Analysis of Independent Monitoring Data from Polio National Immunization Day Campaigns in Kinshasa Province, Democratic Republic of Congo: Proportions of Missed Children from 2010 – 2013

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ABSTRACT

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Poliovirus transmission has been interrupted from many parts of the world by mass vaccination. However, polio can re-emerge due to importation from endemic areas. To prevent this, concerted vaccination efforts are still required. In 2010 the Democratic Republic of Congo had a reintroduction of polio virus that took 2 years and many high-quality supplemental immunization activities (SIA) to stop transmission. To ensure high campaign quality, end-process independent monitoring is conducted to rapidly estimate if the number of children vaccinated reached the established target. The key indicator of success is the vaccination of at least 90% of the target population (typically the <5 years population). If more than 10% of the target population surveyed are found to be unvaccinated, immediate revaccination of the area is conducted.

A longitudinal analysis was conducted of independent monitoring data collected between 2010 and 2013, following supplemental immunization activities in 35 districts in Kinshasa Province, Democratic Republic of Congo. There was an overall decrease in the proportion of missed or unvaccinated children from 2010 to 2013, with 2013 reflecting the lowest proportion of missed children was identified and found to be statistically significant through univariate analysis ($F= 16.74$, $P<0.0001$, $F=15.79$, $P<0.0001$). A more detailed investigation performed on district level data revealed instances where the proportion of unvaccinated children was greater than determined by the aggregated provincial level data. The poorer performing districts identified greater than 10% unvaccinated children in 8 of the 12 (75%) campaigns performed during 2010 – 2013 as shown by two reporting methods. To improve campaign quality and performance in Kinshasa province, future monitoring should include more descriptive questionnaires including expanding the vaccine refusal categories from four to 10 to allow for more targeted interventions to reduce the number of unvaccinated children. Additional actions include targeted training of monitors on survey methodology, and the timely disbursement of funds to the local levels to allow for adequate planning, training and implementation of OPV campaigns.

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Finally, I would like to thank my wonderful husband Dr. David Boyle and children, Isla and Calum Boyle for their love, support over the past two years. I would not have been able to complete this without their continued words of encouragement.

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LIST OF ACRONYMS AND ABBREVIATIONS

Acronym	
AAV	Anti-Amaril Vaccine (Yellow fever)
ACPE	American College of Physician Executives
AFRO	Regional Office for Africa
BCG	Bacillus Calmette-Guérin
CNS	Central nervous system
DRC	Democratic Republic of Congo
DTP	Diphtheria, tetanus, pertussis
EPI	Expanded Programme on Immunization
GPEI	Global Polio Eradication Initiative
HepB	Hepatitis B
Hib	Haemophilus influenzae type B
IM	Independent Monitoring
IPV	Inactivated polio vaccine
IRB	Institutional Review Board
LQAS	Lot Quality Assurance Sampling
NIDs	National immunization days
OPV	Oral Polio Vaccine
PCV	Pneumococcal conjugate vaccine
PV	Polio virus
RI	Routine immunization
RNA	Ribonucleic acid
SIAs	Supplemental immunization activities
tOPV	Trivalent Oral Polio Vaccine
TTV	Tetanus toxoid vaccine
VAPP	Vaccine associated paralytic poliomyelitis
VAR	Varicella
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus

BACKGROUND

History

Dating as far back as the 19th Dynasty (1580 - 1350 BC), there have been accounts of paralytic disease compatible with poliomyelitis such as the Egyptian stele portraying a priest with a withered leg [3]. However the first account of polio was not recorded until 1789 when British physician Michael Underwood described the disease as "debility of the lower extremities" [4,5]. In 1840 John von Heine, a German physician wrote a monograph not only describing the clinical features of poliomyelitis, but proposing that the symptoms suggest the involvement of the spinal cord, terming the disease infantile spinal paralysis, which was later generally known as Poliomyelitis [4].

Virology

The polio viruses (PV) are of the Enterovirus C species, within the genus Enterovirus which is part of the *Picornaviridae* family of viruses [6]. The PV are very small viruses (20 nm) and consist of a single-stranded, positive sense ribonucleic acid (RNA) genome of only 7,500 nucleotide bases in length [7]. The composition of the PV viron is very basic and consists of only of the short RNA genome and a non-enveloped icosahedral protein coat. The PV are classified into three distinct serotypes, PV1, PV2, and PV3, with each serotype based upon the antigenicity of the capsid proteins which are highly specific. This is reflected in the efficacy of PV vaccines where there is very limited cross-immunity against infection by other the serotypes [8,9]. PV is transmitted via the fecal oral route and the viruses typically infect the pharyngeal and gut epithelial monocytes via binding to the surface protein CD155 [10], and then rapidly replicate [11]. The entire PV RNA genome

is translated within an infected cell to produce a single large polypeptide which is subsequently cleaved by proteases to create over 10 proteins. These include several proteases, $2A^{pro}$ and $3C^{pro}/3CD^{pro}$, that cleave the original polypeptide into its constituent parts. The replication of the viral RNA genome is performed by an RNA dependent RNA polymerase in conjunction with a replication complex formed with the 2BC, 2B, 2C, 3AB, 3A, 3B proteins. The viral capsid consists of a further four viral proteins VP1 – VP4. The processes and the coordination of viral replication and assembly of the virons is not fully understood but it is estimated that a single infected cell will produce up to 10,000 virons which are then shed in the feces of the infected host [12].

Clinical Characteristics

These three serotypes of PV are all known to cause poliomyelitis, a disease that can be fatal or can result in permanent paralysis of limbs in children and infants causing lifelong disability. The median incubation period from infection to onset of paralysis is around 10 days, but can range anywhere from 3 to 35 days [13-15]. Transmission of PV occurs from person to person following the virus's entrance and replication in the pharynx and gastrointestinal tract and the subsequent shedding of high titers of virus [13]. From the sites of infection and multiplication in the mucosa, the virus can enter into the cervical and mesenteric lymph nodes and so onto the blood, creating transient viremia [11].

In some instances the virus will further invade the central nervous system (CNS) and destroy lower motor neurons, causing a clinically distinctive flaccid paralysis without permanent sensory loss [13,16]. Depending on the site of infection and paralysis, poliomyelitis can be classified as spinal, bulbar, or as a spino-bulbar disease [17]. The vast majority of PV infections are non-specific, with up to 72% of polio infections being asymptomatic, and less than 1% resulting in paralysis [18]. Infected individuals without symptoms still shed virus in their stool and are able to

continue the transmission of the virus to others [13]. Estimates of the ratio of poliovirus infection to paralytic illness vary widely from 50:1 to 500:1 and are depend on the patient age and viral serotype, with highest case-to-infection rate being reported in WPV1 infections [19]. On average for all serotypes, estimates suggest that only 1 in approximately 200 infections cause paralytic poliomyelitis [7,14]. The death to case ratio for paralytic polio ranges from 2-5% among children and between 15-30% for adults, however this may increase to 25-75% with bulbar poliomyelitis [13].

Polio Vaccines

Oral Polio Vaccine (OPV)

Trivalent Oral Polio Vaccine (tOPV) contains the attenuated Sabin strains of PV serotypes 1, 2 and 3 and was fist licensed for use in 1963 [20]. This vaccine is used for routine immunization and supplementary immunization activities in most low and middle income countries for a variety of reasons. OPV induces both mucosal and humoral immunity, the mucosal immunity prevents further PV infection and therefore replication and shedding of PV is limited, and humoral immunity prevents the spread of infection to the CNS thereby preventing poliomyelitis. As the viruses in OPV are attenuated, they replicate in the vaccine recipients and are shed in stool, which can infect others in the community and immunize or boost immunity through secondary spread (herd immunity). OPV is a very inexpensive oral vaccine to manufacture, and is easy to administration without a need for additional consumables. As an orally administered vaccine, parental/caregiver acceptance is generally found to be greater than with injectable vaccines. Because OPV is administered orally, highly trained vaccination staff is not required. OPV is a heat sensitive vaccine. OPV supplied by WHO accredited manufactures must be documented to retain potency for at least 48 hours at an ambient temperature of 37 degrees Celsius. While the heat

sensitivity of the vaccine can make implementation of high quality campaigns challenging, [21] the use of OPV in short campaigns (3–5 days) allows for new approaches to maintain the cold chain and preserve vaccine potency. In the late 1990s vaccine vial monitors became a standard way for vaccinators to monitor OPV potency prior to administration to a recipient [22]. These attributes of OPV allow effective mass vaccination of at risk populations [20].

