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## Editorial

# Need for Citizens Group to Monitor National Iodine Deficiency Disorders Control Programme in India

India and Bangladesh are two of United Nations declared 18-priority countries (UNGASS II\*) who are yet to achieve Universal Salt Iodization. Paradoxically, India is the country that gave sustained and significant contribution to all aspects of IDD control in many other countries worldwide. Some of them have done remarkably well - Bhutan, China, Thailand, Sri Lanka, but India lags far behind<sup>1</sup>. Despite the historical presence of an adequate programme and legislation, according to the latest National Family Health Survey-3, only 51% of the India's population has access to adequately iodized salt<sup>2</sup> based on the measurements by salt testing kits. This fact is more than thought provoking. This is especially crucial if we observe the results of the previous survey (NFHS-2), which showed 49%<sup>3</sup>. There is hardly any progress, statistically definitely insignificant! Climbing up 2% points in six years is not an achievement makes one proud of. It is disheartening to know that India's quest to become a superpower and the effort to keep its prestigious role in shaping the global economy will face serious obstacles, as the country is unable to defeat chronic iodine deficiency by 2015.

As per the Goldman Sachs BRIC (Brazil, Republic of South Africa, India, China) projection, 2007, India is poised to show unprecedented economic growth by 2050<sup>4</sup>. However in the region, India is the worst performer after Pakistan and Afghanistan<sup>5</sup> in consuming adequately iodized salt, which has a well-known effect of preventing the population from mental and physical impairment, brain damage, and endemic goiter. How can a country like ours, coexist with this development paradigm? Why does India not care about its greatest asset - the intellectual capacity of its people?

Notably, that the rural population and those living in the low income segment continue to have poor access to adequately iodized salt (41.2%)<sup>6</sup>. The fact that salt that is predominantly transported by rail has better levels of iodization as compared to the ones that are transported by road is evidenced in the case of the north eastern states where the households have high percentage of coverage of adequately iodized salt

(Coverage Range of Adequately Iodized Salt in North East States: Assam: 71.8% to Manipur 93.8%)<sup>6</sup>.

Not surprisingly, the household coverage is better in those states that have iodized salt available in their public distribution system (PDS). Chhattisgarh is an example where iodized salt is available in the PDS at a price of 25 paise per kg. Channeling the product from the small and medium scale producers to large scale consumers like state PDS and the Integrated Child Development Services (ICDS) scheme would generate a market for these producers. Chhattisgarh initiative should be replicated. This in turn would encourage the producers to make a higher quality product and since large scale transportation would invariably require railway wagons, it would be better monitored.

Ensuring consistent quality delivery and assurance, our suggestion is to simultaneously engage All India Institute of Medical Sciences (AIIMS), New Delhi, National Institute of Nutrition (NIN), Hyderabad and National Institute of Communicable Diseases (NICD), New Delhi as the National Institutes for carrying out Quality Assurance of iodized salt and introduce Annual Cyclic Monitoring for the three indicators (Goitre, Urinary Iodine & Salt).

We should give priority to advocacy and Behavioral Change Communication (BCC) in the low-income population. "Polio - Cause of Physical Disability" gets attention, whereas, almost negligible importance is given to "IDD - Cause of Preventable Mental Disability". Thus there is an urgent need for sustained implementation of BCC.

Subsequently, it is obvious that in order to architect permanent and sustainable solutions, we should take action to start multi-stakeholder alliances addressing the most critical issues. Continuing the current inertia means; every year we lose the intellectual capital of 13 million new born children.

Formation of National Coalition for Sustained Iodine Intake: Need for Citizen's Group to Monitor National Iodine Deficiency Disorders Control Programme (NIDDCP):

The Hon'ble Prime Minister of India launched National Rural Health Mission (NRHM)<sup>7</sup> on 12<sup>th</sup> April, 2005 throughout the country with special focus on 18

\*United Nations General Assembly Special Session on Children

states, including eight Empowered Action Group (EAG) states, the North-Eastern States, Jammu & Kashmir and Himachal Pradesh. The NRHM seeks to provide accessible, affordable and quality health care to the rural population, especially the vulnerable sections. It also seeks to reduce the Maternal Mortality Ratio (MMR) in the country from 407 to < 100 per 1,00,000 live births, Infant Mortality Rate (IMR) from 60 to < 30 per 1000 live births and the Total Fertility Rate (TFR) from 3.0 to 2.1 within the 7 year period of the mission.

The key features in order to achieve the goals of the Mission include making the public health delivery system fully functional and accountable to the community, human resources management, community involvement, decentralization, rigorous monitoring and evaluation against standards, convergence of health and related programmes from village level upwards, innovations and flexible financing and also interventions for improving the health indicators. One of the main approaches of NRHM is to communitize for example Hospital Management Committee/PRLs at all levels, Untied grants to community/PRI bodies, Funds, functions & fuctionaries to local community organizations, Decentralized planning, Village Health & Sanitation Committes<sup>8</sup>.

On 20<sup>th</sup> April, 2006, during the 21st ICCIDD Board Meeting in New Delhi, one of the main events was the announcement of the formation of National Coalition for Sustained Iodine Intake (NCSII). The coalition aims to ensure sustained iodine intake by monitoring iodine status of the population, monitoring of the implementation of rules and regulations, information sharing and advising involved institutions and sectors so as to achieve and sustained elimination of IDD in India. The board proposed that the coalition would have representation from the Government of India, Judicial bodies, Civil Society organizations and Salt Producers from across the country, besides the scientists and the programme managers involved in the elimination of IDD in India. As a follow up of the announcement, the first meeting of the NCSII supposed to take place in the month of December, 2006. However the event could not take place due to super annuation of the secretary health.

The two National Goitre committees have never met. In the effort to eliminate iodine deficiency and the experience over the past two decades has taught us a lot about identifying and addressing the problem; through universal salt iodization (USI). Planning Advocacy and coordinated national action are critical to sustain the progress.

It is timely to focus attention and resources on the need for sustained success. However, it is important to understand that the management and oversight which a sustainable achievement demands, differ from those needed for elimination of the deficiency. Instead of spending too many resources on the action plan, the focus should be on making the change permanent. This explains the 'backsliding', lowered quality, or inadequate oversight and public reporting and, thus, lack of accountability in many places.

We strongly suggest that the Government should call for a national advocacy event for meeting with the salt producers and write to the Chief Ministers of Gujarat, Tamil Nadu and Rajasthan for increased political commitment.

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*Original Article*

## Immunogenicity and Safety of Abhay M<sup>™</sup> and M-Vac<sup>™</sup> Vaccines in Healthy Infants: A Phase III Multicentric Randomized Single Blind Trial

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### Abstract

**Objective:** To study immunogenicity and safety of Abhay M<sup>™</sup> and M-Vac<sup>™</sup> vaccines in prevention of measles in healthy infants. **Methods:** In a randomized, single blind, comparative, multi-centric phase III trial, a total of 600 healthy infants between 9 – 15 months of age were recruited in the study from seven participating sites during five months. The block randomization design was used for randomizing the subjects into 2 vaccine groups (Investigational Vaccine - Abhay M<sup>™</sup> and Control Vaccine - M-Vac<sup>™</sup>) in the ratio 2:1. At base line (visit 1) a venous blood sample 1.5 ml was collected and subjects were then administered a single dose 0.5 ml of measles vaccine (Abhay M<sup>™</sup> or M-Vac<sup>™</sup> vaccine) subcutaneously according to randomization. Following administration of vaccine, subjects were observed closely for 30 - 60 minutes at the study hospitals for local reactions and systemic events. At visit 2 (follow up visit) another venous blood sample 1.5 ml was collected and the paired sera (both pre and post vaccination serum) were tested concurrently. Safety and immunogenicity were assessed through follow-up of adverse events and anti measles antibody response respectively. **Results:** Overall 95.7 % seroconversion was achieved in both the groups, 96% in Abhay M<sup>™</sup> vaccine group and 95.1% in M-Vac<sup>™</sup> vaccine group. There were no statistically significant differences in the observed seroconversion rates. In Abhay M<sup>™</sup> vaccine group, the pre vaccination geometric mean titers (GMT) significantly increased from 35.5 mIU/ml to 486.9 mIU/ml after vaccination. The observed significant increase of GMT in M-Vac<sup>™</sup> vaccine group was from 33.3 mIU/ml to 375.8 mIU/ml. Overall 459 (82.5%) out of 556 subjects were seroprotected after vaccination i.e.  $\geq 200$  mIU/ml (Protective levels). Of the 459 seroprotected, 315 (84.9%) subjects were in Abhay M<sup>™</sup> vaccine group and 144 (77.8%) subjects were in M-Vac<sup>™</sup> vaccine group. The frequencies of the reported local and general symptoms were similar between the Abhay M<sup>™</sup> vaccine group and M-Vac<sup>™</sup> vaccine group. **Conclusion:** Human Biologicals Institute's Abhay M<sup>™</sup> vaccine is equally immunogenic and as safe as M-Vac<sup>™</sup> vaccine when administered to healthy infants in single dose schedule.

**Key words:** Abhay M<sup>™</sup> vaccine, M-Vac<sup>™</sup> vaccine, immunogenicity, safety, measles

### Introduction

Measles is one of the most important causes of morbidity and mortality among under-five children in the developing countries. Data generated from several

developing countries including India indicate that measles is not only a major cause of immediate mortality in children, but also its residual effects contribute to malnutrition and increased mortality from other diseases for many subsequent months<sup>1</sup>. The most

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effective intervention for primary prevention of measles is vaccination. The widespread use of measles vaccine in many developed countries has resulted in greater than 90% reduction in incidence rate<sup>2</sup>; in contrast, little success has been observed in many developing areas due to low vaccination coverage and measles continues to kill more than one million children each year<sup>3</sup>. Furthermore, measles transmission remains a problem in many countries<sup>4</sup>.

Since 1976, the WHO has recommended that measles vaccine be integrated into routine health services and be administered at 9 months of age in developing countries<sup>5</sup>. This recommendation is based on studies demonstrating sero conversion rates of over 90% in children 9 months of age or older in developing countries<sup>6</sup>. In India, measles vaccine, administered at 9 months, has been incorporated in the national immunization programme since 1985-86<sup>7</sup>.

Recently live attenuated Measles vaccine (lyophilized) - Abhay M™ was produced by Human Biological Institute. Abhay M™ vaccine contains live attenuated measles virus (Edmonston-Zagreb) propagated on Human Diploid Cells (MRC-5). Each dose of 0.5 ml vaccine contains not less than 1000 CCID<sub>50</sub> of measles virus, 2.5% of gelatin and 5% of Sorbitol are added as stabilizers.

Another vaccine for measles prevention - M-Vac™ vaccine - is manufactured and marketed by Serum Institute of India Ltd. This is the commercially available vaccine in the country and its immunogenicity and safety are well established in Indian population. M-Vac™ vaccine contains live attenuated measles virus (Edmonston Zagreb Strain) propagated on Human Diploid Cells (HDC). Each dose of 0.5 ml contains not less than 1000 CCID<sub>50</sub> of Measles virus on reconstitution with the diluent provided (0.5 ml of sterile water for injection).

The measles vaccines are available from 1960s and their immunogenicity and safety are also well established. However, local data to establish the safety and immunogenicity is required for the newly developed Measles Vaccine (Abhay M™) by Human Biologicals Institute, in Indian subjects. Against this background the present study was carried out to evaluate the Immunogenicity and Safety of the Abhay M™ (Measles Vaccine) developed and manufactured by Human Biologicals Institute in comparison with a commercially available M-Vac™ vaccine in healthy infants.

## Materials and Methods

### Study Design

This was a randomized, single blind, comparative, multi-centric phase III trial to assess the immunogenicity and safety of the Abhay M™ (measles vaccine) developed by Human Biologicals Institute in comparison with commercially available M-Vac™ vaccine in healthy infants.

### Study Subjects and Randomization

The present study recruited 600 subjects. The block randomization design was used for randomizing the subjects into 2 Vaccine Groups (Investigational Vaccine and Control Vaccine) in the ratio 2:1 and was randomized using PROC PLAN in SAS. Vaccine arms were assigned as per randomization, and stratified by study hospital and age. The randomization codes were provided to each study site. After obtaining the informed consent from the parents or legal representative and ascertainment of eligibility, the eligible subjects were recruited into the trial as per the randomization sequence provided.

### Sample Size

The sample size of 600 was determined based on a non-inferiority test of Human Biologicals Institute's Abhay M™ Vaccine versus M-Vac™ vaccine in terms of the primary efficacy parameter (immunogenicity). The assumptions on which the sample size estimate was based are as follows:

- Seroprotection rate of 92% for both randomized trial vaccines, Human Biologicals Institute's Abhay M™ vaccine and M-Vac™ vaccine<sup>8</sup>.
- Limit of non-inferiority of Human Biologicals Institute's Abhay M™ vaccine versus M-Vac™ vaccine of 10% (clinically meaningful limit)<sup>9</sup>.
- Type I error probability ( $\alpha$ ) = 0.05 (two-sided), and Type II error probability ( $\beta$ ) = 0.10 (power =  $1 - \beta$  = 0.90).

H<sup>1</sup> (Alternative Hypothesis): Seroprotection rate three to five weeks after administration of the Human Biologicals Institute Abhay M™ vaccine is not inferior by more than 10% (not-inferiority) to of M-Vac™ vaccine.

Participating Study Centers: Following seven centers across the country participated in the present study. Government Medical College, Nagpur; Dr. D. Y. Patil Medical College, Pimpri, Pune; Niloufer Hospital, Red Hills, Hyderabad; Gandhi Medical College & Hospital, Padmarao Nagar, Secunderabad; Kasturba Medical College Hospital, Attavar, Mangalore; Kempagowda Institute of Medical Sciences, Banshankari, Bangalore; M.S. Ramaiah Medical College, Bangalore.

#### Inclusion and Exclusion Criteria

The study included healthy infants between 9 – 15 months of age. Infants receiving vitamin A as supplement were also included. Legally acceptable representative had provided informed consent as per ICH –GCP (International Commission on Harmonisation and Good Clinical Practice) Guidelines.

Exclusion Criteria for the subjects included administration of immunoglobulin or any blood products since birth, use of any investigational or un-registered drug or vaccine other than the study vaccine during the study period or within 30 days preceding the first dose of the study vaccine, previous vaccination or evidence of infection with measles, history of allergic disease or reaction likely to be exacerbated by any component of the study vaccines including allergy to antibiotics, infants having any intercurrent illness, infants having history of rash and conjunctivitis suggestive of viral exanthema, major congenital or hereditary immunodeficiency, infants having evidence of disease or fever, history of allergic disease or persistent haematological, hepatic, renal, cardiac or respiratory disease and signs of a CNS disorder prior to and at the time of vaccination. The above criteria were ascertained by the investigator based on clinical judgment.

#### Procedure

The recruitment of subjects was carried out from June to November 2006. Thus the total recruitment period for the study was 5 months.

At base line (visit 1) consenting subjects, meeting the inclusion/exclusion criteria were enrolled in the study. From the eligible subjects a venous blood sample 1.5 ml was collected in vacutainer tubes before administering the vaccine. The serum was stored at –

20° C to determine the anti measles antibody (IgG) using commercially available enzyme immunoassay kits (Enzygnost®, Dade Behring Marburg GmbH, Germany)<sup>1</sup>.

Subjects were randomized in 2:1 ratio for Human Biologicals Institute measles vaccine (Abhay M™) and M-Vac™ vaccine. Randomized subjects were administered a single dose 0.5 ml of measles vaccine (Abhay M™ or M-Vac™ vaccine) subcutaneously according to randomization.

