

Acceptability and feasibility of a screen-and-treat programme for hepatitis B virus infection in The Gambia: the Prevention of Liver Fibrosis and Cancer in Africa (PROLIFICA) study



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Summary

Background Despite the introduction of immunisation for hepatitis B virus (HBV) in the 1990s, HBV-related morbidity and mortality remain high in sub-Saharan Africa. Identification and treatment of asymptomatic people with chronic HBV infection should reduce the disease burden. We therefore assessed the feasibility of a screen-and-treat programme for HBV infection in The Gambia, west Africa, and estimated the proportion of HBV-infected people who had significant liver disease in need of treatment.

Methods Between Dec 7, 2011, and Jan 24, 2014, individuals living in randomly selected communities in western Gambia were offered hepatitis B surface antigen (HBsAg) screening via a point-of-care test. The test was also offered to potential blood donors attending the central hospital in the capital, Banjul. HBsAg-positive individuals were invited for a comprehensive liver assessment and were offered treatment according to international guidelines. We defined linkage to care as visiting the liver clinic at least once. Eligibility for treatment was judged in accordance with the 2012 European Association for the Study of the Liver guidelines.

Findings HBsAg screening was accepted by 5980 (weighted estimate 68.9%, 95% CI 65.0–72.4) of 8170 adults from 27 rural and 27 urban communities and 5559 (81.4%, 80.4–82.3) of 6832 blood donors. HBsAg was detected in 495 (8.8%, 7.9–9.7) individuals in communities and 721 (13.0%, 12.1–13.9) blood donors. Prevalence was higher in men (239 [10.5%, 8.9–12.1] of 2328 men vs 256 [7.6%, 6.5–8.7] of 3652 women; $p=0.004$) and middle-aged participants. Linkage to care was high in the communities, with 402 (81.3%) of 495 HBsAg-positive individuals attending the clinic. However, only 300 (41.6%) of 721 HBsAg-positive people screened at the blood bank linked into care. Of those who attended the clinic, 18 (4.4%, 2.5–7.7) patients from the communities and 29 (9.7%, 6.8–13.6) from the blood bank were eligible for treatment. Male sex was strongly associated with treatment eligibility (odds ratio 4.35, 1.50–12.58; $p=0.007$).

Interpretation HBV infection remains highly prevalent in The Gambia. The high coverage of community-based screening, good linkage into care, and the small proportion of HBsAg carriers who need treatment suggest that large-scale screening and treatment programmes are feasible in sub-Saharan Africa.

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Introduction

Hepatitis B virus (HBV) infection is highly prevalent in sub-Saharan Africa, where 80 million people are chronically infected with the virus.¹ Hepatocellular carcinoma remains one of the most common cancers in the region and is mainly attributable to HBV.² Hepatitis B vaccine coverage in sub-Saharan Africa is imperfect³ and many people born before the introduction of the vaccine continue to carry the virus, which confers a risk of cirrhosis and hepatocellular carcinoma.⁴

In 2015, WHO has published its first guidelines on chronic HBV infection, but the recommendations for sub-Saharan Africa are very limited due to insufficient data.⁵ In sub-Saharan Africa, screening and treatment for hepatitis B are rarely accessible^{6,7} and blood banks are the

only places where people are offered free HBV testing. However, these free tests are to ensure the safety of the blood products, and deferred donors are rarely linked to care.⁸ Although the prevalence of infection is high in the general population in sub-Saharan Africa,⁹ people have very little opportunity to be tested for HBV unless they are infected with HIV or develop advanced liver disease. Screening and treatment interventions that target the general population have never been assessed in sub-Saharan Africa.

Prevention of Liver Fibrosis and Cancer in Africa (PROLIFICA), the first screen-and-treat programme for HBV mono-infected people in sub-Saharan Africa, was started in June, 2011, in The Gambia, west Africa.¹⁰ As part of this programme, we investigated whether mass

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Research in context

Evidence before this study

We searched MEDLINE and Embase for articles written in French or English and published before Sept 1, 2015, with terms incorporating "hepatitis B", "mass screening", and "Africa". We were unable to find any previous studies describing screen-and-treat interventions for hepatitis B virus (HBV) infection that targeted the general population in Africa.

