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Compliance to timely vaccination in an Expanded Program on Immunization center of Pakistan

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ABSTRACT

The importance of childhood immunization in prevention of highly fatal diseases and disability cannot be overemphasized. Pakistan has a national Expanded Program on Immunization but the compliance is far below the international benchmark for achieving a herd immunity. Monitoring the compliance to timely receipt of vaccinations is crucial to establishing and preventing disease and disability associated risk in children. There is little or no evidence that reports the timeliness of the vaccinations according to the EPI schedule in Peshawar. The primary objective of the study was to evaluate rate of Fully Immunized Children and to report compliance to the timeliness of vaccine specific schedule during the study period in the EPI center in the capital city of Peshawar, Khyber Pakhtunkhwa province of Pakistan. We collected consecutive retrospective data of the infants enrolled from June 2014 to December 2015 in one EPI center for our study. Out of the total 157 (n) children, fully immunized children (FIC) were 62 (39.5%) and only 19 (12.1%) were FIC with timely visits. Dropouts increased with successive vaccinations with highest for Measles 1 (42%). On-time vaccinations decreased over time, while the proportion of children receiving vaccination outside the ideal window period reaches as high as 46%. The study reports a low compliance to EPI schedule, and also highlights that immunization coverage is not a good indicator of age appropriate vaccinations.

1. Introduction

The importance of childhood immunization in prevention of highly fatal diseases and disability cannot be overemphasized. According to World Health Organization (WHO), immunization averts 2–3 million deaths every year [1]. Pakistan has a national Expanded Program on Immunization (EPI) which follows WHO and Center for Disease Control and Prevention (CDC) guidelines for vaccination [2]. The EPI guidelines recommend that all children receive a BCG vaccination against tuberculosis; three doses of DPT vaccine for the prevention of diphtheria, pertussis (whooping cough), and tetanus; three doses of polio vaccine; three doses of the hepatitis vaccine; and two doses of vaccination against measles during the first two years of the child's life [3]. The WHO's Global Vaccine Action Plan aims at achieving 90% national coverage of routine immunization in order to achieve herd immunity [4–6]. WHO and UNICEF regularly monitor the coverage of routine immunization services and report an improvement in routine immunization coverage during recent years in Pakistan from 74% in 2000 to 85% in 2015 for BCG, 62–72% for DTP3, 65–72% for Polio 3 [5].

Despite the improvements, the coverage in Pakistan is not up to par and there is an observed high rate of missed and delayed vaccinations [6,7]. The number of infants missing out on routine immunizations worldwide is 19.4 million, 60% of whom belong to 10 countries of the world including Pakistan [8]. According to WHO, almost 3 million children miss out on a full basic course of routine immunization every year in Pakistan [8]. Deaths of children under 5 years of age due to vaccine preventable diseases contribute about 25% of the total under 5 mortality rate in Pakistan [8]. Table 1 shows the EPI vaccination schedule with immunization windows in Pakistan.

As far as coverage is concerned, timeliness of vaccination is important because it not only affects the infant mortality and morbidity but also the fraction of vaccinated population necessary to

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Table 1
EPI Schedule.

Age of child	Vaccine	Window (min–max days from Date of birth)
At birth	BCG OPV-0	0–40
6 week	OPV-1 Penta-1 PCV-1	42–70
10 week	OPV-2 Penta-1 PCV-2	70–98
14 week	OPV-3 Penta-3 PCV-3 IPV	98–126
9 month	Measles-1	270–298
15 month	Measles-2	450–478

create a herd immunity [9]. A delayed vaccination puts the infant at risk of disability and death from a preventable disease during the time the vaccine is delayed [10,11]. High coverage rates for immunization do not imply timely administration of individual vaccines [11,12]. Complying to age-appropriate receipt of vaccinations is equally crucial to prevent and eliminate disease and disability associated risk in children [13,14]. CDC reported an increased number of infant deaths due to pertussis during 1990′s in United States, despite high reported vaccination coverage levels [15,16]. Approximately 40% of the infants who contracted pertussis in 1990′s in US were under vaccinated for their age [15]. Therefore, it is of paramount importance to provide immunization in time to infants.

The current national surveillance system for the childhood immunization in Pakistan does not report the delayed vaccinations. This overestimates the coverage compared to the age appropriate vaccination coverage as some children are considered fully immunized even if some of the vaccines were administered later than the recommended age [17]. Monitoring the age appropriate immunization status of population is of great significance to establish the disease associated risk in the population [18].

The EPI coverage for fully immunized children in Khyber Pakhtunkhwa (KP) is reported to be 52.7% [19]. Literature review reports various studies on EPI coverage in KP, but there is little or no evidence that reports the timeliness of the vaccinations according to the EPI schedule [20–23].