Following administration of vaccine, subjects were observed closely for 30 - 60 minutes at the study hospitals for local reactions and systemic events. Soon after administering the vaccine, parents or legally acceptable representative were provided with a diary card in a language which they understand, by the investigator, to record the presence of local and general symptoms for the three to five weeks follow up period. Parents or legally acceptable representatives were advised by the investigator to return to the study site along with the diary card for follow up visit after three to five weeks of administration of the vaccine.

At visit 2 (follow up visit, three to five weeks after administering the vaccine) another venous blood sample 1.5 ml was collected and the paired sera (both pre and post vaccination serum) were tested concurrently to determine the anti measles antibody (IgG) using commercially available enzyme immunoassay kits (Enzygnost®, Dade Behring Marburg GmbH, Germany)<sup>1</sup>.

#### Efficacy and Safety Criteria Assessment

Safety and immunogenicity were assessed through follow-up of adverse events and anti measles antibody response respectively.

Analysis of immunogenicity was done by estimating the antibody titers of Anti-measles (IgG) by using commercially available ELISAs (Enzygnost®, Dade Behring Marburg GmbH, Germany)<sup>1</sup>. Sero-conversion rate at each group three to five weeks after vaccination were compared between groups. Geometric mean titres of antibodies against measles virus were calculated at the end of the study in each group. Seroconversion was defined as significant rise of post vaccine antibody titre levels in comparison with pre vaccination. The subjects were considered protected if the antibody levels are  $\geq 200$  mIU/ml<sup>1,10</sup>.

Seroconversion rates and seroprotection rates were calculated before and three to five weeks after vaccination and the rates were compared between the groups using z-test for proportions. Geometric mean titers were calculated for anti measles antibody titers for both the groups and the titers were compared between the groups before and three to five weeks after vaccination using the two independent sample t-test. Also 95% confidence intervals were estimated wherever necessary.

Reported solicited and unsolicited adverse events were summarized, using frequencies and percentages, by event severity and event relationship to the study vaccines during the study period. Reported serious adverse events were listed. Frequency and percentage of subjects with at least one adverse event after vaccination and during the study follow up were calculated. The adverse events were calculated at the end of study and the rates were compared between the study vaccine groups for proportions.

## Results

In this prospective randomized comparative trial, 600 subjects was recruited of which 400 received the study vaccine and 200 received the comparative vaccine. The demographics profile of the subjects is shown in Table 1 with respect to the study vaccine groups.

All the subjects who received the vaccine were included for safety analysis whereas 556 subjects who eventually completed the study were evaluated for efficacy as per protocol. Of these 556 subjects, 371 subjects belonged to the Abhay M™ vaccine group and the remaining 185 subjects belonged to M-Vac™ vaccine group. Overall 44 (7.3%) subjects discontinued from the study, of which 29 subjects were in

Abhay M™ vaccine group and 15 subjects in M-Vac™ vaccine group. The various reasons for discontinuation reported in the Abhay M™ vaccine group were loss-to follow up - 24 (82.8%) subjects, 1(3.4%) subject expired due to septicemia and for 4 (13.8%) subjects, their blood samples were collected but not analyzed. In the M-Vac™ vaccine group, various reasons for discontinuation reported were loss-to follow up 14 (93.3%) and subject's decision 1 (6.7%).

**Table 1: Demographic profile of study subjects**

Parameter	Statistics	Abhay M™ Vaccine (N = 400)	M-Vac™ Vaccine (N = 200)	p- value*
Age (months)	Mean + SD Range in days (min, max)	9.7 + 1.32 (240,510)	9.6 + 1.1 (240,480)	0.928
Sex	M: F	1 : 1.02	1 : 0.65	

\*The p-value was calculated for comparing means between ABHAY M and M-VAC using unpaired t-test (two tailed,  $\alpha = 0.05$ ).

The immune response to the Abhay M™ vaccine and M-Vac™ vaccine are depicted in Table - 2. Overall 95.7 % seroconversion was achieved in both the study vaccine groups, 96% in Abhay M™ vaccine group and 95.1% in M-Vac™ vaccine group. There were no statistically significant differences in the observed seroconversion rates. In Abhay M™ vaccine group, the pre vaccination geometric mean titers (GMT) significantly increased from 35.5 mIU/ml to 486.9 mIU/ml after vaccination. The observed significant increase of GMT in M-Vac™ vaccine group was from 33.3 mIU/ml (pre vaccination) to 375.8 mIU/ml (post vaccination).

**Table 2: Immune response in study subjects**

	Geometric Mean Titer (IU/ml)		(% of subjects seroconverted	
	Abhay M™ Vaccine	M-Vac™ Vaccine	Abhay M™ Vaccine	M-Vac™ Vaccine
Pre Vaccination (N)	35.5 (371)	33.3 (185)	—	—
Range (Min, Max)	(1.2,11232.3)	(7,8735.8)		
Post Vaccination (N)	486.9 (371)	375.8 (185)	95.9	95.1
Range (Min, Max)	(9.2,19904.1)	(16.7,26230.9)		

It was observed that 32 (5.8%) subjects in the present study had pre vaccination titers  $\geq 200$  mIU/ml (Protective levels). In the Abhay M™ vaccine group 20 (5.4%) subjects and in M-Vac™ vaccine group 12 (6.5%) subjects had protective antibody titers before vaccination. Overall 459 (82.5%) out of 556 subjects were seroprotected after vaccination i.e.  $\geq 200$  mIU/ml (Protective levels). Of the 459 seroprotected, 315 (84.9%) subjects were in Abhay M™ vaccine group and 144 (77.8%) subjects were in M-Vac™ vaccine group.

The pre and the post vaccination geometric mean titers (GMT) for Abhay M™ vaccine group were 35.5 mIU/ml and 486.9 mIU/ml respectively. For M-Vac™ vaccine group the observed pre and post vaccination Geometric Mean Titers (GMT) were 33.3 mIU/ml and 375.8 mIU/ml. Overall  $\geq 4$  fold rise was observed in 312 (78%) and 70 (73.5%) subjects in Abhay M™ vaccine group and M-Vac™ vaccine group respectively. In comparison with pre -vaccination antibody titers, there was up to a 10 fold rise was observed in both the study vaccine groups.

The frequencies of the reported local and general symptoms were similar between the Abhay M™ vaccine group and M-Vac™ vaccine group. The most commonly reported local reaction was pain at the injection site in 32 (8%), 10 (5%) subjects and induration in 29 (7.3%), 9 (4.5%) subjects in Abhay M™ vaccine group and M-Vac™ vaccine group respectively. In Abhay M™ vaccine group and M-Vac™ vaccine group, mild rash was observed in 10 (2.5%), 4 (2%) subjects respectively. Among the systemic events, fever following vaccination was reported in 60 (15%) subjects in Abhay M™ vaccine group and 38 (19%) subjects in M-Vac™ vaccine group. Fever was moderate in nature and subsequently subsided within 48 hours following vaccination and did not recur. There was one serious adverse event of septicemia and cerebral edema with syndrome of inappropriate secretion of anti diuretic hormone reported during the entire duration of the study. This event was not related to the study vaccine.

## Discussion

Measles remains an important cause of childhood morbidity and mortality worldwide and primary prevention strategy adopted is delivery of the live attenuated vaccine to susceptible populations<sup>11</sup>. The global recommendation for measles immunization in

developing countries is to apply a single dose of standard titer of measles vaccine at the age of 9 months or as soon as possible thereafter<sup>12</sup>. Measles vaccine is one of the most important vaccines used in our country and is incorporated in national immunization program. Considering the role of vaccines in effective prevention of measles, recently new vaccines are being developed. It is essential to evaluate efficacy of these vaccines before they are put in community use. Recently live attenuated Measles vaccine (lyophilized) - Abhay M™ was produced by Human Biological Institute. Abhay M™ vaccine contains live attenuated measles virus (Edmonston-Zagreb) propagated on Human Diploid Cells (MRC-5).

In the present prospective study, the safety and efficacy of Abhay M™ (Measles Vaccine) developed and manufactured by Human Biologicals Institute was evaluated and compared with the commercially available M-Vac™ vaccine in healthy infants.

An overall 95.7 % seroconversion was achieved in both the study vaccine groups, of which 95.9% in Abhay M™ vaccine group and 95.1% in M-Vac™ vaccine group. The seroconversion rate achieved with Abhay M™ vaccine is similar with other reported studies<sup>13</sup>.

The priority of immunization is to immunize the children as soon as possible after the maternal antibody is lost. In the present study it was observed that, before vaccination 94.6% and 93.5% of subjects did not have protective levels of antibody titers in Abhay M™ vaccine group and M-Vac™ vaccine group respectively. After vaccination, protective levels ( $\geq 200$  mIU/ml) of anti-measles antibody titers were achieved in 84.9% of subjects in Abhay M™ vaccine group and 77.8% of subjects in M-Vac™ vaccine group.

In Abhay M™ vaccine group, the pre vaccination geometric mean titers (GMT) significantly increased from 35.5 mIU/ml to 486.9 mIU/ml after vaccination. The observed significant increase of GMT in M-Vac™ vaccine group was from 33.3 mIU/ml (pre vaccination) to 375.8 mIU/ml (post vaccination). The seroconversion rates observed in the Abhay M™ vaccine group (95.9%) and M-Vac™ vaccine group (95.1%) are found to be equal. There were no statistically significant differences in the observed seroconversion rates. In the present study both the vaccine groups showed a four to ten fold rise in antibody levels as shown in earlier study<sup>14</sup>. Thus there

is no significant difference between the Abhay M™ vaccine and M-Vac™ vaccine with respect to Immunogenicity.

The frequencies of the reported local and general symptoms were similar between the Abhay M™ vaccine group and M-Vac™ vaccine group. There were no statistically significant differences for the reported adverse events in both the vaccine groups.

Thus the null hypothesis is rejected and based on the results obtained in the present study it could be concluded that Human Biologicals Institute's Abhay M™ vaccine is equally immunogenic and as safe as M-Vac™ vaccine which is being used in our country for many years. Overall it is concluded that the candidate Abhay M™ vaccine is immunogenic and safe when administered to healthy infants in single dose schedule.

### Acknowledgements

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*Original Article*

## Prevalence and Some Epidemiological Factors of Beta Thalassaemia Trait in Sindhi Community of Nagpur City, India

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### Abstract

**Objective:** To study the prevalence of Beta thalassaemia trait ( $\beta$ TT) in Sindhi community of Nagpur City and to study association between  $\beta$ TT and some epidemiological factors like age at menarche in females, past history of diagnosis and treatment of anaemia and the current haemoglobin concentration. **Methods:** The present cross-sectional study was undertaken among 446, young, apparently healthy, unrelated (by blood) Sindhi individuals before marriage or before reproduction. Blood samples were processed for Beta thalassaemia trait ( $\beta$ TT) using two stage approaches. Two screening tests namely Naked Eye Single Tube Red Cell Osmotic Fragility Test (NESTROFT) and RBC indices including Mean Corpuscular Volume (MCV) were performed on all samples and those positive for either one or both screening tests were further investigated for HbA<sub>2</sub> level estimation by Haemoglobin electrophoresis on Cellulose acetate paper. HbA<sub>2</sub> level of > 4.5 % was taken as confirmatory of  $\beta$ TT. **Results:** The prevalence of  $\beta$ TT in Sindhis of Nagpur was found to be 16.81 %. No significant association was found between  $\beta$ TT & a delayed age at menarche, however a significantly higher number of trait carrier females had past history of diagnosis and treatment of anaemia while a significantly higher number of both male and female trait carriers had current haemoglobin concentration in anaemic range. **Conclusion:** The present study confirmed high prevalence of  $\beta$ TT in Sindhis.

**Key words:** Beta thalassaemia trait ( $\beta$ TT), Prevalence, Epidemiological factors, Sindhis.

### Introduction

Beta thalassaemia is the most widely spread single gene haemoglobinopathy in world and a high frequency of around 5-15 % of trait carriers has been reported among Sindhis, who had migrated to India from Sindh province of Pakistan at the time of partition. Such a high prevalence necessarily draws a public health concern<sup>1</sup>. As the major disease is a grave haemolytic anaemia with a definite fatal outcome even after regular blood transfusions and iron chelation therapy and as the only cure namely bone marrow transplantation has severe limitations, it is essential that the emphasis must shift from treatment to prevention of such births in future. The prospective prevention incorporates identification of individuals carrying Beta thalassaemia trait and counseling them about mate selection and prenatal diagnosis, so as to defer birth

of a child with major disease<sup>2</sup>. Secondly many trait carriers have mild to moderate anaemia, which is misdiagnosed as iron deficiency anaemia and treated with iron that is absolutely unnecessary as well as harmful. For above reasons, trait carriers are needed to be detected and as majority of carriers are asymptomatic, population survey for mass screening of blood is best to identify them. Thus a strong case could be made for this study, which comprised of knowing prevalence of  $\beta$ TT in high risk Sindhi community of Nagpur city. An attempt was made to look for association between  $\beta$ TT and some hypothesized epidemiological factors.

### Materials and Methods

The present cross-sectional study was undertaken in Sindhi community in Nagpur city. The inclusion

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criteria for participants were based on WHO guidelines for a study of a genetic character like Beta thalassaemia, suggesting that participants should be apparently healthy, unrelated by blood, young individuals either unmarried or if married, should be planning to have children. Thus unmarried and married individuals (both partners) of 10 years & above age group were included in the study on a voluntary basis.

A pilot study was carried out in the form of a camp arranged in a randomly selected Sindhi locality, to estimate the approximate prevalence of  $\beta$ TT for calculating sample size for the final study. The prevalence of  $\beta$ TT in pilot investigation came out to be 18.75 %. Thus a sample size of 433 was arrived at considering this prevalence and 20% allowable error. However, a total of 446 Sindhi individuals including 388 unmarried school & college students of both sexes and 58 (29 couples) married individuals planning to have children were finally included.

Camps were arranged in various Sindhi localities including schools and colleges with Sindhi students with the help of voluntary leaders. A beforehand awareness regarding the grave nature of disease and the need of identification of trait carriers by a blood test in the camp etc. was brought about by distributing pamphlets containing date & site of the camp. At the campsite, posters were put with information on Beta thalassaemia.

Blood samples were collected in vials and the pre-tested proformas were filled with questions about completed age at menarche & past haematologic history of diagnosis and treatment of anaemia. In the laboratory, initially two screening tests were carried out on each sample namely Naked Eye Single Tube Red Cell Osmotic Fragility Test (NESTROFT) using 0.36 % saline<sup>3</sup> & red cell indices including Mean Corpuscular Volume (MCV) using a particle counter<sup>4</sup>. The samples positive in either one or both screening tests (NESTROFT - cloudy saline solution in test tube & MCV < 79 Fl) were further processed for HbA<sub>2</sub> level estimation by Haemoglobin electrophoresis on Cellulose acetate paper at pH 8.9. A HbA<sub>2</sub> level > 4.5 % (as per our laboratory standard) was considered to be confirmatory of Beta thalassaemia trait<sup>5,6</sup>.

Confidential written reports of laboratory findings were given to all participants at earliest possible after

each camp. To the carriers of  $\beta$ TT, genetic counseling was done regarding mate selection in unmarried individuals in the presence of their parents and about prenatal diagnosis to married carrier couples. The data was analyzed by Chi square test and its Yate's correction wherever necessary.

## Results

The overall prevalence of Beta thalassaemia trait in Sindhis of Nagpur was found to be 16.81% (75/446) with no difference between males (16.31%; 31/190) and females (17.18 %; 44/256). It was observed that out of 29 married couples who were studied, 7 (24.13%) couples had either husband or wife as carrier of Beta-thalassaemia trait, while in 2 (6.89%) couples both partners were found to be carrier of  $\beta$ TT (Table 1).

