Policy and Practice

Hepatitis B vaccination in prisons

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Abstract The opportunities and problems for hepatitis B vaccination programmes in prison settings are discussed. In particular, the advantages of modelling are stressed and an active case-finding approach is advocated. Measures for maintaining good case-holding are also discussed, and a 0, 1, 2 months vaccination regimen with 20 µg doses of vaccine is advocated for prison settings. A higher reference level for inferring adequate immunization is also recommended, with booster injections for inmates who do not meet the higher reference after a primary course of vaccination.

Keywords Hepatitis B vaccines/utilization/administration and dosage; Prisons; Immunization programs/organization and administration; Immunization schedule; Seroepidemiologic studies; Models, Theoretical; Hepatitis B/prevention and control; Program evaluation; Australia (*source: MeSH, NLM*).

Mots clés Vaccin anti-hépatite B/utilisation/administration et posologie; Prison; Programmes de vaccination/organisation et administration; Calendrier vaccination; Etude séro-épidémiologique; Modèle théorique; Hépatite B/prévention et contrôle; Evaluation programme; Australie (*source: MeSH, INSERM*).

Palabras clave Vacunas contra hepatitis B/utilización/administración y dosificación; Prisiones; Programas de inmunización/ organización y administración; Esquema de inmunización; Estudios seroepidemiológicos; Modelos teóricos; Hepatitis B/prevención y control; Evaluación de programas; Australia (*fuente: DeCS, BIREME*).

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Voir page 573 le résumé en français. En la página 573 figura un resumen en español.

Introduction

Infection with hepatitis B virus is common among prison inmates (1, 2), mainly because many come from marginal sections of the population, such as intravenous drug users, with high rates of exposure to the virus. For example, Christensen (3) estimated the incidence of hepatitis B infections in Europe to be 2-10 per 100 000 population per year in the general population, compared with 10-20 per 100 population per year among cohorts of injecting drug users, and 1-3 per 100 population per year among prisoners with no history of injecting drug use. A stratified random survey of inmates in the New South Wales Corrections Health Service (CHS) also showed that 64% (85/132) of females and 40% (264/657) of males reported a history of injecting drug use within one year of imprisonment (4). Another study estimated that 60% of all fulltime prison inmates in New South Wales prisons had a recent history of injecting drug use (5). Similarly, a cross-sectional survey of 1205 prison inmates in Ireland indicated that 9% of the inmates were carriers of the hepatitis B surface antigen, while 43% had a history of injecting drug use (6).

The large pool of carriers facilitates transmission of the virus in prison through high-risk activities, such as needle sharing and unprotected anal sex (2, 7), and approximately 30% of those with acute hepatitis B reported a history of incarceration (7). In addition to immunization programmes, there are complementary strategies for minimizing the risk of

hepatitis B transmission in prisons, including education measures to encourage drug users to stop injecting and nondrug injectors not to take it up, the use of condoms, needle exchange programmes, and bleach programmes. This paper examines major facets of hepatitis B vaccination in prisons, as well as how such vaccination programmes may be complemented by the above strategies.

Management of hepatitis B vaccination programmes in prisons

Eligibility criteria and modelling estimates

For two reasons, it is important to screen inmate populations for hepatitis B markers prior to vaccination. First, seroepidemiological studies indicate that drug injectors (who are overrepresented in most prison settings) have widespread exposure to hepatitis B virus (δ). Second, vaccination of individuals positive for hepatitis B antigen may lead to a false sense of security among such carriers, thereby increasing the risk that they will transmit the virus to others, which can lead to legal action. In countries where there is no effective vaccination for high-risk groups in the general community, it is probably sufficient to screen first with hepatitis B core antibody, and then screen positives for hepatitis B surface antigen. Individuals who test negative for these markers should be vaccinated.

However, in countries like Australia, where effective community-based programmes are in place for injecting drug

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users, it is more cost-effective to screen additionally for the hepatitis B surface antibody, to exclude those with prior immunity. In New South Wales correctional facilities, we prescreen for all three primary markers to minimize a one-week delay associated with a two-stage screening process. Also, in this programme an eligible inmate for hepatitis B vaccination is defined as an inmate who is willing to be vaccinated against hepatitis B; who has negative primary serological markers for hepatitis B; and whose earliest date of release at the start of vaccination is later than the minimum period for completing vaccination.

