Frequency and efficacy of EngerixB booster and Fendrix in HIV positive patients with inadequate anti-HB s-antibody response

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Background

All Hepatitis B Virus (HBV) negative HIV positive patients should be offered HBV vaccination (BHIVA immunisation guidelines). However, response to HBV vaccination amongst HIV positive people can be poor, with response rate ranging from 7-88% (1).
EngerixB (GSK) boosters should be offered to those without an adequate response. Fendrix (GSK) was developed for use in renal patients and may be an effective alternative HBV vaccine. We audited the frequency and efficacy of EngerixB booster and Fendrix in patients with poor and inadequate HB s-Ab response to one course of EngerixB (0, 1 & 6 months).

Methods

Retrospective case-note review of all patients attending our HIV centre. Adequate post-vaccination HBV immunity was defined as HB sAb>100iU/ml. Data collected: demographics, age, baseline, CD4 T lymphocyte count, HIV-1 RNA viral load, HBV status pre- and post vaccination.

Results

Seventy-one patients were included. Table 1 details their baseline characteristics: Median age was 43 years (range15-71), 73% were male and 42% MSM. The HBV vaccination pathway is represented in figure 1: HBV vaccination was not indicated in 40/71 (56%); 24 (60%) were HB c-Ab positive and 16 (40%) had HB s-Ab >100iU/ml. HBV vaccination was indicated in 31 patients: 24 (77%) completed a standard course of EngerixB, 7 (23%) did not complete a course.
In those patients who completed one EngerixB course just 3/24 (13%) achieved HB s-Ab>100iU/ml. Thirteen (54%) were non responders (HB s-Ab <10iU/ml) and 7 (29%) poor responder (HB s-Ab 11-99iU/ml) and HB s-Ab was not recorded in one patient.
Compared to those who responded to EngerixB, those who did not respond had comparable baseline CD4 cells, CD4 nadir and HIV viral load (table 2).
Of the non & poor responders, 16 patients received one EngerixB booster: 7 (44%) achieved immunity with HB s-Ab>100iU/ml, 10 (56%) did not achieve immunity. Five/nine patients received a second booster, and of whom four (80%) achieved immunity. One patient received HepB Vax Pro and did not achieve immunity.
In total Fendrix was given to seven patients who had not achieved immunity: four have completed the course and 100% have achieved HB s-Ab >100iU/ml.
Table 3 depicts the time to immunity depending on vaccine regime and cost associated with different regimes.

Table 1: Baseline demographics

	Number	Percentage
Gender		
Female	19	27%
Male	52	73%
Risk Factor		
None recorded	11	15%
MSM	30	42%
MTCT	2	3%
IVDU	1	1%
UPSI high risk country	26	37%
UPSI known HIV+	11	15%
Ethnicity		
White British	39	55%
Black African	26	37%
Other white	2	3%
Other	1	1%
Not recorded	3	4%

