Lack of Compliance with Hepatitis B Vaccination among Canadian STD Clinic Patients: Candidates for an Accelerated Immunization Schedule?

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From 1985 to 1988 the reported incidence of hepatitis B in Canada increased from 8.4 to 12.9 cases per 100,000 and then decreased slightly to 11.3 cases per 100,000 in 1995.^{1,2} Most studies looking at the effectiveness of vaccination programs have been based on the postvaccination response among health care workers, infants, public safety personnel, and haemodialysis patients.³⁻⁷ In 1991, the Ontario Ministry of Health expanded its free hepatitis B vaccine program to include high risk groups, comprising homosexual/bisexual men, heterosexual people having multiple sexual partners, injection drug users, and STD clinic attendees. A vaccination program for STD clinic clients may be problematic since these vaccinees may not be as likely as health care workers to complete the vaccination series. To determine the effectiveness and any limitations of a hepatitis B vaccination program in an STD clinic, we studied our clinic attendees in Hamilton, Ontario, from July 1992 to March 1994.

A total of 853 consecutive clients with a mean age of 27.1 (SD 9.9) years, 66% of whom were male, were approached by the

public health nurse at the clinic and offered vaccination free of charge (Engerix-B, SmithKline Beecham Pharma Inc., Oakville, ON) on a schedule of three doses given at 0, 1 and 6 months. The clinic receptionist gave clients a reminder card for their next appointment, and mailed reminders to clients who were more than two months late for their second dose. A reminder letter was not sent for the third dose. Often, the clients agreed to receive the first dose at the time of the serologic testing.

Of the 853 clients, 668 (78%) agreed to testing for anti-HBs and HbsAg, and 611 (91%) were seronegative for both. No clients tested positive for HbsAg. In a subset of 212 consecutive clients who were tested for both anti-HBc and anti-HBs, 10 people were positive for anti-HBc, 9 of whom were also positive for anti-HBs. Five hundred and fifty (90%) of the seronegative clients were vaccinated (20 mcg/1 mL) intramuscularly in the deltoid area. The presence or absence of antibodies was determined for 150 people at the time of the third dose (after two doses), and 22 (15%) of them did not have anti-HBs. The 85% seroconversion (seronegative to seropositive) rate after the second dose was higher than in other studies, which report about 33%⁸ to approximately 70%⁹ and 79%¹⁰ of vaccinees seroconverting after two doses. Seventy of 88 men (80%) and 58 of 62 women (94%) had detectable antibodies after the second dose of vaccine (p=0.03). Titres were determined for only 91 of the 128 clients who seroconverted after the second dose of vaccine. Seventy-one (78%) of 91 people had levels of antibody considered protective (≥ 10 mIU/mL)

and 20 (22%) had levels under 10 mIU/mL.

Overall, seroconverters were significantly younger than those who did not seroconvert (mean age 26.9 vs 34.1 years, $p = 0.001$). When gender had been controlled for, the mean age of men who showed humoral responses was significantly less (28.2 years) than that for men who did not (34.3 years) ($p = 0.02$). Among the 58 women who seroconverted, the mean age was 25.3 compared with 33.0 years for the three women who did not seroconvert ($p = 0.14$).

Evaluation of compliance for subsequent doses showed that of the 550 people who accepted the first dose, 334 (61%) completed two doses and 157 (29%) three doses. The mean age of those who completed the vaccine series was higher than of those who did not (28.1 years, SD 9.8, vs. 25.2 years, SD 8.5, $p = 0.005$). The acceptance of the second and third doses of vaccine was strongly associated with the repeated visits required for the treatment of genital warts. Clients with genital warts diagnosed at the time of the first dose were 2.5 times more likely than those without warts to come for the third dose (unadjusted odds ratios = 2.5, 95% confidence intervals 1.3-5.0, $p = 0.008$).¹¹

STD clinic attendees were not only at increased risk of exposure to hepatitis B but were also at risk of failing to complete a six-month vaccine schedule. Our completion rate of 28.5% was similar to that of Yuan and Robinson, who found that 25% of heterosexual men attending an STD clinic completed a six-month hepatitis B vaccine series,¹² and to Weinstock et al, who reported that 31% of vaccinees at an STD clinic completed a three dose series.¹³

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STD clinic clients who do not agree to vaccination or serologic testing are an additional problem for an STD clinic-based vaccination program. When asked why they refused testing and/or vaccination, 67% (202/303) of our clients gave reasons that included not being able to return because of living far away, fear of needles, pregnancy or attempting to conceive, worries about adverse effects, and perception of self as not at high risk.

One strategy for improving the rate of return for the second dose in the vaccine series has been evaluated in a recent randomized controlled trial by Sellors et al.¹⁴ This study demonstrated that an "enhanced" follow-up consisting of reminder phone calls by the clinic receptionist and/or public health nurse and a letter at three months to nonresponders after the first dose resulted in 48% of overdue vaccinees returning, as compared with 25% in the regular follow-up group given only the reminder letter ($p = 0.008$). This strategy appears to be a low cost method of improving compliance with vaccination in this population. Another strategy is a shortened schedule of 0, 10 and 21 days, which has been shown to result in protective levels of antibody in 90% of vaccinees, measured at one year after primary vaccination.¹⁵⁻¹⁸

In our relatively low prevalence STD clinic, it could be argued that it is more cost-effective to administer the vaccine without universal serologic testing, but

selective testing may also be an efficient strategy.¹⁹ Future research should address ways of providing better education and counselling to refusers, investigate compliance with a shortened vaccination schedule in the STD clinic setting and the necessity of boosting these short schedule vaccinees at 6 months, and should develop better ways to improve immunization programs.

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