One way to monitor a prison-based hepatitis B vaccination programme and estimate vaccine requirements is to develop models for hepatitis B vaccination in each programme. The role of modelling in planning includes ideation, prediction, identification, integration, systemization and coordination (9). Models have both representational and assessment purposes, providing the planner with a picture of possible solutions. Models can also act as surrogates for a pilot programme, permitting the planner to test various solutions without the cost and delay required to evaluate the proposal in an operational setting (9).

Using historical vaccination records in the New South Wales prison population, it was possible to estimate that for every 100 new prisoners incarcerated in New South Wales correctional facilities 60 individuals would decline or be ineligible for testing because of short sentences or because of prior exposure. Of the remaining 40 prisoners tested for the three primary hepatitis B markers, 13 would be ineligible for vaccination because of previous exposure and 2 because of vaccination prior to incarceration. Of the 25 inmates eligible for the programme, eight (32%) were expected to complete the primary course within the minimum completion period and 19 (76%) within three months following the minimum completion period, depending on the vaccination schedule in use. Of the eight inmates that completed vaccination within the minimum period, at least four were expected to be available for postvaccination estimates of surface antibody titres. It was also estimated that more than 75% of the vaccinees would have a seroconversion titre of at least 10 IU/l. The costs of vaccines were estimated to be US\$ 20 per vaccinee that completed the primary vaccination course and US\$ 10 for those that did not. It was also estimated that measurements of surface antibody titres would cost US\$ 6 per test, while measurements of the two other primary markers would cost US\$ 5 per test.

The above modelling estimates were used to predict and monitor the performance of the New South Wales hepatitis B vaccination programme as follows. A total of 11 920 inmates were incarcerated in 1999. Assuming the same number of inmates were incarcerated in 2000, we expected to test about 40% of these inmates (4768), 62.5% (2980) of whom were expected to be eligible for the programme. Of those eligible, 75% (2235) were expected to complete the primary course of vaccination within three months following the minimum completion time, while 33% (993) were expected to complete within the minimum completion period, depending on the vaccination schedule used. Of the 993 inmates expected to complete the vaccination within the minimum completion period, 50% (497) were expected to be available for measurements of postvaccination seroconversion titres, and at least 75% (372) of them were expected to have sero conversion titres of 10 IU/l or greater. The direct costs of this exercise

would be US\$ 52 150 (US\$ 44 700 for those who complete the primary course + US\$ 7450 for those who do not complete it) for vaccines, US\$ 76 288 for prevaccination serological tests, and US\$ 2982 for postvaccination serological tests. The estimated total direct cost of the programme for the year 2000 was thus US\$ 131 420.

The actual performance of the programme for 2000 in the New South Wales Corrections Health Service was as follows. Of the 11 087 inmates actually incarcerated, approximately 35% (3875) were tested and 22% (869) of those were eligible and started the vaccination regimen. Follow-up, using the average of four cohort analyses, revealed that about 40% of the vaccinees completed within the minimum period for the vaccination regimen, while two cohort analyses revealed that, on average, 77% completed within three months of the minimum period. Of the 339 inmates that began vaccination in 2001 and had their postvaccination surface antibody titres estimated, 259 (76%) had seroconversion titres of 10 IU/1 or greater.

There were significant differences between the modelling estimates based on historical records and the performance recorded for 2000. The number of inmates incarcerated fulltime in New South Wales correctional facilities in 2000 was 7% lower than that in 1999, partly due to changes in sentencing guidelines which diverted more inmates into periodic detention programmes in 2000. About 35% of incarcerated inmates were tested to determine eligibility in 2000, compared with a modelling estimate of 40%, partly due to improvements in targeting inmates expected to meet eligibility criteria. The most significant disparity was between estimates of inmates expected to start the programme (62.5%) and those that actually commenced (22%). One reason for the disparity was that the model underestimated the number of inmates who already had serological markers for hepatitis B exposure. Two unpublished surveys, conducted between 1995 and 1999, showed that 31% of inmates in New South Wales prisons were positive for hepatitis B core antibody, while 2% were positive for hepatitis B surface antigen. When the percentage of inmates on short sentences and those already vaccinated in community programmes were included, an eligibility ratio of 1-in-5 appeared more realistic than the modelling estimate of 3-in-5.

