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Preparing for safety monitoring after rotavirus vaccine introduction – Assessment of baseline epidemiology of intussusception among children <2 years of age in four Asian countries

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Abstract

Intussusception is the invagination of one segment of the bowel into a distal segment, characterized by symptoms of bloody stool, vomiting, and abdominal pain. Previous studies have found regional differences in incidence but the etiology of most intussusception cases is unknown. Rotavirus vaccines were associated with a slightly of increased risk of intussusception in post-licensure evaluations in high- and middle-income countries, but not in low income African countries. To describe the baseline epidemiology of intussusception in young children prior to rotavirus vaccine implementation, active sentinel hospital surveillance for intussusception in

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children <2 years of age was conducted in 4 low income Asian countries (Bangladesh, Nepal, Pakistan and Vietnam). Over a 24-month period, 15 sites enrolled 1,415 intussusception cases, of which 70% were enrolled in Vietnam. Overall, 61% of cases were male and 1% (n=16) died, ranging from 8% in Pakistan to 0% in Vietnam. The median age of cases enrolled ranged from 6 months in Bangladesh and Pakistan to 12 months in Vietnam. The proportion of cases receiving surgical management was 100% in Bangladesh, 88% in Pakistan, 61% in Nepal, and 1% in Vietnam. The high proportion of males and median age of cases around 6 months of age found in this regional surveillance network are consistent with previous descriptions of the epidemiology of intussusception in these countries and elsewhere. Differences in management and the fatality rate of cases between the countries likely reflect differences in access to healthcare and availability of diagnostic modalities. These baseline data will be useful for post-rotavirus vaccine introduction safety monitoring.

Keywords

rotavirus; intussusception; diarrhea; safety; intestinal obstruction

Introduction

Intussusception, the invagination of one segment of the bowel into a distal segment, is the most common cause of bowel obstruction in children <1 year old [1]. It is characterized by signs and symptoms of bloody stool, vomiting, and abdominal pain. Intussusception can result in vascular compromise and necrosis of the intestine if not reduced by enema or surgery; when left untreated, intussusception may lead to death, although some cases resolve spontaneously [2, 3]. Intussusception is diagnosed by air or liquid contrast enema, abdominal ultrasound, or during surgery or autopsy [4, 5]. The etiology of most intussusception cases is unknown. Respiratory adenovirus has been associated with intussusception; conclusive evidence for other infectious and non-infectious etiologies is lacking [6]. Incidence of intussusception peaks at 5 to 7 months of age and is more common among males [7]. Regional variations exist in diagnosis, treatment, and incidence; reasons for differences in incidence between regions are unknown [7]. The rate of intussusception in Asia has been estimated to range from 9 per 100,000 infants in Bangladesh to more than 300 per 100,000 infants in South Korea and Vietnam [7].

The World Health Organization (WHO) recommends all countries introduce a vaccine against rotavirus, the leading cause of diarrhea deaths in children <5 years old globally [8]. There are 4 live, oral rotavirus vaccines pre-qualified by WHO: RotaTeq (Merck & Co., West Point, PA, USA), Rotarix (GlaxoSmithKline Biologicals, Rixensart, Belgium), ROTAVAC (Bharat Biotech International Ltd., Hyderabad, India), and Rotasiil (Serum Institute of India, Pune, India) [9–12]. An earlier live, oral rotavirus vaccine, RotaShield (Wyeth-Lederle), was withdrawn from the US market in 1999 because an increased risk of 1 excess case of intussusception per 10,000 vaccinees was found after its introduction into routine use [13]. RotaTeq and Rotarix were licensed in 2006 following large pre-licensure safety trials that showed no increased risk of intussusception [9, 10]. However, in the 12 years since their licensure, observational studies from Australia, Brazil, Mexico, Singapore,

