



# Lower Coverage Rates of Full Rotavirus Vaccine Series in Libyan Children: A Prospective Cross-Sectional Study, 2016

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## Abstract

**Background:** There are little data on the current condition of national immunization programme (NIP) in Libya. In 2013, pentavalent rotavirus vaccines were added to the NIP. Incomplete rotavirus vaccine series may result in lower vaccine effectiveness. The study aimed to assess timeliness and coverage rates of routine NIP vaccinations including the newly introduced rotavirus vaccine in Libya.

**Methods:** A prospective cross-sectional study of children aged 0 to 18 months was carried out in vaccination centers of two north-western cities. Data were collected during Nov-Dec 2016 from vaccination cards of children. Child age and doses received in previous visits were documented.

**Results:** Overall, we included 1023 children assessed in 29 visits at six vaccination centers. In children aged 18 months, coverage rates for all doses of BCG, OPV, HepB, pneumococcal, Meningococcal and MMR vaccines exceeded 95%. Coverage rates for second and third doses of rotavirus vaccines were 89% and 68%, respectively. Most (75%) children who missed the third dose of rotavirus vaccine were aged >8 months when at the time of appointment for the third dose.

**Conclusion:** Overall, the coverage rate for routine vaccination in children assessed at immunization centers in northwest Libya was high. Lower coverage of full pentavalent rotavirus vaccine series may have been the result of exceeding the age restriction. Measures to improve timeliness of vaccination appointments should be assessed. Lifting the age restriction on rotavirus vaccines should be considered for at-risk population.

**Keywords:** Routine vaccination; Coverage rate; Rotavirus vaccine; Age restrictions; Libya

## Introduction

Vaccines play a significant role in averting the global disease burden, saving more than 2 million lives every year (1, 2). Vaccination is safe, effective and recommended by WHO and the Centers for Disease Control and Prevention (CDC) as well as many other organizations (2, 3). Two oral live-attenuated rotavirus vaccines are widely available: RotaTeq, a three-dose human-bovine reassortant pentavalent vaccine licensed in 2006; and Rotarix, a two-dose human attenuated mon-

ovalent vaccine licensed in 2008 (4-6). Rotavirus vaccines were shown to substantially reduce the burden of severe gastroenteritis in a variety of settings including high and low income countries (7-14). Both rotavirus vaccines are safe and effective against severe rotavirus infection (5, 6, 11, 12, 15-18).

Rotavirus vaccine series should be initiated by age of 15 wk and completed before 32 wk of age because of potential increased risk for intussus-

ception. These restrictions may adversely vaccine impact due to lower coverage rates, particularly in the developing countries since the delay is common (13, 19-23). In low and low-middle income countries with high infant mortality rates, removing age group restrictions for rotavirus vaccine may potentially avert 154 rotavirus deaths for only one death could occur by unrestricted schedule of rotavirus vaccine (22).

In Libya, the last update of childhood vaccination was in Oct 2013 in which the pentavalent rotavirus vaccine (RotaTeq) and conjugated pneumococcal vaccines have been added to the routine vaccination schedule (24, 25). Rotavirus vaccine age restrictions were implemented in Libya and no doses are allowed after age 32 wk (26). Both vaccines were introduced through national immunization program (NIP) which currently provides 13 compulsory vaccines given from birth to 15 yr old free of charge for citizen and foreigners living in the country (26, 27). Only public health vaccination centers are permitted by the Ministry of Health to carry out vaccination on infants and children (28). The National Centre for Disease Control (NCDC) has the technical legal authority to guide the NIP by providing technical support and training as well as estimate the coverage rate of all vaccines given by NIP (28). Currently, the NCDC estimates the coverage rates of routine vaccinations based on monthly reports and population data. Because the country has been suffering from civil unrest resulting in internal displacement, there are limited data evaluating NIP and specifically coverage rates. This study aimed to assess timeliness and estimate the coverage rates of routine vaccines and the effect of the delay of time visit for routine rotavirus vaccination appointment through NIP.

## **Materials and Methods**

This was a cross-sectional study conducted prospectively to estimate the coverage rates of 13 vaccines given to children from birth to 18 months old and assess timeliness of rotavirus vaccine doses. The study was conducted at NIP public vaccination centers, children in two big

cities, Alkhoms and Zliten located in north-western region of Libya. The population of the two cities is estimated at 420,000 (7% of the estimated total population of Libya). Six public vaccination centers were randomly in the two cities: 3/13 (23%) vaccination centers in Alkhoms and 3/15 (20%) in Zliten.