Added value of this study

To our knowledge, PROLIFICA is the first screen-and-treat intervention programme to be implemented in Africa. In addition to showing the feasibility of such an intervention, our results provide new data on screening coverage for HBV testing, the prevalence of hepatitis B surface antigen positivity,

linkage of screening to health care, and the proportion of chronically infected people with clinically significant liver disease who need treatment.

Implications of all the available evidence

By providing further evidence for the high prevalence of HBV infection and the good coverage achieved with HBV screening and care, our results show the feasibility of a large-scale screen-and-treat programme for HBV infection in The Gambia. This approach deserves to be assessed in other resource-limited HBV-endemic countries. National health departments in sub-Saharan Africa and WHO should consider integrating such a programme into public health strategies to fight against the epidemic of HBV infection in Africa.

screening for HBV infection is justified by referring to the Wilson and Jungner WHO criteria for disease screening.¹¹ We previously reported that hepatitis B surface antigen (HBsAg) point-of-care tests perform well in field conditions in the African community setting.¹² We validated inexpensive and simple diagnostic tools for the assessment of liver disease.¹³ We also identified risk factors for liver disease progression by following up a population-based cohort in rural Gambia.¹⁴

In this study, we assessed the acceptability and feasibility of a screen-and-treat HBV intervention programme in west Africa by analysing screening coverage, prevalence of HBsAg, the proportion of HBsAg-positive individuals linked to care, and the proportion of chronically infected people with clinically significant liver disease in need of treatment in community-based and facility (blood bank)-based settings in The Gambia.

Methods

Community screening

We did the community-based screening in the western part of The Gambia (figure 1) where 750 000 people live in 1450 census enumeration areas defined by the Gambia Bureau of Statistics. We used enumeration area as a sampling unit, and one enumeration area can consist of an entire village, part of a large village or town, or a cluster of small hamlets. Because HBV prevalence might differ between urban and rural populations, we first stratified the 1450 enumeration areas into urban (n=1197) and rural (n=253) communities. Then, we selected 27 enumeration areas from each stratum by simple random sampling with a random number generator (Stata). In the selected enumeration areas, all inhabitants aged 30 years or older were eligible for screening. We excluded people younger than 30 years because the national hepatitis B vaccination programme started in 1990 so these people should be covered.¹⁵ We organised a meeting in each enumeration area with the help of the

village head. After community approval was obtained, a team of fieldworkers did a census by visiting all households to register the name, age, and sex of all eligible people and to invite them for screening. Pre-test counselling was delivered and written consent obtained. Ethics approval for the study was granted by the Government of The Gambia and MRC Gambia Joint Ethics Committee.

We did finger-prick whole blood test for HBsAg using a point-of-care test (Determine, Alere, Waltham, MA, USA), the performance of which has been validated in the field (sensitivity 88.5%, specificity 100%).¹² We provided the results to the participants on site with post-test counselling, and those who tested positive for HBsAg were referred to the liver clinic at the Medical Research Council (MRC) unit in Fajara (figure 1). People who were invited, but did not attend screening were reminded by the fieldworkers up to three times. Reasons for non-attendance to the screening were captured in a standardised form. Additional questions about knowledge of HBV infection and past experience of HBV testing were administered to all individuals screened between Aug 18 and Nov 1, 2013.

Facility-based screening

Since 2011, in addition to HIV testing, the Edward Francis Small Teaching Hospital (EFSTH), the only tertiary care hospital in Banjul, the capital of The Gambia, started HBV screening at its blood bank by use of a point-of-care test (Onsite Combo Rapid Test, CTK Biotech, San Diego, CA, USA). The manufacturer of the test reports its sensitivity to be 96% and its specificity to be 100%. Blood donors at the EFSTH blood bank must be healthy and aged at least 16 years. Individuals who tested positive for HBsAg were referred to a study nurse posted at EFSTH who provided post-test counselling and advised them to visit the MRC clinic in Fajara. Individuals who were co-infected with HIV and HBV were referred to the national HIV programme.

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