Impact of vaccine stock-outs on infant vaccination coverage : a hospital-based survey from South Africa

IMPACT OF VACCINE STOCK-OUTS ON INFANT VACCINATION COVERAGE: A HOSPITAL-BASED SURVEY FROM SOUTH AFRICA

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ABSTRACT

Introduction: National population-based immunisation coverage surveys provide data for validating official administrative coverage figures. However, these costly and logistically challenging surveys are infrequently conducted. This hospital-based records-review determined coverage of birth-dose vaccines; fully immunised under one year-old coverage (FIC) of 12-59 month-old children; and reasons for missed vaccinations.

Methods: Rotavirus surveillance in South Africa is based on under five year-old children being treated for diarrhoea, and includes photocopying the official vaccination document, and collecting data on reasons for missed vaccinations. These data were captured from all 508 records collected from 2011-2014, and subjected to descriptive statistical analysis.

Results: Bacille Calmette Guérin coverage was 99.4%; oral polio vaccine birth dose (OPV(0)) coverage was 99.2%. Coverage for 12-59 month-olds ranged from 74.8% for the pneumococcal conjugate vaccine third dose, to 99.1% for OPV(0). Several instances of subsequent doses being recorded without prior doses being received resulted in a FIC of 55.1%. In total, 207 vaccinations were missed by 88 children. Vaccine stock-outs were responsible for 62.3% of missed vaccinations.

Conclusion: Efforts to improve vaccine stock management at facility and higher levels should be implemented and should include vaccinator training and supervision to eliminate vaccine stock-outs and missed vaccination opportunities.

KEY WORDS:

immunisation coverage; hospital-based survey; vaccine stock-outs; missed vaccination opportunities; South Africa

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INTRODUCTION:

In 1974 the World Health Organization (WHO) established the Expanded Programme on Immunisation (EPI), which through its global policies, over the following two decades provided universal immunisation against six vaccine-preventable diseases (VPDs) (tuberculosis, polio, diphtheria, tetanus, pertussis and measles) to children under the age of 6 years.[1] When the EPI of South Africa (EPI-SA) was launched by the National Department of Health (NDoH) in 1995, it provided free immunisation against the traditional six VPDs and hepatitis B.[2] EPI-SA has subsequently closely followed WHO guidelines to incorporate new and underutilised vaccines,[1] and currently provides free immunisation against 11 VPDs, having added vaccines against *Haemophilus influenzae* type b [Hib] infection (1999), invasive pneumococcal disease (2009), rotavirus diarrhoea (2009) and cervical cancer (2014).[2,3]

Since its inception EPI-SA has been very successful, having (a) eliminated neonatal tetanus by 2002;[2,3] (b) reported no wild-type poliovirus transmission since 1989 while meeting the WHO's polio surveillance criteria since 2003, which was officially recognised by the Africa Region Certification Commission in 2006;[2,3] (c) and decreased the prevalence of hepatitis B virus in the population who were born after the 1995 introduction of the hepatitis B vaccine (HepB).[4] Furthermore EPI-SA has been at the forefront of introducing new and underutilised vaccines, being the first African country to introduce the pneumococcal conjugate vaccine (PCV) and rotavirus vaccine (RV),[2,5] and amongst the first to introduce the human papillomavirus vaccine (HPV).[2] Also, the programme was considered strong enough by 2009 to allow the simultaneous introduction of PCV, RV[5] and a pentavalent vaccine (Penta) containing diphtheria, tetanus, acellular pertussis, inactivated polio vaccine and Hib.[2]

Despite these significant achievements there have been concerns about the immunisation coverage in South Africa and the reliability of the official administrative coverage figures that are generated by the District Health Information System (DHIS). For a number of years the WHO and United Nations Children's Fund Estimates of National Immunization Coverage (WUENIC) for South Africa have been more than 15% lower than DHIS figures.[3,6] This suggests that there may be problems with data quality,[3] a notion that is supported by sporadic measles and diphtheria outbreaks, and a fully immunised under one year-old coverage (FIC) of only 61% reported in the South Africa Demographic and Health Survey (SADHS) 2016.[7] While regular national population-based immunisation coverage surveys could provide data for

validating official administrative coverage figures,[8] these surveys are (a) very costly; (b) logistically challenging; (c) prone to methodological flaws which impact on their validity; and (d) subsequently sometimes of questionable value.[8,9] To supplement such data, hospital-based surveys could provide valuable insights into several aspects of immunisation coverage and health system performance at facility level. This study investigated EPI-SA immunisation coverage, using rotavirus surveillance data collected by a tertiary hospital. Objectives included determining (1) overall Bacille Calmette Guérin (BCG) and birth dose oral polio vaccine (OPV(0)) coverage; (2) FIC and individual immunisation coverage of children aged 12 to 59 months; and (3) reasons for missed vaccinations.

