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## Findings from a hepatitis B birth dose assessment in health facilities in the Philippines: opportunities to engage the private sector

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### Abstract

**Background**—Hepatitis B vaccination in the Philippines was introduced in 1992 to reduce the high burden of chronic hepatitis B virus (HBV) infection in the population; in 2007, a birth dose (HepB-BD) was introduced to decrease perinatal HBV transmission. Timely HepB-BD coverage, defined as doses given within 24 hours of birth, was 40% nationally in 2011. A first step in improving timely HepB-BD coverage is to ensure that all newborns born in health facilities are vaccinated.

**Methods**—In order to assess ways of improving the Philippines' HepB-BD program, we evaluated knowledge, attitudes, and practices surrounding HepB-BD administration in health facilities. Teams visited selected government clinics, government hospitals, and private hospitals in regions with low reported HepB-BD coverage and interviewed immunization and maternity staff. HepB-BD coverage was calculated in each facility for a 3 month period in 2011.

**Results**—Of the 142 health facilities visited, 12 (8%) did not provide HepB-BD; seven were private hospitals and five were government hospitals. Median timely HepB-BD coverage was 90%

(IQR 80%–100%) among government clinics, 87% (IQR 50%–97%) among government hospitals, and 50% (IQR 0%–90%) among private hospitals ( $p=0.02$ ). The private hospitals were least likely to receive supervision (53% versus 6%–31%,  $p=0.0005$ ) and to report vaccination data to the national Expanded Programme on Immunization (36% vs. 96%–100%,  $p<0.0001$ ).

**Conclusions**—Private sector hospitals in the Philippines, which deliver 18% of newborns, had the lowest timely HepB-BD coverage. Multiple avenues exist to engage the private sector in hepatitis B prevention including through existing laws, newborn health initiatives, hospital accreditation processes, and raising awareness of the government’s free vaccine program.

## Keywords

hepatitis B vaccine; birth dose; Philippines; private hospitals; perinatal transmission

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## Introduction

The Philippines is considered to be highly endemic for chronic hepatitis B virus (HBV) infection, with a population seroprevalence of 9%; this translates to approximately 60,000 newborns being at risk of acquiring a perinatal hepatitis B infection yearly [1, 2]. In order to address this problem, hepatitis B vaccine was introduced in the Philippines in 1992, though coverage has been variable over the years due to problems with funding and vaccine supply. Hepatitis B vaccine initially was given at 6, 10 and 14 weeks of life; a birth dose (HepB-BD) which is recommended to be administered within 24 hours of birth to all newborns was introduced nationally in 2007 to prevent mother-to-child transmission of HBV [3]. The global measure of HepB-BD program performance is coverage of hepatitis B vaccine administered within 24 hours of birth; in 2011, the national Expanded Programme on Immunization (EPI) reported HepB-BD coverage in 24 hours was 40%, one of the lowest in the World Health Organization’s Western Pacific Region [4]. Efforts need to be made to improve 24 hour HepB-BD coverage if hepatitis B control is to be achieved in the Philippines. The Philippines has pledged to reduce chronic HBV infection prevalence to <1% among children and is committed to implementing vaccination strategies to reach this target, including finding ways to improve HepB-BD coverage to prevent perinatal transmission [5, 6].

The HepB-BD, given within a very short window of time soon after birth, and followed by at least 2 subsequent doses, is highly effective as both pre- and post-exposure prophylaxis [3, 7]. However, this short time frame and the fact that it is given around birth makes it challenging to achieve high coverage. EPI staff as well as midwives and other obstetrical staff, who are not normally part of the vaccination program, are vital to ensuring that every child is vaccinated. The HepB-BD must be given by staff in inpatient maternity/neonatal units as well as at outpatient health facilities through outreach visits for newborns born at home. Furthermore, location of birth can impact administration of HepB-BD; infants born in a health facility are more likely to get a HepB-BD within 24 hours of birth than infants born at home, as they already have access to the health care system [8–10]. In the Philippines, only 44% of infants are born in health facilities; an additional 18% are born at home in the presence of a skilled birth attendant (SBA), and 38% are born at home without any SBA present [11].