### **Data Collection**

Data were collected from Nov 13, 2016, to Dec 28, 2016. Immunization sessions were scheduled once or two times a week in each center. Researchers visited the centers in 29 times for data collection. Vaccination cards of children were abstracted during the vaccination meeting using a standardized data collection questionnaire.

All children in any age under 18 months who came to have vaccine during the date of the site visit were included in the study. According to the NIP, children should receive vaccinations at 7 appointments scheduled at ages: birth, 2 months, 4 months, 6 months, 9 months, 12 months and 18 months (Table 1). During the vaccination meeting, current child's age (in weeks) and dates (age) at previous and current required vaccine doses were documented from vaccination card.

### **Data Analysis**

The coverage rate by vaccine and dose was calculated as the proportion of children who received the vaccine recommended for the age-appropriate appointment divided by the number of children who attended the appointment. The proportion of vaccinated children by age was calculated by dividing the number of vaccinated children (numerator) of all children who visited the center who were eligible to be vaccinated (denominator) by child age (in weeks). Cumulative proportion vaccinated was plotted by vaccine and child age in weeks.

### **Ethics**

Medical Technology College at the University of Elmergib has provided official letters for conducting the research. Management of vaccination centers and parents gave us permission for data collection, and oral consent was obtained from child's parent or legal guardian before enrolment.

**Table 1:** Routine immunization schedule in Libya (27)

<i>Age</i>	<i>Vaccine</i>
Birth	BCG (Birth dose), OPV (Zero dose), HepB (Birth dose)
2 months	Hexa (First dose), Pneumococcal (First dose), Rota (First dose)
4 months	Hexa (Second dose), Pneumococcal (Second dose), Rota (Second dose)
6 months	Hexa (Third dose), Rota (Third dose)
9 months	Meningococcal (First dose), OPV (Booster dose)
12 months	MMR (Basic dose), Meningococcal (Second dose), Pneumococcal (Third dose)
18 months	DTaP (Booster dose), MMR (Revaccinate), OPV (Booster dose)

## Results

Overall 1,023 children were included in the study: 478 from Alkhoms city and 545 Zliten city. Cov-

erage rates of vaccines for birth age group were high, calculated as 100% for BCG Birth dose, 99.9% for OPV zero dose and 98.8% for HepB birth dose (Table 2).

**Table 2:** Coverage rates of all compulsory vaccinations (birth to 18 months)

<i>Age / Vaccine</i>	<i>No. of Im- munized</i>	<i>No. of Non- immunized</i>	<i>Total</i>	<i>(%)</i>	<i>Range (%)</i>
			Birth		
BCG (Birth dose)	1,02	0	1,02	100	100
	3		3		
OPV (Zero dose)	1,02	1	1,02	99.9	99.4 - 100
	2		3		
HepB (Birth dose)	1,01	12	1,02	98.8	96.3 - 100
	1		3		
			2 Months		
Hexa (First dose)	1,01	7	1,02	99.3	98.8 - 100
	6		3		
Pneumococcal (First dose)	983	40	1,02	96	90.4 - 99
			3		
Rota (First dose)	1,00	15	1,02	98.5	97.5 - 99.3
	8		3		
			4 Months		
Hexa (Second dose)	788	29	817	96.4	95 - 98.9
Pneumococcal (Second dose)	786	31	817	96.2	95.2 - 96.9
Rota (Second dose)	730	87	817	89.4	86.9 - 95.4
			6 Months		
Hexa (Third dose)	618	24	642	(96.3)	94 - 100
Rota (Third dose)	434	20	642	(67.6)	51.8 - 85
		8			
			9 months		
Meningococcal (First dose)	468	13	481	(97.3)	95.6 - 100
OPV (Booster dose)	466	15	481	(96.9)	94.9 - 100
			12 Months		
MMR (Basic dose)	309	5	314	(98.4)	97.1 - 99.4
Meningococcal (Second dose)	304	10	314	(96.8)	94.9 - 98.3
Pneumococcal (Third dose)	310	4	314	(98.7)	97.8 - 99.4
			18 Months		
DTaP (Booster dose)	136	1	137	(99.3)	-
MMR (Revaccinate)	136	1	137	(99.3)	-
OPV (Booster dose)	136	1	137	(99.3)	-

Coverage rate of other routine vaccines except rotavirus vaccine for age groups from 2 months to 18 months were high (range 95%-99%). Coverage for doses 1,2 and 3 of rotavirus vaccine were 98.5%, 89.4% and 68%, respectively. Timeliness of routine rotavirus, pneumococcal pneumonia and Hexa vaccination at age of 2, 4

and 6 months were presented in Figs. 1, 2 and 3 which illustrated the delay in vaccination appointments. While the proportion of children vaccinated with Hexa vaccine continue to rise after age 32 wk that is not the case for the third dose of rotavirus vaccine.

