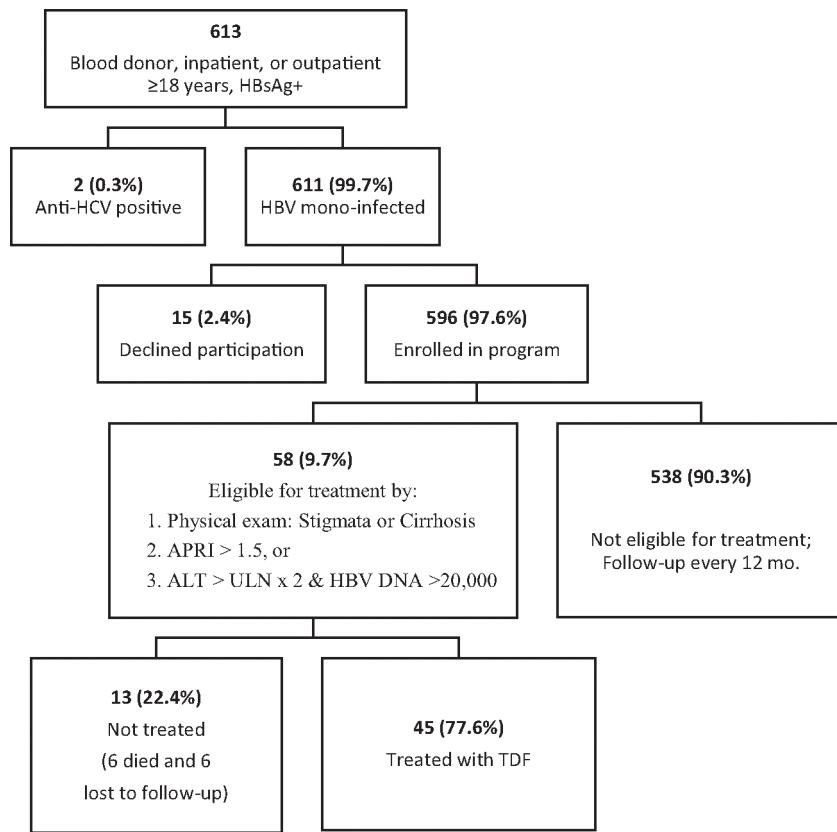
ALT	alanine aminotransferase
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<b>anti-HBs</b>	antibody to hepatitis B surface antigen
<b>anti-HCV</b>	hepatitis C antibody
<b>APRI</b>	AST to platelet ratio index
<b>AST</b>	aspartate aminotransferase
<b>HBsAg</b>	hepatitis B surface antigen
<b>HBV</b>	hepatitis B virus
<b>HCC</b>	hepatocellular carcinoma
<b>IQR</b>	interquartile range
<b>TDF</b>	tenofovir disoproxil fumarate
<b>U/L</b>	units per litre
<b>ULN</b>	upper limit of normal
<b>WHO</b>	World Health Organization

