Measles vaccine effectiveness in standard and early immunization strategies, Niger, 1995
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≪ Safety and immunogenicity of a combined diphtheria-tetanus-acellular pertussis-inactivated polio vaccine-Haemophilus influenzae type b vaccine administered at 2-4-6-13 or 3-5-12 months of age.
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Abstract

Background. An Expanded Programme on Immunization was started in late 1987 in Niger, including vaccination against measles with one dose of standard titer Schwarz vaccine given to infants after 9 months of age. During epidemics an early two-dose strategy was implemented (one dose between 6 and 8 months and one dose after 9 months). From January 1, 1995, until May 7, 1995, 13 892 measles cases were reported in Niamey, Niger.

Methods. A retrospective cohort study was conducted in a crowded area of Niamey at the end of the outbreak to assess the effectiveness of measles vaccine in standard (after 9 months) and early (before 9 months) immunization strategies under field conditions.

Results. Highest measles incidence rates were observed among children <1 year of age. Vaccine effectiveness estimates increased with age at vaccination from 78% with a single dose administered at 6 months of age to 95% at 9 months. Vaccine effectiveness with the early two dose strategy was 93%.

Conclusions. Immunization with a single dose of standard titer Schwarz vaccine before 9 months of age provided higher clinical protection than expected from seropositivity studies. The early two dose strategy is justified in contexts where measles incidence is high before 9 months of age. Our results raise the issue of lowering the recommended age for measles vaccination in developing countries.

BACKGROUND

Despite the availability of a safe and effective vaccine, measles remains a public health problem world-wide. The World Health Organization (WHO) estimates that ~40 million cases and >1 million deaths occur annually,[1] the majority in developing countries.

In African countries high birth rates and high contact rates among infants combined with an early decrease of maternal antibodies result in high incidence of measles during the first year of life.[2] This is of major concern because of high case:fatality ratios in that age group. Few cases occur in infants <6 months of age because of the protection of maternal antibodies. However, infection between 6 and 9 months of age remains a problem in some areas as a result of moderate measles vaccine coverage with one dose given after 9 months.[3, 4]

In developing countries WHO recommends routine immunization at 9 months of age with a single dose of standard titer measles vaccine.[5, 6] In areas at high risk for early measles, WHO recommends an early two dose schedule with one dose between 6 and 8 months and a second dose after 9 months of age.[7] The efficacy of measles immunization with one dose of a standard titer vaccine before 9 months of age is generally assumed to be poor because of studies showing 50 to 80% seroconversion in this age group.[8, 9] The choice of 9 months for routine immunization was recently questioned by authors, suggesting that immunization at 7 or 8 months of age could protect more children.[10, 11] To date there have been no published field trials evaluating the clinical efficacy of early two dose measles schedules in developing countries,[12] and more data on clinical protection are needed.[11, 13]

INTRODUCTION

Niger is a sub-Saharan country with an estimated population of 9.3 million in 1995. The Expanded Programme on Immunization (EPI) was started in late 1987. Measles immunization is based on the Schwarz standard titer vaccine administered as early as 9 months of age. All children younger than 5 years are eligible for immunization. This strategy theoretically switches to an early two dose schedule at 6 and 9 months during outbreaks. A cluster sampling survey was performed in June, 1992, in the capital city of Niger, the Urban Community of Niamey (UCN; mid-1992 population estimate, 466 208). The survey showed an overall measles vaccine coverage of 61% among children ages 12 to 23 months (both one dose and two dose coverage).[3]

A weekly official telegram information system provides the number of measles cases reported by each district of Niger. There is no breakdown by age and deaths are not reported. It is used for early warning purposes. Routine surveillance data showed that three major measles outbreaks occurred in the UCN in the previous decade: one in 1985; one in 1990 to 1991 (3 years after the EPI started) and one in 1995 (Fig. 1). The 1990 to 1991 outbreak accounted for >13 000 cases and an estimated 900 deaths.[3] An early two dose schedule for measles immunization was implemented during that outbreak from March 1, 1991, to June 30, 1991, and the standard immunization schedule was resumed until 1995. A total of 900 cases was reported in the interepidemic period between July 1, 1991, and December 31, 1994. In February, 1995, the official telegram system reported a rise in the number of measles cases from the UCN.

