Age appropriateness of vaccination with recommended childhood vaccines in Sri Lanka

Hanna Lindqvist [a],*, Galmangoda Najith Duminda Guruge [b], Birger Trollfors [c]

[a] Gothenburg University, Sahlgrenska University Hospital, 416 85 Gothenburg, Sweden
[b] Faculty of Applied Sciences, Rajarata University of Sri Lanka, Sri Lanka
[c] Department of Pediatrics, Sahlgrenska University Hospital, 416 85 Gothenburg, Sweden

ABSTRACT

Vaccination status is conventionally measured by up-to-date coverage. This method does not take in to account whether the vaccines were received at the correct age and interval which is essential for optimal disease protection. Sri Lanka – a lower middle-income country in the Indian Ocean, has previously presented with high vaccination coverage for all childhood vaccines. However, few studies investigating timeliness of vaccinations have until now been carried out in Sri Lanka.

Aim: This study was carried out to investigate the individual coverage and age appropriateness of vaccination, in two different demographic settings in Anuradhapura district, Sri Lanka. The study of cross-sectional descriptive design included 633 children born in 2011. Public Health Midwives kept hand-written documentation of the birth and vaccination dates on each child in her geographic area. Vaccination ages were then compared to the timelines of vaccination provided by the Epidemiology Unit of Sri Lanka.

The vaccination coverage for all antigens was 97.5% (94.2–99.7%) at age 5–6 years. Timeliness of doses was between 65.0 and 88.6 % (median 80.7%; 65.0–88.6) and significantly lower in the urban population compared to the rural. The present study shows that the vaccine coverage in both urban and rural areas in Sri Lanka was high and that the timeliness predominantly followed national recommendations.

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1. Introduction

Numerous studies focus on the childhood vaccine coverage at 2 years of age, which is not ideal since pertussis, *Haemophilus influenzae* type b (Hib) and measles must be prevented before that age, due to the high risk of complications and mortality [1–3]. Little emphasis has been devoted on age-appropriateness of vaccination. However, in order to achieve optimal protection, it is vital that the vaccines are administered at a certain age and interval. During the first months of life the child is partly protected by maternal antibodies, and these may in some cases interfere with the immune response generated by vaccination too early. Furthermore, administering a vaccine too closely to the previous dose may lead to a weak immune reaction [4]. If it is given too late, the child is left inadequately protected during the time of delay [5]. Late administration of BCG has been shown to be connected with reduced survival [6]. Moreover, the gains of timeliness, in terms of optimal

protection and efficacy, has been confirmed in clinical studies [4,7]. Age-appropriateness of vaccination is vital to maintain sufficient immunity on an individual level and in a population [8]. Therefore, exclusively using up-to-date coverage to measure immunization status has been questioned [8–10].

As of today, vaccination coverage statistics for Sri Lanka are mainly provided by the Epidemiology unit of Sri Lanka and the WHO/UNICEF. According to above mentioned sources, the overall vaccination at 2 years coverage in Sri Lanka is adequate and well-coordinated. Surveys conducted in 2010 showed a coverage rate between 92.0 and 96.9% for all childhood vaccines, and only slim differences were discovered between districts which indicates equality in terms of access to health. However, according to the epidemiology unit, the immunization rate may differ within regions, leaving pockets of under-vaccinated children. Also, a trend was noticed indicating a decrease in coverage with increasing age of the child, also found in previous studies [11–13].

A study investigating timeliness of vaccination in the northern parts of Sri Lanka was carried out in 2012 and showed an alarmingly low age-appropriateness of vaccination among children aged 12–23 months due to the civil war. Even though coverage levels

* Corresponding author.
E-mail addresses: hanna.lindqvist@vgregion.se (H. Lindqvist), birger.trollfors@vgregion.se (B. Trollfors).

were comparable to national levels, the age-appropriateness found was below 50% for all vaccines except BCG (94%) [14].

Furthermore, a study conducted in 2014 showed a noteworthy difference in coverage between three distinguished demographic areas in Colombo district. The study population comprising of 400 children aged 2–5 years, displayed great differences in vaccination status depending on place of residence, mothers education level and parents' knowledge on vaccinations [13]. This indicates, despite the overall national coverage being satisfactory, differences are found within the country.

Sri Lanka, with a population of 21 million, has recently faced multiple great challenges. During the years of 1983–2009 it was ravaged by a civil war with more than 80,000 deaths [15] and the island was struck severely by the tsunami of 2004, with over 35,000 deaths [16]. The country is now on the rise and is today considered a lower middle-income country with a GNI of 3780 USD per capita in 2015 [17]. According to WHO 78% of the population reside in rural areas, 17% in urban and 5% in estate areas [18].

