Impact of free on-site vaccine and/or healthcare workers training on hepatitis B vaccination acceptability in high-risk subjects: a pre-post cluster randomized study

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Abstract

Despite recommendations for adults at high-risk of hepatitis B virus (HBV) infection, HBV vaccine uptake remains low in this population. A pre-post randomized cluster study was conducted to evaluate the impact of on-site free HBV vaccine availability and/or healthcare worker training on HBV vaccination acceptability in high-risk adults consulting in 12 free and anonymous HIV and hepatitis B/C testing centres (FATC). The FATC were randomly allocated into three groups receiving a different intervention: training on HBV epidemiology, risk factors and vaccination (Group A), free vaccination in the FATC (Group B), both interventions (Group C). The main outcomes were the increase in HBV vaccination acceptability (receipt of at least one dose of vaccine) and vaccine coverage (receipt of at least two doses of vaccine) after intervention. Respectively, 872 and 809 HBV-seronegative adults at high-risk for HBV infection were included in the pre- and post-intervention assessments. HBV vaccination acceptability increased from 14.0% to 75.6% ($p < 0.001$) in Group B and from 17.1% to 85.8% ($p < 0.001$) in Group C and HBV vaccine coverage increased from 9.4% to 48.8% ($p < 0.001$) in Group B and from 11.2% to 41.0% ($p < 0.001$) in Group C. The association of training and free on-site vaccine availability was more effective than free on-site vaccine availability alone to increase vaccination acceptability (ratio 1.14; from 1.02 to 1.26; p 0.017). No effect of training alone was observed. These results support the policy of making HBV vaccine available in health structures attended by high-risk individuals. Updating healthcare workers' knowledge on HBV virus and its prevention brings an additional benefit to vaccination acceptability.

Keywords: hepatitis B virus vaccine, intervention study, training, vaccination strategies, vaccine acceptability, vaccine coverage
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The ANRS-FORMVAC Study Group members are listed in Appendix 1.

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Introduction

France is located in an area of low endemicity for hepatitis B virus (HBV) infection (0.65% in the adult population), yet hepatitis B remains a public health problem [1–3]. In line with the WHO recommendations [4], the French HBV vaccination policy in the general population includes the routine vaccination of infants/children before they reach 15 years of age and adolescents/adults at high-risk of HBV

infection [5]. HBV vaccine coverage is much lower in France than reported in other European countries [6–8]. Several studies have shown that a concern surrounding HBV vaccine safety had a significant impact both on the motivation of practitioners to offer the vaccine and on the acceptability of vaccination [9–11]. The French Ministry of Health has therefore recently embarked on a policy of strengthening the promotion of HBV vaccination for individuals at high-risk for HBV infection [12].

The free and anonymous HIV and hepatitis B and C testing centres (FATC) were set up by the French Health authorities to facilitate access to anonymous, confidential and free HIV testing. Since 1999, their role was extended to encompass the screening and prevention of hepatitis B and C infections.

The aim of the present study was to evaluate the impact of two public health interventions and their combination to improve HBV vaccination acceptability and vaccine coverage in subjects at risk for hepatitis B who are seen in FATC. As those interventions were implemented at the level of the FATC, a cluster design whereby the FATC were randomized to receive a different intervention was used.

Materials and Methods

Participants

In the pre-intervention phase, FATC were randomly selected from the national FATC activity database. FATC were excluded if they did not screen HBV infection, saw fewer than 1400 subjects per year or already proposed on-site HBV vaccination (Fig. 1). FATC were asked not to change their current practices regarding HBV screening and vaccination during the pre-intervention assessment phase. At the end of the pre-intervention phase, the FATC were randomly assigned to each of the three intervention groups: training of healthcare workers on HBV infection and its prevention (Group A), free HBV vaccine administration in the FATC (Group B) or both interventions (Group C).

In participating FATC, in both phases, all men and women aged ≥18 years, with an HIV-negative test, with no immunity against HBV (i.e. negative for HBV surface antigen (HBsAg), anti-HBs and anti-HBc antibodies testing performed in the FATC) and at high risk for HBV infection were consecutively enrolled if they agreed to participate. Patients at high-risk for hepatitis B infection were defined according to the list of individuals targeted by the hepatitis B vaccination recommendations, mainly persons who have sex with multiple partners, injecting drug users, travellers to countries of intermediate or high HBV endemicity and close contacts of chronic carriers of HBsAg [5]. Written informed consent was obtained from each subject. The protocol was conducted in accordance with the Declaration of Helsinki and French law for biomedical research and was approved by the French Data Protection Agency (CNIL) and by the 'Ile-de-France 3' Ethics Committee (Paris, France).

Interventions

For healthcare worker training on HBV infection and its prevention, one referral physician and one referral nurse were designated from each FATC of groups A and C and received a 1-day training outside the FATC in a specialized healthcare centre committed to the prevention of HIV infection and other sexually transmitted infections, including hepatitis B and C, substance abuse and risk behaviours in young people (Regional Centre for Information and Prevention of Aids; CRIPS Ile-de-France, Paris, France). The training team included a clinician, an epidemiologist and a health education officer, all specialized in hepatitis B infection and control. The main topics addressed during the training included general information about hepatitis B, risk factors of HBV infection and at-risk populations, missions of FATC, serological markers of hepatitis B and their interpretation, HBV vaccination and the controversy over its safety. In addition, a 2-h on-site training that focused on key messages to motivate patients targeted by HBV vaccination was performed on-site for all healthcare worker in each FATC of Groups A and C by two clinicians specialized in hepatitis B infection and control.

Objectives

We aimed to compare the effectiveness of improving the acceptability of HBV vaccination by making the vaccine available in the FATC, with that of increasing the capacity of health staff to motivate the patients through a refresher training. The third group, where both interventions were implemented at the level of the FATC, aimed to test the potential synergy between the two interventions.

Outcomes

The primary and secondary outcomes were the increase, between the two phases, in the proportion of subjects that received at least one dose (vaccination acceptability) or two doses (vaccine coverage) of HBV vaccine.

Vaccination acceptability and vaccine coverage were assessed, before and after intervention, following a similar methodology. During the initial visit (visit V1), the physician completed a case-report form for all subjects (willing or not to participate in the study). The physician was free to prescribe HBV vaccination and propose to the subjects that they