Home delivery of heat-stable vaccines in Indonesia: outreach immunization with a prefilled, single-use injection device

A. Sutanto,[1] I.M. Suarnawa,[2] C.M. Nelson,[3] T. Stewart,[4] & T. Indijati Soewarso[5]

Extending immunization coverage to underserved populations will require innovative immunization strategies. This study evaluated one such strategy: the use of a prefilled, single-use injection device for outreach immunization by village midwives. The device, UniJect, is designed to prevent refilling or reuse. Stored at ambient temperatures for up to 1 month in midwives' homes, vaccine-filled UniJect devices were immediately available for outreach. Between July 1995 and April 1996, 110 midwives on the Indonesian islands of Lombok and Bali visited the homes of newborn infants to deliver hepatitis B vaccine to the infants and tetanus toxoid to their mothers. Observations and interviews showed that the midwives used the device properly and safely to administer approximately 10 000 sterile injections in home settings. There were no problems with excessive heat exposure during the storage or delivery of vaccine. Injection recipients and midwives expressed a strong preference for the UniJect device over a standard syringe. Use of the prefilled device outside the cold chain simplified the logistics and facilitated the speed and efficiency of home visits, while the single-dose format minimized vaccine wastage.

Voir page 124 le résumé en français. En la página 125 figura un resumen en español.

Introduction

Recent surveys in developing countries have revealed that up to 30% of injections given for the purpose of immunization are not sterile (*1*). Disposable syringes are reused, and reusable syringes are often improperly sterilized, resulting in a significant risk of transmission of bloodborne pathogens (*2–5*). Autodestruct syringes and single-use, prefilled devices can reduce disease transmission by averting inappropriate reuse (*6–8*). In addition, single-dose formats avoid the wastage associated with multi-dose vials.

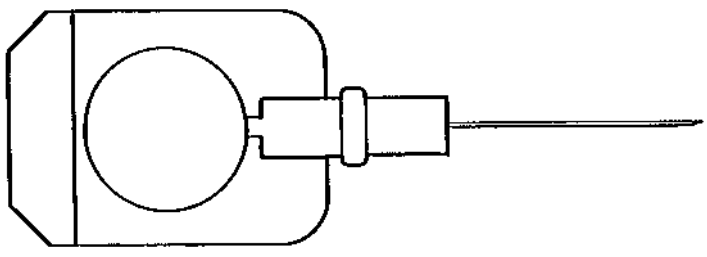
Tetanus toxoid and hepatitis B vaccine are relatively heat-stable and have shown only a small loss in potency when stored for 2–6 months at 37 °C (*9–11*). WHO considers both vaccines to be candidates for removal from the cold chain because of their thermal stability and their vulnerability to freeze damage during refrigerated storage and transport (*12*). This strategy could increase immunization coverage in areas not reached by the cold chain. Nevertheless, concerns that lack of immediate supervision could foster unsafe injection practices, and that cold-chain discipline for heat-sensitive vaccines could be jeopardized, have discouraged widespread implementation of immunization beyond the cold chain. This article describes an immunization approach that takes advantage of the heat stability of tetanus toxoid and hepatitis B vaccine without compromising safety: the use of a prefilled, single-use injection device in conjunction with heat-stable vaccines in an outreach programme conducted beyond the cold chain.

Materials and methods

Syringes and vaccines

UniJect is a plastic disposable syringe, prefilled with a single dose of medicament (Fig. 1). The medicament is enclosed in a sealed blister, and a permanent needle is attached. UniJect is specifically designed to prevent attempts at reuse, and was developed by the Program

Fig. 1. **UniJect prefilled, single-use injection device**



[1] Head, Disease Prevention and Health Promotion, NTB Province, Ministry of Health, Indonesia.

[2] Head, Disease Prevention and Health Promotion, Bali Province, Ministry of Health, Indonesia.

[3] Program Manager, Program for Appropriate Technology in Health, 4 Nickerson Street, Seattle, WA 98109, USA. Requests for reprints should be sent to this author.

[4] Medical Epidemiologist, Macfarlane Burnet Centre for Medical Research, Fairfield, Victoria, Australia.