We evaluated age-appropriate compliance to childhood vaccination in one EPI center located in a private tertiary care hospital in Peshawar, the capital city of KP province (Pakistan) using measures defined by WHO. The primary objective of the study was to evaluate compliance to EPI by calculating total number of Fully Immunized Children (FIC) and dropout rates in our study setting. We also aimed to report compliance to the timeliness of individual vaccinations (true compliance) during the study period by reporting rate of defaulter (i.e. delayed) visits, dropout (i.e. missed) visits, and timely visits.

2. Methods

This cross-sectional study collected consecutive retrospective data of the infants enrolled from June 2014 to December 2015 from a hospital-based EPI center in Peshawar (Pakistan). EPI program in our study setting is part of the government program, and is free of charge just as all other EPI centers. EPI center maintains a daily and permanent register. All immunizations given in the EPI center are entered in the daily register and is then transferred to permanent register manually by EPI staff after every session. Permanent register has the data for all the immunization activities in one union council with immunization entries of the children who are permanent residents of that union council. Any immunization given to child who is resident of another union council is recorded separately and the report is sent to the child's union council of residence through a stamped letter. Every child gets an immunization card with demographics and vaccination date stamps, and instructions to retain card. Card has a unique identifier number that matches the child's entry in the permanent registers. All the vaccination date entries on the card also match the corresponding information in the permanent register. If a card is lost, new card is issued with the same identifier number and entries as on the permanent register.

The criterion for inclusion was any infant who is enrolled in EPI center during the study period. The exclusion criteria was if the infant had only BCG and/or OPV 0 at date of birth and never showed up again for the entire period of data collection, and if children who were in window for Measles 1 vaccine at the end of study period. Total 322 children enrolled in EPI center during the study period, of which 94 only received BCG/OPV0 vaccine and never showed up again, and 71 children were still in the window of receiving Measles-1 at the end of the study period. After exclusions, the final sample size came out to be 157.

Data were entered and analyzed using SPSS software (version 6.1, SPSS, Chicago). The rules for timely visits are set according to the WHO and CDC guidelines for immunization plan (Table 1). The Fully Immunized Children (FIC) and dropout rates were calculated using the following definitions: FIC is one who has received at least one dose of BCG, three doses of OPV, three doses of pentavalent and one dose of measles vaccination in the first year after birth [24]. A dropout rate is defined as the number of children who received an early vaccination for example, BCG as compared to number of children who received a later vaccination for example Measles or Penta 3 [24].

Formula of dropout rate:

$$\frac{BCG - Measles\ 1}{BCG} \times 100 \quad \frac{BCG - Penta\ 3}{BCG} \times 100$$

We also calculated number of defaulter visits (i.e. the one being out of window for the respective vaccine or a delayed visit), dropout visits (i.e. missed visits) and timely visits (age specific) for each vaccine in the schedule. The dropout and defaulter proportions at different time points for each vaccine were compared using Cochran's Q test. Where difference between proportions was statistically significant at an alpha value of 0.05, paired McNemar tests with bonferroni corrected p-values were run to identify the paired proportions with statistically significant differences.

Approval was obtained from institutional review board before start of the activity. No identifiers were recorded. All ethical guidelines were followed to ensure data confidentiality. This was an investigator initiated study with no outside support. None of the investigators have any conflict of interest to report.

3. Results

Out of the total 157 children, 62 (39.5%) were fully immunized children (FIC) and only 19 (12.1%) were FIC with timely visits. Analysis of dropouts showed a generally increasing proportion with successive vaccinations (reported in Table 2) with highest dropouts for Measles 1 (42%). Conversely, the number and rate of on-time vaccinations decrease over time, while the number of children receiving vaccination outside the ideal window period reaches as high as 46% (Table 2). Inter-vaccination dropout rates range from low (8%) between Penta 1 and Penta 2, to high overall dropout (41.7%) between BCG and Measles 1 (Table 2). We found considerable variation in the timeliness of vaccination in our study sample,

Table 2
Dropouts, defaulters and on-time visits, and respective dropout rates.

