Providing monovalent oral polio vaccine type 1 to newborns: findings from a pilot birth-dose project in Moradabad district, India

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Problem Poliovirus transmission remained a public health challenge in western Uttar Pradesh, India in late 2005 and early 2006. In 2006, the India Expert Advisory Group for Polio Eradication concluded that, given the peak incidence of polio among children 6 to 12 months of age, a targeted birth dose of oral polio vaccine may be necessary to interrupt intense poliovirus transmission in high risk areas.

Approach The Government of Uttar Pradesh, the National Polio Surveillance Project and the United Nations Children's Fund (UNICEF) implemented a pilot birth-dose project aimed at identifying and vaccinating all newborns with a dose of oral polio vaccine within 72 hours of birth in an effort to evaluate operational feasibility and potential impact on population immunity.

Local setting The project was piloted in Moradabad district: zone 7 in Moradabad City (urban setting), Kunderki block (rural setting) and in select birthing hospitals.

Relevant changes Between July 2006 and February 2007, 9740 newborns were identified, of which 6369 (65%) were vaccinated by project personnel within 72 hours of birth. Project coverage (for total newborns vaccinated) ranged from 39% (in zone 7) to 76% (in Kunderki block) of the estimated number of newborns vaccinated during previous supplemental immunization activities.

Lessons learned Birth-dose coverage among newborns was lower than expected. Expansion costs were estimated to be high, with marginal impact. The project, however, provided opportunities to strengthen newborn tracking systems which have increased the number of newborns and young infants vaccinated during supplemental immunization activities and enrolled in routine programmes.

Une traduction en français de ce résumé figure à la fin de l'article. *Al final del artículo se facilita una traducción al español.* الترجمة العربية لهذه الخلاصة في نهاية النص الكامل لهذه المقالة.

Introduction

Despite repeated campaigns using oral polio vaccine (OPV), wild poliovirus (WPV) transmission continued in certain high-risk areas of India, particularly in western parts of Uttar Pradesh, during 2005 and 2006. Young children < 2 years of age were most affected by this ongoing transmission. WHO recommends an OPV dose at birth or at first contact with health services in polio endemic countries[1] based on evidence suggesting that early immunization results in "protection earlier" (higher proportion of young infants with polio antibodies) therefore reducing the immunity gap among young infants.[2–7] In developing countries such as India, however, delivery of a birth dose can be complicated, as most newborns do not have contact with personnel trained to administer vaccines soon after birth and, apart from the small minority who are born in hospitals, there is currently no mechanism to routinely identify newborns for any health intervention in India.

After reviewing the status of polio eradication in India in May 2006, the India Expert Advisory Group for Polio Eradication recommended a new intervention, the targeted administration of monovalent OPV type 1 (mOPV1) at birth in western Uttar Pradesh communities with ongoing poliovirus transmission. Monovalent OPV1 was recommended due to its greater efficacy against WPV1 compared with trivalent OPV;[8] 96% of polio cases in western Uttar Pradesh during 2005 and 2006 were due to WPV1 and 77% were in rural areas.[9] In July 2006, the Government of India and the WHO National Polio Surveillance Project, in collaboration with the United Nations Children's Fund (UNICEF), conducted a birth-dose pilot project in high-risk areas of Moradabad district in western Uttar Pradesh.

Methods

Local setting

Moradabad district is a densely populated region in western Uttar Pradesh that has had continuing WPV transmission despite ongoing polio eradication efforts, including supplemental immunization activity (SIA) targeting all children aged < 5 years roughly every 6 weeks. The low OPV coverage achieved through routine immunization activities (~38%),[10] and the combination of crowding, high diarrhoea rates, poor sanitation as well as a warm and humid climate have contributed to persistent poliovirus transmission. Two sites in Moradabad district were selected: Kunderki block, primarily a rural agricultural area; and zone 7, one of seven urban zones in Moradabad City, with 2006 population estimates of roughly 288 000 and 180 000, respectively (Table 1).[11] Twelve birthing hospitals in Moradabad district, 10 in Moradabad City and two in Kunderki block, also participated in the project.