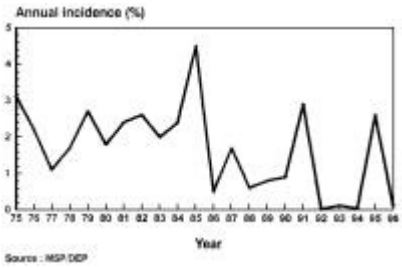

Fig. 1. Annual incidence rates of reported measles, 1975 to 1996: Urban Community of Niamey, Niger. MSP/DEP, Ministère de la Santé Publique/Division de l'Epidemiologie et de la Planification.

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In April, 1995, an outbreak investigation was requested by the National Division of the EPI. This report describes the epidemiologic characteristics of

the outbreak and the results of an observational study of clinical measles vaccine effectiveness (VE) in standard and early immunization schedules.

METHODS

Descriptive epidemiology. Measles cases occurring between January 1 and May 7, 1995, were retrospectively identified with data from the official telegram information system. We also reviewed the clinic log books of 29 of 30 public and private health facilities of the UCN (the dispensary of the civilian prison could not be visited). A measles case was defined as a person diagnosed with measles as written in the clinic log book by attending physicians or nurses. Information collected from the log books included the weekly number of cases by age.

Between January 1 and May 7, 1995, we estimated crude and age-specific measles incidence rates per person month. The age distribution of the cases was also calculated. Population distribution figures from the 1988 census were updated with a 4.9% annual growth rate for the UCN (1995 population estimate, 555 516).[14]

Vaccine effectiveness. Retrospective cohort study. To assess measles VE we conducted a retrospective cohort study in a crowded area of the UCN with a high incidence of measles (quartier Boukoki, estimated population in 1995: 48 000). The study period was defined as January 1, 1995, to the time of the survey (April 25 to May 9, 1995). Each compound of Boukoki was visited (2945 compounds, each including 1 to 13 households), and a census of children <60 months of age resident of the area was performed. Households with no one at home were revisited twice if necessary; 12 households refused to participate in the survey. Children alive and those deceased since January 1, 1995, were included in the census (n = 6919). Information regarding age, sex, vaccination, measles-related symptoms and outcome was collected. Children enrolled in the census and older than 5 months during the study period were eligible for the VE analysis (n = 6188).

Measles status. Measles status was assessed through a mothers' interview using the following case definition: temperature >=38.5°C (if measured, otherwise fever as reported by the mother); and generalized rash lasting >=3 days; and one or more of cough, conjunctivitis or coryza.

Immunization status. Vaccination dates were transcribed from vaccination cards. Children with no card were considered to be unprotected after confirmation by the mother that they had never been vaccinated against measles. Vaccinated children were considered protected 14 days after the injection. Four immunization statuses were defined. Children were considered unprotected if they had never received a dose of vaccine or during the 14 days after the date when they received their first dose; children with standard protection had received a single dose as soon as possible after they had reached the age of 274 days (9 months); children with early two dose protection had received one dose between the age of 183 and 273 days (6 and 8 months) and had also received a second dose after the age of 274 days; children with early one dose protection had received one dose between the age of 183 and 273 days and had not received a second dose by the time of the study.

Exclusion criteria. We excluded from analysis all children whose mothers did not remember whether the child ever experienced measles (n = 5), children with a history of measles before January 1, 1995 (n = 266), children with a

history of measles before 6 months of age (n = 146), children vaccinated before the age of 183 days (n = 77); those having received a second dose within 28 days of the first dose (n = 1); those having had two doses of vaccine before the age of 274 days (n = 15); those with a doubt as to their immunization status (i.e. the mother said the child was immunized against measles but no such vaccination was recorded on the vaccination card or no card was available) (n = 539). Some children had more than one exclusion criterion.

Incidence density rates. VE was calculated by comparing incidence density rates among vaccinated (IRV) and unvaccinated (IRU) children during January through May, 1995. The number of days contributed by each child into the cohort of vaccinated or unvaccinated was computed for each of the following age groups: 6 to 8 months; 9 to 11 months; 12 to 23 months; 24 to 35 months; 36 to 47 months; and 48 to 59 months. Incidence density rates were expressed as a number of cases per child day.

Statistical analysis. Vaccine effectiveness was measured as VE = 1 - (IRV/IRU)[15, 16] and 95% confidence limits were calculated with the approximate Poisson method.[17] A stratified analysis of VE per age group was also performed according to the pooled estimator method.[17] The age of cases was calculated as the age at disease minus 14 days for the incubation period.