	Dropouts n (%)	Defaulter/Early n (%)	On time n (%)
BCG	1 (0.6)	18 (11.5)	138 (87.9)
OPV0	32 (20.4)	7 (4.5)	118 (75.2)
OPV1, Penta1, PCV1	20 (12.7)	51 (32.5)	86 (54.8)
OPV2, Penta2, PCV2	31 (19.7)	71 (45.2)	55 (35)
OPV3, Penta3, PCV3	47 (29.9)	72 (45.9)	38 (24.2)
Measles1	66 (42)	36 (22.9)	55 (35)
Total visits (n = 942)	197 (20.9%)	255 (27.1%)	490 (52%)
Inter-vaccination Dropout Rates	Percent		
BCG to Penta-1	12.2%		
Penta-1 to Penta-2	8.0%		
Penta2 to Penta-3	11.9%		
Penta-3 to Measles-1	18.0%		
BCG to Penta-3	28.8%		
BCG to Measles-1	41.7%		

which is visualized in Fig. 1. The median number of days from birth for BCG, Penta-1/OPV1 and Measles-1 were 13, 57 and 287 days, which fall within their respective ideal window periods. However, for Penta-2/OPV2 and Penta-3/OPV3 these figures are 99 and 141 days respectively, which are outside of their ideal window periods (Fig. 1).

The dropout and defaulter proportions (when compared only to timeout proportions) for all individual vaccines were significantly different ($p < .001$) (see Table 3). The paired comparisons of dropout proportions between individual vaccines identified statistically significant differences between OPV0-OPV2, OPV0-OPV3, OPV1-OPV3, Penta1-Penta3, and PCV1-PCV3 at respective bonferroni corrected p-values. In case of pair comparisons of defaulter proportions for different vaccines, all paired comparisons of OPV0-OPV1, OPV0-OPV2, OPV0-OPV3, OPV1-OPV2, OPV1-OPV3, OPV2-OPV3, Penta1-Penta2, Penta2-Penta3, Penta1-Penta3, PCV1-PCV2, PCV1-PCV3, and PCV2-PCV3 were significantly different.

4. Discussion

Expanded Program on Immunization was launched in Pakistan in 1978 [25] and has improved tremendously as well as becoming more inclusive of available vaccinations over the time. Extensive and effective public service messaging campaign, catch-up immunization and health camps by UNICEF have also helped improve the coverage of EPI program nationwide. Despite the efforts made by government and the partners, immunization indicators in Pakistan have yet to achieve the recommended benchmarks [25]. The main aim of EPI is to protect children from contracting preventable diseases by immunizing them at the youngest possible age. However, the immunization coverage is not only low but the internationally reported coverage is overestimated, which affects the disease associated risk in population.

In our results the FIC rate observed is 39.5% which is far below the WHO recommendation of above 90% but comparable to 40.2% reported in another study based on EPI Cards, in a different hospital of the same city [26]. This shows that more than half of the children are not getting all of the recommended doses of vaccines that are essential to protect them against the preventable diseases. The FIC rate in urban children of KP was 58% according to Pakistan Demographic and Health Survey (PDHS) 2012–13 [19]. However, the survey used either mother's verbal account or EPI card as a source and therefore is likely to overestimate coverage. A cross sectional study done in twenty primary health centers in Punjab reports 52% of FIC confirmed by EPI cards [27]. Another study from Rawalpindi district reports 57.1% FIC [28], while a 45% age appropriate FIC coverage is reported from Karachi [29].

Compliance to the age appropriate immunizations is critical for the effectiveness of the vaccines against the preventable diseases. However, the prevalent surveillance system in Pakistan focuses on the coverage of the immunizations regardless of their timeliness. Compared to the overall FIC rate of 39.5%, age appropriate FIC (vaccination within allowable window) in our results was found to be only 12.1%, which points toward the actual effectiveness of EPI vaccination in this setting. The overall dropout rate (BCG-Measles 1) in our results was 41.6% which is much higher that the BCG- Measles 1 dropout rate of 29.3% in urban children of KP calculated from PDHS 2012–13 [19]. Similarly the BCG to Penta 3 dropout rate in our results was 29% as compared to 14.9% from PDHS [19]. The pentavalent dropout rate increases with subsequent visits in our results with Penta1-Penta 2 dropout rate of 8%, Penta 2- Penta 3 dropout rate of 12%, and an overall Penta1-Penta 3 dropout rate of 18%, which is again higher than the 8% reported in [19]. As noted earlier, the PDHS survey relied on a looser definition of vaccination (mother's verbal account or EPI card), and this is a likely reason for the lower dropouts reported therein. We believe our study, albeit center-based, uses more reliable source (confirmed vaccinations in EPI register).