the UK, and the US have shown 1 to 5 excess cases of intussusception per 100,000 vaccinated infants following vaccination with RotaTeq and Rotarix [14–18]. These data have been reviewed by WHO’s Global Advisory Committee on Vaccine Safety, which has recommended no changes in vaccination policies given that the health benefits of vaccination greatly exceed the risk of intussusception [19]. For example, it was estimated that more than 600 deaths due to rotavirus diarrhea would be prevented for every 2–3 additional intussusception deaths due to rotavirus vaccine in Mexico and Brazil [15]. In clinical trials, no increased risk of intussusception was observed with ROTAVAC or Rotasiil, but the trials were not sufficiently large to detect the low level of risk found in the post-marketing evaluations with RotaTeq and Rotarix [11, 20]. ROTAVAC has been introduced into 9 states and Rotasiil in 1 state in India since 2016, and safety evaluations are ongoing [21]. The pathophysiological mechanism behind the association of rotavirus vaccines and intussusception is not well understood.

By the end of 2017, more than 90 countries worldwide had introduced rotavirus vaccine into their national immunization programs, but only 8 of these countries are in Asia [21]. Additionally, none of the RotaTeq or Rotarix pre-licensure safety trials or early post-introduction safety evaluations were conducted in low-income African or Asian countries. Recently a surveillance network in 7 lower-income African countries that use Rotarix vaccine showed no increased risk of intussusception following Rotarix vaccination [22]. Given regional variation in the epidemiology of intussusception and the performance of rotavirus vaccines and in anticipation of rotavirus vaccine introduction, we established an intussusception surveillance network in 4 Asian countries (Bangladesh, Nepal, Pakistan and Vietnam) to describe the baseline epidemiology of intussusception in each country. Using 2 years of prospective, active sentinel hospital intussusception surveillance data from each country, we describe the epidemiology and clinical characteristics of intussusception hospitalizations among children <2 years old.

Methods

Active sentinel surveillance for intussusception was conducted using a common protocol in 4 Asian countries (Bangladesh, Nepal, Pakistan and Vietnam). Children were eligible for enrollment if they were <2 years old at the time of hospital admission to one of the sentinel sites and they were diagnosed with intussusception meeting the Brighton Collaboration criteria for level 1 of diagnostic certainty for intussusception at the time of admission or during the hospitalization [4]. Briefly, the Brighton Collaboration Level 1 case definition includes intussusception where invagination of the intestine is seen during surgery, autopsy, or ultrasound-guided enema or when a pre-enema ultrasound showed invagination and a post-enema ultrasound showed resolution. Intussusception cases diagnosed only by clinical signs and symptoms are included in other levels of diagnostic certainty and were excluded from this analysis. Children transferred from another facility to a sentinel site for management of intussusception were eligible for inclusion. Only first episodes of intussusception were eligible to be included.

A standardized case report form documenting demographic, clinical signs and symptoms, management, and outcome information was collected for each enrolled child using the

medical record and parental report. Data were entered into an EpiInfo database and analyzed using SAS v9.4. In this analysis, we present descriptive statistics using percentage and median with interquartile range (IQR). We used chi square tests where p-values are presented. All sentinel sites enrolled children for at least 24 continuous months; to account for any seasonal variation in intussusception incidence, we included exactly 24 months of data from all countries. Because of differing years of participation in the network, the exact surveillance period included in the analysis varies by country; exact time periods by country are shown in Figure 1.

This activity was approved by the institutional review boards at icddr,b in Dhaka, Bangladesh, Nepal Health Research Council in Kathmandu, Nepal, Aga Khan University in Karachi, Pakistan, the National Institute of Hygiene and Epidemiology in Hanoi, Vietnam, and the Centers for Disease Control and Prevention in Atlanta, USA.