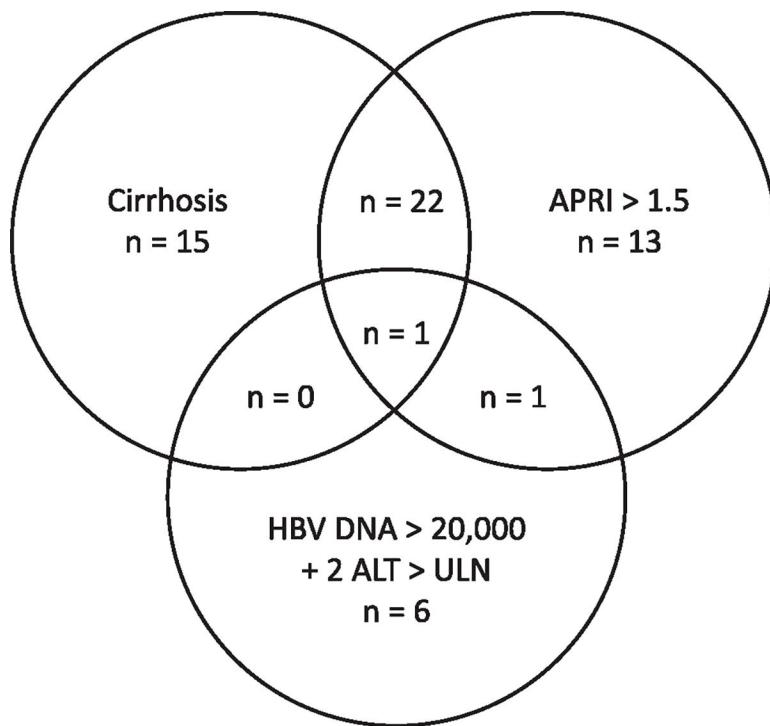
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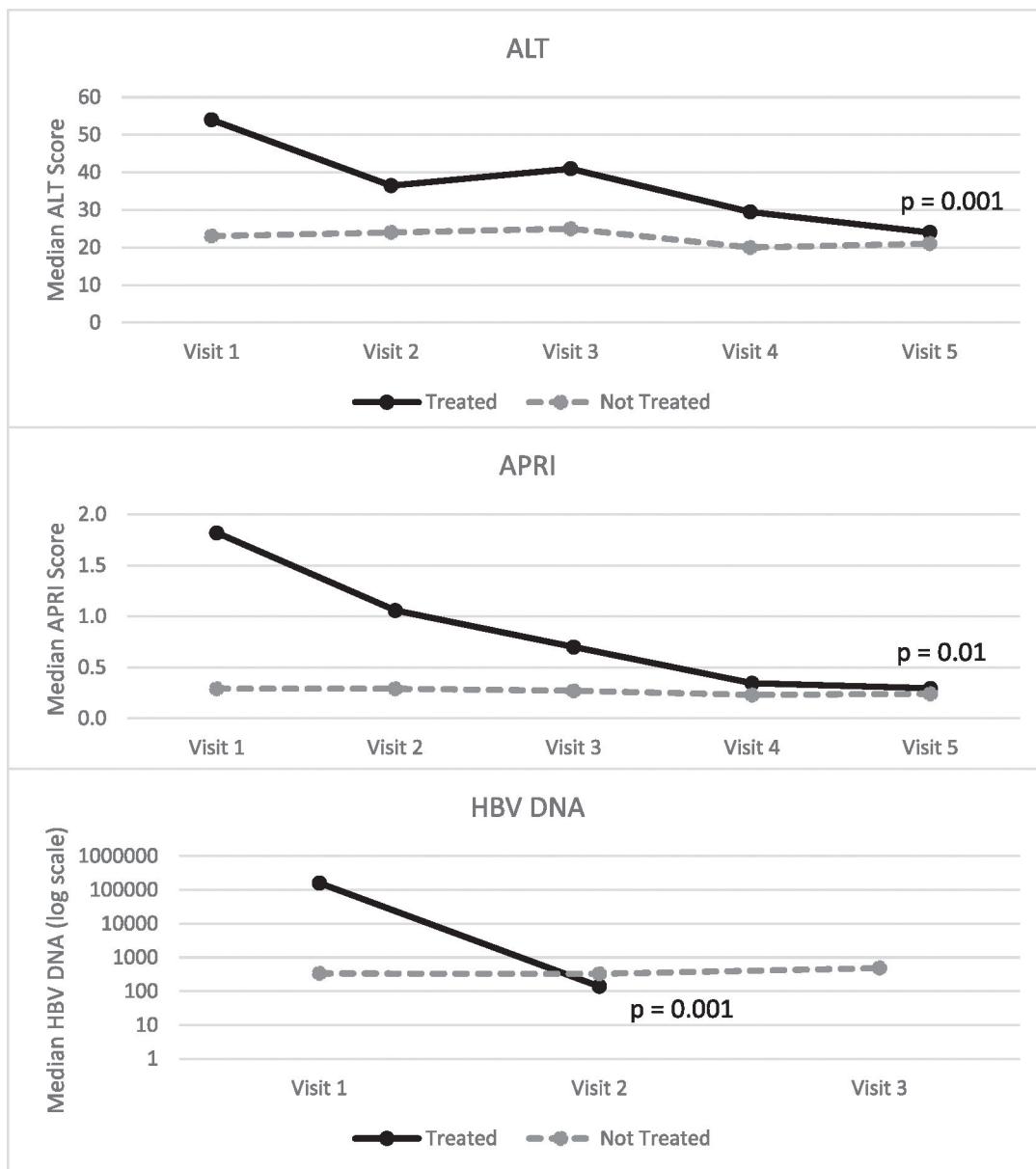
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**FIGURE 1 |.**