Of those that began the vaccination regimen in 2000, 77% completed within three months of the minimum completion time, in line with the modelling estimates, while 40% completed within the minimum period for the vaccination regimen used, compared with 33% estimated by the model. The 76% of inmates with seroconversion titres of 10 IU/l in the 2000 cohort was in line with the 75% minimum estimate in the model. The direct costs of this programme were US\$ 15381 for vaccines, US\$ 62000 for prevaccination screening tests, and US\$ 2034 for postvaccination screening. Total direct costs were therefore US\$ 79 415, compared with US\$ 131 420 estimated by the model. Based on actual performance, the direct cost of fully vaccinating each inmate in New South Wales correctional facilities in 2000 was estimated to be US\$ 90-100. The major reason for the disparity in the total direct cost is that the model overestimated the number of inmates expected to start vaccination.

Case-finding — the number of inmates starting vaccination regimens

For most individuals at the lower end of the socioeconomic scale, who are overrepresented in prison populations, diminu-

tion of their health does not usually act as a spur to seek medical advice, but merely adds to the catalogue of disadvantage and suffering (10). Most prison inmates are therefore unlikely to seek preventive health services and it is important that vaccination programme managers in correctional settings adopt an active approach to coopting prison inmates into hepatitis B vaccination programmes.

In the CHS, case-finding for the hepatitis B vaccination programme was done through the Targeted Screening Programme. This programme focuses on four infectious diseases of high public health priority in New South Wales correctional facilities: hepatitis B, hepatitis C, AIDS and syphilis. As part of the programme, all inmates received into correctional facilities are interviewed, educated and, where applicable, tested by health staff. Only inmates that meet eligibility criteria begin vaccination. Inmates that are negative for all hepatitis markers, but who are likely to be released before the completion of three doses of primary vaccination, are not started on the vaccination regimen in prisons, but are referred to the vaccination centre nearest to their usual place of residence and are encouraged to attend upon release from prison. Although the above process of screening is both labour- and capital-intensive, it is cost-effective as it enables programme managers to focus only on inmates that are most likely to benefit from a full course of primary vaccination.

Case holding — monitoring inmates on vaccination regimes

In the New South Wales prisons' programme, inmates started on a vaccination regimen are monitored at three levels: there is self-monitoring by the inmate; monitoring by the clinic nurses who administer the vaccination regimen; and central monitoring of the programme state-wide. Inmates enrolled in the programme are given appointment cards and are urged to attend a prison clinic on the date their vaccination is due. An evaluation of the use of these vaccination cards revealed that only about 38% of inmates requested to visit the clinic on their due date without prompting or reminders.

Monitoring at the clinic level is conducted by the nursing staff. Every inmate commenced on vaccination is recorded in a "vaccination diary," which indicates the date the inmate is due for his subsequent dose of vaccine. Typically, one day before the scheduled vaccination date an inmate list is drawn up and given to prison officers, who inform the inmates about their clinic appointment. Where it is determined that an inmate has been transferred, a referral is normally faxed to the clinic in the facility to which the inmate has been transferred. In 2000, about 20% of inmates who started vaccination were not given a subsequent dose on the due date, even though they were in the prison where their vaccination began. The reasons relate to clinic staff (e.g. vaccination nurse on leave and relief nurse unaware of the appointment), inmates (e.g. decided to discontinue vaccination, or away at work on the vaccination day) and administrative factors (e.g. prison "lock-down").

At the central level, monitoring is facilitated by the use of the Offender Management System (OMS) database, introduced and maintained by the New South Wales Department of Corrective Services since 1997. Basic demographic and personal information, as well as comprehensive information on prison movements and earliest release dates, are stored in this confidential database, which is updated regularly. Through the OMS database, the central CHS Public Health Unit is able to verify the monthly vaccination reports received from the clinics, and identify progress and problems in each clinic, thus providing a basis for working with clinic nurses to address context-specific issues.