The results of our study also reported the age appropriate administration of the vaccines by breaking down the results to vaccine specific compliance. Our results reveal that only about 52%

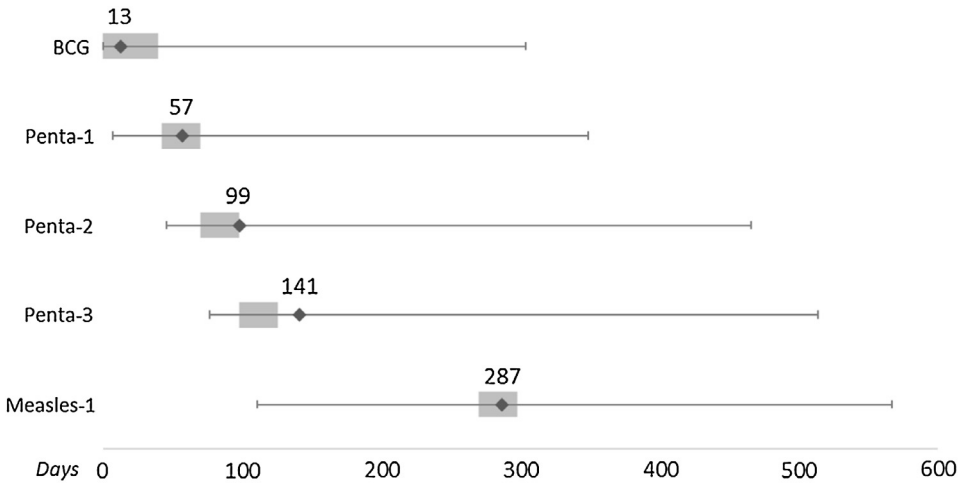

Fig. 1. Minimum, median and maximum days from birth till vaccination. (Shaded area shows ideal window period).

Table 3
Dropouts and defaulters vs. on-times for OPV, Penta, PCV, and Measles immunizations, n (%).

Vaccines	At birth (0) dose	Dose 1	Dose 2	Dose 3	Cochran's Q p-value
Dropouts vs. on-times					
BCG	1 (1)				
OPV	32 (21)	20 (19)	31 (36)	47 (55)	<0.001
Penta	–	20 (19)	31 (37)	46 (55)	<0.001
PCV	–	20 (19)	30 (35)	45 (54)	<0.001
Measles	–	66 (55)	NA[a]		
Defaulters vs. on-times					
BCG	18 (12)				
OPV	7 (6)	41 (32)	62 (53)	70 (65)	<0.001
Penta	–	42 (33)	63 (54)	71 (65)	<0.001
PCV	–	41 (32)	63 (53)	71 (65)	<0.001
Measles	–	33 (38)	NA[a]		

Abbreviations: OPV – Oral Polio Vaccine, Penta – Pentavalent vaccine, PCV – Pneumococcal Conjugate Vaccine.
[a] Most (90%) of the children were in still in their window period for Measles' 2nd (i.e. booster) dose.

visits were timely, about 27.1% were out of window, and 20.9% were the missed visits. If, however, we only rely on the administration of the vaccines, regardless of the timeliness of the administered vaccines, our results would be overestimated to 79% (regular + delayed visits) which overestimates coverage. Coverage is not the goal of childhood immunizations, maximum and earliest protection from the debilitating diseases however is. Overestimation of the coverage on a provincial or national level by counting the delayed vaccinations with timely ones for calculating FIC, poses a great threat to the achievement of a herd immunity.

The reported BCG coverage in urban children of KP, irrespective of timeliness, is 89.3% [19]. In comparison, 99.4% of children in our study received BCG vaccination. However, when considering timeliness, we found that only 87.9% of the BCG vaccinations were done within the recommended window. The study EPI center was based in a tertiary care hospital and thus had substantial proportions of infants with BCG vaccination on time. We expect that our results would be higher than corresponding figures for a primary care EPI center that mainly tend to home deliveries. On-time BCG vaccination is more likely to be low in primary care EPI centers due to lower skilled birth attendance and poor healthcare access in most of rural Pakistan (30). On the other hand, it is important to consider the methodology used for calculating BCG coverage. The officially reported BCG coverage of 35.4% in KP is determined by availability of vaccination cards [3]. While, the reported BCG coverage in KP in National Nutrition Survey and Pakistan Demographic and Health Survey do not take into account confirmation of vaccination by BCG scar [3,19] and are thus, higher. The results reveal that 75.2% of the OPV-0 vaccinations were timely. This however is interesting to note that there is a difference between coverage of BCG (88.6%) and OPV-0 (75.2%) vaccines despite the fact that both vaccines are administered on the same day in the study setting. This difference might be attributed to the refusal of parents to administer Polio vaccine, a common reason of low OPV coverage in Pakistan as evident from various studies [31–33]. There is a need of a qualitative study to explore the reasons for the difference in BCG and OPV-0 coverage in our study setting.