OPV has been proven to be effective at inducing intestinal immunity to poliovirus with a single dose in approximately 50% of recipients. In developing country settings, seroconversion was observed in greater than 95% of infants after 3 doses [23]. Immediate adverse events to OPV are very low but it has been reported that vaccine associated paralytic Poliomyelitis (VAPP) can occur upon the first dose of OPV. This can be due to either the host being immune compromised and so more susceptible to infection of the CNS or by the virus regaining fitness for virulence via random mutation during production. Such VAPP events are however, quite rare, being estimated at one case per 1.5- 2.4 million doses [24,25].

Inactivated Oral Polio Vaccine (IPV)

An alternative vaccine to PV is the inactivated polio vaccine (IPV) which consists of virulent PV serotypes representing PV1, PV2 and PV3 that are inactivated after production. The administration of this vaccine requires intramuscular injection and unlike OPV, humoral immunity is the primary immune response. As the viruses are inactivated cases of VAPP cannot occur with this type of vaccine. Although effective in producing humoral immunity and preventing paralytic polio, IPV produces considerably less intestinal immunity than OPV. As a consequence, IPV recipients are more likely to become infected and shed WPV in stool than OPV recipients [26] IPV is currently not used in mass campaign settings as the vaccine is more expensive to manufacture

than OPV and its administration requires trained staff and needles/syringes for delivery which create additional challenges such as disposal and accidental needle sticks.

Global Polio Eradication Initiative

In 1988, the World Health Assembly (WHA) resolved to eradicate polio globally by the year 2000 and in doing so established the Global Polio Eradication Initiative (GPEI) as the vehicle to achieve this lofty goal. At that time it was estimated that over 125 countries were considered to be endemic with poliomyelitis with an estimated 350,000 children being paralyzed each year [27]. Since its inception, GPEI has administered more than 10 billion doses of OPV to more than 2.5 billion children globally, preventing an estimated 10 million cases of paralytic polio and 1 million childhood deaths [28].

In 2001, the successful implementation of polio eradication strategies via the GPEI resulted in a 99% reduction of reported cases of poliomyelitis globally [17], which included the successful eradication of the wild polio virus (WPV) serotype 2 in 1999 [29].

The transmission of WPV was significantly reduced through tailored GPEI strategies such as the use of mass immunization campaigns through the implementation of National Immunization Days (NIDs) and Supplemental Immunization Activities (SIAs), and the development of sensitive systems of epidemiologic and laboratory surveillance [30]. An important component of this success can be attributed to the widespread use of Sabin oral poliovirus vaccine (OPV). Due to OPV's ease of administration, low levels of adverse immune events, low cost (US$0.13 dose), and immunogenic properties, it remains the vaccine of choice for most developing countries [23].

In 2006, the 59th WHA passed resolution WHA59.1 urging member states in which poliomyelitis is endemic to act on their commitment to interrupt transmission of WPV through the

use of appropriate OPV [27]. This resolution strongly urged member states to implement a minimum of three large-scale rounds of immunization using OPV within 4 weeks of a confirmed index case, with an interval of 4 weeks between each round. All children under age 5 in the affected and adjacent geographical areas, or a minimum of two to five million children in large populations are to be targeted for vaccination. Independent monitoring after each round of vaccination is used to determine if the minimum coverage, at least 90% has been reached. In addition to the progress made toward the eradication of WPV 2, WPV 3 has not been found in either clinical or environmental samples since November 2012 [31]. In 2014, only WPV 1 remains endemic in three countries: Afghanistan, Pakistan, and Nigeria in Africa [1,2].

Although significant progress toward eradication has been achieved, polio remains a public health emergency. Polio has been eradicated from much of the world, however as long as the virus exists in any setting, the risks of further importation and continued circulation in under-vaccinated populations remain. One example in which importation and re-established transmission was particularly challenging is the Democratic Republic of Congo (DRC), where prior to 2001 wild poliovirus (WPV) had been endemic [32]. Although DRC had been conducting SIAs at the subnational and national levels (beginning in 1999 and 1996 respectively), and had not seen a case of WPV between the years of 2001 to 2005, a combination of events contributed to reoccurring outbreaks of WPV type 1 and WPV type 3 (2006-2010). These events included poor surveillance performance, proximity to a then endemic country, population movement, and poor population immunity (e.g. proportion of children under 5 years of age who have received zero doses of OPV, routine immunization coverage below 80%, and time since last polio SIA). The outbreaks were later identified as importations from the neighboring country of Angola [32].

Polio Campaigns

The objective of mass immunization campaigns known as SIAs or NIDs are to interrupt circulation of poliovirus by immunizing ever child under five years of age (< 5 years of age) with two drops (or one dose) of oral polio vaccine, regardless of previous vaccination history [33]. SIAs provide an additional opportunity to identify and vaccinate those eligible children who may have not received OPV via the routine program. These mass immunization campaigns are planned in advance and not exclusively conducted in response to an outbreak situation.

The strategy is to vaccinate children who are either not immunized, or only partially protected, and therefore boost immunity in those children who have been immunized. Through this approach, every child in the most susceptible age group (< 5 years of age) is protected against polio at the same time – thus removing the sub population that PV requires to sustain its infection and transmission on which its survival depends [11,20]. Therefore if such a strategy is to succeed, it is imperative that vaccinators ensure that every dwelling is visited, including isolated communities, slums, and any area teams may have difficulty accessing or are unlikely to visit and every targeted child within these areas receives the appropriate dosage of OPV.

To best implement this strategy, polio campaigns are conducted as either fixed post or house-to-house campaigns and are typically conducted over the course of two to three days. Fixed post campaigns occur in stationary locations that are well known to the population such as health centers or schools. The term fixed post refers to the fact that the vaccination teams are not mobile. Conversely, house-to-house campaigns are conducted with mobile vaccination teams going house-to-house to reach every eligible child for vaccination.

Independent Monitoring History

For the evaluation of SIA, reliance on coverage figures may be unreliable. Acute Flaccid Paralysis (AFP) surveillance is considered the gold standard for evaluating campaigns in the longer term, however IM is a tool designed to provide an objective independent source of rapid and reliable quantitative data for each campaign [28]. IM is used to identify reasons for missed children and guide future interventions specific to the needs of the area. The degree of scientific validity should not be a major concern for monitoring as the purpose is to identify weak areas and a certain level of subjectivity is inevitable [33]. Independent monitoring data should also be used in the planning and development of upcoming immunization activities. Data generated through independent monitoring should be reliable and timely in order to effectively evaluate progress and take corrective action [33].

The basic elements of monitoring include documenting the number of children monitored, the percentage of children vaccinated as assessed by finger marking of the nail bed of the left little finger with silver nitrate permanent marker pens lasting approximately 90 days from the time of vaccination (both in house-to-house monitoring and out-of-house) and the proportion of districts monitored [33].

Due to the lack of credible and timely SIA coverage data to assess risks and guide improvements in both endemic and in re-infected countries, in November 2009, the American College of Physician Executives (ACPE) recommended the implementation of new guidelines, protocols requiring the use of standardized modules of data, and criteria for re-vaccination of areas. These recommendations were designed to facilitate real-time independent monitoring as a way to rectify the problem of unreliable and delayed SIA data. As a result, governments as well as GPEI would have a more accurate way to measure SIA performance through a combination of finger

marking and independent monitoring [34]. As a way to address the timely receipt of data, the new guidelines required IM to be made available within 15 days of each immunization round [3].

In 2010, GPEI institutionalized standardized real-time IM as part of the GPEI Strategic Plan (2010-2012). Reports were required to include the number and source of monitors, the number of children monitored, the percentage of children found unimmunized (i.e. without finder marking) through both methods of monitoring (house-to-house and out-of-house), the reasons children were not vaccinated, whether parents/care takers were aware of the SIA prior to the commencement of the campaign, and the number and percent of districts were monitored [3]. Actions resulting from data analysis may include corrective measures such as immediate revaccination of areas identified as having <90% campaign vaccination coverage [28].

There are two types of monitoring associated with OPV campaigns, in process monitoring which occurs during the course of the campaign and end process or post campaign monitoring. In process independent monitors observe the performance during the SIA and may include supportive supervision through direct monitoring of vaccination teams. The data derived from in process monitoring can be used to identify vaccination teams as well as areas requiring immediate corrective action in order to reach unvaccinated children [3]. End process or post campaign monitoring occurs after the SIA has been completed. During this process monitors visit houses and other areas such as large markets or crowded areas to check the vaccination status of children based on finger marking. The data generated through end process monitoring provides an independent estimate of campaign coverage as well as reasons for unvaccinated children. [33] Both in process and end process monitoring are designed to evaluate campaign quality.