Vaccination schedule

Generally, there are three conventional vaccination schedules: Standard (0, 1, 6 months); By Exposure (0, 1, 2, 12 months); and Accelerated (0, 7, 21 days + 12 months) (3). However, modifications have been made to these regimens to account for the nature of the population being vaccinated, with variable results. For instance, in New South Wales, a study of the response to hepatitis B vaccination using a modified regimen (0, 2, 6 weeks) showed that "seroconversion rates were excellent for those who completed the course of three immunizations, and were able to be contacted for follow-up serology" (11). In this study, 14 of the 20 youths who completed the primary course and were followed up for postvaccination titres had surface antibody titres of above 100 IU/l. Results from another community-based study of hepatitis B vaccination among Italian intravenous drug users led the authors to suggest that "the high risk of infection and traditional mobility of Italian intravenous drug users (frequent change of residence, accidents, imprisonment, admittance into therapeutic community etc.) strongly suggest shorter vaccination schedules (for example: 0, 1, 2 months rather than 0, 1, 6 months)" (12). The Australian National Health and Medical Research Council recommends that, apart from the accelerated regimen, any vaccination schedule used in Australia should consist of at least three doses, with an interval of one or two months between the first and second dose, and a third dose administered two to five months after the second dose (13). The gold standard for a good vaccine and vaccination regimen is the induction of protective levels of neutralizing antibody to hepatitis B (over 10 IU/l) in at least 85% of recipients (14). However, among cohorts of intravenous drug users (who tend to be overrepresented in Western prison populations), protective immunity following hepatitis B vaccination is consistently lower and found in only 40-85% of recipients (3).

In prison-based hepatitis B vaccination programmes, a major issue with regard to the choice of vaccination schedule is how to balance the trade-off between seroprotection (postvaccination surface antibody titres of at least 10 IU/l) and compliance. Several studies have shown that, for a given vaccine used in prison settings, the longer the duration of the vaccination regimen, the greater the seroprotection but the lower the compliance (β) . Given that studies using even 12-month long regimens have not resulted in seroprotection levels of above 85% in cohorts of prisoners or injecting drug users, schedules which lead to seroprotection levels of 75% or more, but which are short enough to maximize compliance, would be ideal in prison settings. At least one study has demonstrated that for early seroconversion in healthy adults, the 0, 1, 2 months schedule was as useful as vaccination at 0, 1, and 6 months (15). Since August 1998, efforts to balance the trade-off led staff at the CHC to begin a 0, 1, 2 month vaccination regimen, also known as a "fast schedule" (16).

Postvaccination surface antibody titres and booster vaccinations

Most studies of trends in postvaccination surface antibody titres in the general population have demonstrated that over 95% of healthy individuals who received a primary course of vaccination became seroprotected. Thus, most national hepatitis B vaccination programmes restrict serological confirmation of postvaccination immunity to specific groups, such as those immunocompromised and haemodialysis patients. However, in view of the high proportion of intravenous drug users in most prison populations, as well as the expected reduced response to hepatitis B vaccination among intravenous drug users, estimating postvaccination surface antibody titres should be an integral part of prison-based hepatitis B vaccination programmes.

Postvaccination surface antibody estimations provide a valuable monitoring tool for determining not only the number of vaccinees that remain unimmunized, but also for monitoring the impact of factors that may influence vaccination. This point is especially relevant if standard vaccination regimens are modified, as with the 0, 1, 2 regimen (a modification of the 0, 1, 2, 12 regimen). While it is generally accepted that the fourth dose of the latter regimen is still needed (and recommended), it has also been scientifically established that the postvaccination development of hepatitis B surface antibody at a level of 10 IU/l or greater "is associated with long-lived immunological memory for hepatitis B surface antigen which provides continuing immunity when antibody levels fall below detectable levels" (*17*).