**Table 1: Distribution of married couples according to Beta thalassaemia trait carrier status (n = 29 couples)**

Individual / Partners	Beta thalassaemia trait No (%)
Husband only	4 (13.79)
Wife only	3 (10.34)
Both husband and wife	2 (06.89)
Total	9 (31.03)

It was observed that out of total 256 females, 97 had not attained menarche, of whom 13 (13.40%) carried Beta-thalassaemia trait. On comparison of age at attainment of menarche between females with Beta-thalassaemia trait and normal females, no statistically significant difference was found. Thus in the current study the difference in age at menarche between females with  $\beta$ TT and normal females was not appreciated as shown by Table 2.

Of the 31 Beta-thalassaemia trait males, 3 (9.67%) and of 159 normal males, 12 (7.54%) had past history of diagnosis of anemia by means of hemoglobin estimation. Similarly, past history of treatment for anemia with iron was present in 3 (9.67%) of 31 Beta-thalassaemia trait subjects and in 11 (6.91%) of 159 normal males. It was seen that a significantly more number of Beta-thalassaemia trait females i.e. 12 (27.2%) as compared to normal females

**Table 2: Distribution of female study subjects according to age at menarche and Beta thalassaemia trait (n= 256)**

Age at menarche (Years)	Total subjects	Beta thalassaemia trait No (%)
Not attained	97	13 (13.40)
11	07	00 (00.00)
12	16	03 (18.75)
13	61	08 (13.10)
14	59	15 (25.43)
15	13	03 (23.00)
16	03	02 (66.66)
Total	256	44 (17.19)

Early menarche (< 13 years) Vs normal (13-15 years) Vs late menarche (> 15 years):  $\chi^2 = 4.86$ ,  $df = 2$ ,  $p > 0.05$

i.e. 27 (12.7%) had been at sometime in past diagnosed as anemic by means of hemoglobin estimation. Similarly, a significantly more number of Beta-thalassaemia trait females i.e. 10 (22.7%) as compared to normal females i.e. 24 (11.3%) had been in past treated for anemia with iron. Thus, Beta-thalassaemia trait females were significantly more likely to have a past hematologic history of diagnosis and treatment for anaemia with iron as compared to normal females however this was not the case with Beta-thalassaemia trait males (Table 3).

On comparison of proportion of non-anemics and

anemics in males with Beta-thalassaemia trait and normal males, a significantly more number of Beta-thalassaemia trait males had anemia as compared to normal males. Similarly, on comparison of proportion of non-anemics versus anemics in females with Beta-thalassaemia trait and normal females, a significantly more number of Beta-thalassaemia trait females had anemia as compared to normal females (Table 4).

## Discussion

India is a rich reservoir of haemoglobinopathies and Beta-thalassaemia accounts for 80% of them. The overall frequency of Beta-thalassaemia in general population is 4.6% (ICMR 1993) but a high frequency of 5-15% is reported in Gujratis, Punjabis, Sindhis and Bengalis. It is estimated that there are 25 million subjects with Beta-thalassaemia trait and about 8000 – 10,000 children with major disease are born in India every year<sup>1</sup>.

Sindhis are reported to carry a high frequency of Beta-thalassaemia. The high prevalence of Beta thalassaemia trait in Sindhis found in this study confirms with high frequencies reported earlier by many investigators namely Manglani (7.7%)<sup>3</sup>, Jain (5.6%)<sup>7</sup> and Sukumaran (12.2%)<sup>8</sup>.

Of 29 couples, two couples with both partners being carriers of  $\beta$ TT were at risk of producing a major child while seven couples with single partner as carrier could transmit the defective gene in its heterozygous form (carrier state) to their offspring. Prenatal diagnosis usually prevents birth of second child with major disorder in a family having an already affected child. On the other hand premarital counseling can altogether

**Table 3: Distribution of male and female participants according to past hematologic history of diagnosis and treatment of anemia and Beta thalassaemia trait**

Past history	Males (n = 190)		Females (n = 256)	
	$\beta$ TT (n= 31) No (%)	Normal (n= 159) No (%)	$\beta$ TT (n= 44) No (%)	Normal (n= 212) No (%)
History of diagnosis of anemia by Hb% estimation	03 (09.67)	12 (07.54)*	12 (27.20)	27 (12.70)#
History of treatment for anemia with iron	03 (09.67)	11 (06.91)**	10 (22.70)	24 (11.30)##

\*  $p > 0.05$ , \*\*  $p > 0.05$ ;

#  $p < 0.05$ , ##  $p < 0.05$

**Table 4: Distribution of male and female participants according to current hemoglobin concentration and Beta thalassaemia trait**

Current Hb% (gm/dL)	Males		Females	
	Total (n= 190) No (%)	βTT (n= 31) No (%)	Total (n= 256) No (%)	βTT (n= 44) No (%)
Non anaemic (Male: ≥13, Females:≥12)	114 (60.0)	09 (29.03)	147 (57.4)	10 (22.7)
Mild anemia(Males: 10-12.9, Females: 10 -11.9)	61 (32.1)	19 (61.3)	70 (27.3)	21 (47.7)
Moderate anemia(Males and Females: 7- 9.9)	15 (07.9)	03 (09.7)	37 (14.5)	12 (27.3)
Severe anemia (Males and Females: < 7 )	0	0	02 (00.8)	01 (02.3)

Males: non-anemics Vs anemics:  $\chi^2 = 14.8$ , df = 1, p < 0.001;

Females: non-anemics Vs anemics:  $\chi^2 = 26.1$ , df = 1, p < 0.001.

prevent birth of such a child. Thus premarital screening and mate selection should always be preferred. However, individuals from high risk communities, having married without knowing about thalassaemia can both very well undergo blood test for βTT before planning for children.

In order to study whether Beta-thalassaemia trait state influences age at attainment of menarche, female study subjects were asked about their age at menarche in completed years. Considering the comparable socio-economic status of all female subjects, the influence of living conditions and food habits on age at attainment of menarche was considered equal in Beta-thalassaemia trait females and normal females. Contrary to K.K. Bhattacharya et al<sup>9</sup> who found in their study in Bengali women a significantly higher mean menarcheal age in trait females than normal females, in the current study the difference in age at menarche between trait females and normal females was not appreciated.

On comparison of proportion of non-anemics and anemics in males and females with Beta-thalassaemia trait and normal males and females, a significantly more number of subjects with Beta-thalassaemia trait had anemia as compared to normal males and females. Similar findings were reported by earlier studies also<sup>10, 11</sup>. However, in the present study reported past history of diagnosis of anemia by means of Hb estimation was considered. In such situations bias may creep in because normal adult Hbg carriers might ignore such history / investigation.

In the current study, a significant number of both male and female trait subjects were anaemic and almost 25% of trait females were misdiagnosed as having iron deficiency anaemia and were treated with iron, which is not only ineffective but also harmful. Thus physicians should have a suspicion of βTT in cases with abnormal RBC indices and HbA<sub>2</sub> estimation should be requested for.

In earlier studies on population screening for βTT, 3 stage approach (All samples for NESTROFT, NESTROFT positives for MCV and those with low MCV for Hb electrophoresis) was followed. However, Manglani (1997)<sup>3</sup> found that NESTROFT with MCV together proved to be a 100 % sensitive screening test. So in the current study we followed 2 stage method with NESTROFT + MCV as screening test and samples positive in either one or both tests were processed for HbA<sub>2</sub> estimation by electrophoresis in order not to miss a single trait carrier. High level of receptivity by families in this study is noteworthy, probably because screening was preceded by distribution of pamphlets for beforehand awareness about Beta thalassaemia.

The present study demonstrates feasibility and potential benefits of a community based education and screening programmes followed by counseling for Beta thalassaemia for the all high risk communities including Sindhis. Success of Cyprus and Sardenia in reducing incidence of birth of major children was also based on population screening followed by ethical counseling. Thus similar dedication in our country also can go a long way in reaching near zero birth of a major Beta thalassaemia child.

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*Original Article*

## A Study on Catch Up Growth among Low Birth Weight Infants in an Urban Slum of Kolkata

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### Abstract

**Objectives:** To study the catch up growth among low birth weight infants in relation to the normal birth weight counterparts in first six months of age. **Methods:** A longitudinal community based study was done in 2004 -05 in an urban slum of Chetla, Kolkata among 126 singleton live born babies. Growth pattern of these babies was followed up at 15±5 days interval by house visit till six months of age. **Results:** The incidence of low birth weight babies was 28.6%. 86.1% LBW infants caught up in length at 3<sup>rd</sup> month, 63.9% in chest circumference at 4<sup>th</sup> month, 66.7% in head circumference at 5<sup>th</sup> month, while 72.2% in weight at 6<sup>th</sup> month. Regular growth monitoring is essential for LBW babies to detect signs of growth faltering at the earliest.

**Key words:** Catch up growth; LBW, birth weight, growth pattern

### Introduction

Growth is an essential component of health surveillance of low birth weight (LBW) infants, because almost any problem within physiologic, interpersonal and social domains can adversely affect growth<sup>1</sup>. Longitudinal assessment of growth of LBW infants entails valuable data about their 'catch up' with their normal birth weight (NBW) counterparts, which is dramatic in the LBW infant who thrives well when given adequate nutrition<sup>2</sup>. The monthly incremental variability of the anthropometric parameters is influenced mainly by gestational age, birth weight, nature and severity of illnesses, calorie intake, ongoing illness and environmental factors at home and heredity. The present study was undertaken to find out the pattern of growth of LBW infants in order to ascertain their catch up potential in relation to the NBW infants.

### Materials and Methods

A community based prospective longitudinal study was undertaken in a slum of Chetla, which is the urban field practice area of All India Institute of Hygiene and Public Health, Kolkata from May 2004 - April

2005, having population of 1.24 lakhs (approx.), with Crude Birth Rate of 6 per 1000 mid year population and 31% of LBW babies (source: Statistical Department Urban Health Centre, Chetla, 2002).

The infants selected were born during the first three months of the study period to a cohort of pregnant women in their third trimester, residing permanently in that area. The estimated number of study subjects (i.e. infants) was calculated to be 132 by the formula

$$N = 4 \left[ \frac{(Z\alpha + Z\beta)\sigma}{\delta} \right]^2$$

Where,  $Z\alpha = 1.65$  (as this was a one sided test);  $Z\beta = 1.28$  which is the value of Z required for the chosen level of  $\beta$  (one tailed) i.e. 0.10;  $\sigma = 172$  (SD of weight at birth of previous study)<sup>3</sup> and  $\delta = 7.5\%$  of difference of mean weight of NBW (3003 gms) and LBW (1771 gms) at birth (data of previous study)<sup>3</sup> which is the clinically important difference under the alternative hypothesis, that the investigator wishes to detect.

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Thus the estimated number of the study subjects was 120 and taking 10% pregnancy wastage into consideration, sample size was  $120 + 10\% = 132$  newborn infants.

132 consecutive pregnant women in their third trimester, attending the MCH clinic of UHC Chetla for antenatal check up, during the first three months of the study period, who consented to take part in the study were registered and a register was prepared including their names and addresses. As and when the information about birth of singleton live born babies to the registered pregnant women was obtained, follow up at the interval of  $15 \pm 5$  days, by home visits was carried out till each baby was six month of age. Multiple births, babies with major congenital malformations and severe birth asphyxia, which were likely to hamper growth velocity pattern were excluded from the study<sup>3</sup>. If the respondent could not be contacted during the visit, two consecutive visits were made in order to minimize the proportion of dropouts. Out of 132 deliveries, 126 babies could be finally followed up (drop out rate 4.5%). Data collection was done from the mother/caregiver in a pre-designed, semi-structured schedule seeking information about demographic particulars, history of morbidity and relevant anthropometric measurements i.e. weight, length, head and chest circumference and clinical examination of the baby where necessary. Birth weight of each infant was recorded from discharge certificate. Subsequently the weight was recorded by a standardized weighing machine, which was checked at regular interval and calibrated by an object of known weight. The infant was undressed and put on the weighing machine and the weight was recorded to the nearest 50 grams<sup>4,5</sup>. The length (nearest 0.1 cm) of the infant was measured with an infantometer. During measurement, the infant was placed supine on the infantometer. Mother/caregiver was asked to keep the vertex snugly touching the fixed vertical plank. The legs were fully extended by pressing over the knees, and feet were kept vertical at  $90^\circ$ . The movable pedal plank of the infantometer was snugly apposed against the soles and length was read from the scale<sup>4,5</sup>. The head and chest circumference was measured with a measuring tape (nearest 0.1 cm). Head circumference (HC) was measured by passing the tape over the occipital protuberance posterior and just above the supra -

orbital ridges anteriorly to get the maximum circumference<sup>4,5</sup>. Chest circumference (CC) was taken at the level of xiphisternum in front, in a plane at right angles to the vertebral column and just below the inferior angle of scapula midway between inspiration and expiration<sup>5,6</sup>.

In this study the growth of the NBW infants was taken as the standard at each month in order to compare the growth of the LBW infants as both the groups were living in more or less homogenous environmental condition. Catch up growth was calculated by taking into account the number of low birth weight infants whose weight, length, head and chest circumference were within the range of the mean values of the normal birth weight infants  $\pm 2$  Standard Deviation at each month.

## Results

The incidence of low birth weight (LBW) neonates (< 2500 gms) among the study subjects was 28.6% (36). The rest of the neonates i.e. 71.4 % (90) had normal birth weight (NBW). The overall mean birth weight of the study subjects was  $2570.60 \pm 391.80$  gms. The mean birth weight of the NBW and LBW neonates was  $2763.33 \pm 238.65$  and  $2088.89 \pm 263.50$  gms respectively and the difference was found to be significant statistically ( $t = 13.91$ ,  $p < 0.05$ ). On recording the anthropometric parameters of the LBW and NBW infants at monthly intervals from birth to six months of age, it was observed that the mean weight, length, head and chest circumference of the LBW neonates was much lower than that of NBW neonates at birth and this difference was retained at each month through out the six months of follow up period.

The mean increments of weight, length, HC and CC calculated at each month from first to six months of age among study subjects revealed that the LBW infants had higher increments as compared to that of NBW infants for each month except at 2<sup>nd</sup> month in case of weight, and at 6<sup>th</sup> month in case of length and CC. Statistically significant difference was observed at 5<sup>th</sup> & 6<sup>th</sup> months between mean weight increments, at 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> months between mean length increments, at 2<sup>nd</sup>, 4<sup>th</sup> and 6<sup>th</sup> month between mean HC increments, and 1<sup>st</sup> to 5<sup>th</sup> months between mean CC increments (Table 1).