[5] Head, Directorate for Epidemiology and Immunization, Ministry of Health, Indonesia.

for Appropriate Technology in Health (PATH), primarily with funding from the United States Agency for International Development (USAID) Technologies for Health (HealthTech) project.

For this study, UniJect devices were prefilled to deliver 0.5 ml of tetanus toxoid or hepatitis B vaccine, and supplied with 23-gauge, 20-mm needles. UniJect is activated by pushing the needle cap towards the body of the device, which opens the fluid path between the needle and the blister. The cap is then removed, the needle inserted into the injection site, and the dose delivered by squeezing the blister until it collapses. The tetanus toxoid and hepatitis B vaccine were produced by Perum Bio Farma (Bandung, Indonesia) and Korea Green Cross Corporation (Seoul, Republic of Korea), respectively, and were subject to standard release testing procedures after filling into UniJect devices.

Study sites and participants

The study was conducted from July 1995 to April 1996 within sites participating in the Indonesian Ministry of Health's Healthy Start for Child Survival project on the islands of Bali and Lombok. Approximately 60 rural villages were included in the study, representing all three districts of Lombok and the Tabanan district of Bali. Since 1989, village midwives have routinely vaccinated newborn infants with hepatitis B vaccine and postpartum mothers with tetanus toxoid during home visits. Village midwives have been trained by the Indonesian Health Department and placed in villages to deliver community-based maternal health care, antenatal care, assistance with births and neonatal care.

During the study, village midwives used UniJect devices rather than the standard disposable or reusable syringes with multidose vials. The midwives were trained by provincial and district supervisors prior to the study. The 4–6 hour training sessions covered the proper use and disposal of the UniJect devices, review of safe injection practices, and data collection procedures. All UniJect injections were given in the homes of newborn infants. Questionnaires and interviews were used to gather data from mothers and midwives. The study organizers also conducted informal interviews with midwives, supervisors and programme managers on the acceptability and appropriateness of the UniJect device for this application.

Device supply and disposal

Once a month, the midwives participating in the study visited the nearest health centre and picked up a supply of vaccine in UniJect devices. The midwives kept the devices in an outreach carrier box. Each carrier box also contained a removable cardboard disposal box designed to prevent contaminated needles from protruding. Midwives were instructed to insert used devices (without recapping) into the disposal box immediately after giving injections. When the midwives visited the health centre each month, the staff removed the disposal box and incinerated it. The midwives were then given a new disposal box and new prefilled UniJect devices.

Storage out of the cold chain

Vaccine-filled UniJect devices were kept under normal cold-chain conditions as they were distributed from Perum Bio Farma to national, provincial and district storage facilities, and finally to local health centres. After the midwives had picked up supplies of vaccine-filled UniJect devices at the health centres, they were allowed to keep them under ambient conditions for up to 1 month. This enabled the midwives to store the vaccine in their homes and travel directly to the homes of newborn infants to deliver the immunizations.

While data support the thermostability of hepatitis B vaccine and tetanus toxoid at temperatures $\leqslant 37\ ^{\circ}C$ for more than one month (*9–11*), added precautions were taken to ensure the safety and efficacy of the storage strategy used in the study. These included conducting potency testing and a serological analysis during the study, as well as the use of threshold heat indicators and training to prevent excessive heat exposure.

Potency testing. Potency testing of hepatitis B vaccine and tetanus toxoid in UniJect devices was carried out on samples stored at a typical field site for 1 month (average temperature 27 °C, range 25–32 °C). Twenty samples of each type were then sent for testing to the Indonesian National Quality Control Laboratory for Drug and Food and the National Centre for Disease Research and Development. Potency tests indicated that tetanus toxoid suffered a 6% loss of potency (cold-chain samples: 107.15 IU/ml; ambient storage samples: 100.25 IU/ml) and that hepatitis B vaccine suffered a 1% drop in potency (cold-chain samples: 100% relative potency; ambient storage samples: 99% relative potency). Both remained within established potency limits and the testing authorities declared them suitable for use after 1 month outside the cold chain.

Serological analysis. Infants received the birth dose of hepatitis B vaccine delivered either with a standard syringe and vaccine stored in the cold chain or with the UniJect device and vaccine stored for 1 month out of the cold chain. Seroconversion rates were identical for the two groups (I.M Suarnawa et al., unpublished data).