The ambition of the immunization program of Sri Lanka is to eliminate measles, neonatal tetanus, rubella and diphtheria as well as to eradicate poliomyelitis. Finally, the program strives to reduce the morbidity and mortality in whooping cough, mumps, hepatitis B, Hib and Japanese encephalitis [11].

The current program includes a pentavalent vaccine against diphtheria, tetanus, pertussis, Hib and hepatitis B. It is given at the age of 2, 4 and 6 months of age (Table 1). The general recommendations for developing countries is, according to the WHO, to vaccinate at 6, 10 and 14 weeks. The optimal time window between doses is, however, determined as 8 weeks [19]. Oral polio vaccine (OPV) is received at the completion of 2, 4 and 6 months. In addition, since 2015, children also receive a dose of inactivated polio vaccine at age 2 and 4 months, to prevent the poliomyelitis potentially induced by type 2 component in the OPV. Additional doses of DTP and OPV are to be given at the age of 18 months, and to achieve lifelong protection booster doses of OPV and DT are given at age five and at 12 years DT [20].

The last cases of both poliomyelitis and diphtheria in Sri Lanka occurred in the beginning of the 1990s. The incidence of tetanus has also decreased significantly. In 2016 there were no reported cases of neonatal or maternal tetanus. Pertussis cases are still reported at low numbers [21]. The concern of measles remains, even though the incidence has declined considerably. In 2013, the country experienced a measles outbreak with nearly 4000 affected children and adults [22]. Prior to 2011, the first measles dose was given at 9 months of age. This vaccine was replaced in 2011 by a vaccine against measles, mumps and rubella (MMR)

introduced at age 1 and 3 years, identifying the WHO recommendations of most appropriate age. However, in consideration of sero-survey data during the outbreak 2013–2015 as well as nation disease patterns, MMR is now given at age 9 months as well as a second dose at age 3 years [23]. In 2016 there were merely 112 cases of measles in comparison to the 1568 cases in 2015 [21].

The risk of developing tuberculosis is highest below the age of three years, during adolescence and among elderly [20]. BCG is given to prevent infant TB but not TB in the elderly. The disease must therefore be prevented as early as possible and BCG vaccination is consequently given within the childs first 24 h of life. Since 99 percent of all childbirths in Sri Lanka take place in healthcare facilities, it is only with a few exceptions, given at the hospital or other medical institution [24]. Despite vaccinating at young ages, tuberculosis still poses as a significant health issue in Sri Lanka, with approximately 9000 newly detected cases each year with 1200 deaths [20,25].

In addition, Sri Lanka has also included live vaccine against Japanese encephalitis since 2011. 18 cases of Japanese encephalitis were reported in 2016 [21].

Sri Lanka is divided in 334 geographic and administrative subunits called MOH areas, which are directed by a Medical officer of Health (MOH). Most peripheral public health work including immunization is carried out by public health midwives (PHM), and each MOH is accountable for 10–20 PHMs. The PHM is responsible for documentation of vaccinations and for making sure all children under her care are properly vaccinated, and in the case of a child not adhering to the immunization schedule, the PHM contacts the caregivers to set a new appointment. In addition, during pregnancy and early years of life the PHM does home visits to follow the health of the mother and child. Each midwife is typically responsible for 100–400 children. All vaccines during the ages 0–5 years are given by the PHM with the exception of BCG, which is given by hospital personnel.

Information on what vaccines the child has received is registered in the Child Health and Development Record (CHDR). One copy is kept by the parents and another copy at the PHM office. In addition, the vaccination status of a child is also recorded in the Birth and Immunization Register (BIR) at the PHM office.

Public health care in Sri Lanka is funded by the government, and all EPI vaccines are free of charge for the recipient/caregiver.

The aims of the present study were to determine vaccine coverage and age at vaccination on an individual level and to compare rural and urban areas.

2. Material and methods

2.1. Study design

The study was a joint project between Rajarata and Gothenburg Universities. A Swedish medical student went to Mihintale in central Sri Lanka where her local supervisor had selected 7 public health centrals where the midwives had kept hand-written records of all births in the area and noted dates of all vaccinations. This cross-sectional study was performed during 17/09/27 – 17/11/08.

Anuradhapura district is divided into 19 MOH areas. These areas were sorted into three groups according to demographic characteristics; rural, semi- urban and urban. The MOHs were divided in rural and urban councils. MOH areas that fell within both rural and urban councils were considered semi-urban and were excluded from the study. Two MOH areas were then randomly selected; one from the rural group and one from the urban group. The student noted dates of births for all neonates with the help of a local interpreter.