Improving the birth dose coverage among home births is challenging. As a first step towards improving the national birth dose program, we assessed the birth dose program in health facilities by evaluating the knowledge, attitudes, and practices surrounding HepB-BD administration. The survey was designed to identify barriers to HepB-BD vaccination and to inform the national EPI how best to strengthen the perinatal HBV prevention program in health facilities.

## Methods

The assessment took place in April-May 2012 in 8 of 18 regions in the Philippines. The regions were chosen based on (1) 2011 reported 24 hour HepB-BD coverage of 50%, (2) population size of >90,000 (range 90,866–321,411) (3) having a large discrepancy (median discrepancy=26%) between skilled birth attendance coverage and HepB-BD coverage, (4) identification as a priority area by EPI based on having the largest number of children failing to receive the 3<sup>rd</sup> dose of DTP vaccine, and (5) being in a secure area of the country. In each region, three provinces or highly urbanized cities (HUCs) were selected based on having a large population (>12,000, range 12,091–71,645) and having a large discrepancy (median 63%) between reported HepB-BD coverage at 24 hours and >24 hours in 2011. In each province/HUC, 6–7 facilities that deliver babies were to be visited; including 2–3 government hospitals, 2 private hospitals, and 2 government clinics. The facilities were selected in consultation with local EPI staff based on low HepB-BD coverage, ease of access, and geographic distribution throughout the province/HUC.

EPI staff were trained to collect data from health facilities on a structured questionnaire. At each health facility, staff were interviewed about hepatitis B vaccination policy, practices, and knowledge; and acceptance of PhilHealth, the Philippines' national government health insurance which, in 2008, covered 39% of women of child bearing age [11]. As way of background, PhilHealth, a free program for the poorest, but open for paid enrollment by all Filipinos regardless of income, provides a health facility with a lump sum payment for maternity and newborn care, which includes the provision of a birth dose. The health facility is not supposed to be paid if the newborn does not receive the birth dose. Questions were also asked about their training in basic or comprehensive emergency obstetric and neonatal care (BEmONC/CEmONC), a global program to improve maternal and newborn health, as well as their training in essential intrapartum and newborn care (EINC), an initiative by the Philippines government to improve newborn care. Both of these programs endorse the provision of a birth dose within 24 hours of birth. Observations of vaccine handling and storage were recorded. Additionally, the number of births was collected from birth registries, and the number of infants receiving a HepB-BD was collected from vaccination log books. Coverage was calculated for each facility by dividing the number of HepB-BD given over a three-month period in 2011 by the number of births in that same three-month period. Two estimates of HepB-BD coverage were calculated: 1) HepB-BD given on the day of birth or the day after (referred to as a “timely HepB-BD”) and 2) HepB doses administered any time between birth and before the 6 week immunization visit (total HepB-BD coverage).

The formal WHO recommendation is for hepatitis B birth dose to be given within 24 hours of birth, but operationally, it has indicated that a birth dose given on either day 0 or day 1 of

life can be counted as birth dose within 24 hours [3, 12]. With this practice, the birth dose could be given almost 48 hours after birth. Reviewed medical records did not include the time of birth dose administration, and thus, following global practice, our data define "timely" doses as those given on day 0 or 1 of life.

Data were double entered into an Epi-Info v.3.5.1 (Atlanta, GA, USA) database; data were compared for mistakes and analyzed using SAS v9.3 (Cary, NC, USA). Government facilities were defined as both government clinics and government hospitals. Frequencies and percentages were calculated for categorical variables, and median and 25–75% interquartile range (IQR) for vaccine coverage by the three health facility categories were calculated. To assess associations between categorical variables, chi-square ( $\chi^2$ ) p-values were calculated, except in cases where an expected cell count was  $<5$ , in which case 2-tailed Fisher's exact p-values were calculated. To assess differences in continuous variables, Wilcoxon rank-sum p-values were calculated to compare two groups and Kruskal Wallis p-values were calculated for more than two groups.

Funding was provided by the World Health Organization. This assessment was a program evaluation and was exempt from human subjects review by an institutional review board.