METHODS:

South Africa has 9 provinces divided into 52 districts, with Gauteng being the smallest (in terms of area) yet most populous province, with 5 districts. The Dr George Mukhari Academic Hospital (DGMAH) in the Tshwane District of Gauteng Province, is one of three Gauteng referral hospitals, and is a sentinel rotavirus surveillance site. Since April 2009 data have been collected for measuring the impact of the RV, based on under 5 year-old children being treated for acute diarrhoea. As from May 2010, data collection includes photocopying the Road to Health Card (RTHC) (the official vaccination document), and where reasons for missed vaccinations are not recorded on the RTHC, collecting these data from caregivers and recording them on Case Report Forms (CRFs). Ethics approval was obtained from the Medunsa Research Ethics Committee for both the surveillance study which included obtaining written informed consent from caregivers,[10] and the current study (MREC/P/398/2014:R).

Data for the current study were collected from archived CRFs (i.e. caregivers' reasons for missed vaccinations) and RTHC photocopies (i.e. sex, date of birth, vaccinations received, and reasons for missed vaccinations recorded by vaccinators [i.e. "out of stock" and "not yet available"]) collected from January 2011 to December 2014. Where a caregiver reason on the CRF differed from the vaccinator reason on the RTHC, only the reason on the RTHC was captured. Caregiver reports of not taking a child to the clinic because either (a) a friend had told them that the vaccines were out of stock, or (b) they perceived that vaccines are always out of stock, were coded as "lack of motivation", not as "out of stock". Personal identifiers were not captured to ensure anonymity. Data were captured using Microsoft Excel 2013 (Microsoft Office, USA). Descriptive statistical analyses were performed using Epi Info™ v7.1 (Centers for Disease Control and Prevention, USA) to determine sex and age distributions, individual

vaccine coverage, drop-out rates between vaccine series, FIC, and frequencies of reasons for missed vaccinations.

RESULTS:

Of the 692 caregivers who had consented to participate in the main surveillance study, 508 were in possession of RTHCs, the photocopies of which were used for the current study. The average age was 13.1 months (range: 0.9-57.9; median: 10.8). The majority (58.9% [299/508]) of children were males. BCG coverage was 99.4% (505/508) (95% confidence interval [CI]: 98.1-99.9%); OPV(0) coverage was 99.2% (504/508) (95% CI: 97.9-99.8%). For children aged 12 months and older (n=214), the coverage for individual vaccines ranged from 74.8% (160/214) (95% CI: 68.4-80.4%) for the PCV third dose (PCV(3)), to 99.1% (212/214) (95% CI: 96.7-99.9%) for OPV(0). Several instances of subsequent doses being recorded without prior doses being received resulted in a FIC of 50.9% (109/214) (95% CI: 44.0-57.8%).

When analysing the reasons for missed vaccinations, it was found that 18 children were not vaccinated with some or all of the vaccines introduced in 2009, because these vaccines were not yet included in the provincial EPI-SA at the time when these children received their vaccines scheduled for 6, 10 and 14 weeks of age. These 18 records were thus removed, leaving 196 records for the final analysis (Table 1), which increased the FIC to 55.1% (108/196) (95% CI: 47.9-62.2%) (Table 2). In total, 207 vaccinations were missed by 88 children. Vaccine stock-outs were responsible for 62.3% (129/207) of missed vaccinations, affecting 87.5% (77/88) of under-vaccinated children (Table 3). Of the missed vaccinations from stock-outs, 86.0% (111/129) were for the vaccines introduced in 2009, with 35.7% (46/129), 27.9% (36/129) and 22.5% (29/129) for RV, PCV and Penta respectively.