Figure 1: Patient pathway through HBV vaccination

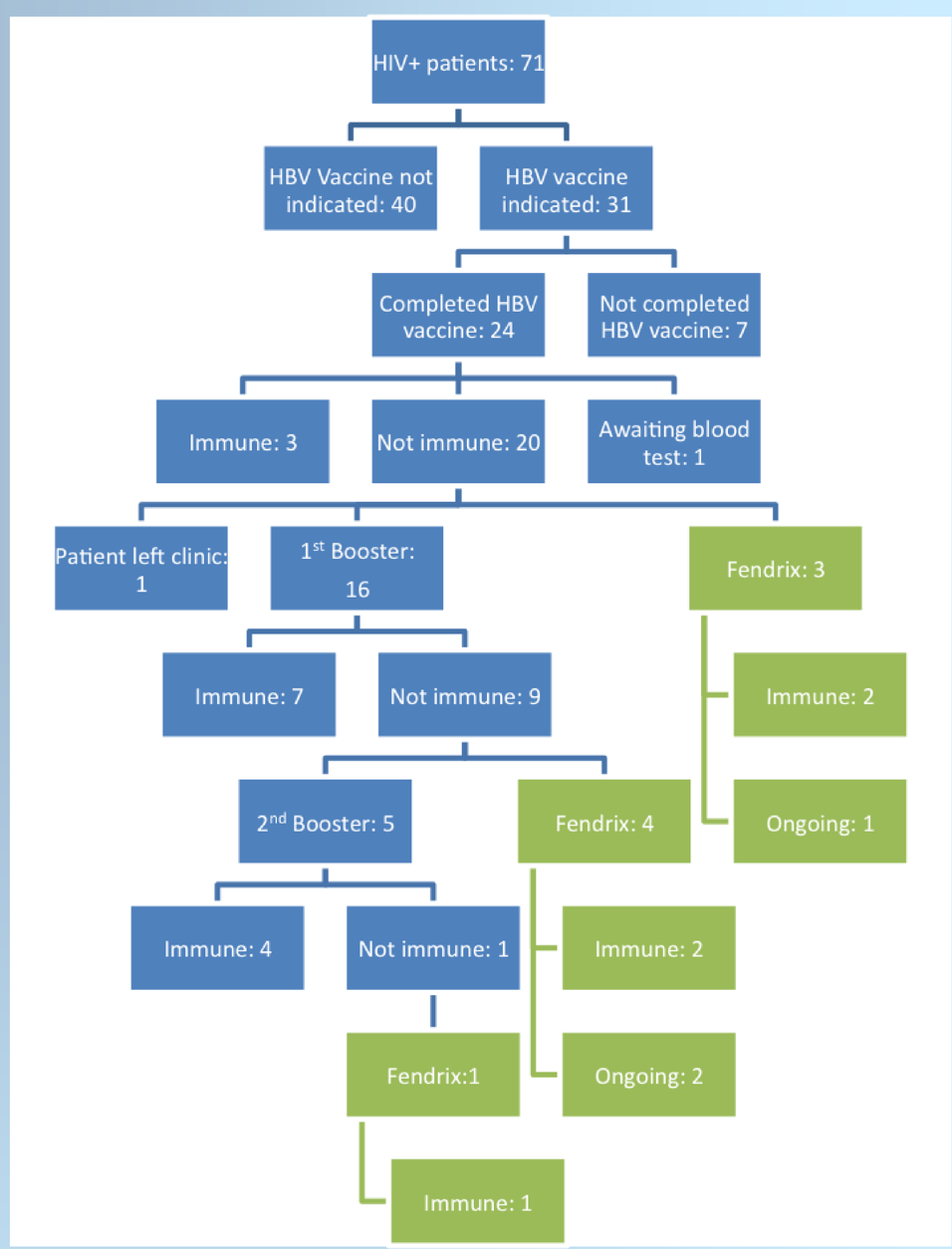

Table 2: Baseline CD4 count and viral load

HB s-Ab afte one course of EngerixB	<10 iU/ml	11-99 iU/ml	>100 iU/ml
CD4 (cells/µl)			
Median	318	313	382
Range	58 – 624	272 - 571	317 - 446
Viral load (x 106 copies/L)			
Median	174	0	8526
Range	0 – 280,000	0 – 110,000	51 – 17,000
CD4 nadir (cells/µl)			
Median	185	157	227
Range	5 – 497	11 – 497	8 – 446
Proportion on ART	58%	50%	50%

Figure 2: Immune status after EngerixB

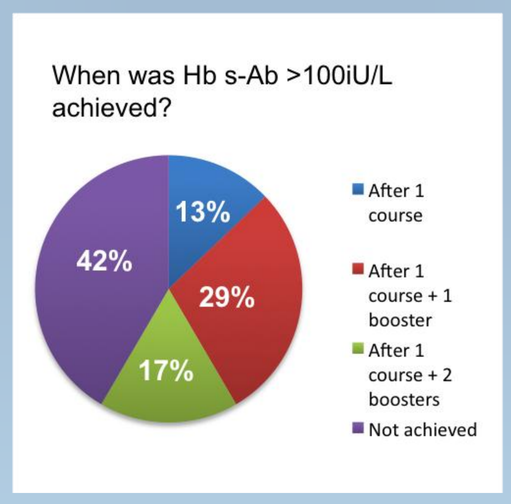

Table 3: Cost and time comparison for different vaccine regimes

Vaccine regime	Months to course completion	Number of clinic visits	Cost of vaccines	Number of patients with HB s-AB > 100 iU/ml (%)
EngerixB (0, 1, 6 months)	6	4	£38.97	3/24 (13%)
EngerixB + 1 booster	8	6	£51.96	7/16 (44%)
EngerixB + 2 boosters	10	8	£64.95	4/5 (80%)
Fendrix	6	5	£152.40	4/4 (100%)

Conclusion

In our cohort a substantial proportion of HIV + patients, despite high CD4 counts, did not achieve a strong HBV immunity after one course (87%) or after one booster with EngerixB (44%). In contrast Fendrix was 100% effective in the small number of observed patients. A course of Fendrix is more expensive than EngerixB (£152.40 vs. £38.97), still Fendrix may be more efficacious and less time consuming in people with HIV. We propose a randomised control trial of Engerix vs. Fendrix to compare their efficacy in HIV positive subjects and to test cost effectiveness.

Acronyms

MSM: men who have sex with men, MTCT: mother to child transmission, IVDU: intra-venous drug use, UPSI: unprotected sexual intercourse

References

1. AM Geretti. 2008. British HIV Association guidelines for immunization of HIV-infected adults 2008. HIV Medicine. 9: 795–848
2. BMJ Group and the Royal Pharmaceutical Society of Great Britain. 2013. British National Formulary. BMJ Group, London.