End process monitoring is comprised of two approaches, house-to-house and out-of-house or convenience surveys. In house-to-house monitoring monitors will visit clusters of houses and

assess the vaccination status of the children who are available. Out-of-house monitoring is a quick method which involves checking the vaccination status of children in crowded areas such as marketplaces within the same district [33].

Country Context

The Democratic Republic of the Congo (DRC), previously known as Zaire (1971–1997), is geographically the largest country in sub-Saharan Africa at 2.3 million km^2, sharing borders with nine neighboring countries Congo-Brazzaville, Central African Republic, Sudan, Uganda, Rwanda, Burundi, Tanzania, Zambia, and Angola) and has an estimated population of 70 million inhabitants [35]. The DRC is emerging from more than four decades of conflicts and mismanagement that have devastated the economy and killed a significant number of its population with an estimated 3.5 million of its citizens having died since 1998. This fragile society continues to struggle to recover from a devastating multi-year conflict that has resulted in mass internal population displacement (estimated at 2.4M people), and significant non-investment and deterioration of the national infrastructure, including roads, schools, access to clean water and a collapse of the public health system [35]. In 2006 a revised constitution defined DRC as a unitary nation but also recognized it as a decentralized country comprised of 11 provinces to be further segmented into 26 provinces. The decentralization framework was envisaged to transfer the responsibilities and competencies in health, primary and secondary education, and agriculture to each of the provinces [36].

In terms of public health structure and organization, the DRC is divided into 43 health districts comprised of 516 health zones. Within the 516 health zones, there are 8,830 health centers servicing 8,830 catchment areas. The Expanded Program on Immunization (EPI) at the federal level is responsible for immunization policy, purchasing of vaccines, and technical guidance. This

program has a management structure compromised of 11 provincial coordination offices in alignment with the transfer of responsibility and control from the national to provincial level and a further 43 antenna offices within these and 43 antenna offices.

The data analyzed for this report was collected between 2010 and 2013 during national SIAs and was limited to the province of Kinshasa, the Democratic Republic of Congo. Kinshasa is located in the southwest of DRC along the river Congo and is the capital and largest city covering an area of 9,965 square kilometers [37]. Although no national census has been conducted since 1984, the population for the years 2010 through 2013 were estimated at 6.9M, 7.2M, 7.1M, and 8.1M people respectively [38-41].

Kinshasa province consists of 1 provincial coordination office, 3 EPI antennas offices and 35 districts or health zones and 400 health centers servicing both urban and rural communities [37]. The data collected for this analysis included all 35 health zones in Kinshasa province (table 1, list of health zones).

Figure 1. Map of Kinshasa province, DRC.

METHODS

IM Methodology

End process IM is conducted after a campaign has been completed and is typically completed within two to three days. The purpose of IM is to provide a crude estimation of the extent of unvaccinated children in the area through house-to-house and out-of-house (or convenience surveys). This is not a truly random population based survey, but it nonetheless provides information to assess areas that are of high risk of transmission. IM identifies reasons for missed children to guide future interventions specific to needs of the area in DRC [3].

The overall responsibility of recruitment, training and management of the monitors lies with the WHO in-country surveillance and monitoring team. The monitors must not be affiliated with the Ministry of Health sector or be directly involved in the SIA operations including participation as a vaccinator or supervisor.

All high risks districts are subject to independent monitoring. Districts selected for independent monitoring are done via a collaborative process between the MOH and WHO and are identified during the planning process prior to the commencement of the SIA. Criteria for identifying high risk districts and sub districts can be found in Table 4.

AFP surveillance	Immunization	Demographic & geographic characteristic
Recent or on-going or suspected wild poliovirus circulation, from AFP surveillance or environmental surveillance	Low immunization coverage (routine and/or SIA)	High risk areas/populations: slums, displaced populations, refugee camps, crowed and highly populated urban area with condensed high-rise buildings, mobile communities including nomads and seasonal workers, conservative communities, areas with Administrative instability, management problems or insecurity, etc.
Clusters of AFP cases	Under-performance in previous campaigns	Border and hard to reach districts/areas
Recent compatible cases	Discrepancies between reported and post-campaign evaluation results of recent rounds	Area with population connection to other countries/areas where circulation of the wild virus is known or suspected
Silent or underreporting areas		

Table 1. Criteria for identifying High Risk districts/sub districts

In a district, six localities are randomly selected by each monitoring supervisor to be visited each of the two to three days. The expectation is that 10 households be randomly selected from each locality for house-to-house monitoring. In addition, out-of-house monitoring or market surveys should be conducted in the same geographic area to obtain a representative estimate of SIA performance. It is recommended that the monitors must check 50 to 120 children under 5 years of age as part of out-of-house monitoring, depending on the density of population. Areas selected for out-of-house monitoring should include large markets or busy streets in an attempt to check vaccination of as many children as possible [3].

The number of IM teams required for a SIA is determined based on a calculation of the SIA target population for a given district. Each team is made up of two monitors who have been

recruited and trained by WHO. Monitors should have some familiarity with polio eradication and be familiar with the area to be monitored. They should be familiar with the culture, and language and should be accepted/respected in the community they are monitoring. Monitors must also be comfortable interviewing parents/child care takers [3]. Each monitor is supplied with survey questionnaire forms in order to collect data on the number of children vaccinated, proportion of children missed (or unvaccinated), and the reasons for lack of vaccination. The gold standard for vaccination is the verification of finger marking with an indelible marker. When independent monitors identify unvaccinated children, they are instructed to mark only one reason on the questionnaire for non-vaccination.

When conducting house-to-house monitoring, if a monitor encounters three houses out of 10 with at least one child unvaccinated, the vaccinator should identify this area as poorly covered and should be flagged for re-vaccination (or mop-up) activities [3]. The identification of a poorly covered area should be investigated by the district and provincial immunization teams and actions such as improved training, development of microplans, and increased social mobilization should be implemented in subsequent rounds to improve coverage.

This study used univariate ANOVA analysis were performed using Stata 13.1 software. The test provides Z statistics and p value showing whether the change is statistically significant or not. Additional analysis was conducted using Microsoft Excel 2013.

Data

Data for this study were provided by the Immunization, Vaccines and Emergencies (IVE) Team, Regional Office for Africa (AFRO), World Health Organization (WHO) country office located in Kinshasa, DRC. Independent monitoring was conducted in accordance with WHO's

Global Guidelines for Independent Monitoring for Polio Supplementary Immunization Activities (SIAs) [33].

The dataset was derived from a completely de-identified and IRB exempt independent monitoring database maintained by the provincial polio team office located in Kinshasa, DRC Office, AFRO, WHO. Fifteen variables were included for analysis in the final dataset, a list of the variables and their descriptions can be found in Table 1.

Variable	Description
Dist_Name	Name of the district
Start_SIA	Start date of the campaign
Hous_Nbr_Check	Number of houses checked by the Independent Monitors
Hous_Nbr_Mark	Of the houses checked by the Independent Monitors, number of houses correctly marked by vaccination team
HH_Nbr_Child_Elig	Number of children under-5 eligible in the households visited
HH_Nbr_Child_Check	Number of children under-5 physically checked by the monitors
%_Unvaccinated_HtH	Percent unvaccinated children house-to-house
HH_Nbr_Child_Mark	Number of children under-5 marked
Out_Nbr_Child_Check	Number of children under-5 physically checked by the monitors (out-of-house)
Out_Nbr_Child_Mark	Number of children under-5 marked (out-of-house)
%_Unvaccinated_Out_House	Percent unvaccinated children Out-of-House
Nbr_Child_HousNotvisitd	Number of children under-5 not vaccinated due to house not visited
Nbr_Child_Absent	Number of children under-5 not vaccinated due to Absence
Nbr_NonCompliance	Number of children under-5 not vaccinated due to Non-Compliance
Nbr_OtherReason	Number of children under-5 not vaccinated due to other reason

Table 2. Complete list of variables and their descriptions included in the final dataset for analysis

All independent monitoring data collected during end process monitoring of polio SIAs conducted in 35 health districts in Kinshasa province from August 2010 to October 2013 was considered for analysis. Between August 2010 and October 2013, Kinshasa province conducted a

total of 12 SIAs. Health districts that presented no IM data in response to campaigns were not included in the analysis.