DISCUSSION AND CONCLUSION:

Since hospital-based immunisation coverage studies are biased towards those who make use of healthcare services, the very high BCG and OPV(0) coverages found in this study were to be expected, as these vaccines are administered to newborns delivered in healthcare facilities. In contrast, the FIC of 55% found in this study was unexpected. Although this result is very similar to the 51.9% FIC for Gauteng reported in SADHS 2016,[7] it is almost half that of the official administrative FIC for Tshwane. From 2013 onwards, the vaccines that were introduced in 2009 were included in the numerator for the official administrative FIC, and for Tshwane the

2013/2014 FIC was 111.2%.[11] A possible explanation for this is the other strong selection bias in this study, i.e. the fact that the study is based only on records of children presenting with acute diarrhoea. This bias may result in an overrepresentation of records of children who have not been fully vaccinated against rotavirus diarrhoea, and indeed this may be the case in this study. Table 2 shows that only 70% of children received both doses of RV, compared to the >90% second dose RV (RV(2)) coverage reported by the DHIS for Tshwane for 2011/2012,[12] 2012/2013[13] and 2013/2014.[11] However, it is highly likely that the official coverage figures for RV(2) do not reflect that both doses of RV have in fact been received, as this study has shown that vaccinators often record RV(2) without the child having received RV(1). Thus it may be more acceptable to compare the RV(2) coverage of 84.2% (Table 1), which is still much lower than the DHIS figures for Tshwane. Interestingly, the 70% coverage for both doses of RV is in line with the national estimates of WUENIC, with 72%, 78%, 64% and 72% coverage for RV(2) being estimated respectively for each year from 2011 to 2014.[6]

This study found 207 instances where catch-up vaccinations were necessary but were not administered. These missed vaccination opportunities affected 88 children, and resulted in the discrepancies shown between Tables 1 and 2, where the lowest coverage for an individual vaccine in children aged 12 months and older was 78.6% for PCV(3), yet only 55.1% had received all the vaccines given in the first year of life. This finding shows that the practice of using coverage of a final dose of a vaccine for a specific age group as a surrogate for full coverage (eg.: using the first dose of measles vaccine (MV(1)) or PCV(3) coverage as a surrogate for FIC), leads to erroneous coverage figures because often an earlier vaccine has been missed and the child has not been caught up at a later date when presenting for later vaccinations. The discrepancy between the official DHIS FIC for 2015/2016 of 89.2%[14] and the SADHS FIC of 61%[7] could perhaps be explained by these missed vaccination opportunities. This finding also points to the urgent need for introducing an electronic data capturing system, which will allow for flagging such missed vaccinations automatically.

Almost 45% of children eligible to have received all the vaccines offered in the first year of life were found to be under-vaccinated in this study, with the vast majority of them being affected by vaccine stock-outs of the vaccines introduced in 2009. This finding is supported by a recent report on vaccine availability conducted at 31 public sector Tshwane clinics, where during 2013, 74%, 65% and 58% of clinics had shortages of Penta, PCV and RV respectively.[15] To ensure validity, care was taken in the current study to capture only true vaccine stock-outs that were

reported by vaccinators. This was accomplished by removing records where one or more vaccines were not yet available, and excluding caregiver perceptions of probable stock-outs. These precautions may have resulted in a slight underestimation of vaccine stock-outs. However, the aforementioned Tshwane clinic survey[15] and the Post Introduction Evaluation conducted jointly by the NDoH and WHO in 2011,[16] reported vaccine shortages in the vast majority of facilities that were visited. In addition, since its inception in 2013, the Stop Stock Outs Project (a consortium of six civil society organisations), has reported vaccine shortages in every province of South Africa every year.[17,18] This project conducts an annual telephonic survey of all public health facilities in South Africa, enquiring about the availability of specific drugs and three vaccines: RV, MV and Penta / hexavalent vaccine (from 2015 Penta was replaced by a hexavalent vaccine containing HepB as the sixth antigen). In 2013, 14.7% of responding facilities reported vaccine stock-outs, ranging from 6.2% of facilities in KwaZulu Natal to 35.6% in Limpopo Province.[17] This decreased to 12% of facilities in 2014, ranging from 2% in the Western Cape, to 31% in Limpopo Province.[18] Another slight decrease to 11% of facilities was reported in 2015, ranging from 4% in the Western Cape, to 17% in North West Province.[18] While district level data were not reported, the figures for Gauteng Province were 8.5% of facilities in 2013,[17] 4% in 2014 and 11% in 2015.[18]

Apart from national shortages of HepB and MV in 2013,[15] and a global shortage of BCG starting in 2014, vaccine shortages are rarely reported by provincial depots.[19] Thus the finding of this study regarding vaccine stock-outs suggests that these are caused by human error, occurring either at district or facility level. This suggestion is supported by the recently published findings on vaccine availability at public sector Tshwane clinics, which identified poor stock management at facility and district depot level as a major reason for stock-outs.[15] The current study shows that these human errors have a devastating effect on vaccine coverage, and are further exacerbated by the failure to catch up the missed vaccinations when the vaccines are back in stock.