**Table 1: Comparison of pattern of increment of weight, length, head circumference and chest circumference between LBW and NBW infants from birth to six months of age.**

[ n of LBW = 36, n of NBW= 90 ]

Variables	Months					
	1	2	3	4	5	6
<b>Weight</b>						
Mean increment (gms) ± S D (LBW)	711.11 ± 91.89	702.78 ± 81.01	645.84 ± 110.43	506.95 ± 93.46	522.23 ± 61.46	423.61 ± 68.12
Mean increment (gms) ± S D (NBW)	703.88 ± 82.18	728.33 ± 103.6	632.78 ± 87.13	482.22 ± 61.94	444.44 ± 51.08	400.56 ± 55.33
t test	0.43	0.89	0.70	1.73	7.27*	1.97*
<b>Length</b>						
Mean increment (cms) ± S D (LBW)	3.19 ± 0.40	2.69 ± 0.52	2.77 ± 0.48	2.19 ± 0.57	1.86 ± 0.59	1.56 ± 0.50
Mean increment (cms) ± S D (NBW)	2.56 ± 0.58	2.43 ± 0.52	2.23 ± 0.61	2.00 ± 0.54	1.78 ± 0.57	1.63 ± 0.56
t test	5.92*	2.53*	4.72*	1.78	0.72	0.71
<b>Head circumference</b>						
Mean increment (cms) ± S D (LBW)	2.05 ± 0.23	1.86 ± 0.38	1.68 ± 0.48	1.25 ± 0.51	1.00 ± 0.46	0.93 ± 0.36
Mean increment (cms) ± S D (NBW)	2.01 ± 0.42	1.67 ± 0.37	1.65 ± 0.39	0.93 ± 0.38	0.89 ± 0.36	0.70 ± 0.31
t test	0.59	2.52*	0.36	3.73*	1.35	3.54*
<b>Chest circumference</b>						
Mean increment (cms) ± S D (LBW)	2.84 ± 0.42	2.52 ± 0.46	1.91 ± 0.57	1.61 ± 0.49	1.16 ± 0.33	0.87 ± 0.30
Mean increment (cms) ± S D (NBW)	2.67 ± 0.46	2.12 ± 0.48	1.67 ± 0.49	0.97 ± 0.39	0.92 ± 0.40	1.01 ± 0.39
t test	2.13*	4.28*	2.50*	7.56*	3.11*	1.94

\* p value statistically significant (&lt; 0.05)

Maximum number of LBW infants (86.1%) caught up within the range of 2 standard deviation of their NBW counterparts in relation to the length parameter at 3<sup>rd</sup> month after which their proportion remained same till six months of age (83.3%); 63.9% caught up in relation to the chest circumference at 4<sup>th</sup> month. At 5<sup>th</sup> month 66.7% of LBW infants caught up in relation to the head circumference and 72.2% caught up in relation to the weight parameter at 6<sup>th</sup> month (Table 2).

## Discussion

The importance of first year of life of a child for its growth is well known, more so for LBW infants who get an opportunity to recover their growth deficit. The mean monthly incremental variability in weight, length, head circumference and chest circumference revealed that the LBW infants had higher increments as compared to NBW infants for each month reflecting

**Table 2: Catch up growth of weight, length, head circumference and chest circumference among LBW infants in relation to NBW infants from first to six months.**

[ n of LBW = 36, n of NBW= 90 ]

Variables	Age (months)					
	1	2	3	4	5	6
<b>Weight</b>						
Mean weight of NBW (gms) $\pm$ 2SD	3467.22 $\pm$ 575.94	4195.56 $\pm$ 714.32	4828.33 $\pm$ 807.82	5310.56 $\pm$ 852.54	5755.00 $\pm$ 866.48	6155.56 $\pm$ 883.98
Catch up growth among LBW	16 (44.4%)	18 (50.0%)	21 (58.3%)	22 (61.1%)	21 (58.3%)	26 (72.2%)
<b>Length</b>						
NBW Mean length (cms) $\pm$ 2SD	50.80 $\pm$ 4.44	53.23 $\pm$ 4.74	55.46 $\pm$ 4.76	57.46 $\pm$ 5.14	59.24 $\pm$ 5.38	60.87 $\pm$ 5.67
Catch up growth among LBW	27 (75.0%)	29 (80.5%)	31 (86.1%)	30 (83.3%)	30 (83.3%)	30 (83.3%)
<b>Head circumference</b>						
NBW Mean HC (cms) $\pm$ 2SD	35.61 $\pm$ 2.16	37.28 $\pm$ 2.06	38.93 $\pm$ 2.30	39.87 $\pm$ 2.32	40.77 $\pm$ 2.28	41.47 $\pm$ 2.14
Catch up growth among LBW	16 (44.4%)	18 (50.0%)	17 (47.2%)	20 (55.5%)	24 (66.7%)	23 (63.9%)
<b>Chest circumference</b>						
NBW Mean CC among $\pm$ 2SD	33.81 $\pm$ 2.46	35.93 $\pm$ 2.36	37.59 $\pm$ 2.10	38.57 $\pm$ 2.12	39.49 $\pm$ 2.14	40.51 $\pm$ 2.12
Catch up growth among LBW	12 (33.3%)	18 (50.0%)	16 (44.4%)	23 (63.9%)	23 (63.9%)	23 (63.9%)

the potential of their catch up growth, except in few months in relation to length, CC, and weight which could be due to the effect of morbidity episodes hampering their growth. However, the head growth of these infants was minimally hampered by the morbidity episodes since brain growth is very rapid during infancy and is unaffected by mild to moderate degrees of under nutrition.

Bavdekar AR et al reported rapid growth of LBW infants in the first six months of life, followed by generally parallel trends with same tendency to rise, while NBW infants showed distinct growth faltering specially after one year<sup>7</sup>. In the present study, the first

anthropometric parameter of LBW infants to catch up was length, followed by CC, HC and lastly weight in relation to the NBW infants. Karim E et al also reported catch up growth at 6 months among 91 poor urban Bangladeshi infants (monthly incremental variability of both infant weight and length increased sharply from 6 to 12 months)<sup>8</sup>. Mc Cowan L from New Zealand reported 84% catch up of LBW infants at 6<sup>th</sup> month<sup>9</sup>. Similarly Harding JE from New Zealand reported 75% catch up of LBW babies at 6<sup>th</sup> month<sup>10</sup>. Contrary to the above said findings by various researchers, Lam B et al reported incomplete catch up growth among 181 Chinese LBW infants at ages 6 and 12 months<sup>11</sup>.

## Conclusion

It is heartening to note that essential care of LBW babies is a highly rewarding experience since despite their earlier disadvantage, LBW children gradually catch up with their NBW counterparts. Hence regular growth monitoring should be an essential component of health surveillance of the LBW babies so that signs of growth faltering could be detected at the earliest. This could be ensured by involving the health workers in monitoring of growth at regular intervals and training the mothers in this regard for ensuring optimum home care of these babies.

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*Special Article***Estimation of Mortality due to AIDS- a Review****\*M. Bhattacharya<sup>1</sup>, S. Bandyopadhyay Neogi<sup>1</sup>****Summary**

HIV/AIDS has emerged as a major public health problem since its recognition as an emerging disease a couple of decades ago. While detection of HIV/AIDS cases remains a problem, ascertainment of AIDS deaths has emerged as a bigger challenge and concern. Despite a plethora of literature focusing on the methods to estimate AIDS deaths, none seems to be fulfilling the requirements for universal acceptance. In this paper, we give a systematic review of various methods used by experts to have a reliable estimate of the number of deaths due to AIDS. Initial assessments were derived from morgue based estimates in Africa which showed that AIDS was a leading cause of death. Its impact on demography was noticed in some of the studies conducted wherein age and sex specific mortality rates, standardized mortality ratios, potential years of life lost and decrease in life expectancy were calculated. "Excess mortality factor" as observed in 1980s and 1990s also indicated the approximate number of AIDS deaths. Besides, orphan hood method and verbal autopsy technique too, emerged as reliable means to identify mortality due to AIDS. Some indirect methods like estimation of deaths due to opportunistic infections like tuberculosis could also be a good indicator. The paper reviews the merits and possible biases encountered with each of the methods.

**Introduction**

Reliable statistics on the causes of death in the population are required for setting priorities in the health sector. Developing countries like India rely on death statistics that have poor coverage and poor adherence to the guidelines<sup>1</sup>. The country is grappling with multitude of diseases- both emerging and non emerging. HIV/ AIDS that was recognized as an emerging disease in 1980s soon evolved into a global pandemic in less than two decades time.

There is an increasing recognition that the impact of HIV /AIDS is no longer confined to the inflicted individuals. Its impact on emotional and social behavior of the family members and economic consequences on the family and the country at large are currently being studied<sup>2</sup>. In order to strengthen this data, it is of utmost importance to ascertain the number of cases and the mortality resulting from it. This would further be useful for advocacy, public health planning (like prioritization for resource allocation) and for

influencing socio economic policies. But this can only be done after estimating the comparative weight of this AIDS mortality. Moreover, we might need to estimate mortality more directly and precisely in order to back-calculate from mortality to get better estimates of prevalence and incidence.

Since beginning, determining the number of cases of AIDS had been a daunting task. The gradual development and sustainability of surveillance system established in different parts of the world provides some answer to the ever growing load of the disease condition.

Mathematical and statistical models have served as tools for understanding the epidemiology of many diseases and HIV/ AIDS for certain, is no exception. Experts have estimated the approximate number of AIDS cases using such models. With the rise in the prevalence of HIV in most of the countries in the world, estimating the number of deaths directly or indirectly attributable to AIDS has become a challenge. Various

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models have been put forth to have a reliable estimate. However, the same model cannot be applied universally since the picture of the dynamics of HIV spread is not clear across the globe. This is primarily due to absence of scientific means of gathering and modeling information on the infectious period of HIV infected, time to the onset of AIDS, sexual behaviour of high and low risk individuals in the population, probability of transmission from the infected to the susceptible per partnership and other relevant parameters<sup>3</sup>. This article gives a review of the various methods adopted by different countries to estimate the number of AIDS deaths.

#### **Evidence from different countries**

To assess the impact of AIDS on mortality, various measures have been put forward viz. decrease in life expectancy, potential years of life lost, disability adjusted life years, standardized mortality ratios etc. Demographic estimation techniques have been used in a number of countries to understand the impact of AIDS on mortality. Models however depend on a number of variables that are either difficult to measure, such as the duration of incubation period, or currently unavailable data, such as the sex and age specific prevalence rates in the general population. Direct enumeration of AIDS deaths from civil registers is also problematic because death registration is often incomplete and declared causes usually unreliable. Hospital based surveys, which use a more reliable source of data on causes of death, are not representative of the general population. Prospective cohort studies require a close follow up of large populations over a relatively long period of time<sup>4</sup>.

Evidence suggests that only about 30-35% of all deaths are captured by vital registration (excluding sample registration schemes)<sup>5</sup>. Even in countries where vital registration system functions reliably, data on the cause of death are usually of poor quality. The reasons for this include inconsistent coding of causes of death by health professionals, reliance on lay reports of the cause of death for those who die outside health facilities, and under reporting of some causes of death, in particular AIDS<sup>6</sup>. For a variety of reasons like stigma, ignorance and insurance problems, the cause is often not put down by the certifying doctor as HIV or AIDS<sup>7</sup>.

In the absence of vital records, health planning and practice rely on epidemiological models and

surveys. Population based data have several advantages over existing vital registration or hospital based data. By recording deaths occurring at home and in facilities they are more complete, and a consistent classification of causes of death is applied to both groups<sup>8</sup>.

#### **Evidence from on morgue based estimates**

In 1990, DE Cock and colleagues directly measured the impact of AIDS on mortality in Abidjan using clinical and serological data collected in hospital morgues. This study showed for the first time that AIDS was a leading cause of death in an African city<sup>9</sup>. These morgues were however receiving deaths occurring in hospitals. This recruitment bias was taken care of in another study wherein all deaths were investigated during a one month period in Brazzaville<sup>4</sup>. All bodies handled by the morgues were examined by a physician. Relatives were interviewed on the circumstances of death, while additional clinical data were gathered from hospital files for cases previously hospitalized. Blood samples were systematically drawn from the bodies and tested for HIV antibodies. Age and sex specific mortality rates were calculated using the population at risk derived from the 2001 census<sup>10</sup>.

To measure the impact of HIV/AIDS on mortality in Ethiopia, a retrospective review of burials at three cemeteries and a prospective review of burials at all cemeteries were carried out in 2001. The age, sex and date of burial were recorded. In the absence of denominators, the ratio of deaths of persons 25-49 versus 5-14 years of age per calendar year was compared using logistic regression adjusting for sex. The age and sex specific mortality were calculated and compared with pre HIV mortality in 1984<sup>11</sup>. Lay diagnoses of death collected at burial sites has also been used for monitoring AIDS mortality. Lay diagnoses were validated against two 'gold standards': the hospital discharge diagnosis of causes of death obtained by a surveillance of hospital deaths (including autopsy results) and the physician review of verbal autopsies that were carried out for a sample of records. The diagnostic indicators were then used to provide estimates of the share of HIV/AIDS attributable mortality. Authors conclude that even in the presence of a reluctance to talk of HIV/AIDS, lay diagnosis of causes of death can be used for monitoring HIV/AIDS mortality<sup>12</sup>.

Morgue based estimates have an advantage over mathematical models since it does not depend on variables like duration of incubation period that are otherwise difficult to measure. However, a correct estimation would require that the morgues under surveillance receive a majority of all deaths reported. This bias was observed in most of the morgue based studies. Cultural and religious practices too influence the surveillance of burials to estimate causes of mortality.

### **Analysis using mortality trend**

An analysis of mortality trend has also been used to estimate AIDS deaths. To measure recent trends in all cause child and adult mortality in national population, secondary analysis of data collected in national household surveys and censuses are carried out. Mortality trends are assessed in three ways: (i) by comparison of data collected in 1990s with those from 1980s (ii) using retrospective reports of the survival of women's children and siblings collected by demographic surveys (iii) by comparing the later estimates with estimates from data on orphanhood<sup>13</sup>.

To examine the trends in AIDS mortality in Canada, the national mortality database was examined for overall number of AIDS deaths by year, age and gender. However, the database lacked demographic data such as country of birth. Information from national AIDS surveillance database at the Centre for Infectious Disease Prevention and Control was used to examine these characteristics<sup>14</sup>. In a descriptive, population based study in Canada, all persons for whom HIV/AIDS was recorded as the underlying cause of death as reported to Statistics Canada between 1987 and 1992 was obtained. For comparative purposes data was obtained on five other leading causes of death including coronary heart disease, motor vehicle accidents, suicides and malignancies. Population figures were obtained from Statistics Canada estimates. Age and cause specific mortality rates, standardized mortality ratios (SMR), potential years of life lost (PYLL) before 65 years and life expectancy lost due to select underlying cause of death were calculated<sup>15</sup>.

In Mexico, the trend was assessed after estimating the crude and adjusted mortality rates. A trend test was performed using the simple linear regression method. Standardized mortality ratios (SMR) and

potential years of life lost were calculated<sup>16</sup>. Similar calculations have also been done to ascertain the burden of the disease in South Africa, British Columbia and Canada<sup>17,18</sup>. National statistics on yearly numbers of reported deaths by cause, in conjunction with census population counts and inter censory estimates, were used to calculate age and sex specific AIDS mortality rates for Brazil<sup>19</sup>.

Trends in mortality statistics in England and Wales with particular reference to AIDS from 1984 to 1987 were obtained from death certificates. Increase in deaths from selected causes likely to be associated with AIDS suggested that in some patients with HIV infection, AIDS was not stated on the death certificates or subsequently notified by the doctor who signed the certificate. From calculation of the excess deaths between 1985 and 1987 compared with the previous years were estimated to have occurred among men during that period<sup>20</sup>.

Combination of routine mortality statistics with reports of AIDS deaths adjusted for underreporting and change of address from time of report to time of death has been used by Hickman to study the impact of HIV on adult mortality in London. Standardized mortality ratios were calculated for males including and excluding HIV comparing different areas in London<sup>21</sup>.

To quantify the mortality impact of AIDS deaths in Abidjan, mortality trends were analysed before and after the onset of epidemic. Data on deaths registered in vital registration centres between 1973 and 1992, and data on causes of deaths in public hospitals were coded and investigated. Life tables were computed for each of the 20 years of the study. The trends in death rates were analysed during the 10 years before the onset of the epidemic (1973-82) and compared with the changing death rates in the following 10 years (1983-92). Deaths attributable to AIDS were defined as those in excess of the original trends<sup>22</sup>.