These two issues raise the question of what to do if titres are above 10 IU/l between six weeks and six months into the four-dose regimen. In the New South Wales hepatitis B programme between August 1998–June 2000, we attempted to resolve this dilemma by administering the fourth dose as soon as possible only if the postvaccination titre was below 100 IU/l after the 0, 1, 2 component of the schedule. This approach was based on the belief that those with titres above 100 IU/l after the third dose do not require the fourth dose, as this level of protection is unlikely to mask significant hepatitis B infection.

Unfortunately, the recent statement by the European Consensus Group on Hepatitis B Immunity (18) did not specifically address this point. A worldwide consensus is needed on whether additional doses of a given schedule are required if inmates develop adequate seroconversion titres after completing only part of a standard vaccination, especially given the rarity of "breakthrough" infections following the development of adequate immunoresponse to a primary course of vaccination (17).

Another important use of postvaccination titre estimates in prison-based hepatitis B programmes is to monitor factors that may diminish the response to hepatitis B vaccine among prison inmates. Two such factors, hepatitis C antibody status and vaccine strength, have been closely studied in the New South Wales vaccination programme (19). At least one study demonstrated that some individuals positive for hepatitis C antibody have relatively low seroconversion status to hepatitis B vaccine (20), a disturbing finding given that 47% of New South Wales prison inmates were seropositive for hepatitis C (21). Also, although the official position of the New South Wales Health Department is that both the 10 µg and 20 µg vaccines are of equal efficacy, we observed a significant drop in the average seroconversion titres for our inmate vaccinees, from 85% (385/455; 95% CI: 81-88%) with the 20 µg vaccine, to 79% (458/582; 95% CI: 75-82%) when a mixture of 10 µg and

20 μg vaccines were used. The difference was significant (5.9%; 95% CI: 1–10.8%; P <0.02).

Analysis of the vaccination status of a cohort of prison inmates revealed that there was no significant difference in post vaccination protective antibody response that was attributable to hepatitis C exposure status, a finding that is in agreement with most other studies of this variable (16). However, our study revealed that inmates vaccinated with a 20 μ g vaccine dose using a 0, 1, 2 month schedule had significantly higher postvaccination surface antibody titres compared with inmates vaccinated with a 10 μ g vaccine dose (19). In prison populations, where known factors associated with reduced responsiveness to hepatitis B vaccine are common (especially injecting drug use), there is thus a strong rationale for using the 20 μ g vaccine.

The term "booster" refers to vaccination given some time after a primary vaccination series, with the aim of providing protective immunity against significant breakthrough infection. Internationally, a postvaccination antibody titre of 10 IU/l or greater is considered to provide adequate immunity for at least 15 years for most population groups, except immunocompromised patients. The recent statement of the European Consensus Group on hepatitis B immunity did not recommend either postvaccination testing or booster vaccinations for intravenous drug users, with the exception of those with reduced immunocompetency (18). Yet only 40%-85% of intravenous drug users demonstrate a positive response to a primary course of hepatitis B vaccination. In this author's opinion, with the use of modified vaccination schedules (such as 0, 1, 2 months) it is advisable to adopt a higher reference level (such as 30 IU/l or 100 IU/l), and to offer additional vaccine doses to prison inmates whose postvaccination titres fall below the higher reference level.

Complementary strategies for preventing hepatitis B infections

In spite of its proven protective effect, less than one-third of the 77% presumably unexposed inmates incarcerated in New South Wales correctional facilities in 2000 were eligible for hepatitis B vaccination. Even after accounting for those that have been vaccinated in the community, it is unlikely that any prison-based hepatitis B vaccination programme would be able to fully cover more than 50% of eligible inmates. Thus, the need for complementary strategies is self-evident. A distinct advantage of most complementary strategies is that they are holistic with regard to the prevention of other bloodborne infectious diseases.

The complementary strategies in use in New South Wales correctional facilities are health education on harm minimization, and providing bleach and condoms to inmates free of charge. One health education strategy for harm minimization that is yet to be fully explored in prison settings is the counselling of recalcitrant addicts to shift from injecting to noninjecting (e.g. sniffing) forms of drug use.