## Results

Twelve to twenty facilities were visited in each of the eight regions. Of 142 health facilities enrolled and visited, 63 (44%) were governmental hospitals, 40 (28%) were private hospitals, and 39 (27%) were government clinics. During 2011, government hospitals had a median of 1403 births (IQR 484–3250), private hospitals had a median of 179 births (IQR 67–333), and government clinics had a median of 298 births (IQR 135–624). Health facilities were located in the three major island groups of Luzon (n=86, 61%), Mindanao (n=20, 15%), and the Visayas (n=36, 25%). Training of health care providers in BEmONC/CEmONC and EINC was more common in government clinics than in government hospitals, and was least common in private hospitals (Table 1).

Of the 142 health facilities, 12 (8%) did not provide hepatitis B vaccine, including 7 (58%) private hospitals and 5 (42%) government hospitals; all 39 government clinics provided vaccine (Fisher's  $p=0.02$ ). Reasons for not giving vaccine included no policy to administer vaccine (3/12, 25%), no trained staff (3/12, 25%), and lack of vaccine supply (8/12, 67%).

Among government clinics, median timely HepB-BD coverage was 90% (IQR 80%–100%), and median total HepB-BD coverage was 100% (IQR 94%–100%). Among government hospitals, median timely HepB-BD coverage was 87% (IQR 50%–97%), and median total HepB-BD coverage was 88% (IQR 57%–98%). Among private hospitals median timely HepB-BD coverage was 50% (IQR 0%–90%), and median total HepB-BD coverage was 80% (IQR 14%–100%). Government facilities had significantly higher timely HepB-BD coverage (Wilcoxon  $p$ -value=0.02) and total hepB-BD coverage (Wilcoxon  $p$ -value=0.01) than private hospitals (Table 2).

HepB-BD-specific knowledge among providers in all three types of facilities was high; 82%–88% of interviewed staff had received training on HepB-BD; 94%–97% knew that

HBV could be transmitted from mother to newborn and 95%–100% knew that HepB-BD should ideally be given within 24 hours of birth (Table 1). Among interviewed staff at government clinics, 5% perceived that they did not provide HepB-BD to every newborn; compared to 16% of staff at government hospitals and 42% of staff at private hospitals ( $\chi^2$   $p=0.0002$ ).

Missed opportunities for HepB-BD vaccination were identified at all three types of facilities, including failure to vaccinate on weekends (6%–26%), and failure to vaccinate newborns who are premature (37%–50%), have low birth weight (18–45%), or who are ill (69%–82%) (Table 1). Ten (26%) of 39 government clinics, 3 (5%) of 58 government hospitals, and 14 (42%) of 33 private hospitals reported having dealt with families who refuse vaccination (government clinics versus government hospitals  $\chi^2$   $p=0.004$ , government clinics versus private hospitals  $\chi^2$   $p=0.13$ , government hospitals versus private hospitals  $\chi^2$   $p<0.0001$ ) (Table 1).

Among 30 private hospitals providing HepB-BD, 11 (37%) reported charging patients with PhilHealth for HepB-BD (median charge 9 USD, IQR 5–19 USD); 22 (79%) of 28 reported charging patients for HepB-BD who did not have PhilHealth (median charge 12 USD, IQR 8–12 USD). Government clinics did not charge patients regardless of their PhilHealth membership status, and government hospitals seldom charged patients.

Of 35 government clinics, 2 (6%) reported not having had an EPI supervisory visit in the past six months, as compared with 12 (31%) of 39 government hospitals and 10 (53%) of 19 private hospitals ( $\chi^2$   $p=0.0005$ ). All 39 government clinics and 56 (97%) of 58 of government hospitals reported obtaining vaccine from EPI as compared with 11 (33%) of 33 private hospitals ( $\chi^2$   $p<0.0001$ ). All 39 government clinics, 55 (96%) of 57 government hospitals, and 12 (36%) of 36 private hospitals reported HepB-BD coverage data to EPI ( $\chi^2$   $p<0.0001$ ). Shortages occurred in all types of facilities with government facilities reporting at least one shortage in the past 17 months more frequently than private hospitals ( $\chi^2$   $p=0.007$ ) (Table 1).