To estimate AIDS related adult mortality using verbal autopsies in rural sub Saharan African setting with high prevalence, AIDS related deaths were identified using a standard World Health Organization (WHO) algorithm. Verbal autopsy data were collected from relatives and neighbors that described the circumstances leading to death. The observed number of deaths was compared with the expected number.

The expected number is derived from a comparison of adult mortality in this sample with the pre AIDS mortality levels<sup>23</sup>. This gives an 'excess mortality factor' that can be considered to be AIDS related.

Evidence of AIDS related mortality in Mumbai, India is available. A growth rate model was used to analyze data on deaths that occurred between 1987 and 1997 in Mumbai. Authors had used data from the death registry of the Public Health Department of the Mumbai Municipal Corporation, which is fairly reliable and efficient in terms of recording deaths within the city. HIV sero-prevalence rates and annual rate of death among HIV infected individuals were used to calculate the number of AIDS related deaths. The death rate per 100,000 population for 1987, adjusted for annual exponential population growth, was used in the estimation of deaths in the subsequent years. The observed number of deaths was substantially greater than the expected number. These excess deaths accord with the estimated number of AIDS related deaths<sup>24</sup>.

The mortality trend, SMR, PYLL are some of the measures to establish the speculation on the demographic impact of AIDS. Characteristics to be noted in particular are: emergence of demographic impacts much earlier than expected, their localization with negative population growth but not at national scale and a greater impact on the number of children than previously predicted<sup>25</sup>. Such demographic impacts in the absence of other reliable statistics may hint at the interdependence of HIV infection and demographic growth.

The main source of information about HIV epidemic is the HIV seroprevalence surveys and the ongoing surveillance programme. However, to have a reliable estimate of AIDS deaths in the face of so many limitations, it became necessary for researchers to develop a method that would not require explicit cause of death details. The methods described above may not give the exact number of deaths, but an analysis of the trend may provide an answer to the program managers and policy makers.

#### **Analysis using orphanhood methods**

Death rates and other mortality indices have been calculated directly and estimated indirectly by the orphanhood method<sup>26</sup>. This technique exploits the fact

that the proportion of the mothers (fathers) who have died for each age group of respondents is a strong predictor of the life table probability of surviving of adult women (men) from age 25 (35) to that age plus the age of the respondents. The date at which the mortality of each cohort of parents equaled period mortality can be estimated<sup>27</sup>.

Numbers of youth in the United States who have been or will be left motherless by AIDS have been estimated. In this case, orphans were defined as youth whose mothers (the usual caregiver) die of HIV/AIDS related causes. A mathematical model was constructed to estimate the number of such motherless youth. Cumulative fertility rates were applied to the number of reported AIDS deaths (1981 through 1990) and projected deaths (1991 through 1995) of adult women less than 50 years old. The results were adjusted for underreporting of AIDS related mortality, pediatric deaths, infant mortality, ethnic and racial variation and decreased fertility associated with late stage HIV disease<sup>28</sup>.

The orphanhood estimates of mortality are based on retrospective reports and it is possible that they underestimate adult mortality. A possible bias is that in some applications of the method the reports about some orphans have referred mistakenly to their living foster parents. Where this occurs, the data on young people are affected most<sup>26</sup>.

#### **Analysis using verbal autopsy techniques**

In a study in rural South Africa, demographic surveillance of the population was made use of. The population and all adult deaths in 2000 were enumerated. Verbal autopsy interviews with the caregivers of those who died were conducted to identify the causes of deaths and the diagnoses were validated on a small sample. Verbal autopsies have been shown to have adequate sensitivity and specificity for a wide range of causes of adult death including AIDS<sup>29</sup>.

An algorithm to measure AIDS mortality using verbal autopsy was created and validated in Zimbabwe<sup>30</sup>. A verbal autopsy questionnaire was administered to caregivers of 381 adults of known HIV status who died between 1998 and 2003. Individuals who were HIV positive and did not die in an accident or during childbirth were considered to have died of

AIDS in the gold standard. Verbal autopsies were randomly allocated to a training dataset to generate classification criteria or a test dataset to verify criteria. Predictors (weight loss, wasting, jaundice, herpes zoster, presence of abscesses or sores, oral candidiasis, acute respiratory tract infections, vaginal tumours) were included in the algorithm. Presence of any one of these criteria gave a post test probability of AIDS death of 0.84<sup>30</sup>. Verbal autopsy technique has also been used in Uganda and Malawi with (WHO algorithm) with satisfactory results<sup>31,33</sup>. Verbal autopsy data can be used to estimate with a reasonable degree of confidence the distribution of AIDS and non-AIDS related deaths in the aggregate, even in a rural population with relatively low levels of education This suggests that the method can be relied upon to estimate HIV associated mortality in population with a relatively high HIV prevalence.

#### **Other methods for AIDS deaths estimation**

Lopman in a study has compared alternative methods for estimating adult mortality in HIV afflicted Zimbabwe. Estimates of adult mortality was obtained from (a) a single question on household mortality (b) repeated household censuses and (c) an adult cohort study with linked HIV testing, with a mathematical model fitted to local age specific HIV prevalence. Each method for estimating adult mortality had limitations in terms of loss to follow up (cohort study), under ascertainment (household censuses), transparency of underlying processes (single question), and sensitivity to parameterization (mathematical model)<sup>32</sup>.

Another indirect measure to study the trend in mortality statistics is the trend in deaths from selected causes that are likely to be associated with AIDS or HIV infection. An increase in deaths due to tuberculosis, influenza and pneumonia among people between the ages of 15 and 49 is indicative of HIV as the underlying cause. In South Africa, the three leading causes of death in children aged under 4 years were intestinal infectious diseases, malnutrition, influenza and pneumonia. Medical statisticians say that the trend in these figures is an indication of the effects of the AIDS epidemic<sup>34</sup>. Increase in the TB mortality particularly among younger women and an increase in the proportion of extra-pulmonary TB of all TB deaths and an increase in multi-drug resistant TB are good pointers of an increase in HIV related TB deaths<sup>35</sup>.

Yet another method for estimation of AIDS mortality was used by Bhattacharya et al<sup>36</sup> in India. A mathematical model by the name of Kink Regression method was used to estimate the excess deaths in the country in the age group of 25-49 years from 1994 to 2002. The regression analysis gives a difference in the death trends as observed with AIDS and that expected, had the death rates declined if AIDS was not there.. The year 1993 has been used as a cut off because deaths due to AIDS in India can be presumed to have started occurring around 1994 after its introduction in the country in 1986<sup>35</sup>. This gave an estimate of the excess deaths that have occurred in India since 1994 to 2002 which could be due to AIDS after analyzing for the deaths due to other causes affecting the age group of 25-49 years.

Pandey et al<sup>37</sup> at national level in India used to calculate AIDS mortality by use of the HIV estimation data for the country which is calculated from the Annual Sentinel Surveillance data, 2006 using the UN projections Workbook method<sup>38</sup>. This software comes as a set of excel workbooks. The first workbook is used to make point prevalence estimates; the second is used to develop an epidemic curve of adult HIV prevalence and to produce projection scenarios. This is then fed into a software known as SPECTRUM<sup>38</sup> which is a policy modeling system that contains modules for a number of reproductive health areas. For the purpose of calculating AIDS mortality Spectrum reads the adult prevalence estimates from the Workbook and calculates additional indicators, such as the number of people infected, the number of new infections, AIDS cases, AIDS deaths, the number of people needing treatment and the number of orphans.

#### **Conclusion:**

The fact that numerous methods have been proposed to estimate AIDS deaths in various countries shows none of the methods are full proof. Also dynamics of HIV transmission varies between countries and the same method will not hold good everywhere. Moreover, the models come out with figures that are only estimates. How valid and reliable those figures are is also a matter of debate. Morgue based estimates, estimates from orphanhood method and verbal autopsies are useful where death reporting is adequate or nearly adequate. But in a country like India where

registration of deaths is incomplete, standardized mortality ratios, or 'excess mortality factor' gives a fair idea about AIDS deaths. Though the softwares like Spectrum are available now but estimation of AIDS mortality and its impact therefore, remains a challenging task for the epidemiologists and public health specialists working in the field.

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*Special Article***Linking Undergraduate Medical Education to Primary Health Care**

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**Summary**

Under graduate medical education aims at producing doctors who are competent in preventive, promotive and curative knowledge and skills. The community medicine curriculum in All India Institute of Medical Sciences, New Delhi has been designed with this objective in view. Students are given community oriented training in urban and rural settings whereby students are taught to carry out various activities under the guidance of faculty members. This curriculum has evolved over many years and provides ample exposure to the students to understand the health problems, and health system of the country especially at the primary and secondary level. There is a sequential teaching of community medicine, which starts from fourth semester through internship. Successful training in community medicine lies outside the walls of the department and the involvement of other partners like the community, health systems etc contribute largely.

**Introduction**

Undergraduate medical education lays the foundation for a future doctor. The Medical Council of India has laid down certain objectives for medical graduate training programme which aims at achieving competence in practice of Holistic Medicine encompassing promotive, curative and rehabilitative aspects of common diseases<sup>1</sup>. In order to achieve this goal, the All India Institute of Medical Sciences (AIIMS) has designed the MBBS undergraduate curriculum in a manner which provides extensive exposure and ample opportunities to the students in all aspects of medical training.

This paper shares the experiences of the AIIMS in undergraduate programme in Community Medicine, wherein the students are exposed to a sequential method of teaching in Community Medicine which starts from the third year of medical training right up to internship.

Teaching and research are the priority areas in the Centre for Community Medicine besides providing

primary health care. In order to fulfill these duties, the Centre for Community Medicine adopted two field practice areas one each in the urban and rural areas. The undergraduate students at the AIIMS go through a rigorous and extensive training programme in Community Medicine from the 4<sup>th</sup> semester onwards (Table 1). Broadly there are two postings: one in the urban area and another in the rural area.

**Urban Programme**

The Urban Health Programme (UHP) runs in Dakshinpuri, a resettlement colony in South Delhi which is 8 kms from AIIMS, where four blocks have been adopted by the AIIMS as its urban field practice area. The Urban Health Team comprises of doctors, Public Health Nurse, Medical Social Worker, pharmacist, Multipurpose health workers and supporting staff which provide medical services daily through a mobile clinic. Regular home visits are made by the MPWs in assigned blocks. This helps in building a rapport with the community and creates an environment conducive for undergraduate students to carry out community based projects.

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**Table 1: Duration & Distribution of postings for MBBS students in Community Medicine**

Semester	1	2	3	4	5	6	7	8	9	Internship	Duration
Urban (FHAS)				■	■						Once a week for 2 hrs for 9 months (afternoon)
Urban (UHP)				■	■						3 hrs a day x 45 days (morning)
Rural							■			■	Residential posting for 6 weeks in CRHSP

The urban posting of the undergraduates is divided into two parts: 1. Family Health Advisory Services (FHAS) and 2. Urban health programme posting.

#### Family Health Advisory Services (FHAS)

The Family Health Advisory Services (FHAS) is a longitudinal follow up of families for a period of about nine months from January –September. It is covered during the 4<sup>th</sup> and 5<sup>th</sup> semester. The objective of this exercise is to study the family structure and health status of the individual members and follow up the family for over a period of time, with specific reference to acute and chronic morbidity. Each student is allotted three families for follow up, and these visits are made once a week, every Monday afternoon from 3-5pm.

FHAS is divided into six exercises each to guide the student in overall assessment of health problems and study the interplay of environmental and social factors in health. At the end of six exercises, they formulate a Community Diagnosis by pooling and analyzing the data of families. They plan, design and implement appropriate intervention programme (“Community Intervention”) in the form of role plays by the entire batch which adds fun to the learning process. All these activities are carried out under the guidance of the faculty members with cooperation from the staff and residents.

#### The Urban Health Programme posting:

This is a more intensive posting wherein batches of students attend for 6 weeks in the mornings from 9 AM to 12 noon. During this posting six areas are covered.

A. Epidemiological Exercise: the objective is to provide first hand experience to the students in carrying out a community based research. The students work as a team, and are encouraged to decide on the topic, plan out the methodology, analyze and present their results under the guidance of the faculty.

- B. Clinico-Psycho-Social Case Review: Here each student is allotted a case with a health problem, and taught to study the social, cultural, economic, environmental, and psychological aspects of the disease and understand the web of causation. This enables them to have a holistic view of a patient and family, and advise appropriate interventions.
- C. Sex & Marriage Counseling Clinic: In this posting, the students learn about the common types of problems related to sexuality and marriage, and the art of counseling.
- D. Health Talks: All students are given relevant topics where they prepare appropriate educational material, and deliver health talks in the community.
- E. Secondary level care: A visit to a secondary level hospital in the urban area is made to introduce them to the system of patient referral in urban areas.
- E. Common health problems: Students are given the opportunity to interact with the doctors and patients attending the mobile clinic to understand the common health problems in the community which represent an entirely different picture from those seen at the tertiary level.

### Rural programme

The rural field practice area is known as Comprehensive Rural Health Services Project (CRHSP) located in Ballabgarh, Haryana about 35 kms from Delhi. This is a collaborative project between the State government of Haryana and AIIMS, and has been in existence since 1967. CRHSP has a 50 bedded secondary level hospital, where all services required of a Community Health Centre / First Referral Unit are provided in Internal Medicine, Obstetrics & Gynaecology, Surgery, Ophthalmology, Pediatrics, Anaesthesiology, Dentistry, Otorhinolaryngology, Psychiatry. Laboratory and X-Ray facilities are also available. A well-equipped library with internet facilities is also available to the students and residents. The AIIMS has also adopted two Primary Health Centres for its field practice area, catering to a population of about 80,000 distributed in 28 villages of Haryana. The purpose is to demonstrate a model health system which functions along the three tier pattern of health care delivery in rural India, in terms of promotive, preventive and curative health care. All the national programmes are implemented through the Primary Health Centres, and a resident of Community Medicine works as a medical officer in charge of the PHC.

The MBBS students are posted in the CRHSP Ballabgarh as a part of their rural training in Community Medicine. This is for a period of six weeks during the 7<sup>th</sup> semester. It is a residential posting where the students are required to stay on campus for the entire period. The components of training programme have been described in details elsewhere<sup>2</sup>, but briefly they are as follows:

- A. Clinical Skills: students are exposed to various kinds of health problems in a rural area which can be managed in a primary and secondary level. This is facilitated by the faculty members from clinical disciplines from AIIMS (namely, Medicine, Obstetrics & Gynaecology, Surgery, Ophthalmology, Pediatrics, Physical Medicine & Rehabilitation) and their respective senior residents.
- B. Epidemiological exercise: The students carry out community based studies in the rural areas. Here too the students take an active part in planning, carrying out the exercises and community

intervention under the guidance of the faculty members, and staff.

- C. Health care delivery system in rural area: Visits are arranged to the District hospital, Community Health Centre and a Primary Health Centre run by the State government of Haryana with the objective of exposing the students to the national health system in the rural areas.
- D. Domiciliary visits: Visits are made to the families with selected health problems to understand the dynamics of health and disease transmission in a family and community setting.

The areas covered in the Community Medicine postings are in tune with the requirements of the Primary Health Care concept. The curriculum has been designed to integrate all the eight components and to orient the students to the various aspects of primary health care.