This study used independent monitoring data collected at the health district level using a standard data collection tool (questionnaire) developed by WHO. The questionnaire includes both open and closed-ended questions designed to evaluate vaccinator performance and campaign quality. The questionnaires were completed by independent monitors based on interviews with caregivers. The completed questionnaires were submitted to WHO personnel responsible for data validation at the federal and health district level within one week of completion of the SIA. From this time, feedback is provided to the provincial and federal level EPI Coordinators. The data were shared with the WHO Regional Office for Africa (WHO/AFRO) and WHO headquarters 10 to 15 days after completion of the SIA (respectively).

This descriptive analysis was carried out to provide a comprehensive evaluation of the end process independent monitoring conducted immediately following polio campaigns in Kinshasa province, DRC from 2010 to 2013.

The key indicator of the success or failure of SIAs is the proportion of children missed during SIAs. With well-coordinated and organized campaigns a vaccination rate of 90% is considered successful. This paper presents the trends in proportion of children missed during polio immunization campaigns between 2010 and 2013 and compares the outcomes among selected districts in Kinshasa, with varying SIA experiences.

RESULTS

The data show a progressive reduction in the proportion of unvaccinated children identified through end process IM of OPV SIAs conducted in Kinshasa province, DRC between 2010 and 2013 (Fig. 2, Fig. 3). The reduction was consistent in both house-to-house and out-of-house monitoring practices.

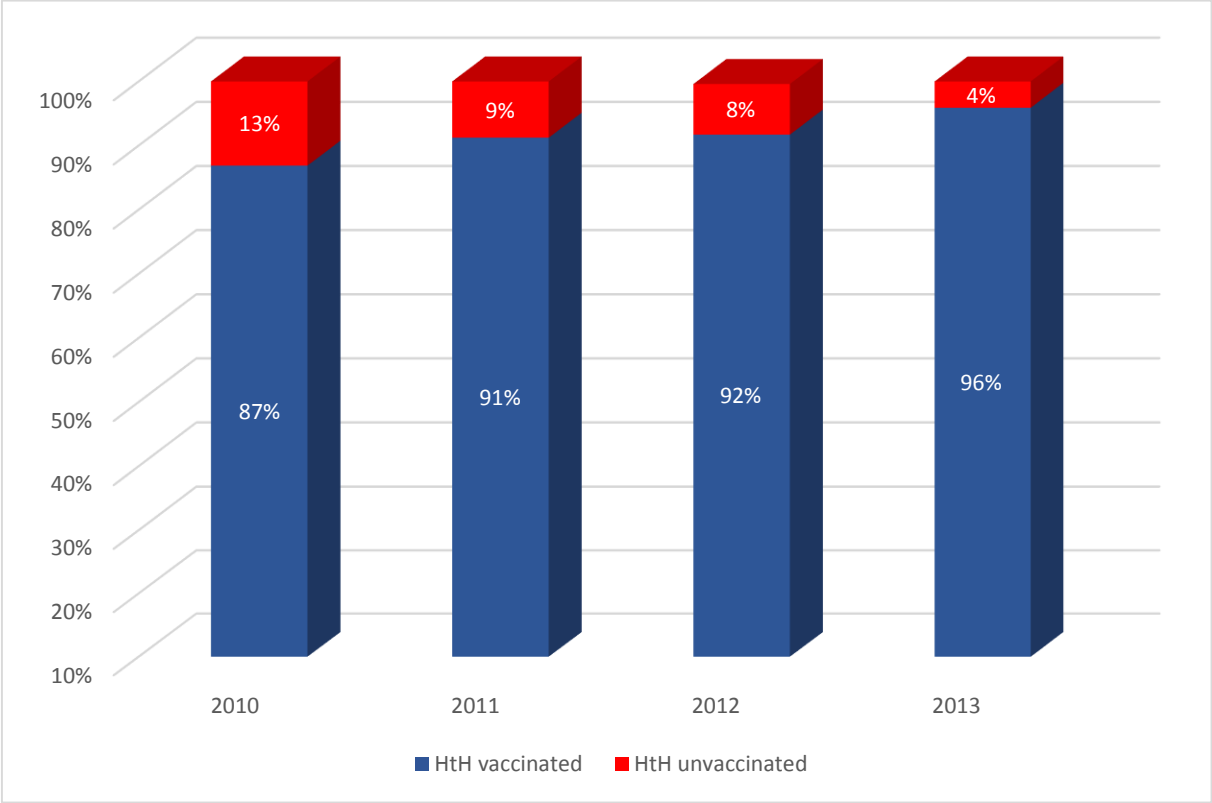

Figure 2. The distribution of proportion of missed children by year (house-to-house method). The blue fill represents children vaccinated (presence of finger marking) as validated through end process house-to-house monitoring, while the red represents children that were identified as missed or unvaccinated through the same method

When the house-to-house data was analyzed using the same method described above, a trend in decreasing proportion of unvaccinated children from 13% in 2010, to 4% in 2013 (Fig. 2) was observed indicating an overall incremental improvement in campaign quality at the province level. Conducting an univariate ANOVA test, a statistically significant difference was observed in

the proportions of unvaccinated children between 2010 and 2013 (F= 16.74, P<0.0001). This metric showed sufficient vaccination coverage in three of the four years.

However, when out-of-house monitoring data conducted in the same districts were analyzed, the sequentially improving trend observed in figure 1 was not consistent (Fig. 3). For the first three years of analysis, more than 10% of those checked were found to be unvaccinated with the largest proportion of unvaccinated children identified in 2012 at 16%. In 2013, a statistically significant reduction in the proportion of unvaccinated children was observed through univariate ANOVA (F=15.79, P<0.0001) had occurred and was more similar to the results seen in house-to-house monitoring (Fig. 2) at 94%.

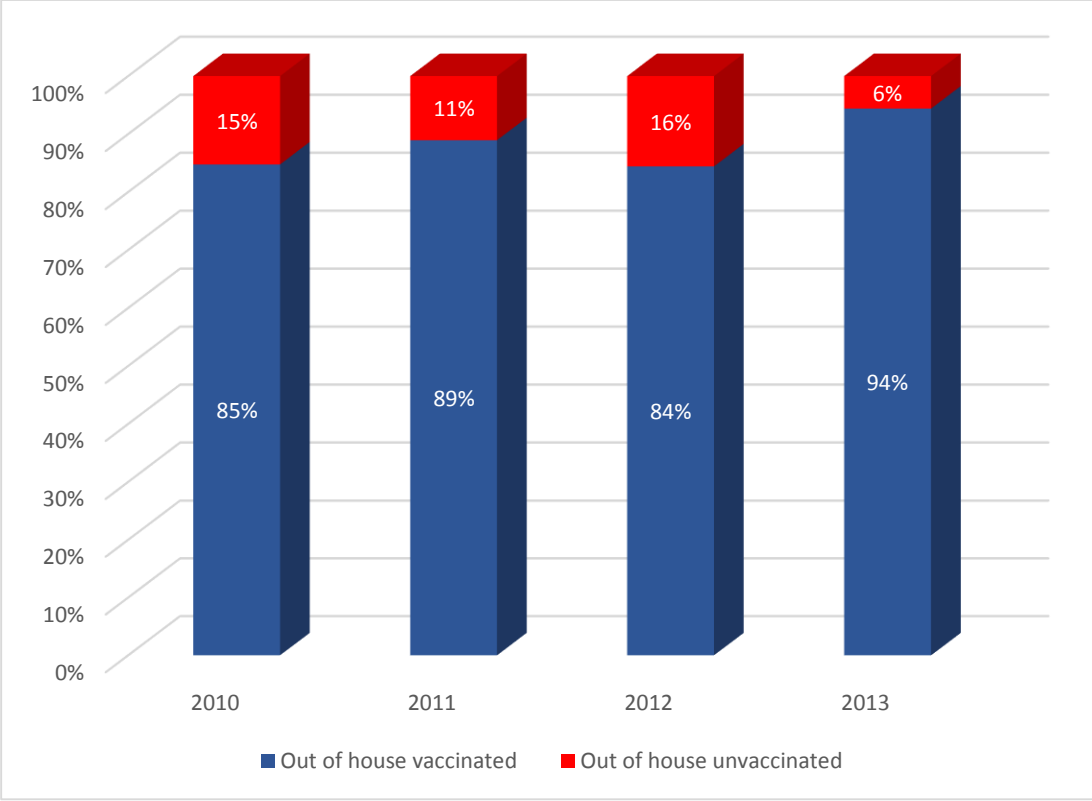

Figure 3. The distribution of proportion of missed children by year (out-of-house method). The blue fill represents children vaccinated (presence of finger marking) as validated through end process out-of-house monitoring, while the red represents children that were identified as missed or unvaccinated through the same method.