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Table 1. **Population projections, birth cohort estimates and supplemental immunization activity campaign data, Moradabad district, India**

	Population estimate for 2006[a]	Newborns per year[b] (based on census data)	Newborns: 7.5-month project period (based on census data)	Newborns per year[c] (based on SIA data)	Newborns: 7.5-month project period (based on SIA data)
Kunderki block (rural)	288 800	9 964	6 227	11 941	7 463
Zone 7 (urban)	180 000	6 210	3 881	4 611	2 882
Total	468 800	16 174	10 108	16 552	10 345

SIA, supplemental immunization activity.
[a] 2006 population estimate based on census of India's population projection from 1991 (block level data from 2001 census of India was not published).
[b] 2001 Moradabad district birth rate (34.5 per 1000 population) applied to 2006 population estimates for Kunderki block and zone 7 to calculate number of newborns per year.
[c] SIA newborn data from December 2006 SIA round.

Approach

The pilot project aimed to vaccinate all newborns with a dose of mOPV1 within 72 hours of birth in selected project areas. Implementation consisted of two phases: (i) identification and documentation of all newborns, and (ii) vaccination of identified newborns. Focal persons and vaccine delivery coordinators were recruited to perform these activities.

In rural villages in Kunderki block, Angandwadi workers (AWWs) and Accredited Social Health Activist (ASHA workers) served as project focal persons. Both AWWs and ASHAs work in community health education and service delivery programmes and could provide information on new births in the village or neighbourhood. In zone 7, UNICEF-sponsored community mobilization coordinators who work to promote immunization services, served as focal persons. Maternity ward nurses served as focal persons in the 12 birthing hospitals. Focal persons for Kunderki block included 184 AWWs, 55 ASHAs and 40 others such as vaccinators from polio SIA teams, traditional birth attendants, school teachers and local health clinic assistants. In zone 7 focal persons included 71 community mobilization coordinators and five AWWs.

Twelve vaccine delivery coordinators were identified from previous SIA monitoring staff and assigned to visit between eight and 10 focal persons per day. During these visits, vaccine delivery coordinators reviewed newborn registries to identify all births occurring within the last 72 hours and accompanied focal persons or traditional birth attendants to administer the mOPV1 birth dose. Each coordinator had a motorbike for personal transport and received a per diem as well as reimbursement for transportation costs. For each newborn identified and vaccinated within 72 hours of birth, the focal person received an incentive of 15 Rupees (Rs) (US$ 0.38) and the traditional birth attendant received a safe delivery kit (value of ~ Rs 5 or US$ 0.13).

Evaluation

Potential impact on the immunity gap and operational feasibility of the pilot project were evaluated by comparing the number of newborns reached and vaccinated by the project and associated costs to existing polio eradication strategies. Two data sources were used to estimate the number of expected newborns identified during the project period in Kunderki block and zone 7. These included: (i) the birth rate for Moradabad district according to the 2001 India census (34.5 per 1000 population per year applied to the total population estimate of Kunderki block and zone 7), and (ii) the number of children < 1 month of age reported during previous SIA in each project area from December 2006.

Results

Identification of newborns

From July 2006 to February 2007, 9740 newborns were identified; 6459 in Kunderki block, 1728 in zone 7 and 1553 at the 12 hospitals (Table 2). According to the birth rate obtained from the 2001 census and previous SIA coverage, the birth-dose project identified 104% (by birth rate) or 87% (by SIA coverage) of all newborns in Kunderki block and 45% (by birth rate) or 60% (by SIA coverage) of all newborns in zone 7.

Vaccination

The project was more successful in identifying and immunizing newborns in Kunderki block, a rural area, than in the urban area zone 7. In Kunderki block, OPV was administered to 4521 (70%) of the 6459 identified newborns within 72 hours after birth compared to 670 (39%) of the 1728 identified newborns in zone 7. Of the 1553 newborns registered at the 12 hospitals, 1178 (76%) were vaccinated within 72 hours of birth.

Estimated coverage

Based on SIA immunization data from December 2006, the birth-dose project identified 87% of expected newborns in Kunderki block and 60% of expected newborns in zone 7. Therefore, based on estimates from above, only 61% (0.87 × 0.70) of expected newborns in Kunderki block and 23% (0.60 × 0.39) in zone 7 were vaccinated by the project within the targeted time frame. Coverage ranged from 38% (in zone 7) to 76% (in Kunderki block) when the total number of newborns vaccinated (before and after 72 hours) by the project were included.