Threshold heat indicators and training. Study training sessions emphasized the importance of keeping the vaccines away from heat or direct sunlight. To determine whether vaccines had been exposed to potentially damaging transient high temperatures, each disposal box was fitted with a threshold heat indicator that changed colour on exposure to $\geqslant 49\ ^{\circ}C$. Midwives and health centre coordinators were advised to monitor the heat indicators and discontinue vaccinations with any devices associated with a heat indicator that had

changed colour. Although sustained intermediate temperatures (e.g. 45 °C for 2 weeks) can damage tetanus toxoid, such temperature exposure was considered unlikely in the trial area, where the average temperature is 26 °C (1996 range: 18–34 °C) (*13*).

Cost–effectiveness study

Concurrently with the field study, a cost–effectiveness study of hepatitis B immunization in Indonesia with the UniJect device was conducted (*14*). The study compared two strategies for achieving hepatitis B immunization coverage in Indonesia. The first approach – based on the model currently used in Indonesian immunization programmes – was three doses of hepatitis B vaccine delivered by disposable syringe at sessions conducted once a month at health centres. The first dose of hepatitis B vaccine was given to infants at approximately 6 weeks of age. The second strategy, based on the field study model, utilized home delivery of hepatitis B vaccine with the UniJect device in the first week of life, the second and third doses being given using a disposable syringe at the health centre. The option of using a standard disposable or reusable syringe with multidose vials for home visits was rejected due to concerns about safety, logistics and vaccine wastage. The option of using a single-dose vial with an autodestruct syringe was also rejected, since although it would have reduced vaccine wastage and improved safety, it would have been prone to the same logistical and diversion problems associated with all separate vial-and-syringe approaches.

Results

Proper use

A total of 110 midwives delivered approximately 10 000 doses of vaccine with UniJect devices during the 10-month field study. To determine whether midwives were using the device properly, study supervisors occasionally observed midwives giving injections and completed a standard questionnaire. Proper use was defined as the completion of several steps of UniJect use in a correct and safe manner (Table 1). Of the 23 midwives observed, 15 used UniJect properly 100% of the time. Accidental expulsion of a small amount of vaccine occasionally occurred (13% of observations) during activation or cap removal. Instances of improper injection angle (13%) were also noted. Injection at a downward angle is recommended for the device, since this prevents the injection of a small air bubble contained within the vaccine blister.

Table 1. **Correct use of the UniJect device by 23 midwives**

Step	% correct use
No accidental vaccine expulsion during preparation	87
Injection at downward angle	87
Complete injection of contents	96
No needle-stick during or after use	96
No recapping after use	83
Proper and immediate disposal	96

Acceptability

After the midwives had used the device for several months, study supervisors surveyed 33 of them using a questionnaire to determine their impressions of the device. All the midwives surveyed preferred UniJect over a standard syringe and all reported its ease of activation and ease of injection to be acceptable; none reported any problems in using the device. When asked what they liked or disliked about UniJect, 67% of the midwives replied that it was more practical and efficient, and 36% stated that it was easier to use and/or carry; none mentioned anything they disliked about the use of UniJect. When asked if they experienced any defect or design problems, 12% of the midwives reported occasional inability to expel vaccine after the device had been activated. This was determined to be a manufacturing defect in the batch of prototype devices used and has since been corrected.

The midwives conducted a questionnaire survey of mothers immediately after the injections had been performed. Of the 860 mothers whose infants had been injected using the UniJect device, 94% said they had experienced no anxiety before the injection and 92% said they would agree to future injections with the device. Of the 456 mothers who had themselves received injections by means of the UniJect device, 94% said they had experienced no anxiety and 97% said they would agree to receive future injections with the device. A total of 56% said they had felt less pain compared with the use of a conventional syringe, while 6% said they had felt more pain.