Results

A total of 15 hospitals in four countries participated in this active, sentinel intussusception surveillance network (Figure 1), including 7 in Bangladesh, 4 in Nepal, 2 in Pakistan, and 2 in Vietnam. Overall, 1,415 cases <2 years of age meeting the Brighton Collaboration level 1 intussusception criteria were enrolled (Table 1). Although all countries had 24 months of enrollment, the number of cases enrolled varied by country; the largest number of cases (n=986, 70% of total) was enrolled in Vietnam. Of all cases, 61% were male; the percentage of male cases ranged from 60% in Pakistan and Vietnam to 69% in Bangladesh. The median number of days from onset of signs and symptoms to admission at the sentinel hospital was 1 day (IQR: 0–1), ranging from the same day in Vietnam (IQR: 0–1) to 2 days in Bangladesh (IQR: 1–5) and Pakistan (IQR: 1–4). About 50% of cases were transferred from another facility to a sentinel hospital in Bangladesh (42%, n=49), Nepal (48%, n=92), and Pakistan (54%, n=70); in Vietnam, 13% (n=125) of cases were transferred to a sentinel hospital from another facility. Overall, 1% (n=16) of cases died; 3 cases each from Bangladesh (3%) and Nepal (2%) and 10 cases from Pakistan (8%). None of the cases in Vietnam died (p<0.001).

The median age of cases enrolled was 6 months (IQR: 5–9) in Bangladesh, 9 months (IQR: 6–16) in Nepal, 6 months (IQR: 5–8) in Pakistan, and 12 months (IQR: 8–17) in Vietnam (Figure 2). In all 4 countries, there were few intussusception cases in the first 3 months of life and a sharp increase in the number of cases at 4–5 months of age. In the second year of life, there were very few cases in Bangladesh and Pakistan and a moderate number of cases in Nepal. However, the 55% of enrolled cases in Vietnam were among children in the second year of life.

Overall, 87% of intussusception cases had at least 1 of 5 signs or symptoms: fever, vomiting, diarrhea, constipation, and bloody stool (Table 2). By country, the percentage of children with at least 1 of these clinical manifestations ranged from 83% in Vietnam to 99% in Bangladesh (p<0.001). In all 4 countries, vomiting and bloody stools were the most commonly reported signs. Ninety-four percent of cases in Bangladesh, 67% of cases in Nepal, 86% of cases in Pakistan, and 76% of cases in Vietnam reported vomiting; 91% of

cases in Bangladesh, 58% of cases in Nepal, 86% of cases in Pakistan, and 20% of cases in Vietnam reported bloody stool.

The proportion of intussusception cases that underwent surgery varied substantially by country, ranging from 1% (Vietnam) to 88% (Pakistan) ($p<0.001$), and the proportion of surgical cases requiring resection also varied, ranging from 11% (Nepal) to 39% (Bangladesh) ($p<0.001$) (Table 2). Enema was attempted but did not successfully resolve the intussusception for 2 children (11% of attempted enemas) in Pakistan and 13 (1% of attempted enemas) in Vietnam. Complications were rare in all 4 countries, with 8% ($n=109$) of cases experiencing any complication. The rate of any complications ranged from 3% in Nepal to 9% in Vietnam. Obstruction was the most commonly reported complication in Bangladesh (4%), Nepal (2%), and Vietnam (2%); wound infection was the most commonly reported complication in Pakistan (4%).

No seasonal variation in incidence of intussusception was noted in any of the 4 countries (data not shown).

Discussion

In this summary of children <2 years of age hospitalized with intussusception, we describe the epidemiology, treatment, and mortality among cases actively enrolled by the 4 Asian Intussusception Surveillance Network participant countries through 2017: Bangladesh, Nepal, Pakistan, and Vietnam. The high proportion of males and median age of cases around 6 months of age found in this regional surveillance network are consistent with previous descriptions of the epidemiology of intussusception in these countries and elsewhere [7, 23–27]. Very few cases of intussusception were reported before 4 months of age in any of the participating countries, which is also consistent with the published literature [7, 23]. This finding will be informative for post-rotavirus vaccine introduction safety assessments as rotavirus vaccine doses will be given in the first few months of life when the risk of intussusception is low.