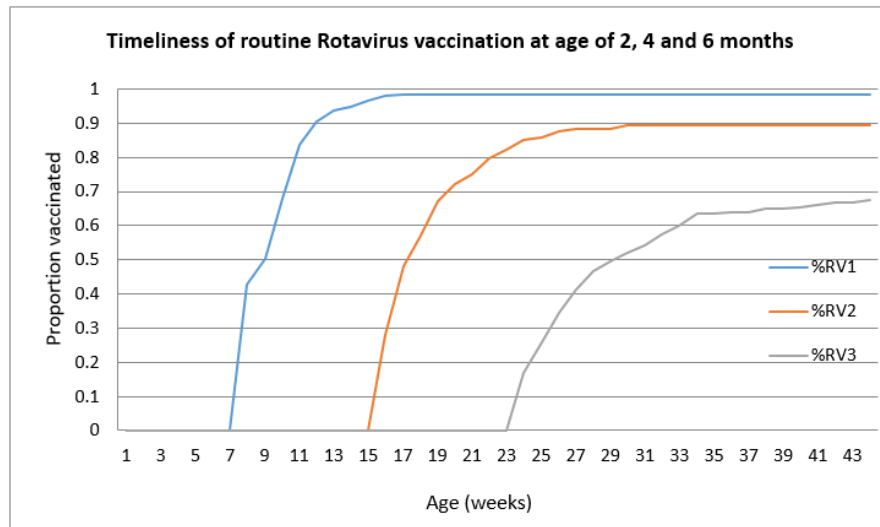


Fig.1: Proportion vaccinated by infant age at routine rotavirus vaccine through NIP, northwest Libya, 2016 (N=1023)

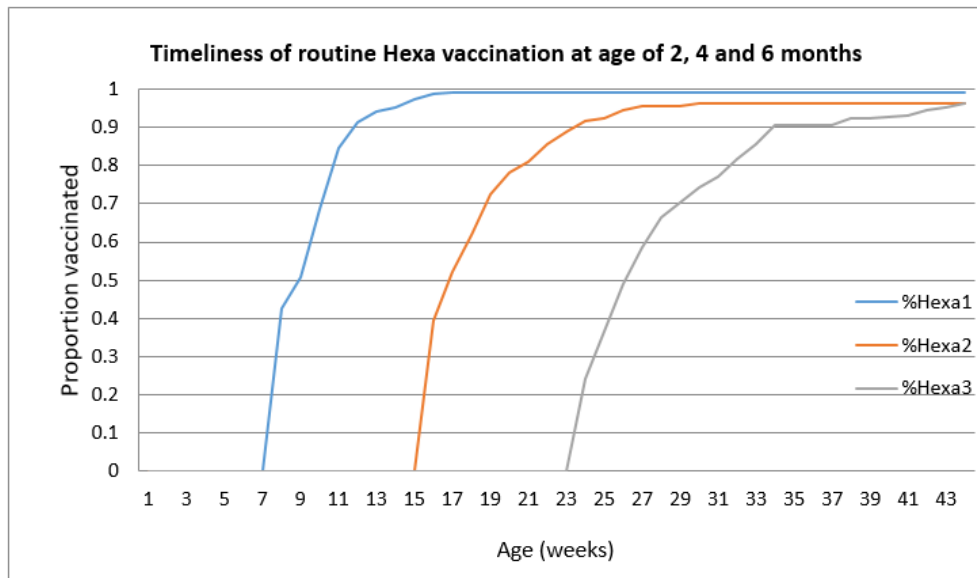


Fig. 2: Proportion vaccinated by infant age at routine Diphtheria - Tetanus - Pertussis - Haemophilus influenza - Hepatitis B - IPV (Hexa) vaccines through NIP, northwest Libya, 2016 (N=1023)

