**The performance of the Expanded Programme on Immunization in a rural
area of Mozambique**

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ABSTRACT

Vaccines are an effective public health measure. Vaccination coverage has improved in Africa in the last decades but has still not reached WHO/UNICEF target of at least 90% first-dose coverage for vaccines in the Expanded Programme on Immunization (EPI) implemented in Mozambique in 1979. There are concerns about reliability of vaccination coverage official data from low-income countries, and inequities in vaccine administration. We randomly sampled 266 under-five years children from Taninga, a poor rural area in Southern Mozambique under a Demographic Surveillance System and collected data directly from the individual national health cards when available (BCG, DTP/HepB/Hib, Polio, Measles). We also collected data on socio-economic variables through an interview. Overall, only 5% of the participants did not receive all the doses of the vaccines included in the EPI in a timely manner (overall vaccination coverage 95%, 95%CI: 93.5%-95.5%). The socio-economic status was homogenously low and no differences were found between vaccinated and unvaccinated children. Vaccination coverage in Taninga was very high, despite the low socio-economic status of the population. The high performance of the EPI in Taninga is an encouraging experience for achieving high vaccination coverage in low-income rural settings.

KEYWORDS

Immunization Programs; Vaccination coverage; DTP3; Children; Developing Countries.

1. BACKGROUND

Vaccines are amongst the most cost-effective public health measures currently available in developing countries (Deogaonkar et al., 2012) where they prevent 2.5 annual million deaths (WHO et al., 2009). Vaccination coverage has improved during the last decade. As an example, average coverage of DTP3 (3 doses of diphtheria, tetanus and pertussis vaccine) was 50% in Africa in 1996 and 72% in 2012 (World Health Organization and UNICEF, 2013). A reason for this is that, since 2000, the Global Alliance for Vaccines and Immunisation (GAVI) has supported a growing number of countries (73 in 2010) through a performance-based grant programme to achieve WHO/UNICEF recommended target: at least 90% first-dose coverage for the vaccines included in the Expanded Programme of Immunization (EPI) in 2015 (Le Gargasson et al., 2013; United Nations, 2013). The “Reaching Every District” (RED) WHO approach, implemented in Africa since 2002, has also contributed to improve childhood immunization services increasing coverage rates from 73% to 94% for different antigens in 2009 worldwide (Tao et al., 2013). The continuous uptake of vaccination will avert over 20 million deaths during the 2011-2020 period worldwide, 52% of which will be in African countries (Lee et al., 2013).

Despite the encouraging figures, two main concerns have arisen. First, different authors have questioned the quality and validity of the official data from low-income countries (Bosch-Capblanch et al., 2009; Murray et al., 2003; Ronveaux et al., 2005). The verification factor quantifies under or over-reporting of vaccine doses at a district level. It is based on the ratio of re-counted DTP3 doses in the health unit records by the number of DTP3 doses reported by the health unit to the district (Ronveaux et al., 2005). Audits of official data in countries from Africa, America, and Asia show a low verification factor in vaccine administration, which hampers the ability to track the performance of the programmes and to detect failures and

weaknesses (Bosch-Capblanch et al., 2009; Murray et al., 2003; Ronveaux et al., 2005). Furthermore, the official data of vaccination coverage is 20 percentage points superior to data obtained through Health and Demographic Surveillance Systems (Murray et al., 2003; Tao et al., 2013). The second concern is that global figures could hide inequities in public health interventions coverage, which could jeopardize the achievement of Millennium Development Goals (MDG) 1 -Eradicate extreme poverty and hunger- and 4 -Reduce child mortality- (Lauridsen and Pradhan, 2011; United Nations, 2013). Regarding immunization (DTP3, Measles, fully immunized), differences of coverage between the poorest and the richest quintile from the same country can be as considerable as 20% (Barros et al., 2012; United Nations, 2013). Determinants impairing vaccination coverage are distance to vaccination site, waiting time, unavailability of treatment services, cost, low parental education level and large family size (Falagas and Zarkadoulia, 2008; Nkonki et al., 2011; Rainey et al., 2011; Van Malderen et al., 2013).