When the house-to-house data was analyzed at the district level by year a markedly reduced variance in proportions of children missed was observed (Fig. 4). The heterogeneity among the districts was also evident by the large spread between the upper and lower bounds.

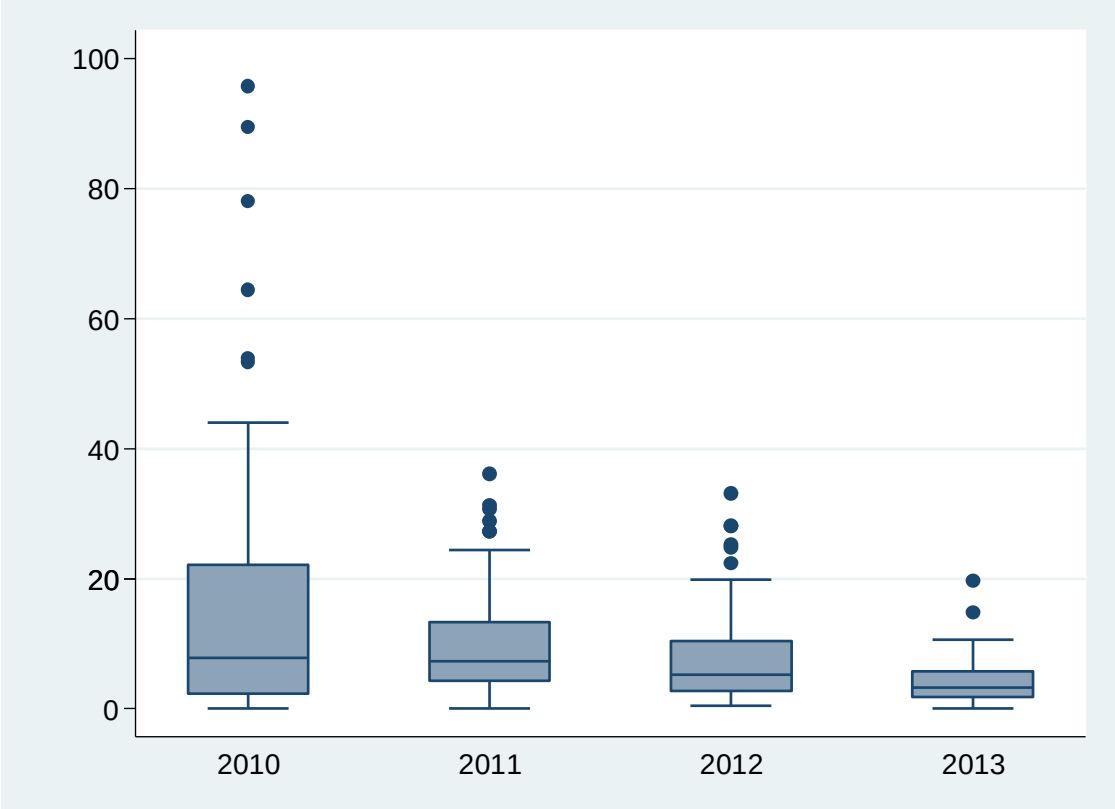

Figure 4. A graphical representation of house-to-house independent monitoring results by district by year (data includes the proportion of unvaccinated children age up to 5 years of age spanning 2010 to 2013).

In contrast, the out-of-house district level data in figure 4 highlights the problem of poor campaign quality based on proportions of unvaccinated children as identified during end process monitoring seen in 2010. It is apparent the vaccine campaigns conducted was inconsistent across years nor was it consistent with the results seen in house-to-house monitoring.

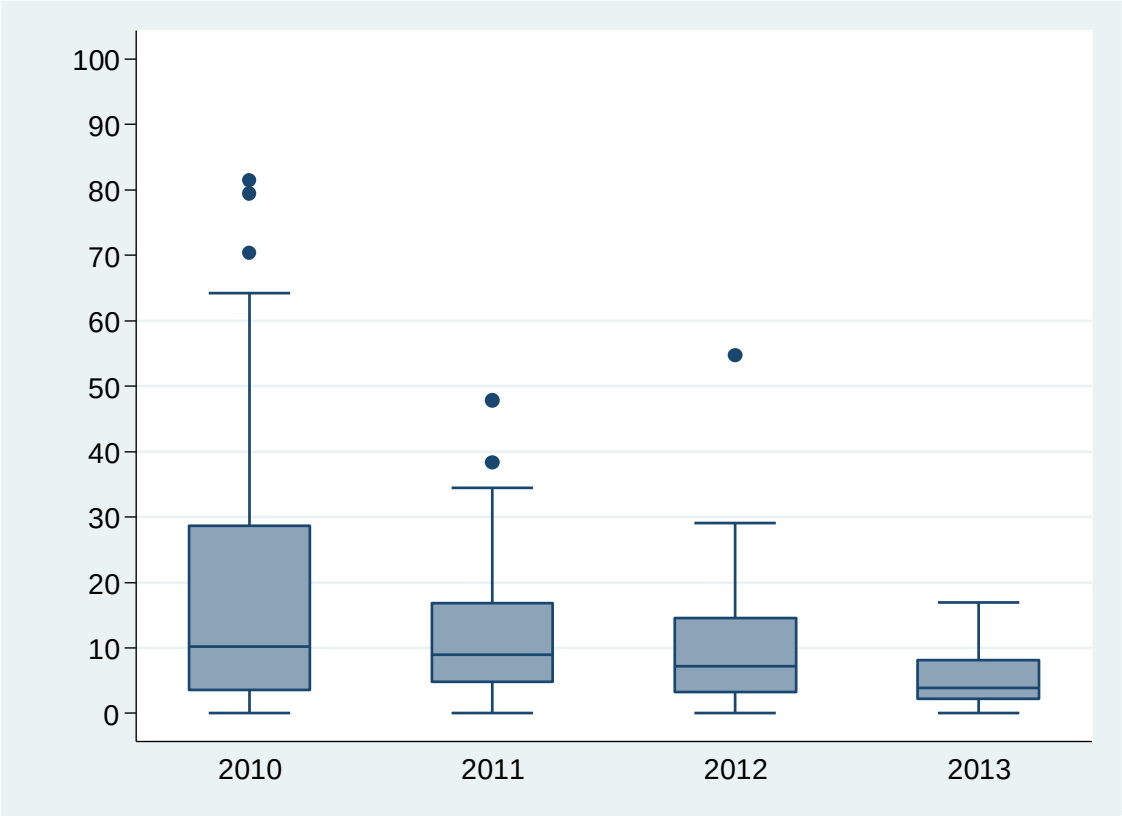

Figure 5. A graphical representation of out-of-house independent monitoring results by district by year (data includes the proportion of unvaccinated children age up to 5 years of age spanning 2010 to 2013)

At the aggregate level, the target vaccination rate of 90% was not met by the province until 2013. However, the progressive decrease in unvaccinated implied consistent improvement in campaign quality. When smaller datasets representing the districts within the province are analyzed, starkly differing trends in campaign quality (as measured by proportion of unvaccinated children) emerge.

The districts were analyzed and ranked individually using proportions of children unvaccinated by either house-to-house or out-of-house monitoring methods. Of the 35 districts in Kinshasa province, only Ngaba, Masina I, and Matete districts were shown to have less than 10%

unvaccinated children when checked by IM (table 2). More importantly, not one district was found to have been successful in meeting the threshold for both house-to-house and out-of-house monitoring methods.

Districts	Type of Monitoring	Campaigns conducted with ≤ 10% unvaccinated children (%)	Average coverage over 4 years (%)
Ngaba	H2H	100	97
Masina I	H2H	92	95
Matete	OOH	91	88

Table 3. Top performing districts

Ngaba district (target population approximately 29,092) performance shown in figure 6, reveals a consistently high level of campaign quality as measured by the proportion of unvaccinated children across the 12 campaigns conducted during the years analyzed. Across all 12 campaigns Ngaba district identified less than 10% unvaccinated children as measured through house-to-house monitoring (Figure 6).