Table 1
The national vaccination program of Sri Lanka included the following primary vaccines for children 0–5 years of age, born in 2011.

AGE	Vaccine	
0–4 weeks	BCG	Bacillus Calmette- Guerin (against tuberculosis)
2 months	OPV1	Oral polio vaccine
	Pentavalent1	
4 months	OPV2	
	Pentavalent2	
6 months	OPV3	
	Pentavalent3	
9 months	JE	Live attenuated vaccine against Japanese encephalitis
12 months	MMR1	Measles, mumps, rubella
18 months	OPV4	
	DTP	Diphteria, tetanus, pertussis
3 years	MMR2	
5 years	OPV5	
	DT	Diphteria, tetanus

Note: Pentavalent = Diphteria, tetanus, pertussis, hepatitis B and *Haemophilus*.

Mothers are assigned unique identification numbers when registering their pregnancy at the PHM, and these were used for book-keeping of the children's vaccinations. In case of a family moving, the card with all vaccination details is transferred to the new PHM office and entered in to the BIR. These cases were included in the study. Children that moved from the PHM area in the study were also included. However, only the vaccines received prior to the move were attainable and used in the study. If the moving date was registered or the PHM had made a mark indicating a move, missing vaccinations after moving date were designated as missing due to moving and missing vaccinations before that date were considered missing (due to other reason than move).

2.2. Vaccination recommendations

Receipt of vaccines were analyzed according to the national immunization program of Sri Lanka, which provides information on recommended ages for routine vaccinations and interval between doses for vaccines given as a series (DTP/hepatitis B/Hib/OPV) as well as the minimum accepted age for each dose. Provided recommendations according to the vaccination schedule were translated into days to enable calculations (Table 2). Comparison between the age of the child at receipt and the recommended ages were performed, as done in previous studies examining timeliness [5,26]. Vaccinations given before the country EPI schedule recommended age, or not in keeping with the recommended gap between doses of the same vaccine (priming or booster doses), were determined as invalid for this research study purpose even though seroconversion effect would be there due to adequate gap between vaccine doses.

The vaccinations included in the national vaccination program of Sri Lanka for children aged 0–5 years, born in 2011 are displayed in Table 2. One dose of BCG is to be given during the first 24 h after birth to be considered "on time". The primary three doses of OPV and pentavalent vaccines were considered "on time" if received upon the completion of 2, 4 or 6 months, and within 2 weeks from that date, as well as at least four weeks after the previous dose containing the same antigen. DTP4, JE and DT5/OPV5 were added a grace period of 1 month after the due date. MMR is to be given at the completion of 12 months and 3 years or within a month following the due date [27].

Pentavalent1/OPV1, Pentavalent2/OPV2, Pentavalent3/OPV3, DTP4/OPV4, DT5/OPV5 are given at the same occasion and a total number of nine occasions of vaccination were therefore studied.

2.3. Inclusion criteria

All children that were born in 2011 and registered at the PHM office in the area were included in the study with the criteria of them having a record of receiving at least one of the childhood vaccines at the current PHM and it was recorded in the BIR.

2.4. Exclusion criteria

Children registered in the BIR but with missing information on birth date or registration date were excluded from the study. Children registered in the BIR but had not yet received any vaccines, due to the family moving to another area or death of the child before registration were not included.

MOH areas that fell within both urban and municipal councils were considered semi-urban and were therefore excluded.

2.5. Statistical methods

Collected data were entered in Excel for calculation and analysis. Two-sided Fisher's exact test was used for comparison between proportions. Statistical analysis was performed using GraphPad calculator [28].

2.6. Ethical considerations

Ethical approval was obtained from the Ethical Review board at the Faculty of Applied Sciences, Rajarata University, Sri Lanka. Permission was also granted from the Provincial Director of Health Services, Anuradhapura. Finally, approval was given by the MOH in Mihintale and Nuwara Gampalatha East. Data on children's vaccinations were entered according to their mother's identity numbers and therefore not possible to connect to the participant.

3. Results

Data from 643 children born in 2011 were collected from 7 public health midwives' offices in Anuradhapura district. 10 children were excluded from the study due to inability of the author (HL) and interpreter to read the records (n = 6) and missing information on vaccinations (n = 4). 633 children that were included in the study (321 girls (50.7%) and 312 boys (49.3%)). 374 came from urban areas (59.1%) and 259 (40.9%) from rural areas. 557 doses in total were not given because the child had left the area or died (Table 3).