Despite some similarities in intussusception epidemiology, our findings point to several key differences in the reported age distribution, clinical manifestations, management, and mortality of intussusception cases between these four countries. During the second year of life, there were dramatic differences between countries; more than half of all enrolled cases in Vietnam were <12 months of age whereas roughly 7% of cases from Bangladesh and Pakistan were <12 months at the time of hospitalization. Previous studies have also reported a substantial number of intussusception cases in the second year of life in Vietnam [27, 28]. Differences in time between onset of clinical manifestations and admission to the surveillance facility and management may reflect differences between the 4 healthcare systems. Intussusception cases enrolled in Vietnam were admitted at the sentinel site a shorter time after symptom onset, had fewer signs and symptoms and were less likely to have been transferred from another hospital than those in the other 3 countries. Anecdotally, clinical suspicion of intussusception and availability of ultrasonography were higher in the sentinel hospitals in Vietnam than other sentinel sites in other countries in this network. In Vietnam, intussusceptions were reduced almost exclusively with enema; in contrast,

enema reduction was not used for management of intussusception cases at the sentinel hospitals in Bangladesh where all of the children enrolled were managed with surgery. In Pakistan, enema reduction became a more common practice in 2017 than earlier years due to increased training and availability of equipment at one site. A longer duration from symptom onset to admission may explain the relatively high percentage of cases in whom at least 1 common sign or symptom of intussusception was reported, higher rates of management with surgery, lower percentage of enema reductions, and higher mortality in Bangladesh, Nepal, and Pakistan as compared to Vietnam.

This study had several limitations. First, we were limited to intussusception cases that were diagnosed at these sentinel facilities. Cases that were misdiagnosed or never sought care were not enrolled. Additionally, because autopsy is rare in the network countries, most children who died due to intussusception before receiving any treatment were not included; during the surveillance time periods, only Nepal enrolled cases based on the autopsy criteria. Conversely, the increased clinical suspicion and an aggressive diagnostic algorithm at the sentinel sites in Vietnam may have led to intussusception cases that would have self-resolved, and not been enrolled, in other settings. In addition, not all cases in Vietnam had a documented post-reduction ultrasound, which may have resulted inclusion of cases that did not meet the Level 1 case definition. Finally, because of unknown hospital catchment populations and a variable numbers of sites in each country, we were unable to calculate country-specific rates or compare numbers of intussusception cases between countries. Similarly, the primary objective of this surveillance network was to describe the baseline epidemiology of intussusception in each of the 4 participating countries rather than to compare findings across countries.

Findings from this regional surveillance network demonstrate that intussusception occurs, and is managed successfully, in Bangladesh, Nepal, Pakistan, and Vietnam in the absence of routine rotavirus vaccination. As these countries introduce rotavirus vaccine into their routine infant national immunization schedules, the network will transition to post-introduction safety monitoring of rotavirus vaccine. A pooled analysis from the countries with planned introductions of Rotarix (Bangladesh, Nepal, and Pakistan) and Rotarix-introducing countries that joined the network in 2018 (Afghanistan, Lao People's Democratic Republic, and Myanmar) will provide an adequate number of cases of intussusception to assess the safety of rotavirus vaccine. These data, as well as future post-rotavirus vaccine introduction data from this network, will provide valuable information to national stakeholders about rotavirus vaccine introduction and post-introduction safety.