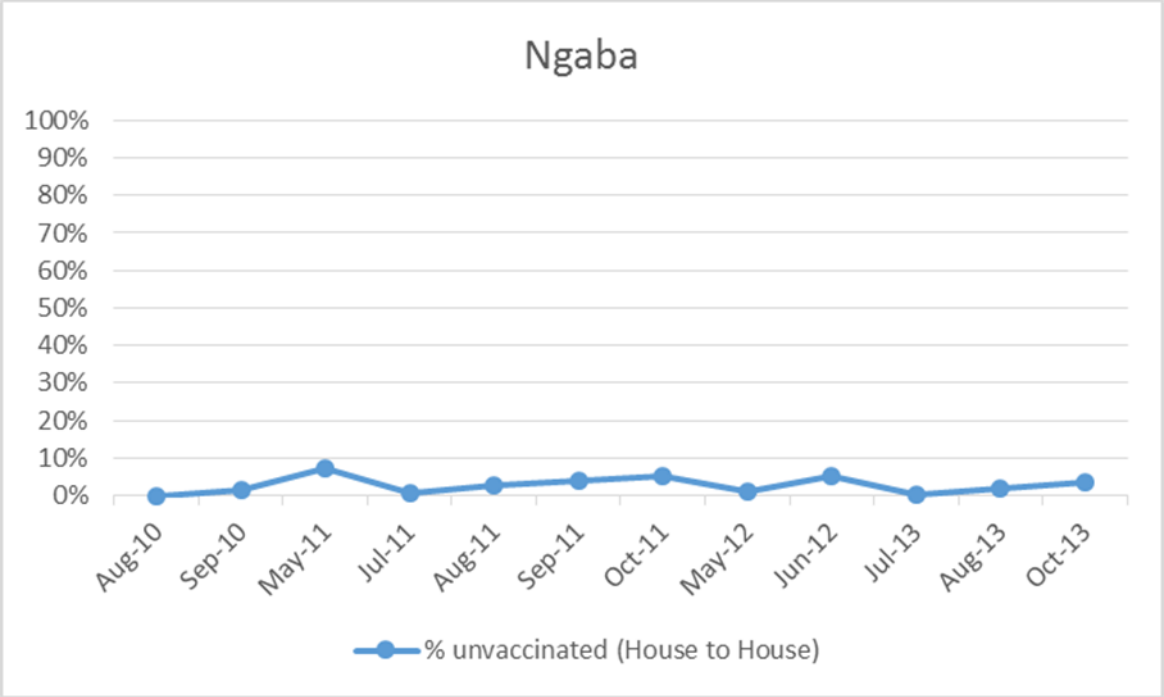

Figure 6. Ngaba district, proportion of unvaccinated children checked during house-to-house monitoring by campaign

The performance of Masina I's district (target population approximately 53,414) shown in figure 7, exhibits a similar level of high campaign quality. The first five campaigns conducted between August 2010 and August 2011 found less than 10% of the children checked to be unvaccinated during house-to-house monitoring. However the September 2011 campaign identified 14% of children checked were unvaccinated. In the six campaigns following September 2011, Masina I had less than 10% of the target population of children unvaccinated children through house-to-house monitoring demonstrating improved campaign quality.

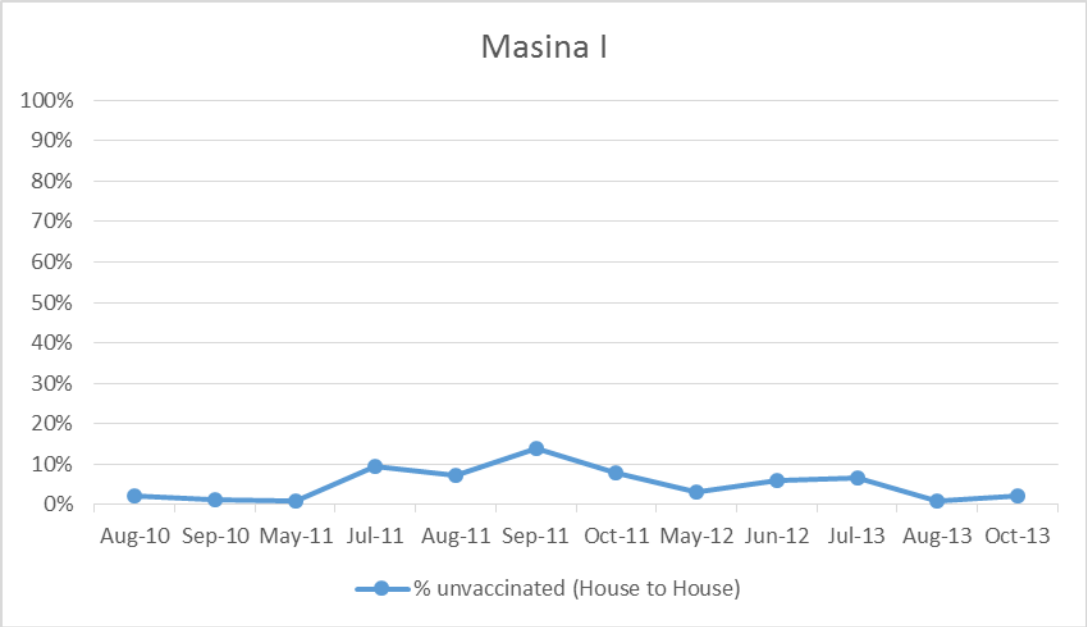

Figure 7. Masina I district, proportion of unvaccinated children checked during house-to-house monitoring by campaign

The performance of Matete district (target population approximately 55,581) as shown in figure 8 began poorly with 70% of the targeted population identified as unvaccinated by out-of-house monitoring in August of 2010. However, the following nine campaigns conducted in Matete were found to have 10% or less unvaccinated children through out-of-house monitoring.

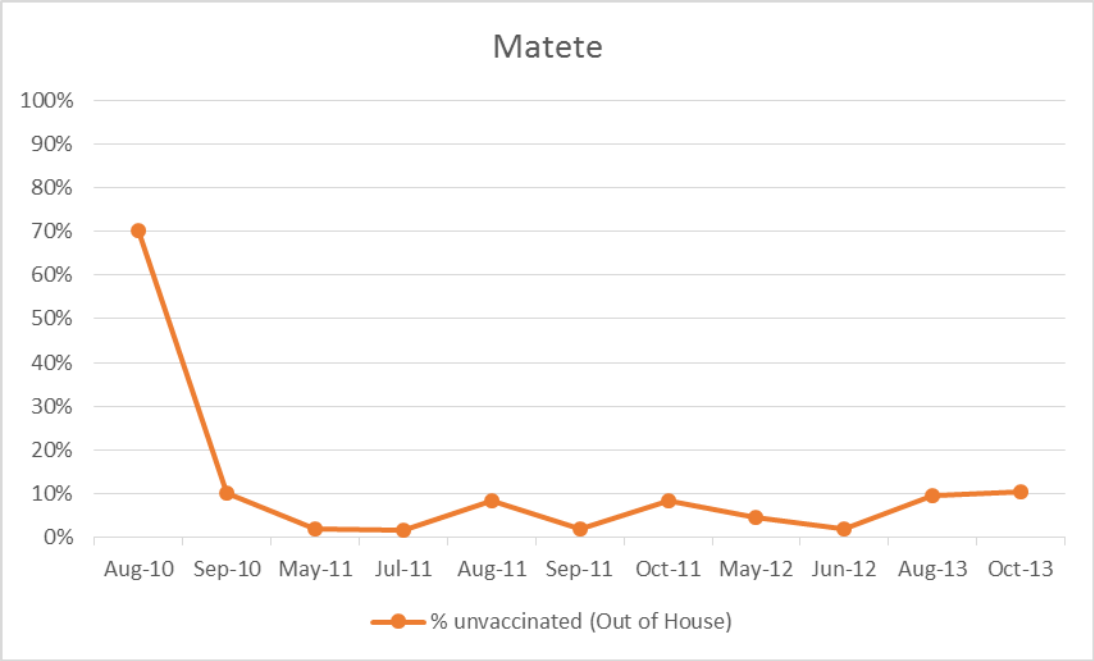

Figure 8. Matete district, proportion of unvaccinated children checked during out-of-house monitoring by camp

The districts that were found to have the poorest levels of performance over the four years were Kimbanseke, Biyela, and Mont-Ngafula II shown in Table 3.

Districts	**Type of Monitoring**	**Campaigns conducted with ≤ 10% unvaccinated children (%)**	**Average coverage over 4 years (%)**
Kimbanseke	OOH	30	82
Biyela	OOH	33	81
Mont-Ngafula II	OOH	33	86

Table 4. Poor performing districts

Kimbanseke district (target population approximately 54,217) shown in figure 8 began poorly with 36% of the targeted population identified as unvaccinated by out-of-house monitoring in August of 2010. Over the next three campaigns there was a progressive decrease in the

proportion of unvaccinated children with one elevated data point which differed from the overall trend.