The overall vaccination coverage was between 94.2 and 99.7 % at age 5–6 years, for all studied vaccines (Table 4) with a median coverage of 97.5%. 2.5% (n = 126) of all doses were never received, due to other reasons than the child having left the area or died. No differences in general coverage at age 5–6 years were found between urban and rural populations. Girls had a mean coverage at 97.7% and boys of 96.8% (p = 0.0486) (Table 5).

Table 2
Recommended and minimum ages for early childhood vaccinations according to the national immunization program of Sri Lanka, 2011.

Vaccine and dose number	Recommended age	Minimum age in days	Maximum age in days	Minimum interval to next dose in days
BCG	0–24 h	0	1	–
Pentavalent-1	2 months	60	74	28 (4 weeks)
Pentavalent-2	4 months	120	134	28 (4 weeks)
Pentavalent-3	6 months	180	194	180 (6 months)
DTP-4	18 months	540	570	–
DT	5 years	1825	1855	–
OPV-1	2 months	60	74	28 (4 weeks)
OPV-2	4 months	120	134	28 (4 weeks)
OPV-3	6 months	180	194	180 (6 months)
OPV-4	18 months	540	570	–
OPV-5	5 years	1825	1855	–
Japanese encephalitis	9 months	270	300	–
MMR-1	12 months	365	395	28 (4 weeks)
MMR-2	3 years	1095	1125	–

Table 3
Characteristics of the sample population.

	Rural n (%)	Urban n (%)	Total n (%)
Residency	259 (40.9)	374 (59.1)	633 (100)
Missed doses due to move	173 (7.4)	384 (11.4)	557 (9.8)
Gender			
Female	133 (51.4)	188 (50.3)	321 (50.7)
Male	126 (48.6)	186 (49.7)	312 (49.3)

Table 4
Vaccination coverage at age 5–6 years.

	Rural n (%)	Urban n (%)	Total n (%)
BCG	259 (100)	372 (99.5)	631 (99.7)
Pentavalent1/OPV1	255 (99.6)	352 (99.7)	607 (99.7)
Pentavalent2/OPV2	248 (98.8)	343 (99.7)	591 (99.3)
Pentavalent3/OPV3	245 (99.2)	335 (98.8)	580 (99.0)
DTP4/OPV4	225 (96.2)	309 (96.0)	534 (96.0)
JE	232 (96.3)	314 (94.0)	546 (95.0)
MMR1	235 (98.3)	316 (96.9)	551 (97.5)
MMR2	214 (96.4)	275 (92.6)	489 (94.2)
DT5/OPV5	197 (94.3)	288 (98.3)	485 (96.6)

Table 5
Vaccination coverage at age 5–6 years. Gender comparison.

	Boys n (%)	Girls n (%)
Received doses	2434 (96.8)	2580 (97.7)
Missed doses	80 (3.2)	60 (2.3)
Total	2514 (100)	2640 (100)

Timeliness for the sample population was 81.0% (median 80.7%; 65.0–88.6). 14.5% (n = 743) doses were received late with a mean number of 45.9 accumulated days of under-vaccination (median 11 days). A total of 106 doses (2.1%) were given too early. The rural group had a median timeliness of 86.5% (71.3–91.0) compared to the urban median timeliness at 77.3% (60.5–88.4; p = 0.0001) (Table 6).

4. Discussion

4.1. General vaccine coverage

The most important findings of this study were the high general vaccination coverage at 97.5% and the timeliness above 80% for most vaccines, as well as a significant difference in timeliness between urban and rural populations.

Sri Lanka present with positive figures for most indicators. A great pillar of strength is the health professionals; the PHMs, PHIs and hospital personnel, who are responsible for childhood vaccinations. They make great efforts in making sure all children adhere to the vaccination schedule. The close cooperation between the PHM and parents, beginning during pregnancy and continuing through out the early years of childhood, build trust and lay ground for a successful relationship.

One notable example is the coverage for BCG vaccination at 99.7%. The coverage is high, especially in comparison to other low- and middle-income countries [29]. One of the main reasons for this could be the high percentage (99%) of deliveries occurring in medical institutions in Sri Lanka, which enables vaccinations of the child before discharge from the hospital [24].