Care cascade among persons invited into the HBV care and treatment programme, Zanzibar, January 2017–December 2021. ALT = Alanine aminotransferase; Anti-HCV = antibodies to hepatitis C virus; APRI = Aspartate aminotransferase to platelet ratio index; HBsAg = hepatitis B surface antigen; HBV = hepatitis B virus; TDF = tenofovir disoproxil fumarate; ULN = upper limit of normal.

**FIGURE 2 |.**

Criteria determining treatment eligibility among 58 eligible enrolled patients diagnosed with hepatitis B, Zanzibar, 2017–2021. ALT = Alanine aminotransferase; APRI = Aspartate aminotransferase to platelet ratio index; HBV = hepatitis B virus; ULN = upper limit of normal.

**FIGURE 3 |.**

Median ALT, APRI and HBV DNA per visit among treated and nontreated patients diagnosed with hepatitis B (with at least two test results), Zanzibar, 2017–2021. ALT = Alanine aminotransferase; APRI = Aspartate aminotransferase to platelet ratio index; HBV = hepatitis B virus.

**TABLE 1 |**

Baseline characteristics of enrolled and treatment eligible patients diagnosed with hepatitis B, Zanzibar, 2017–2021.

	<b>Enrolled</b>		<b>Treatment eligible</b>		<b>Chi-squared p-value for treatment eligible vs. not</b>
	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>	
Total	596	100.0	58	100.0	
Age group <sup>a</sup>					
18–29	235	39.6	13	22.4	<0.001
30–39	213	35.9	23	39.7	
40–49	99	16.7	10	17.2	
50–59	33	5.6	9	15.5	
60+	14	2.4	3	5.2	
Sex <sup>a</sup>					
Male	365	61.4	40	69.0	0.22
Female	229	38.6	18	31.0	
Baseline HBV DNA <sup>a</sup>					
< 2000	372	67.5	16	35.6	<0.001
2000–20,000	98	17.8	1	2.2	
> 20,000	81	14.7	28	62.2	
Baseline APRI score <sup>a</sup>					
< 0.5	435	75.8	13	22.8	<0.001
0.5–1.5	105	18.3	10	17.5	
> 1.5	34	5.9	34	59.7	
Baseline ALT <sup>a</sup>					
40	417	74.9	17	30.4	<0.001
41–80	97	17.4	13	23.2	
> 80	43	7.7	26	46.4	
Baseline AST <sup>a</sup>					
40	467	80.9	13	22.8	<0.001
41–80	71	12.3	15	26.3	
> 80	39	6.8	29	50.9	
Baseline platelet <sup>a</sup>					
< 150	78	13.4	27	46.6	<0.001
150–450	489	84.0	29	50.0	
> 450	15	2.6	2	3.4	
Cirrhosis					
Yes	49	8.2	48	82.8	<0.001
No	547	91.8	10	17.2	
HCC					
Yes	2	0.3	2	3.4	<0.001

	<b>Enrolled</b>		<b>Treatment eligible</b>		<b>Chi-squared <i>p</i>-value for treatment eligible vs. not</b>
	<b><i>n</i></b>	<b>%</b>	<b><i>n</i></b>	<b>%</b>	
No	594	99.7	56	96.6	

*Note:*

<sup>a</sup>Missing values not shown.

Abbreviations: ALT = Alanine aminotransferase; APRI = Aspartate aminotransferase to platelet ratio index; HCC = Hepatocellular carcinoma; HBV = hepatitis B virus.