Mozambique is one of the poorest countries in the world. In 2011, it had the fourth lowest Human Development Index worldwide (UNPD, 2013). The EPI was introduced in Mozambique in 1979, and the RED approach in 2008. However, RED has only been implemented in 66 out of 144 Mozambican districts (Ministry of Health, 2011). The verification factor of the vaccines administered (DTP3) was less than 0.70 in 2002-2003, which implies over-reporting and inability to verify the administration of DTP3 (Ronveaux et al., 2005). Furthermore, among 54 countries monitored by Countdown to 2015, Mozambique was the 14th in terms of income-specific inequity in measles vaccine administration (Barros et al., 2012). The official national estimate for DTP3 coverage was 76% in 2011 (GAVI Alliance, 2013). Administrative data showed DTP3 coverage of 49.2% in Maputo province, and 90.2% in Maputo city, which provides an idea of differences in rural and urban settings

110 (Ministry of Health, 2011). It is important to determine the validity of this figure before
111 introducing new vaccines.

112

113 The aim of the study was to determine the coverage of the EPI vaccines in a rural area of
114 southern Mozambique included in a Demographic Surveillance System (DSS), and to
115 describe the socio-economic determinants of vaccination within this area.

116

2. MATERIAL AND METHODS

2.1. Study population

The study was conducted by the *Centro de Investigação em Saúde de Manhiça* (CISM), located in Manhiça, Maputo Province, Southern Mozambique from September to November 2012. CISM runs a DSS in its study area and a morbidity surveillance system at Manhiça District Hospital (MDH) and other health posts in the area. Manhiça District Hospital and the peripheral health posts are facilities from the national public health system that receive support from CISM. The DSS covers a 500-km² area with 90,000 people, who are individually given a unique and permanent identification number, and 18,000 households, which are geopositioned. A field worker fills a demographic questionnaire at each household at least once a year. Independently from the DSS, each child has a national health card with information about vaccination. Taninga is a rural area of the DSS 30 km north from Manhiça, and it only counts with one health post providing clinical assistance to the neighbouring population. CISM does not directly intervene in EPI administration, but it provides support to Taninga health post with health workers (medical agents, microscopists and nurses) since 2005. Since then, the health post has been open and available 24/7 for medical assistance. CISM has also established community councils with community leaders of the study area on a regular basis. Taninga was chosen as the site for this study as example of a very rural area. At the time of the study, there were 1096 children under five years of age in Taninga according to the DSS.

2.2. Selection of participants

This sub-analysis is part of a larger study designed to determine the prevalence of viral infections among healthy children in the community, approved by the Institutional Ethics Committee of CISM, the National Ethics Committee of Mozambique, and the Institutional

Review Board of Hospital Clinic in Barcelona. Sample size was calculated according to the primary endpoint of the larger study, and thus was not based on any predefined hypothesis on expected vaccination coverage rates. We obtained the sampling frame selecting from the DSS database all the children aged less than 5 years living in Tanninga. Selection of participants was done by simple random sampling using STATA with the permanent identification number as identifier. A field worker visited the participant household to invite the legal guardian and the child. If the legal guardian was absent during the visit, a maximum of two more visits were done to invite the child. In case of repeated absence or refusal to participate in the study, another child of similar age and household location was approached. If the guardians accepted the invitation, they were taken with their child to the Tanninga health post on the next day. Guardians were interviewed and children examined only after they had signed the informed consent form.