### Internship

As per the MCI requirement the total duration of posting is for 12 weeks and this is only in the rural area. It is divided into two parts

- a. CRHSP Hospital: in this 6 weeks posting, the students get first hand opportunity in patient management in the specialities of Medicine, Obstetrics & Gynaecology, Surgery, Ophthalmology, Pediatrics, under the guidance of residents and faculty members.
- b. Primary Health Centre: This posting gives the students a different perspective of health in rural set up e.g. an exposure of the health system in the rural area at close quarters since they are required to stay in the Primary Health Centre, for 6 weeks. This also helps them to understand the intricacies of factors influencing health in rural areas e.g socio-economic, political, cultural factors etc. and the importance of promotive and preventive medicine.

### Monitoring & evaluation

#### Log book

A log book has been designed to keep a record of all the activities of the undergraduates in Community

Medicine on a daily basis. It also provides the details of the postings e.g. objectives, methodology, assessment, etc.

#### Assessment

The assessment of students' performance is carried out in an objective manner. Different faculty members are assigned responsibility of individual activities and all components are evaluated separately. The detailed breakup of marks is given in Table 2.

**Table 2: Distribution of Theory & Practical Marks in M.B.B.S. in Community Medicine**

Semester	Posting/Examination	Theory	Practical	Total No. (%)
IV-V	Urban Health Centre Posting	25	25	50 (8.33)
IV-V	Family Health Advisory Service	25	25	50 (8.33)
VII	Comprehensive Rural Hospital Services Project, Ballabgarh	25	25	50 (8.34)
IX	Pre-professional Examination	75	75	150 (25)
IX	Professional Examination	150	150	300 (50)
MBBS	Total	300	300	600 (100)

The evaluation of Interns is done by senior residents who supervise them in their daily activities and an overall assessment by the faculty members. An award in the name of the former Director, AIIMS, Prof V Ramalingaswami Award is also conferred on the best intern posted at CRHSP, Ballabgarh.

#### Dissemination

The AIIMS mandate is to develop a model of teaching and share its experiences; it is in this context that this paper is written to disseminate information about this programme. The department as a policy also encourages publications in peer-reviewed journals for all levels of students. Some of the studies done by fourth semester, seventh semester and voluntarily by interns have been published<sup>3,4,5,6</sup>, and presented in National Conferences as well. This not only motivates the students to carry out good quality research, but also prepares them for their future career.

#### Discussion

The curriculum and teaching approach in Community Medicine at AIIMS is in tune with the

objectives laid down by the Medical Council of India Regulations on Graduate Medical Education, 1997<sup>7</sup>, with the aim of preparing students to function as community and first level physicians. The whole process of developing the curriculum of teaching has evolved over a long period of time and has not been accomplished overnight. There were periodic reviews of the curriculum, teaching methodology, assessment techniques from time to time. Regular feedback is given by the students at the end of each posting. Provision

of curative health services is an integral part of the programme without which acceptance by the community of various health promotion programmes would not have been possible. There is a good intra-departmental cooperation in terms of teaching and provision of clinical services by the faculty members and residents.

The field practice area under Community Medicine is a community laboratory for teaching and research. The added advantage of the rural field practice

area is that it is a stable population; therefore a good ground for longitudinal studies. This can be used as a platform for training of health team under one roof (ASHA, TBA, AWW, RHP, MPW, HA, Pharmacist, Physicians etc). Other areas like school health, occupational health & industrial medicine, application of Information Technology (telemedicine, e-learning) can be expanded.

Besides AIIMS, there are examples of other successful community oriented training in Community Medicine in other medical colleges of the country as well. Few examples are the Community Health and Development (CHAD) Program in Christian Medical College Vellore, which Community based postings are held in pre-clinic year and twice in the clinical year. The emphasis is on team work and problem solving skills in a community setting in block posting of medical students. Another example is the Mahatma Gandhi Institute of Medical Sciences Wardha, in which local villages are adopted, and small groups of students, few teacher-facilitators and some ancillary health staff

are made responsible for comprehensive health care to the population of those villages. Besides, other places like St. John's Medical College, Bangalore, Christian Medical College, Ludhiana, JIPMER, Pondicherry etc also have good community based trainings in Community Medicine.

### Conclusion

AIIMS as a premier teaching institute has a responsibility of grooming a student and produce a doctor who is competent in all respects: promotive, preventive and curative. It has been demonstrated that medical education, especially the discipline of Community Medicine cannot be treated as an independent entity. It has to be seen in the wider context of healthy interaction between various players areas like, health infrastructure, media, and more importantly the community itself.

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*Short Communication*

## **Studies on the Residues of Terramycin and Furazolidone in Broiler Meat- A Public Health Concern**

**H. K. Tiwari<sup>1</sup>, \*Jully G. Tiwari<sup>1</sup>**

### **Summary**

The concentration of Terramycin and Furazolidone residues in broiler meat following their subtherapeutic use in the ration of the birds were detected as 296 ng/g, 174 ng/g, 40 ng/g, 60 ng/g and 124 ng/ml in kidney, liver, thigh muscle, breast muscle and serum for Terramycin and 270 ng/g, 160 ng/g and 88 ng/ml in kidney, liver and serum for Furazolidone. One week of withdrawal period from the antibiotic in feed/water was sufficient to render the meat free from residues.

The antibiotic residues persist in poultry meat and eggs for a very long time and poses serious health hazards to consumers which include conditions from allergic reactions to fatal anaphylactic shock. In addition, these residues may erode the bacterial flora normally present and thus may expose the consumers to the adverse effects of opportunistic pathogens<sup>1</sup>. Nitrofurans are mutagenic and (pro) carcinogenic and their use have been strictly regulated in many countries and tolerance levels of 1-2 mg/kg have been set for parent Nitrofurans<sup>2</sup>. At present among all the antibiotics used in poultry industry, Terramycin and Furazolidone are routinely used for broilers. So the present investigation was designed to study the residual level of Terramycin and Furazolidone in poultry meat and determination of the withdrawal period of both the drugs for safe consumption of meat.

The study was done during September 1996 - October, 1997 in the Deptt. of Veterinary Public Health & Epidemiology, Punjab Agricultural University, Ludhiana, Punjab. Sixty broiler chicks (day-old) were purchased from Chopra Hatcheries, Jalandhar. They were divided into two major groups of 24 birds each according to the treatment i.e. Terramycin and Furazolidone they received through water/feed. Each group was further divided into subgroups of 6 birds each according to the week of slaughter. Rest of the birds (12 numbers) were supplied feed/water that was

free from antibiotic and these birds acted as controls.

#### Drugs:

(a) Terramycin : The water soluble Terramycin poultry formula (registered trade name Oxytetracycline) was used for the broilers. The active ingredient of this preparation is Oxytetracycline hydrochloride. As this available commercial preparation is readily soluble in water, it was as such used for the preparation of the standard curve. Terramycin poultry formula was given to the birds in drinking water at the recommended dose rate of 4 g/4.0 ltr of water daily from day old age to 8th week of age (market age). The feed supplied was antibiotic free. Antibiotic medication was continued till 8th week of age in one group of birds consisting 6 numbers to enable evaluation of residue at market age and in the rest 3 groups medication was stopped at 6th week of age and birds were slaughtered at 6th, 7th and 8th week to detect the withdrawal period of the respective drugs.

(b) Furazolidone : The feed supplement Neftin-200 (registered trade name Furazolidone) was used as the source of Furazolidone. Neftin was found to be insoluble in water and only partially soluble in organic solvents like Ethyl acetate and Dimethyl formamide. To prepare standard curve of Furazolidone by microbiological assay technique the pure base of Furazolidone was received on request from Dr. Steven

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A. Barker, Louisiana State University, Louisiana, USA. Neftin was added to feed as premix and supplied to the birds from day old to 8th week of age. The dose rate of mixing was as per the recommendation of the manufacturers i.e. @ 200g/1000kg feed. The water supply was completely free from any antibiotics. Three groups of birds consisting 6 numbers each were supplied antibiotic treated feed for 6 weeks and then slaughtered in the 6th, 7th and 8th week to determine the withdrawal period. Rest one group received medicated feed upto 8th week and then slaughtered to determine the antibiotic residue level in different organs.

#### Collection of samples:

(a) Blood: The feathers on the neck were plucked and blood was collected in clean dry glass tubes from the jugular vein. The blood was allowed undisturbed to clot for 1 hour at room temperature. Then the tubes were placed in the refrigerator overnight. After pipetting the serum from the clot it was clarified by centrifugation at 2000 rpm for 10 mins. The serum thus obtained was transferred to 15ml sterile screw capped serum vials and stored at -20°C till analysis.

(b) Tissue: Liver, kidney, breast muscle, thigh muscle and cartilages were collected for determination of residues. These tissues were collected by cutting out portions of respective organs of adequate size and stored at -20°C in labelled sterilized polythene bags till analysis.

#### Processing of samples :

The serum collected from blood samples were suitably diluted before analysis. For processing the tissues, 25 g of the organ was weighed and blended. Hundred ml of phosphate buffer of PH 4.5 for Oxytetracycline 3 or dimethyl formamide for Furazolidone was added and blended at high speed for 2 minutes. After blending, the homogenate was taken out and centrifuged at 3000 rpm for 10 mins. The supernatant was collected and used for analysis.

#### Assay procedures :

The estimation of Terramycine and Furazolidone was done by microbiological assay using 10mm filter paper (Whatman no.4) discs<sup>4,5</sup>. In some samples, the residues of drug were determined by its modified method<sup>6</sup>.

(a) Preparation of bacterial suspension: *Bacillus cereus* (ATCC-I 1778) was used to estimate Terramycin and *Staphylococcus aureus* (ATCC- 6538) was used to estimate Furazolidone. The organisms were maintained on slants of media no. 1 and subcultured every 15-20 days.

*Saphylococcus aureus*: The microorganisms were cultured at 35°C for 24 hours on a freshly prepared slant of media no.1 The bacterial growth was then washed with 3ml of sterile normal saline and poured onto roux flask containing 250ml of solidified media no.1 The roux flask was then incubated at 35°C for 24 hours. The residual growth in roux flask then washed with 50ml of sterile normal saline solution and transferred to a glass stoppered sterilized volumetric flask. The bacterial suspension thus obtained was then stored at 4°C till drug analysis.

*Bacillus cereus*: Culture of bacterial growth was washed with 3ml of sterile normal saline and poured onto roux flask containing 250ml of solidified media no.1. The roux flask was then incubated at 30°C for 6-7 days. The resultant growth was washed with 50ml of sterile normal saline and transferred to conical flask. Bacterial suspension was then processed for heat shock for 30 min at 70°C. It was then centrifuged thrice, each time washing the spores with distilled water and decanting the supernatant. After final centrifugation, the supernatant was decanted and spores were reconstituted with 50ml of sterile normal saline. The spore suspension was then stored at 4°C till drug analysis.

(b) Preparation of standard curves: The standard curve of Terramycin was prepared at concentration of 2.0, 1.5, 1.0, 0.5 and 0.1 mg/ml of Oxytetracycline base in phosphate buffer of 4.5 PH. For Furazolidone, concentrations of 2.0, 1.5, 1.0, 0.5 and 0.1 mg/ml in dimethyl formamide, PH 6 was used for preparation of standard curve.

(c) Preparation of assay plates: 10ml of Media no. 1 was poured into sterile petri plates with the help of a continuous pipetting device and allowed to solidify at room temperature. This comprises the base layer. After solidification of base layer, 4ml of seed layer containing the suitable bacterial suspension was poured over the base layer and allowed to set and solidify on the flat surface. The clarity and dimension of the zone

of inhibition by the reference concentration were the criteria to fix the amount of bacterial suspension used in preparation of seed layer. After solidification of seed layer, the filter paper discs immersed in the sample tissue fluid or drug solution of known concentration is placed equal distances. The plates were incubated at 35°C for 24 hours for *Staphylococcus aureus* and 30°C for 24 hours for *Bacillus cereus*. The zone of inhibition are measured in mm and compared with zone of inhibition of known concentration to evaluate the residual concentration. For each sample, 3 plates with 3 replicates i.e. total nine replicates were used.

The concentration of Terramycin and Furazolidone detected in serum, liver, kidney, thigh muscle, breast muscle and cartilages of broiler chicken are shown in the Table I and the detection of withdrawal period by stopping the medication at 6 th week of the birds is shown in the Table 2. No residues of Terramycin and Furazolidone were detected in the birds of control group.

The acceptable limits of Oxytetracycline (Terramycin) residues in meat as recommended by WHO is 250 ng/g<sup>7</sup>. The present study reveals a residue range of 40-320 ng/g in the various tissues of the birds that include kidney, liver and edible muscles (Table 1). The pattern of decline of residual concentration in various tissues in different weeks of the birds is in the similar fashion as shown by Katz. et.al.<sup>8</sup> As the broilers were supplied water that was medicated with Terramycin strictly according to the recommended dose, the residue range is found to persist almost within the limits set by WHO. The limits are violated only by the kidney tissues of birds that received medication continuously upto 8 weeks (Table 1). Kidney, however, does not occupy the same place in human diet as the muscles do. Nevertheless, the residues can be kept within the recommended WHO limits by stopping the supplementation of the drug in drinking water one week prior to the slaughter. In comparison to Oxytetracycline the concentration of Furazolidone residues were found to be less. There was absence of residues in serum and body tissues at 7th week of

**Table 1: Concentration of Oxytetracycline and Furazolidone in serum and other tissues after 8 weeks continuous medication (Mean + SD)**

Serum / Tissues	Concentration of drugs (ng/g)	
	Oxytetracycline	Furazolidone
Serum	124± 5	88± 3
Liver	174± 12	160
Kidney	296± 24	270± 3
Thigh Muscle	40	Not detected
Breast Muscle	60± 11	Not detected
Cartilage	Not detected	Not detected

age (Table 2). This finding is in accordance with the Winterlin et. al<sup>9</sup>. The maximum residue limit of Furazolidone recommended by WHO is 1000ng/g<sup>2</sup>. However, the residues were present within the recommended level. As Furazolidone is readily metabolisable and the metabolites do not possess potent antibacterial activity as the parent compound. Thus, the Furazolidone residues showed little or no residual properties<sup>10</sup>. Nevertheless, for both the medicines one week of withdrawal was found to be suitable to render the meat free from residues (Table 2).

**Table 2: Detection of the withdrawal period for Terramycin (Oxytetracycline) and Furazolidone in broiler chicken\***

Serum/Tissues	Concentration of drugs (ng/g)					
	After 6 weeks		After 7 weeks		After 8 weeks	
	O	F	O	F	O	F
Serum	81± 3	63± 2	26± 4	ND	ND	ND
Liver	140± 11	60	ND	ND	ND	ND
Kidney	220± 13	142± 6	ND	ND	ND	ND
Thigh Muscle	40	ND	ND	ND	ND	ND
Breast Muscle	40	ND	ND	ND	ND	ND
Cartilage	ND	ND	ND	ND	ND	ND

\* In all the 3 groups of birds the medication was continued only upto 6th weeks. Then the 3 groups of birds were slaughtered at 6<sup>th</sup>, 7<sup>th</sup> and 8<sup>th</sup> week, respectively to determine the withdrawal period of the drugs. Note: O= Oxytetracycline, F= Furazolidone, ND= Not detected

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*Short Communication***Status of Cold-chain Maintenance in Chandigarh****\*N. K. Goel<sup>1</sup>, R. Pathak<sup>2</sup>, A. Galhotra<sup>3</sup>, C. Dankal<sup>4</sup>, H. M. Swami<sup>5</sup>****Summary**

An effective cold chain maintenance system is the backbone of success of any immunization program. This study compares the state of cold chain maintenance during intensive pulse polio immunization campaign in union territory of Chandigarh in the year 2001 with that of 2006. The study was conducted during pulse polio rounds of December 2001 and January 2002 and another in April and May 2006 by Department of Community Medicine, Govt. Medical College, Chandigarh. Data was collected from different levels of cold chain maintenance; OPV vials were also collected and sent for potency testing at Central Research Institute, Kasauli in all the rounds. Cold chain sickness rate has decreased from 9.8% in year 2001 to 6% in year 2006. Icepacks were neatly stacked in all the deep freezers (DF) and ice-lined refrigerators (ILR). 94.71% DF's & ILR's were defrosted periodically, 95.36% temperature charts were up-to-date and signed by supervisors and no day carriers were being used in 2006 round. Whereas in 2001, the periodicity of defrosting ILR & DFs was 76.9%, vaccines were stacked neatly in only 38.46% and day carriers were being used. All the randomly selected vaccine samples were reported potent.