One of the motivations behind conducting this study was to find evidence to support anecdotal claims by vaccinators,[21] and evidence from an Internet-based study,[22] that a growing number of South African caregivers are refusing to vaccinate their children because of fears regarding vaccine safety, or the belief that vaccines are unnecessary. While none of the caregivers in this study reported that they refused vaccines for their children, caregivers refused to give reasons for 12% of the vaccines that were not received. If these caregivers were vaccine refusers, a

possible explanation for why they did not admit this is because they feared the negative repercussions that this may have on the current treatment of their children.

There were a few reasons for not vaccinating given only for the vaccines received at 9 months, and not mentioned for the earlier vaccines. These include "lost RTHC", yet the RTHC was present at the time when the child had acute diarrhoea and was brought to hospital, which suggests that the caregiver perhaps forgot to bring the child for vaccination. Together with the reasons summarised as "lacked motivation" and "forgot and busy", this suggests that caregivers need to be better informed and reminded about the importance of booster doses required in later life. As suggested by others, the NDoH's free mobile application for pregnant women called MomConnect could be extended to reminding caregivers about infant vaccination appointments.[15]

In conclusion, despite suffering from selection bias, this hospital-based study has provided valuable insights into modifiable aspects of immunisation coverage and health system performance at facility level in the Tshwane district of Gauteng. These insights give rise to two major recommendations: (a) Eliminate missed vaccination opportunities by training vaccinators to check the RTHC at each visit, until such time as electronic data capturing replaces this manual system,[15] with close supervision to ensure correct recording of doses and dose numbers; (b) Eliminate vaccine stock-outs by ensuring that interventions addressing the reasons identified by the previous study in Tshwane public sector clinics[15] are put into place. It is clear from that study that vaccinators are not trained in stock management, thus training should be a priority for facilities where there are no trained pharmacists. The current pilot to implement a web-based DHIS (personal communication) is certainly a move in the right direction, and it is hoped that features such as linking it to vaccine stock levels, and flagging and following up on those children who have missed some vaccine doses will also be added in the near future.

AUTHORS' STATEMENTS: This study is a sub-study of a larger project on anti-vaccination lobbying (AVL) in South Africa. RJB conceptualised the over-arching study and developed the original over-arching protocol. MJM, CD, LMS and GM reviewed and made input into the final over-arching study protocol. GM collected the data for both the RV surveillance study and the AVL study. MJM and LMS are co-investigators in the RV surveillance study and the AVL study. RJB analysed the data and wrote the first draft of the manuscript. NJN assisted with the

literature review and interpretation of the results. All authors reviewed the first draft of the manuscript and made substantial contributions to the development and finalisation thereof. All authors have read and approved the final manuscript. RJB and MJM are guarantors of the manuscript.

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COMPETING INTERESTS: None declared.

ETHICAL APPROVAL: Ethics approval was obtained from the Medunsa Research Ethics Committee for both the surveillance study which included obtaining written informed consent from caregivers,[10] and the current study (MREC/P/398/2014:R).

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Table

Table 1: Individual vaccine coverage in children 12 months and older (n=196)

Age	Vaccine	n	%	95% CIs
At birth	BCG	194	99.0	96.4 - 99.9%
	OPV (0)	194	99.0	96.4 - 99.9%
6 weeks	OPV (1)	188	95.9	92.1 - 98.2%
	RV (1)	169	86.2	80.6 - 90.7%
	HepB (1)	194	99.0	96.4 - 99.9%
	Penta (1)	187	95.4	91.5 - 97.9%
	PCV (1)	190	96.9	93.5 - 98.9%
10 weeks	HepB (2)	191	97.4	94.2 - 99.2%
	Penta (2)	183	93.4	88.9 - 96.4%
14 weeks	RV (2)	165	84.2	78.3 - 89.0%
	HepB (3)	189	96.4	92.8 - 98.6%
	Penta (3)	178	90.8	85.9 - 94.5%
	PCV (2)	182	92.9	88.3 - 96.0%
9 months	MV (1)	175	89.3	84.1 - 93.2%
	PCV (3)	154	78.6	72.2 - 84.1%