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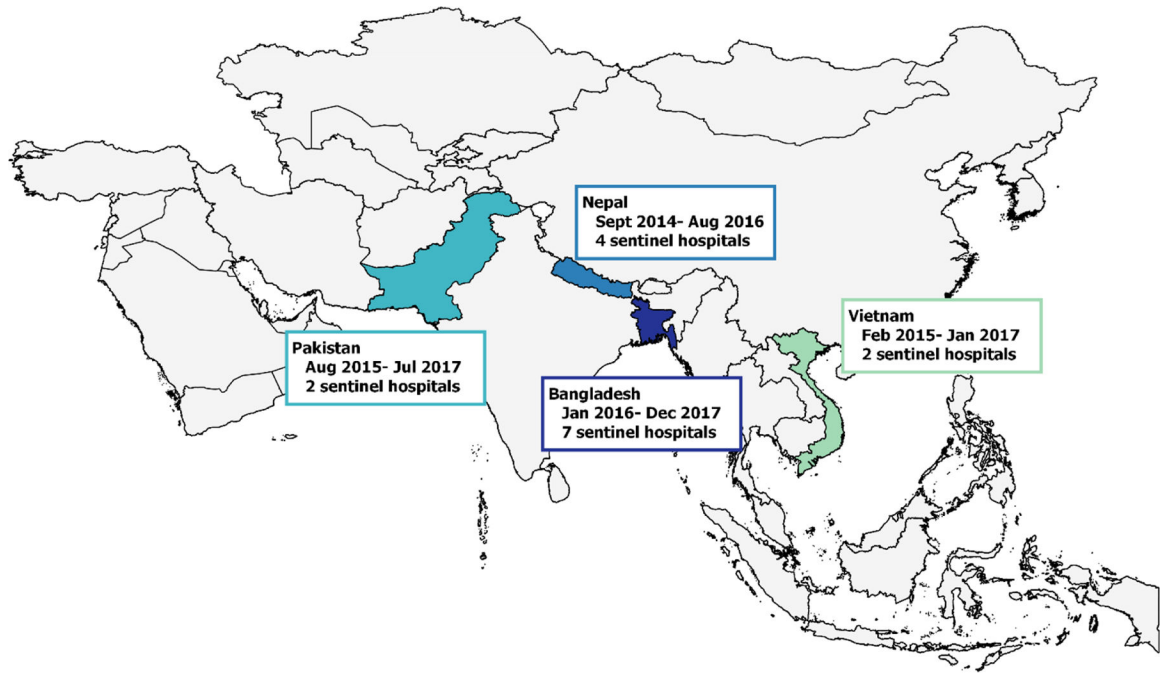


Figure 1.
Map of countries participating in the Asian Intussusception Surveillance Network 2014–2017.