## Discussion

Over the past decade, an increasing number of vaccines have been introduced in the Philippines with most reaching at least 75% coverage, but HepB-BD coverage has never exceeded 40% [4]. Part of the reason is that 56% of births occur at home where the provision of a timely HepB-BD is challenging [11]. However, even among infants delivered in health facilities, HepB-BD coverage is suboptimal. In this assessment, we found a median timely HepB-BD coverage of 86% and a total HepB-BD coverage of 93% among the 142 health facilities visited. Timely HepB-BD coverage in health facilities should reach 100% since hepatitis B vaccine is provided at no cost from the government, skilled personnel are on staff to administer vaccine, and hepatitis B vaccine is contraindicated only for individuals with a history of allergic reactions to any of the vaccine's components, and this does not factor in for newborns [3].

This evaluation revealed opportunities to improve HepB-BD coverage. This assessment along with several others found that providers cite false contraindications as a reason for not vaccinating a newborn [10, 13, 14], and HepB-BD coverage can be increased by ensuring good understanding of appropriate contraindications to HepB-BD vaccination. Vaccine shortages were commonly identified during this evaluation and resulted in newborns missing HepB-BD vaccination which has also been seen in several other countries [10, 14]. In 2012, the Philippines' national EPI, which is not donor-supported and procures its own vaccine, had a vaccine shortage of monovalent hepatitis B vaccine from January to April and from June to December. A contingency plan for a continuous supply of monovalent hepatitis B vaccine is essential. Other studies have found that simple changes can further improve HepB-BD coverage in health facilities, such as standing orders, improved supervision, and vaccine availability in delivery rooms [15, 16].

This study indicates that private health facilities were more likely to do a poorer job of providing HepB-BD. Reasons for this are probably multifactorial, such as failure to provide any HepB-BD, poor knowledge/training about HepB-BD, and failure to vaccinate on weekends. Additionally, private facilities are more likely to charge for hepB-BD which probably causes some families to refuse vaccination on the basis of cost exclusively. Even if these families seek free vaccination at a government facility, the timing of HepB-BD has been delayed.

Little is known about private sector vaccination delivery in low and middle income countries, especially with regards to HepB-BD. A few studies have found gaps in quality of routine immunizations and regulation [17]. In Cambodia, an assessment of private sector providers' involvement in vaccination services found gaps in immunization knowledge, high wastage, poor vaccine management, and inadequate reporting of vaccination coverage [18]. Our assessment found that only 36% of private hospitals reported vaccination coverage to EPI which leads to inaccurate national vaccine coverage estimates and impacts resource allocation and future planning. Additionally, only half of the private hospitals had supervisory visits by immunization staff in the six months prior to the assessment visit, which are essential to ensure that vaccine is handled and stored properly, appropriately administered, and that vaccination coverage and adverse events are reported. For example, during one site visit, a private provider stored hepatitis B vaccine in the freezer, which inactivates the vaccine; another was unaware that the dark color on the vaccine vial monitor signified that the vaccine has exceeded its heat threshold and should not be used.

We identified four areas that provide opportunities for EPI to engage the Philippines' growing private health sector. First, working with nursing, pediatric, and obstetrical societies, EPI should develop a strategy to increase awareness about their free vaccine program which allows private providers to obtain routine infant vaccines for free from EPI; in exchange, the private sector reports their vaccination data to EPI. Many of the private sector facilities included in this survey purchased vaccine and transferred the cost to the patient leading to possible vaccine refusal by the parent for financial reasons. Second, the 2011 Republic Act Number 10152, act calls for every child to be vaccinated and makes special mention that all infants should be vaccinated with a HepB-BD within 24 hours of birth [19]. This new law has implementing rules and regulations to accommodate

strengthening HepB-BD vaccination. Specifically, improved implementation will require generating a greater awareness of the law among practitioners and parents, and providing adequate training, supervision and monitoring. National guidelines for HepB-BD administration should be developed to help improve birth dose practices at all types of health facilities. Third is to strengthen the HepB-BD component of the hospital accreditation process. PhilHealth has an accreditation process that includes HepB-BD vaccination as part of its monitoring process. However, anecdotal evidence indicates that the HepB-BD evaluation component is not clear to the PhilHealth accreditors. EPI should work with PhilHealth to standardize accreditation and educate accreditors on acceptable HepB-BD practices. Finally, the timing and need for HepB-BD vaccination should be emphasized in the two major maternal and neonatal care programs in the Philippines: the EINC initiative and the BEmONC/CEmONC programs. These programs educate health care workers on a variety of maternal and neonatal interventions that are needed around the time of birth. Further integration of HepB-BD into these programs is important for preventing perinatal HBV transmission as well as for providing coordinated newborn care.