All calculations were made with EFFVAC-EPISURV®, a software developed by Epicentre and especially designed for VE analysis with incidence density rates.[18]

RESULTS

Incidence rates in the UCN. From January 1 until May 7, 1995, 11 737 measles cases were reported through the official telegram system whereas 13 892 cases were identified through the review of the clinic log books of the UCN health facilities for the same period. The sensitivity of the official telegram system could therefore be estimated as 84.5%. The peak of the epidemic was observed during the first week of April with >2200 cases notified. The overall incidence rate was 6.25 cases/1000 person months with the highest rates observed among the 6- to 8- and 9- to 11-month age groups (Fig. 2).

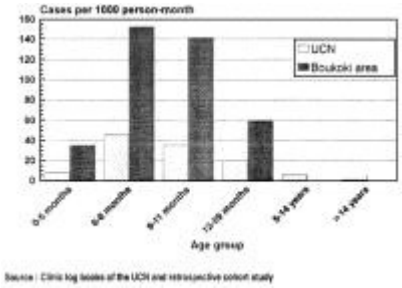

Fig. 2. Estimated measles incidence rates per age group in the Urban Community of Niamey and in Boukoki area, Niger, 1995.

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From the review of the clinic log books, the proportion of cases was 18% in the <1-year age group, 48% in the 1- to 4-year group, 27% in the 5- to 14-year group and 7% in the >14 years group.

Retrospective cohort study in Boukoki. Measles incidence rates. Among the 6919 children <5 years of age enrolled in the retrospective cohort study in Boukoki, 1597 (23.1%) had a history of measles between January 1 and May 9, 1995. The incidence rate was 64.8 cases/1000 child months with the highest estimated rates in the 6- to 8-month and 9- to 11- months age groups (Fig. 2).

Case-fatality ratio (CFR). Information on outcome was provided for 1554 of the 1597 measles cases. Thirty-eight children were reported to have died of measles, 18 of whom were between 12 and 23 months old, giving an overall CFR of 2.4% for children <5 years old and 4.9% for children 12 to 23 months old. The CFR among infants was 1.5%. The average age at death was 22 months (range, 4 to 49 months).

Vaccine coverage. Measles vaccine coverage among children between 6 and 59 months in Boukoki is presented in Table 1. Eighty-five percent of vaccination information was obtained from cards, the remaining 15% was obtained from parental history. Coverage with one dose given at or after 9 months of age was 29% in the 9- to 11-month age group and stabilized around 56% in children 12 to 23 months or older. It did not differ between boys and girls in any age group considered (data not shown). In most age groups fewer than 3% of children had received 2 doses of vaccine, the maximum being 7.4% in children ages 48 to 59 months (Table 1). Among 485 children older than 9 months who had received a first dose between 6 and 8 months, 135 (27.8%) had received a second dose after 9 months. Return rate for the second dose was 54.5% (73 of 134) among children born between July 1, 1990, and January 31, 1991, and who had received one dose between 6 and 8 months of age. Median age at vaccination was 9.9 months (range, 9 to 58 months) for children vaccinated with standard strategy. Median age at receipt of second dose was 12.7 months (range, 9 to 56 months) for children vaccinated with early two dose strategy.

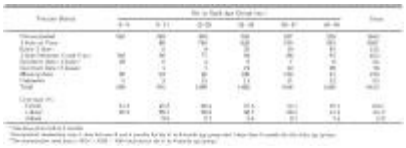

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TABLE 1. Measles vaccine coverage per age group among children ages 6 to 59 months, Boukoki, 1995

Vaccine effectiveness. Overall 5178 children (83.7% of eligible children) met the inclusion criteria for VE analysis.

VE with the standard strategy was 94.5% among children aged 9 to 59 months. VEs per age group ranged between 82.8% for children ages 9 to 11 months and 97.0% for 36 to 47 months (Table 2). The stratified analysis yielded a global VE of 93.9%.

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TABLE 2. Vaccine effectiveness according to the age group and the immunization strategy, Niamey, Niger, 1995

VE with the early two dose strategy was 93.3% among children ages 12 to 59 months (Table 2). VE by age at first dose was 89.5 and 96.7% when the dose was given at 6 and 7 months, respectively. No case occurred in the group who received the first dose at 8 months. VE by age at second dose was 92.8% for a dose given between 9 and 11 months and 96.1% for a dose given after 11 months.

When a single dose of vaccine was given before 9 months of age, VE was 86.9% among children ages 6 to 59 months. The highest value was 93.7% for children ages 12 to 23 months at the time of the study (Table 2). It rose progressively from 66% when the dose of vaccine was administered at 5 months of age to 89% when the dose was administered at 8 months (Fig. 3).

