Accelerated Vaccination Schedule for Hepatitis B Virus in a Population of Substance Abusers – Assessing Compliance and Immunogenicity

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**Background:**
Hepatitis B virus (HBV) can have serious clinical consequences and is associated with long-term complications such as cirrhosis and hepatocellular carcinoma. High rates of disease are seen in high-risk adults (substance abusers, prisoners, the homeless). High-risk groups have difficulty adhering to the standard 6-month vaccination schedule (0,1,6 months). Super-accelerated (0,7,21,360 days) schedules have been shown to increase the uptake of Hepatitis B vaccine (defined as the proportion who achieve the first 3 doses) and result in a higher proportion of vaccinees reaching seroprotection (defined as anti-HBs levels ≥ 10IU/mL). In current at-risk populations, with known patterns of nonadherence, rapid early protection from Hepatitis B makes a super-accelerated vaccination schedule highly desirable.

**Specific Aim:**
Explore the use of a super-accelerated Hepatitis B vaccination schedule (0,5,21 days) among a population of substance abusers, in terms of adherence (assessed by vaccine uptake) and immunogenicity (measured as seroprotection four months after the vaccination series).

**Hypothesis:**
Adherence with the first three doses of a super-accelerated vaccination schedule will be limited by reliance on outpatient follow-up, but of those who complete the program, seroprotection will be adequate for at least short-term protection, with poor vaccine response being related to co-existing chronic disease.

**Methods:**
This is a prospective, nonrandomized pilot study conducted at South Central Rehabilitation Center, an inpatient, short-term detoxification unit for abusers of drugs and alcohol. On admission (Day 0), baseline demographic information is collected, all subjects are offered a first vaccination against HBV, and are tested for HAV, HBV, and HCV serological markers. The vaccine schedule is discontinued in those who have been previously exposed to HBV or previously vaccinated against HBV, which is confirmed by the presence of antibodies to HBV core antigen (HBcAb) and/or antibodies to HBV surface antigen (HBsAb). The second injection is administered on the day of discharge (Day 5). Subjects return for a third vaccine (at 21 days) and serum collection for HBsAb titers (at four months) to the primary care center.

**Results:**
Forty-five subjects were enrolled in the vaccination protocol between 8/12/09 and 11/12/09. 28/45 (62%) were male, 17/45 (38%) female, 16/45 (36%) age 20-35, 24/45 (53%) age 36-50, 5/45 (11%) age >50. 14/45 (31%) had confirmed HCV, 3/45 (7%) had a history of HIV, 2/45 (4%) had HIV and HCV. 20/45 (44%) had prior incarceration. 8/45 (18%) were homeless. 35/45 (78%) had been enrolled in a detoxification program within the last 3 years. 28/45 (62%) were positive for ≥ 2 abused substances on urine/serum toxicology screens. 45/45 (100%) received the first vaccine, 27/45 (60%) received the second vaccine, 6/45 (13%) received the third vaccine. 7/45 (16%) prematurely left the detoxification center against medical advice. Five of the six third doses were administered during readmission to detoxification and 1 was administered during routine primary care. As none of the 45 patients returned for labwork to measure HbsAb titers at three to four months, vaccine immunogenicity could not be assessed.

**Conclusions:**
As expected, adherence with the vaccine series was severely limited by outpatient follow-up in the primary care center. However, this population does have high rates of readmission to detoxification centers, as evidenced by 78% of this cohort having been in a prior detoxification program in the last three years, as well as a significant presence in the prison system, and we must take care not to overlook these missed opportunities for vaccination. More subjects are currently being recruited to investigate vaccine immunogenicity.