Many of the HepB-BD practices at government hospitals were similar to those at government clinics. EPI staff have made a concerted effort to work with government hospitals, conducting training of maternity and nursery staff, and helping to ensure that protocols are in place to vaccinate every child [15]. This assessment highlights areas where improvements can still be made, such as re-training about false contraindications as well as improving supervision.

This assessment had several limitations. First, this was a convenient sample of health facilities in regions with the lowest reported HepB-BD vaccination coverage and therefore might not be generalizable to the whole country. We were unable to distinguish newborns delivered at home and subsequently vaccinated at health facilities from those born in the facility. However, it is uncommon for a newborn delivered at home to present within 24 hours for vaccine, and thus, this bias is limited with regards to timely HepB-BD coverage. Additionally, infants born at home are more likely to be vaccinated at a government clinic rather than a hospital, and private health facilities did not vaccinate infants born at home. Finally, due to the limited sample size, we were unable to correlate specific practices with HepB-BD coverage.

Prevention of mother-to-child HBV transmission can be strengthened in both public and private health facilities in the Philippines by implementing policies and procedures to vaccinate all babies born in these facilities. Although private facilities represent only 18% of total births [11], this sector is rapidly growing. It would be a health service failure if a baby born in a health facility was not vaccinated and acquired chronic HBV infection during birth.

## Acknowledgements

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## Abbreviations

<b>BEmONC</b>	Basic Emergency Obstetric and Neonatal Care
<b>CEmONC</b>	Comprehensive Emergency Obstetric and Neonatal Care
<b>DTP</b>	diphtheria-tetanus-pertussis
<b>EINC</b>	Essential Intrapartum and Newborn Care
<b>EPI</b>	Expanded Programme on Immunization
<b>HepB-BD</b>	Hepatitis B birth dose
<b>HBV</b>	Hepatitis B virus
<b>HUCs</b>	Highly urbanized cities
<b>IQR</b>	Interquartile Range
<b>SBA</b>	Skilled Birth Attendant

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### Summary Box

#### **Opportunities for private sector facilities to increase administration of hepatitis B vaccine birth dose in the Philippines**

- Develop a strategy to increase awareness among private sector providers about the national Expanded Programme on Immunization's free vaccine provision program
- Improve implementation of the 2011 Republic Act Number 10152, which calls for all infants to be vaccinated with hepatitis B vaccine within 24 hours of birth by implementing standard policies and procedures.
- Standardize and educate hospital accreditors on acceptable birth dose practices so that each health facility must meet a minimum standard birth dose program in order to achieve accreditation
- Emphasize the importance of administering a birth dose of hepatitis B vaccine to all infants in maternal-newborn-child health programs

**Table 1**

Facility background characteristics and hepatitis B birth dose (HepB-BD) vaccine knowledge, practices, vaccine management and supervision, Philippines, 2012. All significant p-values (  $0.05$  ) are bolded.