Project cost and potential for expansion

By combining project expenses associated with the per diem and transportation for vaccine delivery coordinators, reporting incentives for focal persons and delivery kits for the traditional birth attendants, the estimated cost of vaccinating one newborn within 72 hours of birth through the birth-dose project was Rs 133 (US$ 3). This is significantly higher than the cost to vaccinate one newborn during an SIA at approximately Rs 13 (US$ 0.31).[12]

Table 2. **Newborns identified and vaccinated, and coverage by birth-dose pilot project area, Moradabad district, India, July 2006 to February 2007**

	Newborns identified	Total vaccinated (%)	Vaccinated ≤ 72 hours (%)	Vaccinated > 72 hours (%)	Total not vaccinated (%)	Percentage coverage based on census data[a]	Percentage coverage based on SIA data[a]
Kunderki block (rural)	6 459	5 618 (87)	4 521 (70)	1 097 (17)	841 (13)	90	76
Zone 7 (urban)	1 728	1 086 (63)	670 (39)	416 (24)	642 (37)	28	38
Institutions[b]	1 553	1 240 (80)	1 178 (76)	62 (4)	313 (20)	NA	NA
Total	9 740	7 944 (82)	6 369 (65)	1 575 (16)	1 796 (18)	66	65

NA, not applicable; SIA, supplemental immunization activity.

[a] Coverage estimates based on total vaccinated as a proportion of expected newborns during 7-month project period according to 2001 census birth rate estimates and December 2006 SIA data.

[b] Institution data not included in calculation of total coverage estimates.

Inconsistencies arise in some values due to rounding.

Expanding the birth-dose project to all 24 districts of western Uttar Pradesh would require more than 2400 staff and would cost about Rs 366 million (US$ 8.1 million) per year.

Discussion

Impact on polio immunity gap

Protective efficacy of mOPV1 per dose in western Uttar Pradesh has been estimated at 30% (95% confidence interval, CI: 19–39), suggesting that > 5 mOPV1 doses might be needed to generate vaccine-acquired population immunity to eliminate poliovirus transmission.[13] The targeted birth-dose strategy would, in theory, provide an additional opportunity for vaccination and result in earlier protection among infants at high-risk for polio. The low coverage achieved, especially in zone 7, however, suggests that the SIA campaign strategy is probably more effective than a targeted birth dose in reaching and vaccinating newborns. The difference between census and SIA-based coverage estimates probably reflects a higher than expected birth rate in the urban areas. Continuing a targeted birth-dose strategy at birthing hospitals may remain beneficial due to minimal labour and/or financial cost.

Factors related to low coverage

Despite social mobilization efforts, between December 2006 and February 2007, roughly 9% of identified newborns remained unimmunized due to the family's decision not to vaccinate; 4% in Kunderki block, 19% in zone 7 and 12% among the 12 birthing hospitals. Reasons for refusal included concern about possible adverse events such as the OPV causing sterility, reluctance to administer a vaccine to newborns and misunderstanding of the number of doses required to protect against polio. Observations from the vaccine delivery coordinators indicate that families refusing the mOPV1 birth dose were those also likely to refuse an SIA-administered OPV dose. Moreover, some newborns were missed because the mother had left the area to give birth at her parents' home. This suggests project impact on reducing the immunity gap would probably be limited, including in rural Kunderki block. Extensive social mobilization efforts to address concerns about OPV are ongoing in these areas as well as other high-risk areas for polio transmission.

High cost of expansion

Implementation of the project, even in rural areas, was more costly per dose administered, compared to SIAs. Expansion of such a targeted approach is unlikely to be feasible. Integrating the vertical pilot birth-dose project with other child health initiatives in high-risk rural communities was deemed more effective based on labour, transport and other health issues impacting these communities.

Newborn tracking strengthened

As a result of the pilot birth-dose project, the National Polio Surveillance Project, in collaboration with the Government of India and UNICEF, began recruiting AWWs, ASHA workers and traditional birth attendants as SIA team members and using booklets similar to the pilot project newborn registries to collect and track vaccination information on newborns identified during SIAs. In Kunderki block, the percentage of children < 2 years of age with ≥ 3 OPV doses administered at routine clinic visits increased from 14% in 2005 to 27% in 2007 according to vaccine coverage data from reported cases of acute flaccid paralysis. During the same time period, the percentage of children with no routine doses of OPV decreased from 68% to 42% (unpublished data from National Polio Surveillance Project, India).