Child immunization is among the most cost-effective ways of preventing premature child deaths<sup>1</sup>. The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines<sup>2</sup>. Good practices to maintain proper vaccine storage and handling can ensure that the full benefit of immunization is realized. The maintenance of vaccines at the appropriate temperatures from the time they leave the manufacturer to the time of administration (the cold chain) is of great importance to ensuring optimal vaccine potency<sup>3</sup>. All vaccines are thermo-sensitive and need to be properly stored and distributed within an efficient cold chain. Exposure of vaccines to temperatures outside the recommended ranges for a considerable period of time can affect potency adversely, thereby reducing protection from vaccine-preventable diseases<sup>4</sup>.

With more than 90% immunization coverage achieved in Chandigarh<sup>5</sup>, it is important that this level is maintained and all components of cold chain system be monitored strictly as per the guidelines, as it is the fundamental link for success of vaccination. This study was conducted to assess and compare the status of

cold chain maintenance in Chandigarh during IPPI campaign of 2001 and 2006.

This study was conducted by Department of Community Medicine, Govt. Medical College and Hospital, Chandigarh. The first study was conducted during pulse polio rounds of December 2001 and January 2002 and follow up study was conducted in the same area during April and May 2006. These were done at different levels of cold chain maintenance, starting from the point from where vaccine vials were supplied at sub depots to the place where it was administered at designated booths on immunization day and during house-to-house activity as well. Information from sub-depots was collected one week before National Immunization Day. The information was collected from all the designated vaccine sub-depots. The total numbers of designated vaccine sub-depots were 13 and 18 in the 2001 and 2006 IPPI rounds respectively. 40 and 50 booths were selected by systematic random sampling technique from a total of 389 and 446 in 2001 and 2006 respectively. In both the rounds, OPV vials were collected from selected booths and sent for potency testing at Central Research

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Institute, Kasauli. The teams involved in house-to-house activity were also monitored. A checklist as recommended by the experts of cold chain system and Govt. of India was used for recording the details<sup>4</sup>. Cold chain sickness rates (proportion of cold chain equipment out of order at any point of time<sup>3</sup>) were calculated.

There was not even a single Walk-in Freezer (WIF) or a Walk-in Cooler (WIC) for the union territory of Chandigarh in 2001 and unfortunately the scenario remains the same in year 2006. In 2001, there were a total of 72 ILRs (40) & DFs (32) and the number have gone up to 95 (ILR-62, DF-33) in 2006. Number of vaccine carrier has also increased from 780 in 2001 to 941 in 2006. Cold chain sickness rate has fallen down from 9.8% in 2001 to 6% in 2006. In 2001, 30% of the sub-depots in which vaccine were stored didn't have exhaust fans, though this problem was also observed in 2006 but it was to an extent of 15% only.

With regards to few parameters of cold chain maintenance like installation of DFs & ILRs with voltage stabilizers, keeping equipments 10 cm away from wall, plugging these in socket permanently and maintenance of separate temperature chart for each ILR and deep freezer, there was no difference in 2001 and 2006. The periodicity of defrosting ILR has increased from 76.9% in 2001 to 94.7% in 2006. (Table 1). Vaccines were stacked neatly in only 38.46% of ILRs & DFs in 2001 but amazingly the number increased to 100% in 2006. Reporting of breakdown and repair of cold chain equipment was low up to the level of 20% in 2001. The condition has dramatically improved and presently 80% of the problems related to cold chain are being addressed in time. The supervision and monitoring of cold chain also improved with nearly 95.36% of the temperature chart being countersigned by medical officer or supervisors in 2006 as against 23% in 2001 (Table 1).

On the day of immunization, 40 (20 in each round) randomly selected booths in 2001 and 50 (25 in each round) in 2006 were visited and level of cold chain maintenance was assessed. In 2006, it was observed that all health workers were using vaccine carriers for carrying vaccines and no day carrier was being used. 95% of vaccine carriers were in good condition. Whereas, in 2001, day carriers were also being used and only 90% of the vaccine carriers were

**Table 1: Monitoring findings: ice lined refrigerators / deep freezers in 2001 and 2006**

Points monitored	2001 (%)	2006 (%)
Correct level of installation	100	100
Locked	38.46	47.36
Away from sunlight	84.60	100
Defrosted periodically	76.9	94.71
Adequately (10cm) away from wall	92.3	100
Plugged to socket permanently	100	100
Installed with the voltage stabilizer	94	100
Used for keeping food/drink/drugs	0	5
Store room fully ventilated	53.84	60
Vaccines stacked neatly	38.46	100
Temperature chart:		
Separate for each ILR	100	100
Up to Date	76.92	97.56
Reporting of Breakdown etc	20	80
Signed by Supervisor/MO	23	95.36

in good condition. Ice packs being used were fully frozen and all the workers were checking vaccine vial monitor before administering vaccine except one (1.3%). 2% of them did not secure lid tightly in 2006 against 10% in 2001. 80% of the vaccine carriers were kept in shade during immunization session in 2001 and the practice improved in 2006 with 90% of these being kept in shade during immunization (Table 2). All these vials that were collected for potency testing were found to be potent as per reports provided by Central Research Institute, Kasauli.

During house-to-house campaign only 5 teams could be met in each round. In 2001, 70% (3 teams) of the teams were carrying day carriers for carrying vaccine but a considerable improvement has occurred in 2006 as no day carriers were being used. In 2001, 60% of the vaccine carriers were filled with partially or fully melted icepacks but the situation improved to a great extent in 2006, where all the vaccine carriers were having four fully frozen icepacks and only one vial was taken out at a time for vaccination.

The polio eradication initiative in India has made major progress since its inception in 1995. Oral polio vaccine is the single most important factor instrumental

**Table 2: Monitoring findings: vaccine carriers in 2001 and 2006**

Points monitored	2001 (%)	2006 (%)
Good condition (no cracks)	90	95
Fully frozen ice packs	40	100
Ice packs wiped before putting in	50	80
Vaccine vials kept in polythene bags before putting in	85	95
VVM checked	90	95
Lids secured tightly	90	98
Kept in shade during immunization session	80	90
Extra ice slabs available	75	85
Extra ice slabs being used	60	75
Status of VVM: Stage I/II	100	99
Status of VVM: Stage III/IV	0	1

in achieving this success. To maintain efficacy of this life saving vaccine, it requires strict maintenance of cold chain, as it is the most heat sensitive vaccine. Thus, success of our war against polio depends upon the extent of efforts put to maintain a high quality of cold chain. The present study has shown that temperature maintenance has improved over time as is shown by the adequacy of maintenance of temperature charts (Table 1) but there is still some room for improvement and constant efforts are required to maintain it. Similar concerns have been raised by studies conducted by other authors<sup>6-10</sup>. The retrospective analysis of cold chain maintenance as indicated by CRI Kasauli report reflects that problems identified in cold chain maintenance in the study area were not to an extent that it could affect the potency of the vaccine. The other probable reason for this could be that the study was conducted in colder months of the year in 2001 and by 2006 we had a heat stabilized vaccine available for immunization. Aggarwal<sup>6</sup> and Sokhey<sup>7</sup> had also reported steady improvement in cold chain in late 1980s and mid 1990s. Vaccine potency tests are very useful for strengthening of cold chain and dealing with any lacunae identified.<sup>11</sup>

Provision of walk-in-cooler and walk-in-freezer for the union territory of Chandigarh, provision of adequate number of exhaust fans and re-orientation

training of cold chain handlers are some of the inputs that may further strengthen the system. Cold chain monitoring devices may be introduced to make the monitoring easier, specific and more effective.

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*Short Communication*

## A Study on Mortality and Morbidity Pattern of Acute Childhood Poisoning Cases Admitted in Block Primary Health Centres of Sundarban, West Bengal

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### Summary

A hospital – record based study was conducted in Sundarban of West Bengal to explore the profile of mortality and morbidity pattern of acute accidental poisoning among children. Sundarban is an underdeveloped coastal region of West Bengal. Three years retrospective (1999 – 2001) data of childhood accidental poisoning cases were collected from the indoor admission registers and case history sheets of 11 Block Primary Health Centers (BPHC) of the region. A total of 1056 children with accidental poisoning were admitted during those three years of which 58% were males. Mean age of males was slightly higher than females in all the three years. Organophosphorus pesticide poisoning was the commonest.

Accidental poisoning represents one of the most common medical emergencies in childhood<sup>1, 2</sup> and the resultant under-5 morbidity and mortality rate is a challenging public health problem worldwide. Poisoning in children is the twelfth common cause of hospital admission<sup>3</sup>. The situation is alarming in developing countries mainly because of the increasing use of different agrochemical substances. In India, this is still a much neglected issue where neither people nor government has consented very actively for any prevention programme especially in the rural areas.

The mortality and morbidity load from childhood poisoning in India is a challenging health problem. Accidental poisoning in children constitutes a major part of the total admissions in the pediatric wards<sup>2, 4</sup>. The incidence of poisoning in children in different parts of India has ranged from 0.33% to 7.64%<sup>5, 6</sup>. One study reported 24% cases ingested kerosene, 9.6% pesticides and 8.4% chemicals and medicaments among childhood accidental poisoning admissions<sup>7</sup>. Others found 46.7% children ingested kerosene<sup>8</sup> and reported a mortality rate of 4.3% with kerosene poisoning<sup>9</sup>.

The present epidemiological study attempts to explore the profile of accidental poisoning among children in a primary health care setting in Sundarban region under South 24 Parganas district, West Bengal, India.

A cross sectional hospital record based study was conducted in Sundarban region of West Bengal.

The Sundarban region, an underserved and backward region of the state of West Bengal, is the largest delta region of the world at the confluence of river Hooghly in the Bay of Bengal. About 88.5% inhabitants are dependent on agriculture. Inaccessibility and transportation problem on land and water stands on the way between existing health services and the people<sup>10</sup>. Sundarban covers 19 Community Development Blocks of which 13 are under South 24 Parganas district and the rests are under North 24 Parganas. Each block has one Block Primary Health Center. The study covered 11 out of 13 blocks of South 24 Parganas District of West Bengal.

Three years (1999-2001) retrospective data on childhood (up to 12 years) accidental poisoning cases

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were collected from the indoor admission registers and case history sheets of the 11 BPHCs ( Basanti, Canning I, Gosaba, Joynagar I & II, Kakdweep, Kultoli, Mathurapur I & II, Namkhana and Patharprotima). Data from Sagar and Canning II blocks were incomplete and thus not included in the study.

following accidental poisoning during the study period as follows: 352 (315 survived; 37 died) in 1999, 361 (326 survived; 29 died) in 2000 and 348 (304 survived; 39 died) in 2001. The age mean for males were  $2.69 \pm 2.01$ ,  $2.72 \pm 2.08$  and  $2.81 \pm 2.13$  years and for females  $2.56 \pm 1.95$ ,  $2.68 \pm 2.05$  and  $2.46 \pm 1.84$  years respectively for 1999, 2000 and 2001.

**Table 1: Distribution of agents in accidental poisoning cases (survived).**

Agents	1999 (n = 315)	2000 (n=326)	2001 (n=304)
	No. (%)	No. (%)	No. (%)
Agrochemical (pesticide)	184 (58.4)	170 (52.1)	150 (49.3)
Household chemicals	108 (34.3)	113 (34.7)	98 (32.2)
Kerosene	94 (29.8)	92 (28.2)	85 (27.9)
Rat killer	4 (1.3)	8 (2.4)	6 (1.9)
Fly/Lice killer	6 (1.9)	4 (1.2)	2 (0.6)
Other chemicals *	4 (1.3)	9 (2.8)	5 (1.6)
Indigenous poisoning**	2 (0.6)	11 (3.4)	5 (1.6)
Other poisoning	21 (6.7)	32 (9.8)	51 (16.8)
Medicine	3 (0.9)	1 (0.3)	0
Unknown poisoning	18 (5.7)	31 (9.5)	51 (16.8)

\* Include - phenyl, carbolic acid, caustic soda, petrol/diesel, detol, naphthalene, spirit/tarpin oil & writing ink.

\*\*Dhatura seeds, Oleander seeds, Vegetable seed, Varendra etc.

**Table 2: Distribution of agents in accidental poisoning cases leading to death of children**

Agents	1999 (n = 37)	2000 (n=35)	2001 (n=39)
	No. (%)	No. (%)	No. (%)
Agrochemical (pesticide)	19 (51.4)	18 (51.4)	19 (48.7)
Household chemicals	14 (37.8)	14 (40.0)	17 (43.6)
Kerosene	7 (50.0)	9 (64.3)	9 (53.0)
Rat killer	1 (7.1)	2 (14.3)	3 (17.6)
Lice killer	4 (28.6)	3 (21.4)	3 (17.6)
Other chemicals	2 (14.3)	0	2 (11.8)
Indigenous poisoning: (Dhatura seeds)	1 (2.7)	0	1 (2.6)
Other poisoning:	3 (8.1)	3 (8.6)	2 (5.1)

A total of 1056 children [male 613 (58%), female 443 (42%)] were hospitalized at the 11 BPHCs

Detailed analysis of records of 2001 revealed that 81% cases were from 0-6 year age group and 19% from 7-12 year age group.

Rate for accidental poisoning in 0-6 year age group ranged from 13.5 to 155.0 per 100000 populations in different blocks with a combined (survived and death) rate of 68.8 per 100000 population for 11 blocks. There were 33 deaths in 0-6 year age group indicating a fatality rate of 8.2 per 100000 populations.

Present study shows that childhood morbidity and mortality from accidental poisoning, especially from pesticides, is highly alarming in this delta region. WHO report stated that one million serious accidental poisonings occur due to insecticide ingestion worldwide every year, mainly from developing countries<sup>1</sup>. Organophosphate poisoning is a significant cause of morbidity and mortality in developing countries like India<sup>12</sup>. Pesticides are the main agent of accidental poisoning in Sunderban. Varieties of pesticide compounds are readily available and are widely used for agriculture and in homes. Most of the pesticide shops in this region are unlicensed and they hardly communicate their buyers about the potential danger or safe custody of pesticides, of which most of the farmers are ignorant and careless. They usually keep pesticides or leftover pesticides openly in the household which are easily accessible to a child. The same is true for kerosene oil or other household chemicals. The toddlers being of inquisitive nature and mostly without any vigilant supervision, very often expose themselves in this unsafe environment and lead to life-threatening danger<sup>8</sup>.

The data presented here were only from BPHC records and there were many unreported cases in the community. In Sunderban, the most common causes of under-reporting were distance and lack of transportation, management by the local health care providers (known as "quack doctors") and disposal of the child if died at home. Parents of a considerable proportion of cases adhere to traditional methods of help seeking and thus not reported to the BPHCs. So, the frequency of accidental poisoning in children is far more extensive than that is reported here.

The need for complete data recording at the BPHC should be instituted so that effective prevention strategies can be formulated.