	<u>Government Clinics</u>		<u>Government Hospitals</u>		<u>Private Hospitals</u>		Chi-square
	Total <sup>a</sup>	Number (%)	Total <sup>a</sup>	Number (%)	Total <sup>a</sup>	Number (%)	
<b>BACKGROUND CHARACTERISTICS</b>							
PhilHealth accredited facility	36	26(72)	63	59(94)	40	33(83)	<b>0.01</b>
Trained in BEmONC <sup>b</sup> and/or CEmONC <sup>c</sup>	39	28(72)	62	22(35)	40	8(20)	<b>&lt;0.0001</b>
Trained in Essential Intrapartum and Newborn Care	38	28(74)	62	38(61)	40	23(58)	0.29
Mothers stay 24 hours post delivery	39	28(72)	62	29(47)	40	19(48)	<b>0.03</b>
<b>KNOWLEDGE</b>							
Health facility provides HepB-BD	39	39(100)	63	58(92)	40	33(83)	<b>0.02</b>
Received training on HepB-BD	39	35(90)	58	51(88)	33	27(82)	0.58
Know that mother can transmit infection to her baby	36	35(97)	55	52(95)	31	29(94)	0.87 <sup>f</sup>
Know recommended HepB-BD administration is 24 hours of birth	38	36(95)	56	55(98)	32	32(100)	0.46 <sup>f</sup>
<b>PRACTICES</b>							
Report NOT vaccinating all newborns with HepB-BD	39	2(5)	58	9(16)	33	14(42)	<b>0.0002</b>
Do NOT vaccinate with HepB-BD on weekends	38	10(26)	56	9(16)	31	3(6)	0.09
Give vaccination card after providing HepB-BD	39	39(100)	53	46(87)	31	26(84)	<b>0.02<sup>f</sup></b>
Do NOT give HepB-BD to low birth weight newborns	38	7(18)	58	17(29)	29	13(45)	0.06
Do NOT give HepB-BD to premature newborns	38	14(37)	56	23(41)	30	15(50)	0.54
Do NOT give HepB-BD to ill newborns	39	27(69)	55	39(71)	33	27(82)	0.43
Can NOT vaccinate some newborns because some families refuse HepB-BD	39	10(26)	58	3(5)	33	14(42)	<b>&lt;0.0001</b>
Charge newborns with PhilHealth <sup>d</sup> for HepB-BD	39	0(0)	54	3(6)	30	11(37)	<b>&lt;0.0001</b>
Charge newborns without PhilHealth for HepB-BD	38	0(0)	53	5(9)	28	22(79)	<b>&lt;0.0001</b>
Vaccinate in the delivery room	39	26(67)	58	35(60)	33	9(27)	<b>0.002</b>
<b>VACCINE MANAGEMENT AND SUPERVISION</b>							

	Government Clinics		Government Hospitals		Private Hospitals		Chi-square	p-value
	Total <sup>a</sup>	Number (%)	Total <sup>a</sup>	Number (%)	Total <sup>a</sup>	Number (%)		
No supervisory visit in the past 6 months	35	2(6)	39	12(31)	19	10(53)	<b>0.0005</b>	
Report number vaccinated with HepB-BD to EPI <sup>e</sup>	39	39(100)	57	55(96)	33	12(36)	<b>&lt;0.0001</b>	
Obtain vaccine from EPI	39	39(100)	58	56(97)	33	11(33)	<b>&lt;0.0001</b>	
Had HepB-BD stock-out in the past 17 months	37	14(38)	55	29(53)	31	6(19)	<b>0.01</b>	

<sup>a</sup>Total health facilities varies for each row as there were instances where the data was not provided by the health facility or erroneously skipped by the study staff.

<sup>b</sup>BEmONC: Basic Emergency Obstetric and Neonatal Care

<sup>c</sup>CEmONC: Comprehensive Emergency Obstetric and Neonatal Care

<sup>d</sup>PhilHealth: Philippine Health Insurance Corporation

<sup>e</sup>EPI: Expanded Programme on Immunization

<sup>f</sup>Fisher's exact p-value

Hepatitis B vaccine birth dose (HepB-BD) coverage administered by day 1 of life (Timely HepB-BD) and between birth and 6 weeks of age (Total HepB-BD) by health facility type, Philippines, 2012.

**Table 2**

	<u>Government Clinics</u>				<u>Government Hospitals</u>				<u>Private Hospitals</u>				<u>p values</u>			
	Number providing data	Median coverage (%)	IQR <sup>a</sup> (%)	Number providing data	Median coverage (%)	IQR <sup>a</sup> (%)	Number providing data	Median coverage (%)	IQR <sup>a</sup> (%)	Number providing data	Median coverage (%)	IQR <sup>a</sup> (%)	Government clinics vs. government hospitals Wilcoxon	Government hospitals vs. private hospitals Wilcoxon	Government clinics vs. private hospitals Wilcoxon	All government facilities vs. private hospitals Wilcoxon
Total HepB-BD coverage	33	100	94–100	52	88	57–98	32	80	14–100	0.0002	0.26	0.0002	0.0002	0.10	0.008	0.01
Timely HepB-BD coverage	32	90	80–100	48	87	50–97	30	50	0–90	0.19	0.10	0.008	0.008	0.008	0.02	0.02

<sup>a</sup>IQR=25%–75% Interquartile Range