Pentavalent vaccine (called "Penta") in Pakistan is a combination of three vaccines (DTP3 + Hepatitis B + Hib). Our results revealed that the compliance to complete three pentavalent vaccine doses is 57.3% which is less than the 64.2% pentavalent coverage reported in another study conducted in Peshawar [34] and 70% reported in province-wide survey [35], which is overestimated as it did not take into account the timeliness of administered doses. This is evident as the National Nutritional Survey(NNS) reports a coverage of 36.6% as confirmed by vaccination cards for pentavalent vaccine in KP [35]. Only 19.7% of the children received all three pentavalent vaccines within the recommended window. The timely pentavalent vaccine reception in our results were 54.8% for penta-1, 35% for penta-2, and 24.2% for penta-3. The reported coverage of penta-1 is 77.1%, penta-2 is73.9% and penta-3 is 69.6% is likely an overestimation of the true and timely coverage of the vaccinations [29]. Our results depict a rather disappointing picture of compliance to pentavalent vaccine in comparison to WHO reported global coverage of pentavalent which is 86% for DTP3, 84% for Hepatitis B, and 70% for Hib [37]. WHO reports that 40% of the 3.8 million infants in the region who did not receive DTP3 belonged to Pakistan in 2015 [38].

According to our results, 35% of the study sample has been compliant to Measles-1 vaccination, compared the reported 31.2% coverage of Measles vaccination in KP as confirmed by the availability of card [36]. The officially reported coverage of Measles in KP is however 57.8%, which again is an overestimated figure [30]. A study in a tertiary care hospital in Peshawar reveals that of all the admitted children who contracted Measles, 39% were vaccinated for Measles [39], which strengthens our argument of under vaccination for age. WHO 2016, however reports a global coverage of 84% for at least one dose of measles vaccine [37]. The compliance to Measles vaccine in KP and in our study setting is far less than the global trends Our study results reveal that the timeliness of the vaccination in EPI in our study setting is far from optimal. This strengthens the argument to monitor the timeliness of the vaccinations and report the age-appropriate EPI coverage.

There is a need of innovative ideas to improve the compliance and timeliness of the vaccination in Pakistan. Studies have revealed that phone call reminders particularly play a vital role in improving the compliance and timeliness of the vaccinations [40,41]. A systematic review on mHealth intervention studies to improve infant vaccination in 21 LMIC countries reports improved vaccination uptake as a result of mobile based interventions including appointment reminders and mobile applications [42]. The mobile phone access in Pakistan shows a considerable potential for mHealth interventions to improve infant vaccination timeliness and coverage. This opens an opportunity for KP to develop and pilot a phone based defaulter tracking system, with an ability of automated call reminders to the parents. This not only will increase the reliability of the surveillance system but is also expected to improve compliance with the age-appropriate administration of vaccinations.

This study has few limitations. First, the study period lasted for 18 months only thus timeliness and dropout status for BCG to Measles-2 and Measles-1 to Measles-2 could not be ascertained. Second, the difference between BCG and OPV-0 coverage despite same vaccination time of 'at birth' couldnot be explained. The hospital-based EPI center did not have any reporting system for documenting and/or reporting polio vaccine refusals. The probable

reasons can be interrupted polio vaccine supply and poor cold chain maintenance due to frequent power shutdowns, and/or parents' reluctance toward polio vaccination. Future mixed method studies can help identify the reasons for this finding. Third, we could not report on IPV coverage as the study EPI center did not offer IPV. As per polio eradication and endgame strategic plan 2013–2018, IPV is being rolled out gradually in Pakistan and has not yet transitioned to IPV only across Pakistan. Lastly, this study reports findings from a single hospital-based EPI center based in a major city and thus its findings should not be generalized across other EPI centers, especially the EPI centers in primary care setups. Nevertheless, this study teases out the timeliness related information for different EPI vaccines as opposed to focusing only on vaccine coverage.

As the data obtained for the study is from an urban EPI center in Peshawar city, which is a large city by population and the capital of KP province, we therefore believe that the results should be similar to other major cities of Pakistan. However, a larger national study may be needed to better access and compare the findings.

5. Conclusion

This study highlights that vaccination coverage is not a good indicator of age appropriate immunization, especially in a setting where compliance to EPI is low. The vaccinated children might still be vulnerable to the diseases at the completion of the EPI schedule due to under vaccination for age. There should be a province-wide prospective study to report true coverage of timely vaccinations.

6. Recommendation

As public health professionals and researchers we believe that there is an urgent need for an automated mobile phone based reminder system that will remind parents of children enrolled in the EPI program when their child is due for immunization. Such system can also include pregnant women for TT vaccination. We believe such reminder system will help achieve the targets set by EPI.

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