2.3. Vaccines received and definitions of correct vaccination

The EPI in Mozambique includes a Bacille Calmette-Guerin (BCG) and an Oral Polio Vaccine (OPV) dose at birth, a tetra/pentavalent (Hepatitis B, Diphtheria, Tetanus, Pertussis, plus *Haemophilus influenzae b* since august 2009) at weeks 6, 10 and 14, and a Measles vaccine single dose at month 9 (Table 1). Pneumococcal conjugate vaccine (PCV-10) has recently been introduced (10th April 2013) but was unavailable at the time of the study. Vaccination is scheduled with the mother at child's birth when the first doses are given and successive vaccinations are done at the nearest health post and recorded in the patient's individual national health card. With the exception of Maputo, the country's capital, there is virtually no private sector in which vaccines can be obtained outside the public health sector. Only valid doses were considered when estimating vaccination coverage, that is, only age-appropriate doses administered that respected recommended intervals between doses. A delay

in vaccination less than 15 days was considered age-appropriate. Data on vaccination was obtained from vaccination cards examined by the study clinician.

2.4. Other data

Years of education and wealth were used as proxies of socio-economic status. Data on household assets and amenities were collected as proxies of wealth. A principal component analysis was performed to determine which assets could be used to build a meaningful SES index. Socio-economic data were obtained through an interview of the legal guardian conducted by a field worker fluent in the local language (changana). Variables selected were (i) related to the house; (ii) related to facilities (water source, availability of electricity, fuel used to cook); and (iii) related to parental education and employment. The education level (primary, secondary, superior) was defined as having completed at least 1 year of primary, secondary, or superior education. Employment was defined as receiving a salary for their professional activity, thus excluding subsistence farming.

Children were examined by the study clinician, and measured and weighted by the study nurse. Mothers' HIV status was recorded from the vaccination cards. Distance to health facility was calculated using the households and Tanninga health post coordinates with ArcGIS® version 9.3.

2.5. Data management and statistical analysis

Questionnaires were double entered in the study database using OpenClinica. Nutritional status was based on weight-for-age Z scores (WAZ), calculated using the least mean square method and the 2000 CDC Growth Reference (Centers for Disease Control and Prevention, 2000). Data were analysed using Stata® (Stata Corp., College Station, TX, USA; version 12.0). The chi-square test and the t-student test were used when appropriate.

3. RESULTS

3.1. Population and socio-economic data

We approached 266 children and recruited 206 (Figure 1). Among participants, mild malnutrition was frequent (31.7%), 20.4% of the mothers were HIV positive and 86.6% were unemployed (Table 2). Overall, 38.5% of the mothers were uneducated, and only 11% had fulfilled at least one year of secondary school. Regarding facilities, 96.5% of the households had traditional latrines, 98.5% had the cooking space located outside, and 97.9% used wood for cooking.

3.2. Vaccination coverage

Two hundred (97.1%) vaccination cards were available. Among them, 190 (95%) children had correct vaccination for their age considering number and timing of doses (Table 3).

There were no significant differences on vaccination coverage by sex (coverage among males 94.3%; coverage among females 95.7%; $p=0.64$). Vaccination coverage was consistently high by age group (95% in the younger group, 100% in the 6-12 months group, and 93.5% in the oldest groups). The DTP3 coverage (coverage of third dose of DTP, variable used by GAVI and WHO/UNICEF) was calculated for comparison purposes. Among 178 children of complete DTP vaccination age (14 weeks of age plus 15 days of accepted vaccination delay), the DTP3 coverage was 98.3% (95% CI: 97.35% - 99.3%).

3.3. Association between vaccination coverage and socio-economic data

The distribution of socio-economic variables within different households was exceedingly uniform, hindering the development of a reliable socio-economic score through principal component analysis (Table 4). Combined with this socio-economic uniformity, the number of non-vaccinated children was too low to allow proper comparisons of socio-economic

218 variables between groups. However, children from households with piped water had
219 significantly higher vaccination coverage than children from households obtaining water from
220 a well (97.6% (120/123) vs. 90.9% (70/77); $p=0.036$).