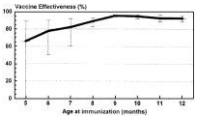

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Fig. 3. Measles vaccine effectiveness according to the month of immunization (single dose strategy) among children younger than 5 years old in Boukoki area, Niamey, Niger, 1995.

Results did not vary when adjusted for age (3 months period) and place of residence at the time of study (data not shown).

VE by sex. When a single dose was given at 6 months, estimated VEs for girls and boys were 65.0 and 87.1%, respectively (chi square 1 = 2.85, P > 0.05). VEs for girls and boys were similar for all the other ages of vaccination.

DISCUSSION

We conducted an observational study of measles vaccine effectiveness after a major urban epidemic in Niger. This measles epidemic 19 occurred after a low incidence period of 4 years. Measles incidence was high among infants. Nonetheless there was a shift toward older cases when comparing the age distribution with the previous outbreak in 1990 and 1991.3

Our results showed satisfactorily high VE with standard and early two dose strategies in all age groups considered. VE values were above the expected range with early one dose immunization and showed an increasing trend as the month of immunization increased.

The main potential bias leading to an overestimation of VE came from the exclusion of children with a history of measles before the outbreak. Indeed

exclusion of vaccine failures but not vaccine successes may falsely decrease the IRV and inflate the VE.[20] However, few children were reported to have had a previous measles history. This was consistent with the very low reported measles incidence in the UCN since the last outbreak in 1991. Another potential bias inflating VE was associated with a higher reporting of measles among unvaccinated children despite the use of the case definition [16] (surveyors aware of the vaccine status and seeking more information about measles for unvaccinated children). Misclassification associated with maternal reporting of measles illness [21] was probably limited because we conducted our survey at the end of the epidemic and measles is a very well-known and feared disease among Nigerian low income populations. Misclassification of vaccination status was more likely to lower the estimated VE. Children with no immunization card were considered unvaccinated. If some were actually vaccinated this would underestimate the IRU and the VE. The CFR observed in Boukoki was low. Although we cannot rule out the possibility that measles-related deaths were underreported or that other mild rash illnesses were reported as measles cases, this may reflect good case management and a widespread use of vitamin A during this outbreak. A measles CFR of 3.3% was recently reported in an urban outbreak in Nigeria.[22]

Problems of return rate for the second dose have been put forward as a major limitation to the use of the early two dose strategy, especially in countries with poor immunization services and weak health infrastructures.[12] After the 1991 measles outbreak in the UCN, Malfait et al.[3] found a return rate of 67% before 24 months of age and similar results in Mozambican refugee camps in Malawi. In our study the return rate was low. However, 70% of children immunized before 9 months were born after the 1991 outbreak, in a context with no recommendation of an early two dose strategy and no incentive to revaccinate children immunized too early. When restricted only to children eligible for the two dose strategy in 1991, the return rate was almost 55%. Because of the reasonably high levels of VE before 9 months of age, an early two dose strategy is justified in contexts where measles incidence is high under 9 months of age, even if the return rate does not exceed 50%.

If our results can be generalized to other countries, our observations raise important questions about measles vaccination policy in Africa. Current measles elimination strategy in the Americas relies on routine vaccination with one dose and targeted supplementary vaccination activities. Addition of a second dose is not considered an appropriate strategy for countries where large segments of the population do not have access to routine health services and where many children do not attend school.[23] Mathematical modeling studies show that a two dose schedule is beneficial only when there is a need to increase net vaccine efficacy, after coverage has been maximized with a one dose schedule.[24] Some authors now suggest vaccinating children against measles at <9 months of age in developing countries.[10, 25, 26] An EPI has been implemented for almost 15 years in most developing countries. More and more children are expected to be born to vaccinated mothers, with lower and more short-lived measles antibody titers than those born to mothers with natural immunity.[27, 28] Their seroconversion rate is greater when a standard titer vaccine is administered.[29, 30] An increase in VE at younger age can therefore be

expected in populations where good coverage is maintained. Furthermore if immunized children have a milder illness,31 it could be justifiable to give the vaccine at 6 months of age despite reduced effectiveness. If the primary objective is to decrease measles severity and measles-associated mortality, it might be better to start vaccination before 9 months. In addition coverage might be easier to increase with an earlier vaccination. If the objective is measles elimination, the current strategy appears well-founded. But is measles elimination a realistic objective for the near future in the current context of some African countries? For more than 10 years recommendations have emphasized the need to increase coverage to >90% at 9 months of age,32-34 but measles coverage remains stubbornly below 50% in many African countries.1 For those countries the potential benefit from an early two dose schedule or a lower age at immunization should be further studied.

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