Syringe cleaning guidelines were introduced into New South Wales prisons in 1993, in spite of the official prohibition of illicit drug use. In the only published study of this programme, 64% of the respondents (n = 102) reported a history of drug injection at some time in the past (22). Of the 31 intravenous drug users in the survey who reported sharing

syringes in prison, 23% reported adopting the revised syringe cleaning guidelines.

The impact of the condom programme on preventing hepatitis B transmission in prisons is difficult to evaluate. All major surveys of sexual activity in New South Wales prisons have so far indicated that less than 7% of all inmates engaged in sexual activity while in prison. These surveys are comparable to a 1998 survey of Irish prisoners, which showed that about 2% of male prisoners reported a history of anal sex with other prisoners while incarcerated (δ). Given the social context in which (male-to-male) sexual intercourse takes place in prisons, it is unlikely that free distribution of condoms would play a major role in preventing hepatitis B transmission in most correctional settings.

One programme which is not in place in most prisons, but which is being advocated by experts in correctional health, is a needle exchange programme. Needle exchange programmes began in 1984 in Amsterdam, started by a drug user advocacy group called the Junkie Union. The programmes have been successfully implemented in 17 prisons in Switzerland, Germany and Spain (23) and in some community outreach programmes (24, 25). In Australia, where an extensive network of needle and syringe programmes have been established, around 700 such programmes distributed 10 million syringes between July 1994 and June 1995. These programmes has been evaluated as generally successful, although the degree of success claimed for them has been questioned (26). It is inappropriate to generalize on the appropriateness of needle exchange programmes in prison settings, and a decision to implement this controversial strategy will require a case-by-case assessment.

Conclusions

The unique nature of prison settings suggests that communitybased hepatitis B vaccination programmes may need to be modified if they are to be effective. The modifications include:

- Adopting an active case-finding approach for enrolling inmates into vaccination programmes.
- Adopting effective management systems to ensure good case-holding.
- Adopting a short (0, 1, 2 months) vaccination schedule, given the dynamics of most prison populations.
- Using a 20 μ g per dose vaccine and a 0, 1, 2 months vaccination schedule, to achieve quality and coverage.
- Adopting a higher reference level for determining seroprotection (e.g. 30 IU/l), with boosters administered to inmates who do not meet the higher reference level after a primary course of vaccination (Peter Robertson, personal communication).

While vaccination programmes provide specific and effective protection, only a minority of susceptible inmates can be fully vaccinated in most prison settings. Complementary strategies, including intensive health education on harm minimization, are thus important measures for controlling hepatitis B transmission in prisons.

Conflicts of interest: none declared.

Résumé

La vaccination contre l'hépatite B en milieu carcéral

Les possibilités offertes et les problèmes posés par les programmes de vaccination contre l'hépatite B en milieu carcéral sont passés en revue. En particulier, les avantages de la modélisation sont soulignés et une stratégie active de dépistage est recommandée. Les mesures à prendre pour assurer une bonne tenue des dossiers médicaux sont également examinées, et un protocole de vaccination fondé sur

l'injection de trois doses de 20 μ g de vaccin à un mois d'intervalle (schéma 0, 1, 2) est préconisé. La recherche d'un taux d'anticorps anti-HBs plus élevé est également recommandée pour obtenir une immunisation véritablement adéquate : pour ce faire, on pratique des injections de rappel sur les détenus qui n'atteignent pas le taux protecteur optimal après la primo-vaccination.

Resumen

Vacunación contra la hepatitis B en las prisiones

Se examinan las oportunidades y los problemas que surgen en los programas de vacunación contra la hepatitis B en los entornos carcelarios. En particular, se subrayan las ventajas de la modelización y se propugna un enfoque activo para la detección de casos. Se examinan asimismo las medidas encaminadas a asegurar un seguimiento de casos satisfactorio, y se propone

aplicar en los entornos carcelarios un régimen de vacunación a los 0, 1 y 2 meses con dosis de 20 μ g de la vacuna. También se recomienda un nivel de anticuerpos de referencia mayor para lograr una inmunización adecuada, con inyecciones de refuerzo para los reclusos que no lleguen a ese nivel después de la primovacunación.

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