221

4. DISCUSSION

According to official data from Mozambique's government (Demographic National Questionnaire 2011), vaccination coverage in rural areas nationwide was 89.9% for BCG, 72.4% for DTP3, 70.9 % for OPV, and 77.7% for measles. Compared to national vaccination coverage in rural areas, the vaccination coverage found in this study is very high. Inequity in vaccination affects illiterate, poor families especially if they have 3 or more children (Lauridsen and Pradhan, 2011; Nkonki et al., 2011; Van Malderen et al., 2013). Tanninga is a rural area where the main economic activity is subsistence farming. Men from Tanninga frequently migrate to South Africa to work in the mining industry that employed up to 70,000 Mozambican miners from Maputo and Gaza provinces in 2012 (Barwise et al., 2013). Study children belong to low-income, uneducated, large families, which make them vulnerable regarding to vaccination coverage. Our data show a different and unexpected situation. The vaccination coverage of the oldest group reflects good immunisation services even 5 years before the survey was done.

In poor populations, indirect costs of vaccination such as day of work loss and transport costs are dissuasive for the families, even if vaccination itself is free (Falagas and Zarkadoulia, 2008; Rainey et al., 2011). A clustered randomised trial in a rural area in India showed a vaccination coverage of 39% in the villages where a humble incentive was given to the families (1 kg of raw lentils and a set of metal plates) in the immunisation camps when their children were vaccinated compared to a coverage of 6% in the villages where no incentive was given nor immunisation camps were held (Banerjee et al., 2010). In Tanninga, no incentive is offered to the families and the indirect costs of vaccination do not seem to dissuade families to have their children vaccinated. In the study done in India, the reliability of the

immunisation camps held monthly seemed to be an encouraging factor for vaccination. In the villages where reliable immunisation camps were held but no incentive was given, the vaccination coverage was significantly higher than the coverage in villages without intervention (Banerjee et al., 2010). In an econometric study based on data from DSS from developing countries including Mozambique, the authors conclude that a higher density of health workers, especially nurses, is related to higher vaccination coverage (Anand and Barnighausen, 2007). The effect of reliability of health facilities on vaccination coverage found in the Indian trial might also apply in a Sub-Saharan setting, although we have no data on vaccination coverage before 2005 to support this hypothesis. The effect of health information provided to the communities on vaccines acceptance has not been assessed in Taninga.

Data of this study are encouraging for the success of pneumococcal vaccine introduction in Taninga, which was implemented in April 2013, although national vaccination coverage cannot be extrapolated from our study. High coverage benefits directly immunised children but also the community through herd immunity. As a recent experience, the *Haemophilus influenza* b (Hib) vaccine introduction in August 2009 led to a significant fall of the number of children admitted to the Manhiça District Hospital with 24 Hib positive blood cultures per year prior the introduction of the vaccine (2001-2009) down to 4.9 cases per year after the introduction (2010-2012, unpublished data).

This study has some limitations. Firstly, comparison between groups is difficult due to the sample size, uniformity of socio-economic determinants and high vaccination coverage. In any case, vaccination coverage and socio-economic data are valid for descriptive purposes since the sample was obtained through simple random sampling of a DSS determined

population. The second limitation is the limited external validity of these data as the population in Tanninga is not representative of the whole population in Mozambique, but this was not the objective of the study. Vaccination coverage could have been overestimated due to the exclusion of 6 children without vaccination cards. If all of them were incorrectly vaccinated, the vaccination coverage would be 92.2% (190/206), which is still higher than expected. Finally, this study cannot determine reasons (such as being part of a DSS area and the special attention it provides) for this unexpected high vaccination coverage.

5. CONCLUSIONS

Vaccination coverage in Tanninga is very high, despite its population being particularly vulnerable to low coverage in terms of socio-economic determinants (poor, uneducated, large families in a rural sub-Saharan area). Understanding the particularities of this population could be useful to improve the vaccination coverage nationwide, and should be explored in an appropriate study. The high performance of the EPI in Tanninga is an encouraging experience for achieving high vaccination coverage in low-income rural settings.