Conclusion

Although the pilot project vaccinated roughly 7944 newborns with a birth dose of mOPV1, evaluation of the project using SIA data and cost projections suggest that the impact of such a strategy would be marginal and costly and is therefore not recommended. Implementation of the project, however, provided the opportunity to improve systems to track newborns in consecutive SIAs as well as to ensure that these infants are enrolled in routine immunization programmes and other child survival initiatives (Box 1). ■

Box 1. **Lessons learned**

- Birth-dose coverage among newborns was lower than expected.
- Costs were high and impact was estimated as marginal.
- The project provided opportunities to strengthen newborn tracking systems.

Competing interests: None declared.

Résumé

Délivrance du vaccin antipoliomyélitique oral monovalent type 1 aux nouveau-nés : résultats d'un projet pilote prévoyant l'administration à la naissance d'une première dose de ce vaccin dans le district de Moradabad, en Inde

Problématique La transmission du poliovirus restait un grand problème de santé publique dans l'Ouest de l'Uttar Pradesh à la fin de l'année 2005 et début 2006. En 2006, le Groupe consultatif d'experts indien pour l'éradication de la polio avait conclu que, compte tenu du pic atteint par l'incidence de cette maladie chez les enfants entre 6 et 12 mois, l'administration ciblée à la naissance d'une dose de vaccin antipoliomyélitique oral pouvait être nécessaire pour interrompre la transmission intense du poliovirus dans les zones à haut risque.
Démarche Le Gouvernement de l'Uttar Pradesh, le Projet national de surveillance de la polio et le Fonds des Nations Unies pour l'enfance (UNICEF) ont mis en œuvre un projet pilote d'administration du vaccin à la naissance, visant à identifier et à vacciner tous les nouveau-nés avec une dose de vaccin antipoliomyélitique oral dans les 72 heures suivant la naissance, dans le cadre d'un effort pour évaluer la faisabilité opérationnelle de cette intervention et son impact éventuel sur l'immunité de la population.
Contexte local Le projet a été mené dans le district de Moradabad : zone 7 de la ville de Moradabad (contexte urbain), agglomération de Kunderki (contexte rural) et dans certaines maternités.
Modifications pertinentes Entre juillet 2006 et février 2007, 9740 nouveau-nés ont été identifiés, parmi lesquels 6369 (65 %) ont été vaccinés par des personnes travaillant pour le projet dans les 72 h suivant la naissance. La couverture par le projet (pour l'ensemble des nouveau-nés vaccinés) se situait entre 39 % (zone 7) et 76 % (quartier de Kunderki) du nombre estimé de nouveau-nés vaccinés pendant les activités de vaccination supplémentaires menées antérieurement.
Enseignements tirés La couverture par une dose à la naissance des nouveau-nés était plus faible qu'attendu. Les coûts d'élargissement de cette couverture ont été évalués comme élevés, avec un impact correspondant marginal. Le projet a néanmoins fourni la possibilité de renforcer les systèmes permettant de retrouver les nouveau-nés, d'où une progression de nombre de nouveau-nés et de jeunes nourrissons vaccinés dans le cadre des activités de vaccination supplémentaires et soumis aux programmes de vaccination systématique.

Resumen

Uso de la vacuna antipoliomielítica oral monovalente de tipo 1 en recién nacidos: resultados de un proyecto piloto de administración de una dosis neonatal en el distrito de Moradabad, India