Storage and delivery beyond the cold chain

The 33 midwives surveyed by study supervisors were also asked questions regarding their experience with storing and delivering the vaccines without refrigerators or cold boxes. All responded that they were able to deliver immunizations earlier in the infants' lives by keeping the vaccines at home. None reported any colour changes in the heat indicators that would have indicated excessive heat exposure. When asked if they had comments regarding storage and use of the UniJect device beyond the cold chain, 24% of the midwives replied that the device was always ready for use and there was no need to get vaccines from the health centre. Some 24% felt the device made home visits easier and more practical, while 21% felt it provided a better service to mothers and infants. There were no negative comments regarding the use of the device outside the cold chain.

Cost–effectiveness

It was estimated that use of the UniJect device would add US$ 0.15 – 0.30 to the cost of a dose of hepatitis B vaccine. There is, however, a high rate of vaccine wastage associated with the use of multi-dose vials, one conservative estimate being 20% wastage in the use of 10-dose vials (J. Lloyd, personal communication). The contact cost for home visits is also lower than that for treatment at a health centre. It was therefore estimated that the total cost per child immunized was US$ 6.57 using the UniJect device for the first injection at home, compared with US$ 7.19 using a standard disposable syringe at the health centre (Table 2). Costs of disposal were considered to be about the same for the UniJect device and standard disposable syringes.

Discussion

Safety

Single-use devices such as UniJect could significantly reduce the incidence of disease transmission between injection recipients (*6*). Nevertheless, they do not offer complete protection to health care workers. While handling hazards are minimized because resterilization is eliminated, the devices must still be disposed of properly. Recapping of needles after injections was common in this study and probably led to the reported needle-stick accidents. It is recommended that future training give additional emphasis to the hazards of recapping. The outreach carrier box provided a safe method of disposing of used devices as well of storing unused devices. There were no reports of new or used UniJect devices being discarded in the community; used devices were safely collected in the disposal box before incineration or burial.

A downward injection angle is recommended with the UniJect device in order to avoid expelling the air bubble within the blister. Some 13% of injections observed were given at an improper angle. A careful review of the literature confirms that intramuscular injection of small amounts of air is not harmful; in fact, many nursing texts recommend the injection of 0.2 ml of air from older types of glass syringe to ensure dose accuracy (*15*). While the maximum volume of an air bubble from a 0.5-ml UniJect injection is much less than 0.2 ml, proper technique can minimize unnecessary risk in the unlikely event that the needle is placed in a blood vessel.

Acceptability

Mothers expressed a strong preference for the UniJect device over a standard syringe and needle. Their perceptions of reduced pain may have been due to the sharpness of the single-use needle, although, the speed of injection may also have played a role in reducing anxiety and perceived pain. It was observed that mothers' anxiety increased while watching the midwife prepare a standard syringe, whereas the UniJect device was prepared and used very quickly. A less painful injection could lead to increased client satisfaction and willingness to participate in immunization programmes. This was reinforced by several midwives, who reported that some mothers were strongly disappointed when post-study injections were performed with a standard syringe. Several midwives commented that the increased client acceptability of UniJect made their jobs more

Table 2. **Costs of delivering three doses of hepatitis B (HB) vaccine: first dose at 6 weeks with disposable syringe and ten-dose vial compared with first dose at birth with UniJect device**[a]

	Cost (US$) when first dose given:			
	At 6 weeks of age at health post with disposable syringe		At birth at home with UniJect	
HB vaccine costs (US$ 1.8 per dose)	3.54	(3 doses)	3.54	(3 doses)
HB vaccine wastage with multidose vials (20% wastage)	0.87	(3 multidose vial injections)	0.59	(2 multidose vial injections)
HB vaccine wastage with UniJect (2% wastage)			0.07	(1 UniJect injection)
Disposable syringes (US$ 0.06 per syringe)	0.18	(3 syringes)	0.12	(2 syringes)
UniJect including filling costs			0.22	(1 UniJect)
Marginal contact costs (approximately US$ in 0.87 health post, US$ 0.30 at home)	2.60	(3 health post visits)	2.03	(1 home, 2 health post visits)
Total costs	**7.19**		**6.57**	

[a] In both cases the second and third injections were given at a health post with conventional disposable syringe.

enjoyable. Improved efficiency, self-reliance and community acceptance could play a role in strengthening the job satisfaction and motivation of midwives conducting outreach programmes.