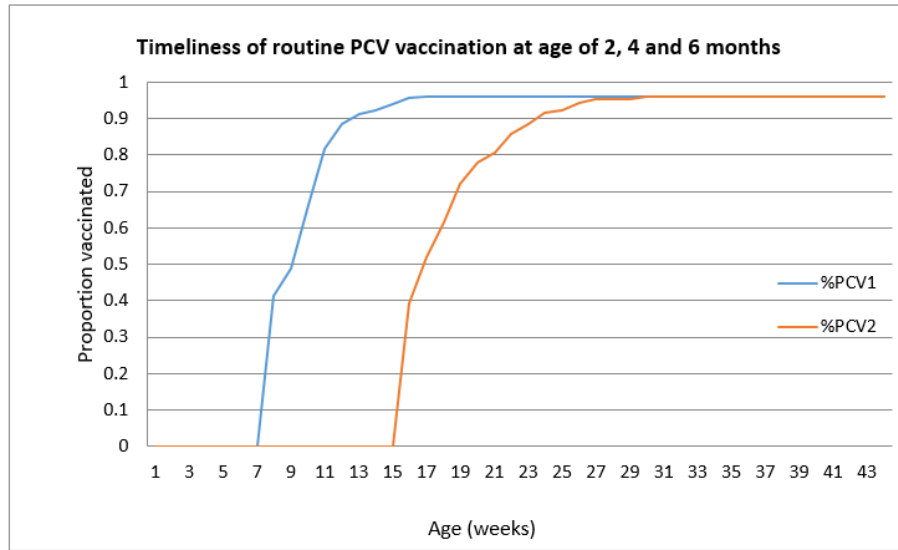


Fig. 3: Proportion vaccinated by infant age at routine Pneumococcal Pneumonia vaccine (PCV) vaccine through NIP, northwest Libya, 2016 (N=1023)

## Discussion

We carried out a cross-sectional study in two cities located in north-western of Libya to document the timeliness and coverage rate of routine vaccination through NIP among children aged 18 months and under. The coverage rate of routine vaccine through NIP were high (95%-100%) except rotavirus vaccine in second and third doses. Lower coverage of second (89%) and third (68%) doses of rotavirus vaccine were mostly attributed to delay in attendance for immunization appointments and exceeding age restrictions.

Prior to rotavirus vaccine introduction, rotavirus disease burden in Libya was substantial (29). In the population we studied complete pentavalent rotavirus vaccine series documented on only two-thirds of eligible infants compared with much higher completion rates for other routine vaccines. Previous studies have shown lower rates of pentavalent rotavirus vaccine series completion compared with other recommended vaccines (23, 30, 31). This discrepancy is unlikely to have been the result of vaccine supply shortages as higher coverage was documented for dose 1 of rotavirus vaccine. The instructions of vaccination provided

from NCDC to all vaccination centers informed that the last age to vaccinate the child by rotavirus is 32 wk (32). The significant low coverage rate of rotavirus vaccine in the third dose was possibly a result of exceeding the age restriction for rotavirus vaccine. Lower coverage rates of the two-dose RV1 rotavirus vaccine compared with DTP-Hib coverage was described in a report from Brazil (33). In this report, age restrictions imposed on rotavirus vaccines contributed to lower coverage compared with other vaccines and suggested developing strategies to improve timeliness of routine immunizations. Similar observations were made in El-Salvador, but to a lesser extent in Norway were introduction of universal rotavirus vaccination did not result in lower coverage rates (34, 35).

The NCDC issues the coverage rates of routine vaccinations annually nation-wide, based on the estimated monthly population statistics and administrative reports. Official coverage rates report, including three doses of rotavirus vaccine, issued by NCDC in 2015 were in range 90%-95% for most vaccines except MMR (87.2%) (36). Overall, the coverage rates of routine childhood vaccination are still in good performance except

for rotavirus vaccine. Coverage rates for rotavirus vaccine in the present study were lower than NCDC reported coverage rates. However, NCDC reporting could be affected by change in population caused by internal doses a result of civil unrest in the country. There were no studies conducted to assess coverage rates based on children's vaccination cards from vaccination centers or house to house surveys in Libya. Thus, although we were only able to study two cities, our findings consist of the most updated information and maybe generalizable because the demographics and traditions are very similar across Libya.

Our study has several limitations. We studied children at immunization centers and over-representation of population with good accessibility and adherences probable. Due to current condition in Libya, a household survey was not feasible. Prospective assessments and surveillance are essential to evaluate the coverage rates, as reported by NCDC. We did not collect data on possible reasons for being late to or missing immunization appointments. This assessment is planned in the near future.

## Conclusion

The lower rates of coverage for complete rotavirus vaccine series was attributed to the lack of parent adherence for vaccination center appointment. High coverage of first rotavirus vaccine doses and other vaccines in children assessed at immunization centers attests to functional vaccination management. Children with good access probably are well immunized. Continued evaluation activities are critical to monitor the NIP during the present economic decline and insecurity situation in the country.

## Ethical considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

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## Conflict of interests

The authors declare that there is no conflict of interests.

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