Problema A finales de 2005 y principios de 2006 la transmisión del poliovirus seguía planteando un problema de salud pública en Uttar Pradesh occidental, India. En 2006, el Grupo Consultivo de Expertos para la Erradicación de la Poliomielitis de la India llegó a la conclusión de que, a la vista de la incidencia máxima de poliomielitis entre los niños de 6 a 12 meses, probablemente se requería una dosis neonatal focalizada de vacuna antipoliomielítica oral para interrumpir la intensa transmisión del poliovirus observada en las zonas de alto riesgo.
Enfoque El Gobierno de Uttar Pradesh, el Proyecto Nacional de Vigilancia de la Poliomielitis y el Fondo de las Naciones Unidas para la Infancia (UNICEF) pusieron en marcha un proyecto piloto de administración de una dosis al nacer basado en localizar y vacunar a todos los recién nacidos con una dosis de vacuna antipoliomielítica oral en las primeras 72 horas de vida, con la finalidad de evaluar la viabilidad operacional y el impacto potencial de esa medida en la inmunidad de la población.
Contexto local El proyecto piloto tuvo como escenario el distrito de Moradabad: la zona 7 de la ciudad de Moradabad (entorno urbano), la aglomeración de Kunderki (entorno rural) y varios hospitales de maternidad.
Cambios destacables Entre julio de 2006 y febrero de 2007 se registraron 9740 recién nacidos, 6369 de los cuales (65%) fueron vacunados por personal del proyecto en las 72 horas siguientes al nacimiento. La cobertura del proyecto (número total de recién nacidos vacunados) se situó entre el 39% (zona 7) y el 76% (Kunderki) del número estimado de neonatos vacunados en las actividades suplementarias de inmunización anteriores.
Enseñanzas extraídas La cobertura de administración de una dosis a los neonatos al poco de nacer fue inferior a la prevista. Se estima que el costo de la expansión fue elevado y su impacto, insignificante. El proyecto, sin embargo, brindó oportunidades para reforzar unos sistemas de seguimiento de los recién nacidos que han permitido aumentar el número de neonatos y lactantes de corta edad vacunados en las actividades suplementarias de inmunización e incluidos en los programas de vacunación sistemática.

ملخص

إعطاء لقاح شلل الأطفال الفموي الأحادي التكافؤ من النمط 1 للولدان: الموجودات في المشروع الارتيادي للتلقيح بجرعة عند الولادة في مقاطعة مراد-أباد، في الهند

المشكلة: ظل انتقال العدوى بفيروس شلل الأطفال تحدياً صحياً عموماً في غربي منطقة آتر باراديش، في الهند، في أواخر عام 2005 وبداية عام 2006. وفي عام 2006، توصلت المجموعة الاستشارية للخبراء المعنية باستئصال شلل الأطفال إلى أنه نظراً لوقوع ذروة انتشار شلل الأطفال بين الأطفال في عمر بين 6 إلى 12 شهراً، فإن إعطاء جرعة من لقاح شلل الأطفال الفموي عند الولادة قد يكون ضرورياً لقطع انتقال العدوى المكثفة بفيروس شلل الأطفال في المناطق المعرضة لخطورة عالية.
الأسلوب: قامت حكومة منطقة آتر باراديش، ومشروع ترصد شلل الأطفال الوطني، ومنظمة الأمم المتحدة للطفولة (اليونيسف) بتنفيذ مشروع ارتيادي للتلقيح عند الولادة ويهدف المشروع إلى تحديد وتلقيح جميع الولدان الجدد

بجرعة من لقاح شلل الأطفال الفموي خلال 72 ساعة من الولادة وذلك سعياً إلى تقييم إمكانية التطبيق عملياً والتأثير المحتمل على المناعة لدى السكان.

الوضع المحلي: أجري المشروع ارتيادياً في مقاطعة مراد-أباد: المنطقة 7 في مدينة مراد-أباد (موقع حضري)، ومجمّع مباني كوندركي (موقع ريفي)، وفي مستشفيات ولادة منتقاة.

التغيرات ذات الصلة: بين شهري تموز/يوليو 2006 وشباط/فبراير 2007، جرى تحديد 9740 مولوداً جديداً، وجرى تلقيح 6369 مولوداً (65%) خلال 72 ساعة من الولادة وذلك عن طريق العاملين في المشروع. وتراوحت نسبة التغطية في المشروع (لكل الولدان الجدد الذين جرى تلقيحهم) بين 39% (في المنطقة 7) إلى 76% (في مجمّع مباني كوندركي) وذلك من العدد التقديري للولدان الجدد الذين جرى تلقيحهم أثناء أنشطة جولات التمنيع التكميلية السابقة.

الدروس المستفادة: كانت التغطية بالتلقيح عند الولادة بين الولدان الجدد أقل من المتوقع. والتكاليف التقديرية للتوسع في التلقيح مرتفعة، وتأثيرها هامشي. وبالرغم من ذلك أتاح المشروع فرصة لتعزيز نظم تتبع الولدان الجدد والتي زادت عدد الولدان وصغار الرضّع الذين جرى تلقيحهم أثناء أنشطة التمنيع التكميلية وتم ضمهم إلى البرامج الروتينية.

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