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8. FIGURE TITLE

Figure 1. Study profile

9. SUPPLEMENTARY MATERIAL

Supplementary Figure 1. Study area location in Manhiça district, Southern Mozambique

Table 1. Immunization schedule in Mozambique

Age	Visit	Antigen
Birth	1	BCG, OPV0
6 weeks	2	DTP-HepB1-Hib1*, OPV1
10 weeks	3	DTP-HepB2-Hib2*, OPV2
14 weeks	4	DTP-HepB3-Hib3*, OPV3
9 months	5	Measles

BCG = Bacille Calmette-Guerin; OPV = oral polio vaccine, DTP = Diphteria, Tetanus, Pertussis; HepB = Hepatitis B; Hib = *Haemophilus influenza* type b

* Hib introduced in August 2009

Table 2. Descriptive of participants (N=206)

Variable	Frequency; n(%)
Sex, Male	108 (52.4)
Nutritional status (weight-per-height, Z-score SD)	
Adequate	133 (64.9)
Mild malnutrition (-1 < Z-score ≤ -3)	65 (31.7)
Severe malnutrition (Z-score < -3)	7 (3.4)
Maternal HIV status	
Negative	121 (58.7)
Positive	42 (20.4)
Unknown	43 (20.9)
Mother's unemployment	178 (86.4)
Father's unemployment	25 (12.1)
	Median (interquartile range)
Age (months)	15.5 (7.9-23.9)
Number of children per mother	3 (2-4)
People living in the household	7.7 (5-9.5)
Distance to health post (meters)	1916 (1122 - 2969)

Table 3. Vaccination coverage for vaccines included in the Expanded Programme on Immunization in children under-five years of age from Tanninga (N=200)

Antigen	Vaccination coverage (95% CI)
BCG	100%
DTP/HepB +/- Hib	98% (97-99)
Oral polio	97.5% (96.4-98.6)
Measles	96.5% (95.2-97.8)

BCG = Bacille Calmette-Guerin; DTP = Diphtheria, Tetanus, Pertussis; HepB = Hepatitis B; Hib = *Haemophilus influenza* type b

Table 4. Socio-economic characteristics, by vaccination status

	Correctly vaccinated 190 (95%)	Not correctly vaccinated 10 (5%)	p-value
Material of the house; n (%)			
Brick	74 (39)	3 (30)	0.91
Sheet iron	113 (59.5)	7 (70)	
Shack	3 (1.5)	0 (0)	
Toilet type; n (%)			
Traditional latrine	184 (96.8)	9 (90)	0.17
Improved latrine	3 (1.6)	0 (0)	
None	3 (1.6)	1 (10)	
Kitchen located outside; n (%)	187 (98.4)	10 (100)	0.83
Average occupation per sleeping room; median (IQR)¹	3.5 (2.6-4.5)	4 (3.3-4.5)	0.93
Water source; n (%)			
Piped water	120 (63.2)	3 (30)	0.036
Well	70 (36.8)	7 (70)	
Electricity unavailable; n (%)	135 (71)	9 (90)	0.19
Fuel used to cook; n (%)			
Wood	176 (92.6)	10 (100)	0.67
Coal	3 (6.8)	0 (0)	
Electricity	1 (0.6)	0 (0)	
Distance to health post (meters); median (IQR)	1849 (1095-2934)	2268 (1382-3218)	0.48
Mother's education; n (%)			
None	72 (37.9)	5 (50)	0.47
Primary	96 (50.5)	5 (50)	
Secondary	22 (11.6)	0 (0)	
Father's education; n (%)			
None	47 (24.7)	3 (30)	0.53
Primary	108 (56.8)	7 (70)	
Secondary	33 (17.4)	0 (0)	
Superior	2 (1.1)	0 (0)	
Mother's unemployed; n (%)	160 (86)	10 (100)	0.2
Father's unemployed; n (%)	24 (13)	1 (12.5)	0.96

¹ Interquartile range

Antigen	Vaccination coverage (95% CI)
BCG	100%
DTP/HepB +/- Hib	98% (97-99)
Oral polio	97.5% (96.4-98.6)
Measles	96.5% (95.2-97.8)