Beyond the cold chain

Storage of tetanus toxoid and hepatitis B vaccine outside the cold chain reduces the likelihood of damage from freezing. Additional advantages of removing these vaccines from the cold chain at the peripheral levels of the health care system include storage of vaccine in local communities for more convenient outreach, increased opportunities for immunization in remote areas, and reduced dependence on ice and insulated vaccine carriers (*12*). Midwives found the UniJect device to be especially appropriate for use outside the cold chain because of its small size, ready-for-use design, and single-dose format.

One concern with the storage of heat-stable vaccines outside the cold chain is that such a practice could mistakenly be used with heat-sensitive vaccines, resulting in a breakdown of cold-chain discipline (*12*). Informal interviews with several midwives revealed no tendency to relax cold-chain standards for other vaccines. They felt that UniJect storage procedures could diverge from normal vial storage procedures without creating confusion.

While the heat stability of tetanus toxoid and hepatitis B vaccine have been established through laboratory testing, the present study confirmed heat stability under delivery conditions. Post-exposure potency testing and a serological survey revealed stability and seroconversion equivalent to that associated with standard cold-chain methods.

Cost–effectiveness

In terms of cost–effectiveness, the study identified seven advantages, discussed below, of injecting newborn infants with hepatitis B vaccine outside the cold chain using the UniJect device.

Reduced wastage. In 1995–96, 36% of the hepatitis B vaccine used in the Indonesian Expanded Programme on Immunization was discarded (*16*) — the equivalent of almost 1.6 million doses per year. Since the UniJect device is opened to provide one dose at a time, unused doses do not need to be discarded and wastage is negligible.

Reduction in missed immunization opportunities. Indonesian health workers report a tendency to turn potential recipients away if the number is insufficient to warrant opening a ten-dose vial. This practice — while reducing wastage — could result in reduced immunization coverage. The UniJect device allows health workers to deliver a dose of vaccine as needed, thus eliminating the need to cluster or reschedule vaccinations.

Reduced cross-infection. Immunization using a single-use device such as UniJect could reduce the transmission of bloodborne pathogens and lead to a reduction in treatment costs for infectious diseases (*6*).

Reduced hepatitis B infection rates. Hepatitis B immunization at home immediately after birth reduces perinatal infection rates and treatment costs compared to a first dose delivered at 6 weeks of age (*17*). Using a World Bank model to evaluate the cost of interventions per disability-adjusted life year (DALY) (*18*), the study concluded that immunization at birth with the UniJect device was about 20% more cost-effective that with a standard syringe beginning at 6 weeks of age (*14*).

Improved integration of health interventions. Immunization at home provides an opportunity to carry out other neonatal and maternal health interventions. It could also strengthen the role and effectiveness of community health workers.

Simplified logistics. Each UniJect device represents a complete and ready-to-use vaccination package, replacing the individual components of vial, needle and syringe. This simplifies the distribution, inventory control and forecasting of immunization supplies. In settings without full immunization facilities such as outreach posts, UniJect could obviate the need for sterilization equipment, refrigerators and cold boxes. Immunization programmes at the peripheral level could thus be more easily established than if standard syringe support systems were required.

Reduced syringe diversion. Since the UniJect device is prefilled with a specific vaccine, and is unusable with any other medicament, it is less likely than standard disposable syringes to be diverted for other uses.

Other considerations

The introduction of the UniJect device into routine immunization practice would require site-specific analysis. Functional supply lines for both vaccine-filled devices and disposal boxes are critical to the availability of vaccine and the proper disposal of syringes. While single-use syringes are effective in reducing syringe reuse, they must be resupplied regularly and effective disposal systems must be available.

Vaccines prefilled into UniJect devices require greater storage space per dose than vaccines in multidose vials; this could have an impact on cold storage capacity. The feasibility of more frequent but smaller shipments from central warehouses should be studied as a method of reducing cold storage requirements.

The introduction of the UniJect device, as well as home vaccination and the use of vaccines outside the cold chain, would require training for health workers and managers. While the half-day training sessions conducted prior to this study were sufficient to give health workers a good understanding of UniJect use, observations of occasional improper use signal the need for more focused training.