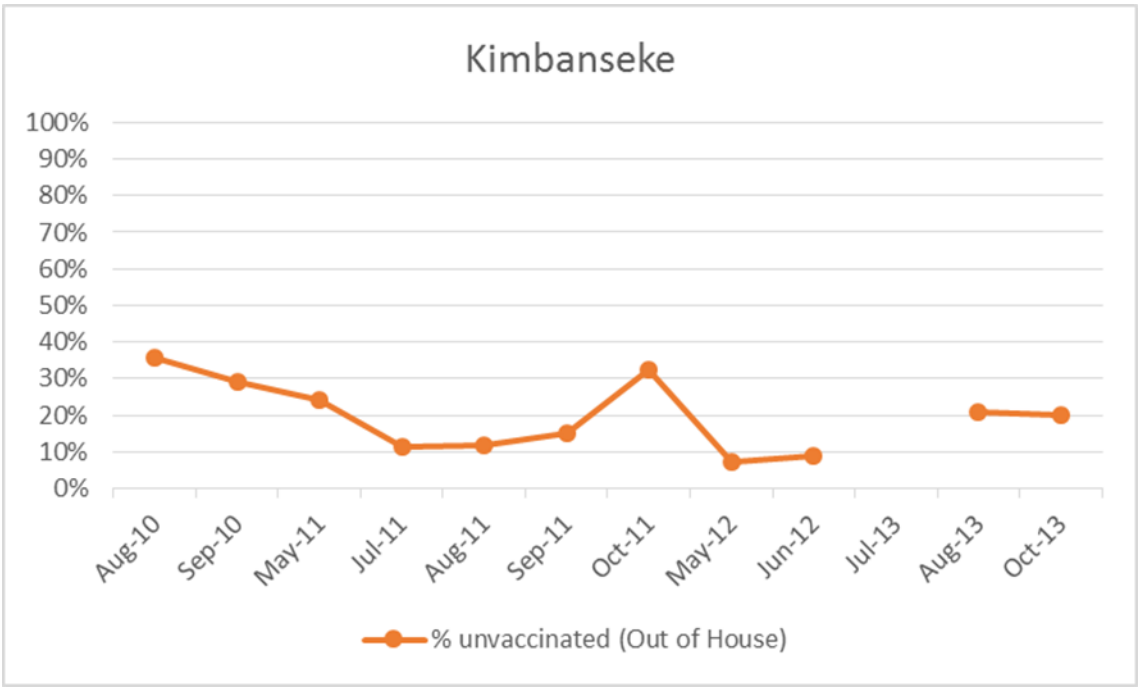

Figure 9. Kimbanseke district, proportion of unvaccinated children checked during out-of-house monitoring by campaign

Biyela district (target population approximately 39, 500) shown in figure 10 has had consistently poor performance with 67% of their SIA identifying 10% or more of the target population as unvaccinated by out-of-house monitoring. This district conducted three successful SIAs (one in 2010 and two in 2011) demonstrating that good campaigns quality is achievable. However, their overall performance coupled with the absence of data for 2013 makes it difficult to accurately understand whether programmatic improvements have occurred. Similarly, Mont-Ngafula II district (target population of approximately 39,500) has also had challenges in maintaining consistently good SIA quality. However, based on the out-of-house monitoring Mont-

Ngafula II has begun to show signs of consistency with the last four SIAs identifying less than 10% of unvaccinated children (figure 11).

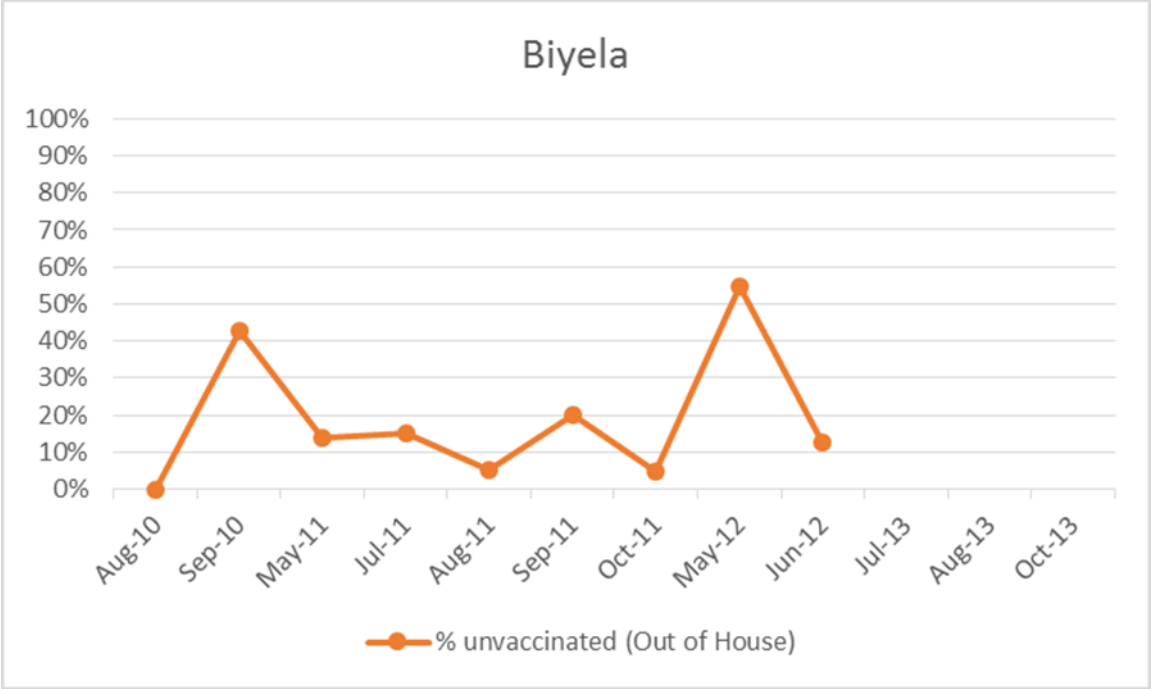

Figure 10. Biyela district, proportion of unvaccinated children checked during house-to-house and out-of-house monitoring by campaign

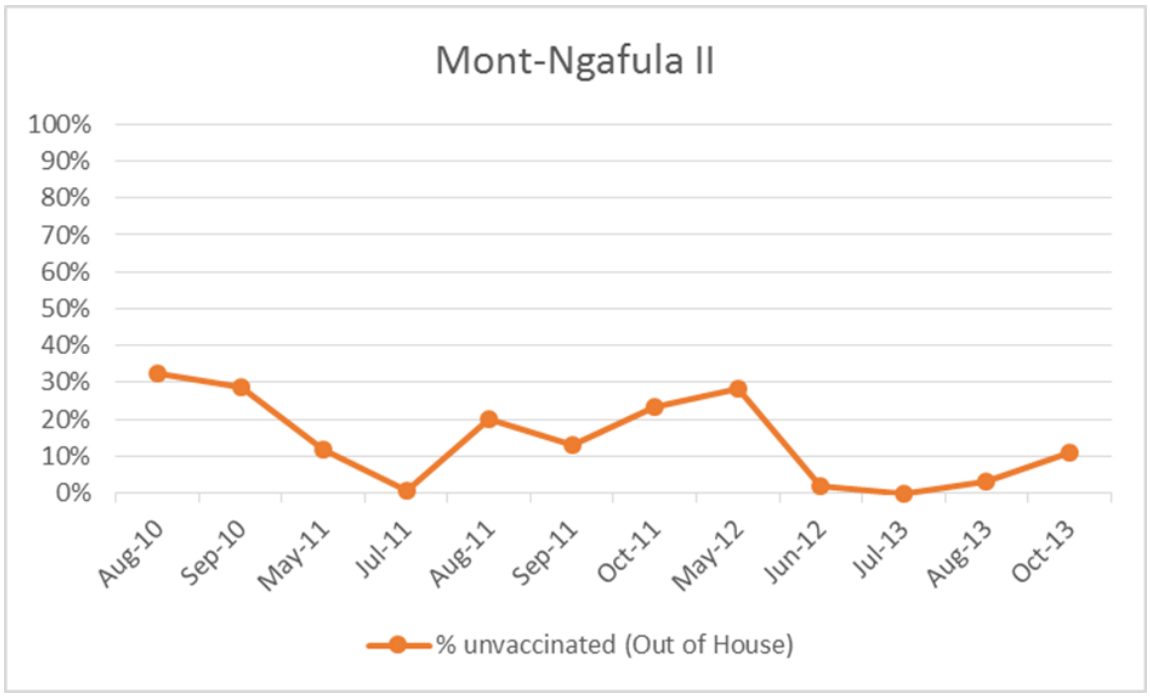

Figure 11. Mont-Ngafula II district, proportion of unvaccinated children checked during house-to-house and out-of-house monitoring by campaign

In addition to identifying the proportion of children unvaccinated, it is very important to understand the underlying reasons for non-vaccination. This form of information can assist with the planning of future campaigns in order to maximize coverages rates. As part of the IM process, monitors are instructed to collect data from parents/care givers on the reasons for non-vaccination (figure 12).