4.2. Timeliness

Timeliness for all vaccinations, except for Pentavalent2/OPV2 and 3, was above 80%. The timeliness ought to be regarded as adequate age-appropriate coverage, also in comparison to similar studies conducted in other countries [10,30,31]. The percentage of timely vaccinations were highest for BCG, Penta1/OPV1 and DTP/OPV5 in both the rural and urban groups. A decrease in timeliness with increasing age was seen during the first year of life, which is in alignment with results from previous studies [11,26]. Lowest levels of timeliness were found for Penta2/OPV2 (74.6%) and Penta3/OPV3 (65.0%) and the highest incidence of late vaccinations was found for Pentavalent3/OPV3 (32.4%). The mean number of late days for Penta3/OPV3 was moderate; merely 10 days (median 5). Thus, in most cases it probably has little clinical relevance. Despite a decrease in timeliness during the first year of life, a high percentage of timely vaccinations were found for the fifth dose of DT5/OPV5.

4.3. Demographic differences

Significant differences between the urban and rural groups were found in terms of timeliness. Geographical location is a known important factor for child health inequalities [32]. However, the connection between equity in health and place of residence is a complicated matter. There are studies suggesting a better coverage in urban populations but, also the opposite [10,33]. The different outcomes may be due to other underlying

Table 6
Timeliness status of doses of the national vaccination program of Sri Lanka at age 5–6 in our sample population.

	Rural				Urban				Total			
	Timely n(%)	Late n(%)	Early n(%)	Never n(%)	Timely n(%)	Late n(%)	Early n(%)	Never n(%)	Timely n(%)	Late n(%)	Early n(%)	Never n(%)
BCG	232 (89.6)	27 (10.4)	– –	0 (0.0)	325 (86.9)	47 (12.6)	– –	2 (0.5)	557 (88.0)	74 (11.7)	– –	2 (0.3)
Penta1/OPV1	233 (91.0)	19 (7.4)	3 (1.2)	1 (0.4)	297 (84.1)	45 (12.7)	10 (2.8)	1 (0.3)	530 (87.0)	64 (10.5)	13 (2.1)	2 (0.3)
Penta2/OPV2	191 (76.1)	51 (20.3)	6 (2.4)	3 (1.2)	253 (73.5)	78 (22.7)	12 (3.5)	1 (0.3)	444 (74.6)	129 (21.7)	18 (3.0)	4 (0.7)
Penta3/OPV3	176 (71.3)	67 (27.1)	2 (0.8)	2 (0.8)	205 (60.5)	123 (36.3)	7 (2.1)	4 (1.2)	381 (65.0)	190 (32.4)	9 (1.5)	6 (1.0)
DTP4/OPV4	210 (89.7)	14 (6.0)	1 (0.4)	9 (3.8)	260 (80.7)	43 (13.4)	6 (1.9)	13 (4.0)	470 (84.5)	57 (10.3)	7 (1.3)	22 (4.0)
JE	208 (86.3)	20 (8.3)	4 (1.7)	9 (3.7)	256 (76.6)	51 (15.3)	7 (2.1)	20 (6.0)	464 (80.7)	71 (12.3)	11 (1.9)	29 (5.0)
MMR1	204 (85.4)	18 (7.5)	13 (5.4)	4 (1.7)	252 (77.3)	55 (16.9)	9 (2.8)	10 (3.1)	456 (80.7)	73 (12.9)	22 (3.9)	14 (2.5)
MMR2	192 (86.5)	12 (5.4)	10 (4.5)	8 (3.6)	226 (76.1)	40 (13.5)	9 (3.0)	22 (7.4)	418 (80.5)	52 (10.0)	19 (3.7)	30 (5.8)
DT5/OPV5	186 (89.0)	9 (4.3)	2 (1.0)	12 (5.7)	259 (88.4)	24 (8.2)	5 (1.7)	5 (1.7)	445 (88.6)	33 (6.6)	7 (1.4)	17 (3.4)

determinants. One possible reason for better timeliness, in the rural compared to the urban group may be the higher prevalence of families moving in the urban population (384 missed doses due to the family moving for the urban population compared to 173 in the rural group). As explained in earlier studies, children in migrating families have a higher risk of incomplete or delayed vaccinations [34]. Another aspect may have impacted timeliness is the number of children under each PHMs care. The PHMs in the urban area had more children to immunize, which could affect the time and effort she can spend on each child/family.

A statistically significant, however not clinically relevant difference in coverage at age 5–6 years was found between sexes (p = 0.0486, girls versus boys; 97.7% versus 96.8%). The present study showed a higher coverage for girls than boys which contradicts previous data from the South-East Asia region where boys generally presented with higher coverage than girls [35].

4.4. Methodological considerations

A strength of this study is the big sample size of 643 children, from 7 different locations. The locations were selected randomly to avoid selection bias. Another strength was the fact that data were taken from written records and not from parental recall. However, it should be mentioned that children that are completely outside the health care system are possibly missed, since these children may have no vaccination records.

Declaration of interests

The authors declared that there is no conflict of interest.

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