Conclusion

The study showed that the introduction of a prefilled, single-use injection device such as UniJect into the Indonesian immunization programme would be welcomed by the health care community and its clients. Midwives, injection recipients and programme managers requested that vaccines be made available in the UniJect device. The device could play a valuable role in situations where access to immunization services is limited. Community outreach programmes could benefit from the safer injection services offered by midwives and other village-level health workers. When used in a programme that would allow vaccines to be stored and delivered outside the cold chain, the UniJect device could be highly effective in extending immunization coverage. ■

Acknowledgements

We thank the following agencies for significant contributions to the study: Indonesian Ministry of Health, United States Agency for International Development, Australian Agency for International Development, National and Provincial Healthy Start for Child Survival Teams, Perum Bio Farma, Korea Green Cross Corporation, Program for Appropriate Technology in Health, the Macfarlane Burnet Centre for Medical Research, Horizon Medical, Inc., Becton Dickinson and Company, and the International Vaccine Institute. Special thanks are due to Ms Debra Kristensen, Ms Rebecca Fields and Dr Anton Widjaya for reviewing the manuscript.

Résumé

Fourniture à domicile de vaccins thermostables en Indonésie : vaccination sur le terrain au moyen d'une seringue-dose préremplie jetable

La réutilisation des seringues comporte un risque important de transmission d'agents pathogènes transmis par voie sanguine. Les seringues autobloquantes et les seringues-doses préremplies jetables peuvent réduire la transmission des maladies en évitant une réutilisation inappropriée. L'anatoxine tétanique et les vaccins anti-hépatite B sont relativement thermostables et leur perte d'activité, après un stockage de 2-6 mois à 37°C, est faible.

Cette étude décrit une stratégie de vaccination qui utilise la stabilité de ces vaccins sans pour autant présenter de danger : l'utilisation d'une seringue-dose préremplie jetable en association avec des vaccins thermostables dans un programme de terrain mis en oeuvre au-delà de la chaîne du froid. La seringue-dose Uniject est conçue pour empêcher tout remplissage ou réemploi. Stockées à température ambiante jusqu'à un mois chez les sages-femmes, les seringues-doses UniJect déjà remplies de vaccin étaient immédiatement disponibles pour la vaccination sur le terrain. Entre juillet 1995 et avril 1996, 110 sages-femmes des îles indonésiennes de Lombok et Bali se sont rendues dans les familles des nouveau-nés pour administrer le vaccin anti-hépatite B aux nourrissons et l'anatoxine tétanique à leur mère au moyen d'UniJect.

Les observations et les entretiens ont montré que les sages-femmes ont utilisé convenablement et en toute sécurité les seringues-doses pour administrer 10 000 (5 000 vaccins anti-hépatite B et 5 000 anatoxines tétaniques) injections stériles dans les foyers. Les personnes vaccinées et les sages-femmes ont nettement préféré UniJect aux seringues standard. Plusieurs avantages de la vaccination contre l'hépatite B à la naissance, au-delà de la chaîne du froid, ont été recensés:

Réduction du gaspillage. UniJect n'est ouverte que pour une dose à la fois, il n'est pas nécessaire de jeter les doses inutilisées et le gaspillage est négligeable.

Réduction des occasions de vaccination manquées. UniJect permet aux agents de santé de dispenser le vaccin par dose nécessaire, évitant ainsi de devoir grouper ou reprogrammer les vaccinations.

Réduction des infections croisées. La vaccination au moyen de seringues jetables, en réduisant le risque de transmission des agents pathogènes par voie sanguine, peut réduire le coût du traitement des maladies infectieuses.

Réduction des taux d'infection par l'hépatite B. La vaccination à domicile contre l'hépatite B immédiatement après la naissance réduit les taux d'infection périnatale. Un modèle de la Banque mondiale a indiqué que l'administration à la naissance d'une dose anti-hépatite B au moyen d'UniJect avait un rapport coût-efficacité supérieur de 20% environ à la vaccination au moyen d'une seringue standard à partir de 6 semaines.

Amélioration de l'intégration des interventions de santé. La vaccination à domicile donne l'occasion d'effectuer d'autres interventions de santé néonatale et maternelle. Elle peut renforcer l'efficacité des agents de santé communautaires.