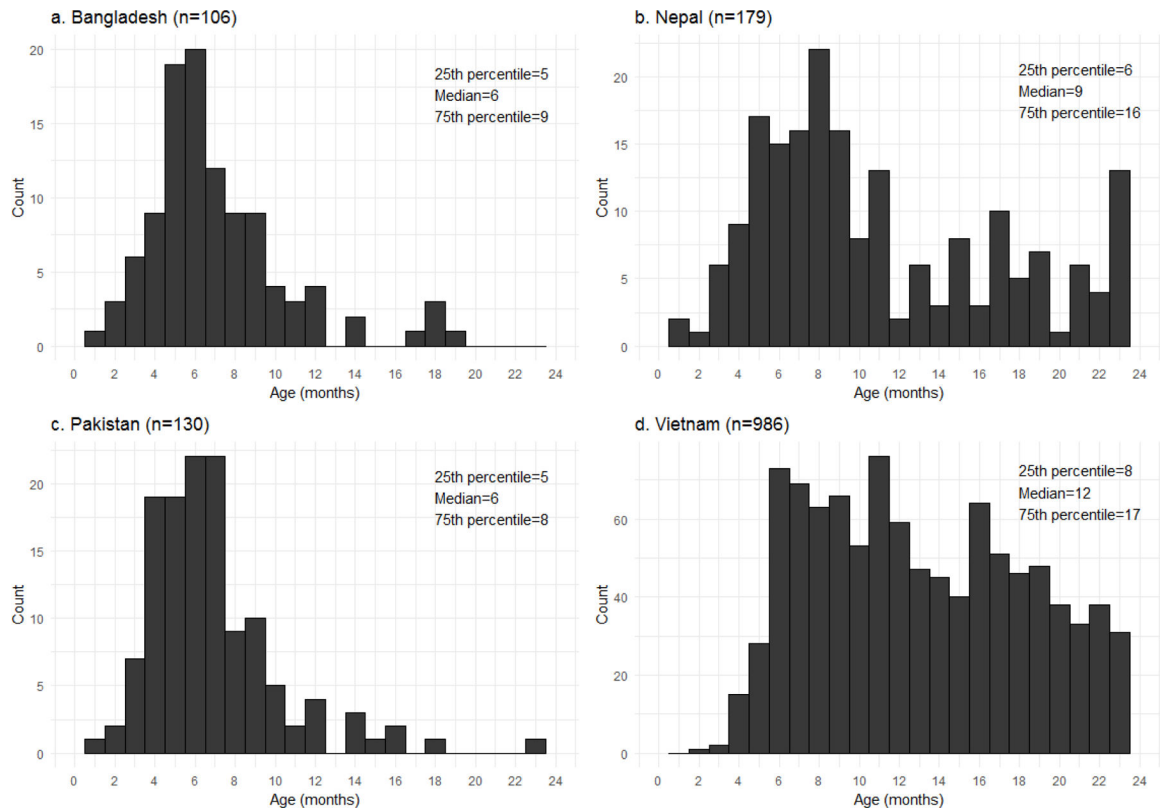


Figure 2.
 Age distribution of intussusception cases among children <2 years old in Bangladesh, Nepal, Pakistan, and Vietnam.

Table 1.

Characteristics of intussusception cases in Bangladesh, Nepal, Pakistan, and Vietnam.

	Bangladesh (n=106)		Nepal (n=193)		Pakistan (n=130)		Vietnam (n=986)		Total (n=1415)	
	n	%	n	%	n	%	n	%	n	%
Sex										
Male	73	69	121	63	78	60	592	60	864	61
Female	33	31	72	37	52	40	394	40	551	39
Reported chronic medical condition	0	0	11	6	13	10	10	1	34	2
Onset to admission (days)	2	(1, 5)	1	(1, 3)	2	(1, 4)	0	(0, 1)	1	(0, 1)
Outcome										
Died	3	3	3	2	10	8	0	0	16	1
Survived	99	93	190	98	120	92	896	99	1305	98
Transferred	4	4	0	0	0	0	6	1	10	1

Signs and symptoms, management, and complications of intussusception cases in Bangladesh, Nepal, Pakistan, and Vietnam.

Table 2.

	Bangladesh (n=106)		Nepal (n=193)		Pakistan (n=130)		Vietnam (n=986)		Total (n=1415)	
	n	%	n	%	n	%	N	%	n	%
Signs and symptoms										
Any	105	99	172	89	128	98	820	83	1225	87
All	1	1	0	0	0	0	0	0	1	0
Fever	65	61	24	12	52	40	157	16	298	21
Vomiting	100	94	129	67	112	86	752	76	1093	77
Diarrhea	26	25	33	17	56	43	54	5	169	12
Constipation	31	29	18	9	22	17	24	2	95	7
Bloody stool	96	91	111	58	112	86	198	20	517	37
Management										
Enema	0	0	75	39	16	12	973	99	1064	75
Surgery	106	100	118	61	114	88	13	1	351	25
Resection	41	39	13	11	37	32	3	23	94	27
Complications										
Any	8	8	6	3	9	7	86	9	109	8
Wound infection	3	3	0	0	5	4	1	0	9	1
Dehiscence	1	1	0	0	2	2	0	0	3	0
Peritonitis	2	2	1	1	0	0	1	0	4	0
Obstruction	4	4	4	2	0	0	19	2	27	2
Other	2	2	1	1	3	2	3	0	9	1