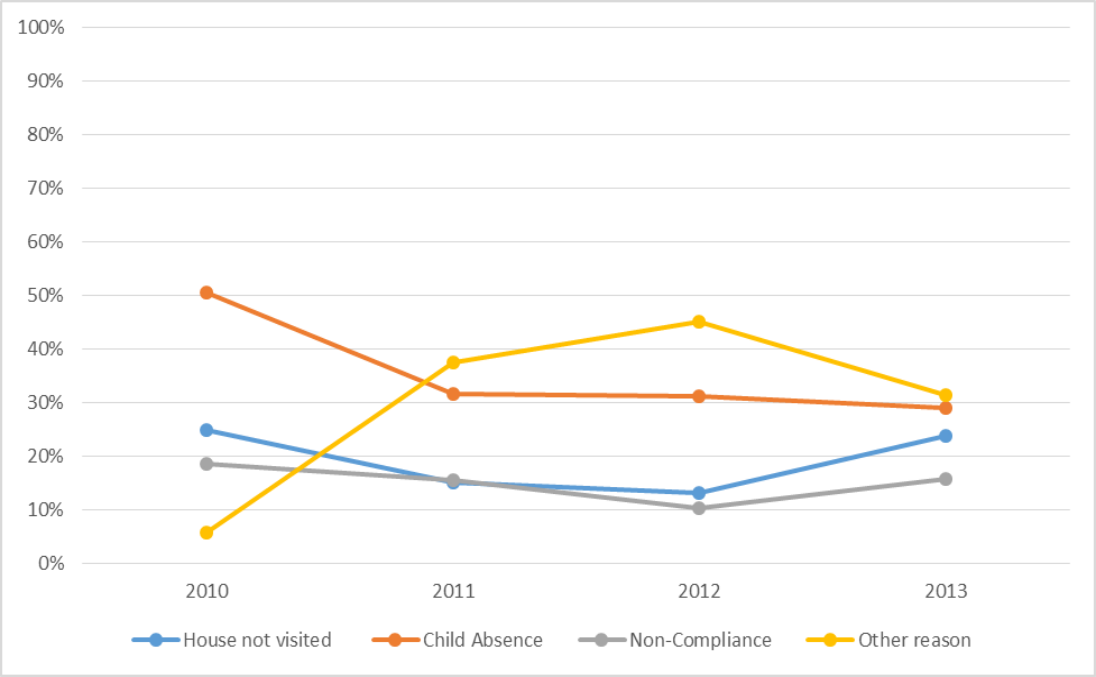

Figure 12. A depicting the overall distribution of reasons for non-vaccination collected during end process IM on-vaccination (2010 2013)

The data represented in figure 12 shows the trend over time of reasons for non-vaccination. Reasons include "child absent", "house not visited", "non-compliance" and "other". The data indicates that in 2010 more than half of the children that were unvaccinated were due to "child absence". In 2011 "child absence" had decreased to ~30%, where it remained through 2013. The

rates of “non-compliance” and “house not visited” were very similar across 2010- 2013 and both fluctuated between 20% – 10%. The category of “other” in 2010 was used in only 5% of all cases, however in 2011-2013 this was shown to be the most commonly cited reason for non-vaccination at just above 30%.

DISCUSSION

The results of this analysis suggests an overall reduction in the proportion of unvaccinated children in Kinshasa province, DRC. The data presented in the first part of the results suggest that as a province, Kinshasa has significantly improved their overall vaccine coverage. In 2013, 5% of the target population checked during house-to-house monitoring was identified as unvaccinated, representing a statically significant reduction in the proportion of unvaccinated children since 2010.

Although inconsistent performance at the district level was identified, all districts conducted at least three SIAs in which 10% or less of the target population checked were unvaccinated. Demonstrating the districts capability to meet the GPEI's global standard for conducting a successful campaign (vaccination rate ≥ 90%), suggesting the problem lies with the districts' ability to maintain good SIA quality on a consistent basis.

In 2011, 33 of 93 cases of WPV confirmed across DRC, were identified in Kinshasa province alone representing 35% of all cases. In response the government launched several SIA campaigns in order to contain the epidemic and interrupt transmission. The data derived from end process IM provided critical information on campaign quality and likely allowed for more directed SIA planning to occur, likely contributing to the interruption of transmission of WPV in Kinshasa province by the end of 2012.

Although the process of independent monitoring is not designed to provide sampling of unvaccinated children appropriate for statistical comparisons, the data generated provides critical information to assess communities of low vaccine coverage and therefore at high risk of WPV. Since its mandatory use and standardization in 2010 IM has demonstrated its utility in providing

a real-time assessment of campaign quality. Though the study presented data on both out-of-house and in-house monitoring, the discrepancies between the two methods should not be overemphasized. Different populations of children likely encountered during out-of-house and in house monitoring: Thus, the discrepancies in rates of unvaccinated children by the two methods are likely due to selection biases inherent in each monitoring method, with the house-to-house method sampling more stable and cooperative families. While this study focused on unvaccinated children as the measure of campaign quality, additional information is also collected through the IM process that collectively provides a comprehensive assessment of campaign and vaccinator quality. Examples of additional variables include whether the caregiver is aware of the disease for which the campaign is being conducted, parental awareness of the campaigns, and number of houses correctly marked. All of these variables impact campaign quality and overall program performance.

An area requiring further analysis, but beyond the scope of this project include the reasons for non-vaccination. In order to improve the quality of campaigns and implement directed interventions to reduce the number of children unvaccinated it is essential to better understand the reasons for non-vaccination. The analysis conducted on the reasons for non-vaccination showed an increase in the other reasons category, however without additional detail into what this actually represents, no effective intervention can be implemented.

RECOMMENDATIONS

From this study, there are immediate IM directed changes that would improve SIA quality in Kinshasa province. The first recommendation is to provide one additional day of training between in-process and end process directed at monitoring. This day should concentration on data

quality. By effectively training the monitors, you provide the monitors with the tools necessary to improve data quality. This analysis revealed poor data quality in 17 of the 35 districts.

The second IM recommendation is to expand the IM questionnaire to address reasons for non-vaccination. Currently the questionnaire lists four categories for non-vaccination. These are "house not visited", "absence", "non-compliance", and "other reasons". As reflected in the data, the "other reasons" category has progressively increased as the response provided by parents when asked why their child was not vaccinated during the campaign. As it currently exists, this category is too generic. One could speculate that it is a catch-all category which masks barriers that could and should be understood to improve SIA coverage. Additional analysis should be conducted to identify underlying reasons for missed vaccination.

The final recommendation is the timely disbursement of funds to the districts for pre-campaign activities to be conducted. The EPI and implementing partners are reliant upon receiving timely and adequate funds to conduct the pre-campaign, campaign, and post campaign activities. By ensuring timely disbursement of funds to district level EPI and implementing partners, coordinated activities that impact campaign quality such as pre-campaign assessments, vaccinator training, social mobilization activities, and independent monitor training can occur in a timely manner.

LIMITATIONS

A major limitation of this study include the fact that independent monitoring is not designed to be a statistical measure, but is intended to provide a rapid objective assessment of program performance based on proportions of unvaccinated children identified through house-to-house and out-of-house surveying. It is used to identify areas of poor vaccine coverage and to implement programmatic corrective action. An additional limitation of the study is poor data

quality and concerns regarding the validity of data from certain communities. Given the limited sample sizes, the true vaccine coverage could not be estimated. Similarly, the generality of the categories to describe reasons for non-vaccination do not appear to allow the program to pin-point problems in reaching children <5 years of age.

CONCLUSION

As eradication of polio gets closer, IM become increasingly more important to address remaining gaps in SIA quality. Being able to identify areas with continuing weak coverage will help the program focus their resources and efforts on high-risk areas and implement corrective action.

The recommendations resulting from this study, including to better train monitors, expand vaccine refusal categories to 10 and ensure timely disbursement of funding to district level EPI and implementing partner programs, if implemented, are likely to increase polio vaccine campaign coverage and reduce the number of unvaccinated children.

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