Simplification de la logistique. Chaque seringue UniJect est un module de vaccination complet, qui simplifie la logistique des approvisionnements. Dans un programme de terrain utilisant un vaccin thermostable, UniJect peut parer à la nécessité de matériel de stérilisation, de réfrigérateurs et de glacières.

L'étude a indiqué que l'introduction d'une seringue-dose préremplie jetable telle qu'UniJect dans le programme de vaccination indonésien serait bien accueillie par les personnels de santé et par les patients. Les sages-femmes, les personnes vaccinées et les administrateurs de programme ont demandé que le vaccin soit fourni dans UniJect. UniJect peut être utile là où l'accès aux services de vaccination est limité. Les programmes d'action communautaire périphérique

pourront tirer avantage de la sécurité accrue des services de vaccination offerts par les sages-femmes et autres agents de santé de village. En cas d'utilisation dans un programme qui permet le stockage et la fourniture des vaccins en dehors de la chaîne du froid, UniJect peut aider efficacement à étendre la couverture vaccinale.

Resumen

Administración domiciliaria de vacunas termoestables en Indonesia: inmunización extrainstitucional con inyector prellenado utilizable una sola vez

La reutilización de jeringas entraña riesgos considerables de transmisión hematógena de patógenos. Las jeringas autodestruibles y los inyectores prellenados no reutilizables pueden reducir la transmisión de enfermedades al evitar una reutilización inapropiada. La anatoxima tetánica y la vacuna contra la hepatitis B son relativamente termoestables y han mostrado sólo una pequeña pérdida de potencia cuando se almacenan durante dos a seis meses a 37°C.

En este estudio se describe una estrategia de inmunización en la que se aprovecha la estabilidad de esas vacunas sin comprometer la inocuidad: el empleo de un inyector prellenado, no reutilizable, junto con vacunas termoestables en un programa extrainstitucional ejecutado al margen de la cadena de frío. El dispositivo, UniJect, está ideado para impedir la recarga o la reutilización. Almacenados a temperatura ambiente hasta un mes en el domicilio de las parteras, estos dispositivos ya llenados con la vacuna estaban en condiciones de ser usados de inmediato. Entre julio de 1995 y abril de 1996, 110 parteras de las islas indonesias de Lombok y Bali visitaron hogares donde había niños recién nacidos para administrar la vacuna contra la hepatitis B a los lactantes y la anatoxina tetánica a las madres, utilizando estos inyectores.

Las observaciones y entrevistas revelaron que las parteras se sirvieron del dispositivo de manera adecuada e inocua para administrar en los hogares 10 000 inyecciones estériles (5000 de vacuna contra la hepatitis B y 5000 de anatoxina tetánica). Los receptores de las inyecciones y las parteras manifestaron una fuerte preferencia por el dispositivo UniJect en comparación con las jeringas estándar. Se señalaron varias ventajas de la inmunización al nacer contra la hepatitis B utilizando el dispositivo UniJect, sin necesidad de la cadena de frío:

Reducción de las pérdidas de vacuna. Como el UniJect administra una sola dosis por vez, no es necesario desechar las dosis no utilizadas, y las pérdidas son mínimas.

Reducción de la pérdida de oportunidades de inmunización. El UniJect permitirá a los agentes de salud administrar las vacunas en función de la dosis necesaria, eliminando la necesidad de agrupar o reprogramar las vacunaciones.

Reducción de infecciones cruzadas. La inmunización con jeringas desechables, al favorecer la reducción de la transmisión hematógena de patógenos, puede redundar en una disminución de los costos de tratamiento de las enfermedades infecciosas.

Reducción de las tasas de infección por hepatitis B. La inmunización contra la hepatitis B en el hogar inmediatamente después del nacimiento reduce las tasas de infección perinatal. Un modelo del Banco Mundial indicaba que el suministro de una dosis de vacuna contra la hepatitis B al nacer con el dispositivo UniJect es un 20% más eficaz en función del costo que la inmunización con una jeringa estándar a partir de las seis semanas de edad.

Mejor integración de las intervenciones de salud. La inmunización domiciliaria proporciona la oportunidad de realizar otras intervenciones en relación con la salud neonatal y materna. Puede reforzar la eficacia de los agentes de salud de la comunidad.