BCG: Bacille Calmette Guérin; OPV: oral polio vaccine; RV: rotavirus vaccine; HepB: hepatitis B vaccine; Penta: pentavalent vaccine containing diphtheria, tetanus, acellular pertussis, inactivated polio vaccine and *Haemophilus influenzae* type b; PCV: pneumococcal conjugate vaccine; MV: measles vaccine

Table 2: Frequency of vaccination combinations received and drop-out rates in children 12 months and older (n=196)

Vaccine combination	n	%	% drop-out
BCG	194	99.0	
BCG+OPV0	194	99.0	0.0
BCG+OPV0+OPV1	187	95.4	3.6
BGC+OPV0+OPV1+RV1	162	82.7	13.4
BCG+OPV0+OPV1+RV1+Penta1	156	79.6	3.7
BCG+OPV0+OPV1+RV1+Penta1+HepB1	156	79.6	0.0
BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1	156	79.6	0.0
BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+ Penta 2	149	76.0	4.5
BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+ Penta 2+HepB2	147	75.0	1.3
BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta 2+HepB2+RV2	138	70.4	6.1
BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2+ Penta 3	132	67.3	4.3
BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2+ Penta3+HepB3	130	66.3	1.5
BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2+ Penta3+HepB3+PCV2	127	64.8	2.3
BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2+ Penta3+HepB3+PCV2+MV1	120	61.2	5.5
BCG+OPV0+OPV1+RV1+Penta1+HepB1+PCV1+Penta2+HepB2+RV2+ Penta3+HepB3+PCV2+MV1+PCV3	108	55.1	10.0

BCG: Bacille Calmette Guérin; OPV: oral polio vaccine; RV: rotavirus vaccine; HepB: hepatitis B vaccine; Penta: pentavalent vaccine containing diphtheria, tetanus, acellular pertussis, inactivated polio vaccine and *Haemophilus influenzae* type b; PCV: pneumococcal conjugate vaccine; MV: measles vaccine

Table 3: Frequency distribution of reasons for missed vaccinations (n=88)

		Don't know		Out of stock		Refused reason		Child sick		Mother sick		Lacked motivation		Lost RTHC		Mother in school		Forgot + busy		Total
Age	Vaccine	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
At birth	BCG	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2
	OPV (0)	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2
6 weeks	OPV (1)	0	0.0	7	87.5	1	12.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8
	RV (1)	4	14.8	22	81.5	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	27
	HepB (1)	0	0.0	1	50.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2
	Penta (1)	1	11.1	7	77.8	1	11.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	9
	PCV (1)	2	33.3	3	50.0	1	16.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6
10 weeks	HepB (2)	0	0.0	2	40.0	2	40.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5
	Penta (2)	2	15.4	8	61.5	2	15.4	1	7.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	13
14 weeks	RV (2)	4	12.9	24	77.4	2	6.5	1	3.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	31
	HepB (3)	0	0.0	4	57.1	2	28.6	1	14.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7
	Penta (3)	1	5.6	14	77.8	2	11.1	1	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	18
	PCV (2)	2	14.3	9	64.3	2	14.3	1	7.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	14
9 months	MV (1)	3	14.3	4	19.0	3	14.3	2	9.5	1	4.8	4	19.0	2	9.5	1	4.8	1	4.8	21
	PCV (3)	4	9.5	24	57.1	3	7.1	2	4.8	1	2.4	4	9.5	2	4.8	1	2.4	1	2.4	42
		25	12.1	129	62.3	25	12.1	10	4.8	2	1.0	8	3.9	4	1.9	2	1.0	2	1.0	207

BCG: Bacille Calmette Guérin; OPV: oral polio vaccine; RV: rotavirus vaccine; HepB: hepatitis B vaccine; Penta: pentavalent vaccine containing diphtheria, tetanus, acellular pertussis, inactivated polio vaccine and *Haemophilus influenzae* type b; PCV: pneumococcal conjugate vaccine; MV: measles vaccine; RTHC: Road to Health Card