Simplificación de la logística. Cada dispositivo UniJect constituye un paquete de vacunación completo, lo que simplifica los suministros. En un programa de inmunización extrainstitucional con vacunas termoestables, la utilización del dispositivo UniJect permitiría obviar la necesidad de esterilizar el equipo, los refrigeradores y las neveras portátiles.

En el estudio se señala que la introducción en el programa de inmunización de Indonesia de un inyector prellenado y desechable como el UniJect sería vista con buenos ojos por el personal de salud y los usuarios. Parteras, receptores de las inyecciones y administradores de programa pidieron que las vacunas se suministraran con el UniJect. Este dispositivo podría cumplir un valioso papel en las situaciones en que el acceso a los servicios de inmunización es limitado. Los programas extrainstitucionales para la comunidad podrían beneficiarse de los servicios de inoculación más seguros que ofrecen las parteras y otros agentes de salud de la comunidad. Utilizado en programas que permitan almacenar y administrar las vacunas sin necesidad de la cadena de frío, el UniJect podría ser muy eficaz para ampliar la cobertura de inmunización.

References

1. **Expanded Programme on Immunization.** *Technet news*, 1994, No.1.
2. **Aylward B et al.** Reducing the risk of unsafe injections in immunization programmes: financial and operational implications of various injection technologies. *Bulletin of the World Health Organization*, 1995, **73:** 531–540.
3. **Anan A.** India: Unhealthy immunization programme. *Lancet*, 1993, **341:** 1402.
4. **Aylward B et al.** Model-based estimates of the risk of human immunodeficiency virus and hepatitis B virus transmission through unsafe injections. *International journal of epidemiology*, 1995, **24:** 446–452.
5. Expanded Programme on Immunization. Changing needles but not the syringe: an unsafe practice. *Weekly epidemiological record*, 1987, **62**(46): 345–346.
6. **Samuels ME, Koop CE, Hartsock PI.** Single use syringes. *New England Journal of Medicine*, 1991, **324:** 996–997.
7. **Evans P.** Auto-destruct disposable syringes and needles. Technet Conference Papers. Geneva, *World Health Organization*, 1993.
8. Safety of injections in immunization programmes: WHO recommended policy. Geneva, World Health Organization, 1994 (unpublished document WHO/EPI/LHIS/94.1; available upon request from Expanded Programme on Immunization, World Health Organization, 1211 Geneva 27, Switzerland).
9. **Rawn C, Hirschhorn R.** *EPI essentials: a guide for program officers.* Resources for Child Health Project (REACH), 1988.
10. **Melnick JL.** Thermostability of poliovirus, measles, and hepatitis B vaccines. *Vaccine research.* 1995, **4**: 1–11.
11. **Van Damme P et al.** Heat stability of a recombinant DNA hepatitis B vaccine. *Vaccine 1992*, **10**: 366–367.
12. Report of 1993 Technet Conference. Geneva, World Health Organization, 1993 (unpublished document WHO/EPI/LHIS/93.1; available upon request from Expanded Programme on Immunization, World Health Organization, 1211 Geneva 27, Switzerland).
13. Data Suhu Udara Tahun 1996 di Daerah Mataram. Badan Meteorologi dan Geofisika, Mataram, Indonesia.
14. *Achieving universal childhood immunization with hepatitis B vaccine: Policy and cost-effectiveness issues.* Program for Appropriate Technology in Health, International Vaccine Institute, April 1996. Unpublished report.
15. **Beyea S, Nicoll L.** Administration of medications via the intramuscular route: an integrative review of the literature and research-based protocol for the procedure. *Applied nursing research*, 1995, **8**: 23–33.
16. Study of integration of hepatitis B immunization into routine immunization programs. Informal meeting, Mataram, Indonesia, 30 July–2 August 1996. Indonesian Ministry of Health.
17. **Ruff TA et al.** Lombok hepatitis B model immunization project: toward universal infant hepatitis B immunization in Indonesia. *Journal of infectious disease*, 1995,**171**: 290–6
18. World Bank. *World development report 1993: investing in health.* New York, Oxford University Press, 1993: 27.