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## Short Communication

# HIV, Hepatitis B and C Infection Status of the Blood Donors in a Blood Bank of a Tertiary Health Care Centre of Orissa

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### Summary

A record based retrospective study was conducted at the blood bank of SCB Medical College, Cuttack. All the donors who had donated blood from June to December 2005 were considered. 91.7% of the donors were males and majority belonged to 21-30 years age group. 1.98% of the donors were positive for hepatitis C, 1.13% for hepatitis B and 0.35% for HIV. For HBV infection, majority belonged to 31-40 years age group. But for HCV and HIV infection more were in the 21-30 year age group. Significantly more number of exchange donors was positive for HBV and HCV in comparison to voluntary donors in blood bank and camp. No voluntary donors from the camp were HIV positive.

There are several infectious as well as non-infectious risks associated with transfusion of blood. However, the transmission of blood borne infection is the most frequent and serious complications of transfusion even today<sup>1</sup>. Among the blood borne infections the major risk is associated with HIV, hepatitis B and C infections. In India the carrier rate of HbsAg in hospital staff has been found to be higher (10.87%) than in voluntary blood donors (6%) and in general population (5%)<sup>2</sup>. Usually all the transfusion centers screen the donors for HbsAg, therefore the incidence of post transfusion hepatitis due to HBV has decreased remarkably. Hence the most common cause of post transfusion hepatitis is Hepatitis C virus<sup>3</sup>.

SCB Medical College hospital is a premiere institute of Orissa and it caters to the health need of a large segment of population of not only Orissa but also of the bordering areas of the neighboring states. Hence an attempt was made to elicit the demographic profile of blood donors and to find out the prevalence of HIV, Hepatitis B and Hepatitis C infections among the blood donors.

A record based retrospective study was conducted during the month of May and June 2006. In a predesigned and pretested proforma data was collected from the record of the Blood Bank of SCB Medical College Hospital, Cuttack. Donors who have donated blood during the period from June to December 2005 were taken for the study.

The donors were categorised in 3 groups. Group I- exchange donors in the blood bank (those who want blood of required blood group from the blood bank and donate blood in exchange); Group II- voluntary donors in the blood bank (those who voluntarily come to the blood bank and donate blood); Group III- voluntary donors in the camp conducted outside the blood bank

During the above-mentioned period 3623 donors donated blood; of them 43.1% were exchange donors,

**Table 1: HIV, HBV and HCV infection status of blood donors, age wise distribution**

Age in years	Infective status of donors		
	HBV No (%)	HCV No (%)	HIV No (%)
< 20 (n= 296)	1 (0.33)	1 (0.33)	0
21-30 (n= 1783)	14 (0.78)	52 (2.91)	8 (0.45)
31-40 (n= 1134)	23 (2.02)	18 (1.58)	5 (0.44)
41-50 (n= 367)	3 (0.81)	1 (0.27)	0
51-60 (n= 43)	0	0	0
Total (N= 3623)	41 (1.13)	72 (1.98)	13 (0.35)

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**Table 2: Comparison of infection status of three different groups of blood donors**

Types of donors	Infective status of donors		
	HBV* No (%)	HCV** No (%)	HIV No (%)
Exchange donors (n= 1570)	25 (1.6)	54 (3.44)	10 (0.64)
Voluntary donors in the camp (n= 1253)	6 (0.48)	1 (0.08)	0
Voluntary donors in blood bank (n= 800)	10 (1.25)	17 (2.13)	3 (0.38)

\* $\chi^2=7.85$ , d.f=2,  $p < 0.05$ , \*\* $\chi^2=41.42$ , df =2,  $p < 0.05$

22% voluntary donors who had donated blood in the blood bank and the rest 34% in the camp. Majority donors were male (91.7%) and only 8.3% were females. 49% belonged to 21-30 years age group followed by 31-40 years age group (31.1%). Least number of donors was in the fifty plus age group (1.5%).

90.6% of the donors were literate, majority (95.8%) were Hindus and only 4.2% were Muslims. Most of the donors (78.2%) were from urban areas. Gupta D et al found 63.8% donors from urban background<sup>4</sup>.

Considering the infection status of the donors (Table 1); 1.13% was found to be positive for hepatitis B, 1.98% for hepatitis C and 0.35% for HIV. More number of males were affected than females in each group. 83.4% infected donors were from urban areas. Age wise distribution of infected donors revealed 2.02% of 31-40 years age group were positive for Hepatitis B followed by 0.81% in the 41-50 years age group and 0.78% in the 21-30 years age group. But in case of HCV and HIV infected donors majority belonged to the 21-30 years age group (2.91% and 0.45% respectively).

Gupta D et al<sup>4</sup> observed similar findings in their study that prevalence of HbsAg positivity was more in case of males. 81.6% of the HbsAg positive donors belonged to the age group of 18-39 years. There was a progressive decline in the incidence with advancing age with only 4.2% positivity above the age of 50 years. Also another study by S. Muralidharan and H Srinivas et al<sup>5</sup> revealed that the age range of seropositive donors for HIV was between 20-40 years and all of them were males. But in another study conducted by Anand Deshpande et al<sup>3</sup>, 0.34% of the donors were found to be positive for HIV. But no significant difference in positivity was observed in different age groups.

Table 2 shows the infective status in 3 different groups of donors. Significantly higher positivity for both HBV ( $\chi^2=7.85$ , d.f=2,  $p < 0.05$ ) and HCV ( $\chi^2=41.42$ , df =2,  $p < 0.05$ ) was found among exchange donors as compared to other groups. But for HIV infection status no significant difference in positivity was observed in different groups of donors. S. Muralidharan et al found in

their study that out of total 40 seropositives for HIV none were voluntary donors<sup>5</sup>. Another study by S.R Joshi revealed that replacement donors showed a higher incidence (0.6%) of HIV positive status as compared to voluntary donors (0.34%)<sup>6</sup>.

The prevalence of hepatitis B, C and HIV are found to be the least among the voluntary donors in the camp in comparison to the voluntary donors and exchange donors in the blood bank. So more blood donation camps should be organized for collection of safe blood.

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*Short Communication*

## Prevalence of Hypertension and its Risk Factors in a Tea Garden Community of Dibrugarh District, Assam

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### Summary

A cross-sectional study was conducted during August 2003- July 2004 to assess the prevalence of hypertension among a tea garden population in a district of Assam and to ascertain the identified risk factors. 510 labourers aged 20-59 years were studied. Overall prevalence of hypertension was 33.3% with no significant sex difference. 30.2 % had history of smoking and 76.7% of tobacco chewing; 78.4% consumed alcohol (regular and occasional), 5.7% were overweight and 14.3% underweight. Waist hip ratio was normal in 89.2% subjects. The association between increasing age and hypertension could be established in univariate analysis. On multiple logistic regression analysis regular alcohol intake was also found to be significantly associated factor with hypertension.

Hypertension, an important public health challenge of both developed and developing nations, is also the most important modifiable risk factors for cardiovascular disease, stroke, end stage renal disease and peripheral vascular disease<sup>1</sup>. Hypertension is considered to be the result of interaction between a genetic predisposition and environmental factors. It is often associated to one or several other cardiovascular risk factors such as overweight, hypercholesterolemia and particularly diabetes. There is increasing evidence that certain environmental factors such as an excessive calorie intake, dietary salt, alcohol, obesity and lack of physical exercise are some of the key determinants of high blood pressure. Changes in lifestyles, urbanization and stress have created new dimensions in health of the people. One such disease is hypertension<sup>2</sup>.

High blood pressure is an arbitrary term used for clinical convenience to delineate a dividing line above which the benefit-risk ratio from intervention becomes acceptable<sup>3</sup>. Our country is also in a stage of epidemiologic transition, with increase in morbidity and mortality due to non-communicable diseases including hypertension. It can be predicted that we, in this

country, are soon going to face an epidemic of cardiovascular diseases<sup>4</sup>. On the above context, it is necessary to study the magnitude of the problem in different ethnic groups with different lifestyles under different environmental conditions. We thus conducted the study to assess the prevalence of hypertension in a tea garden of Dibrugarh district of Assam and to ascertain the prevalence of identified risk factors in the tea garden population and its association with hypertension, if any.

The study was cross-sectional in nature, conducted during August 2003 – July 2004 in Nahortoli tea estate situated in Dibrugarh District, about 20 Km from Dibrugarh town and is a field practice area of department of Community Medicine, Assam Medical College. The study population comprised of labourers of 20-59 years employed in the garden. Required sample size of 530 was calculated considering expected frequency 17%, worst acceptable 14%, confidence limit of 95% using Epi info version - 6 for population study. From among a total of 4400 populations, study subjects were selected by systematic sampling. Finally 510 could be studied (response rate 96%).

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The study subjects were interviewed using pre-tested questionnaire regarding demographic profile like age and sex, marital status, education, physical activity, dietary habits, tobacco use, alcohol consumption. Blood pressure was measured following standard procedure and JNC-7 classification of hypertension was followed<sup>5</sup>. BP measured in right arm of subject (who seated for 5 minutes before measurement), using a standard manometer. The first phase of Korotkoff sound considered as SBP and fifth phase of the Korotkoff sounds recorded as the DBP. Subjects seated in chair with backs supported and arms bared and supported at heart level, asked to refrain from smoking or ingesting caffeine 30 minutes preceding measurement. Appropriate cuff size used. Two or more readings, separated by two minutes interval, averaged. If, first two readings differ by > 5 mm.Hg, additional readings were obtained and averaged<sup>5,6</sup>. Hypertension diagnosed if there was current or past treatment for hypertension, or on the basis of threshold values of 140 mm Hg SBP and 90 mm Hg DBP<sup>7,8</sup>.

Anthropometric measurements were done by recommended methods taking height in meters and weight in kg and body mass index was also calculated. Waist and hip circumference were measured with the standard non - stressable tape and waist hip ratios were calculated<sup>8</sup>.

Smoking was assessed using a standard set of questions in a self administered questionnaire<sup>9</sup> and classified as regular, occasional i.e., less than 1 cigarette/day and nonsmoker. Alcohol consumption was recorded and the frequency of consumption asked and classified as: regular i.e., daily / more than thrice weekly and occasionally as once/ twice weekly consumption<sup>10</sup>.

The odds ratio (OR) and their 95% confidence intervals (CI) were calculated to ascertain the association of risk factors with hypertension and the chi-square test was used for testing of the hypothesis. Multiple logistic regression analysis was also done for assessing the risk factors.

In the present study the overall prevalence of hypertension was found to be 33.3% (Table 1) with no significant difference in sex specific prevalence (male 34.15%; female 31.44%). The mean systolic blood pressure (SBP) was 131.98 mm of Hg (SD = 16.47) and ranged from 90-240 mm of Hg. The diastolic blood pressure (DBP) ranged from 66 to 140 mm of Hg with a mean of 84.52 mm of Hg (SD = 8.08). A positive trend with increasing age was observed. On univariate analysis for different age groups, it was shown that odds ratio for age group 30-39, 40-49 and 50-59 years were highly significant. In both the sexes there was a positive relationship of prevalence with age. Prevalence is lowest in younger age, as hypertension is a chronic disease; the cumulative effect at successive age group may be one of the reasons for such correlation.

In different studies conducted in India by different author the prevalence varies<sup>4, 11</sup>. The variation was due to the following factors; selection of cut off point, age group included in the study population and location of study area urban or rural. In Assam the study conducted in tea garden population by Regional Medical Research Centre (ICMR), utilizing similar WHO criteria for diagnosis of hypertension observed a prevalence of 60.8%<sup>12</sup>. The possible reason for higher prevalence in the ICMR study was inclusion of higher age group of population i.e., elderly population aged above 60 years were also included.

**Table-1 : Prevalence of Hypertension amongst the Study Subjects by Age and Sex**

Age(years)	Male		Female		Total	
	Total	Hypertensives No (%)	Total	Hypertensives No (%)	Total	Hypertensives No (%)
20-29	49	2 (4.08)	54	5 (9.27)	103	7 (6.80)
30-39	93	26 (27.96)	111	22 (19.82)	204	48 (23.53)
40-49	80	39 (48.75)	63	33 (52.38)	143	72 (50.35)
50-59	24	20 (83.33)	36	23 (63.89)	60	43 (71.67)
All ages	246	87 (34.15)	264	83 (31.44)	510	170 (33.33)

Regarding behavioural risk factors among studied population, 30.2 % were smoker and 76.7% chews tobacco (regular and occasional smoker); 78.4% consumed alcohol (regular and occasional). In India the use of tobacco varies from 14 -51% as observed in different studies (Chadha et al<sup>2</sup> as 14.34%, Reddy KS et al<sup>7</sup> as 17.4%, Gupta et al<sup>4</sup> as 32% in different areas).

BMI in the study population shows 5.7% were overweight and in contrast, 14.3% were underweight. Waist hip ratio was normal in 89.2%, 10.3% around 0.95, and in 0.39% ratio was above 1. Diabetes mellitus found in 1.18%. Gupta et al<sup>4</sup> reported obesity in 6% of the population & trunkal obesity in 5% of the population and Chadha et al<sup>2</sup> reported 25.2% in males & 34.6% in females. Unlike other studies the population under study was manual labourer and also of tribal origin, their built is ectomorphic with less body mass. So, no positive association found between BMI and prevalence of hypertension.

In the univariate analysis of risk factors only the association between age and hypertension could be established. But applying the multiple logistic regression analysis, age and regular alcohol intake (OR= 6.71) were identified as the significant risk factor of hypertension; whereas the association of sex, tobacco chewing, smoking, BMI and waist hip ratio with hypertension was found to be insignificant.

The 33.3% prevalence of hypertension in a population devoid of obesity and other major dietary risk factors needs further exploration. The effect of foetal and chronic under-nutrition during early life on the prevalence of hypertension may also be looked into. A package of early diagnosis and proper low cost management of hypertension may be initiated.

#### Acknowledgements:

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*Short Communication***Seroprevalence of Toxoplasmosis in a District of Assam, India****\*H. Rahman<sup>1</sup>, H.V. Murugkar<sup>2</sup>, A. Kumar<sup>2</sup>, M. Islam<sup>2</sup>, S. Mukherjee<sup>2</sup>****Summary**

Toxoplasmosis is one of the important zoonoses of man and has been known to cause serious problems particularly in females. A study on seroprevalence of toxoplasmosis was undertaken amongst the human population in Assam to determine the level of exposure of the population to the infection by using commercial ELISA kits. Of the 241 sera belonging to different age groups, sex and religion and having varying levels of exposure to the animals examined, 23 (9.54%) were positive for toxoplasmosis. No significant difference in the prevalence amongst males and females was observed. Some occupational groups like veterinarians, pet keepers and farmers were found to infect more frequently. Although the overall prevalence rate of toxoplasmosis was relatively low, higher prevalence rate of toxoplasmosis amongst the exposed groups warrants due care by these groups when they are handling the animals.

Toxoplasmosis, caused by *Toxoplasma gondii*, is an important zoonotic disease of worldwide distribution. The natural host of *T. gondii* is the cat, but it also occasionally infects humans<sup>1</sup>, a large number of domestic mammals (dogs, swine, sheep, cattle, goats)<sup>1,2,3,4</sup> and some birds<sup>5</sup>. Toxoplasmosis has been known to be acquired both through ingestion of tissue cysts in undercooked meat or via ingestion of oocysts excreted from the definite host, the cat. However, it is not clearly known by which route the infection is more commonly acquired<sup>3,6</sup>. Although, the occurrence of toxoplasmosis has been reported from different parts of the world<sup>7,8</sup> and from several states of India<sup>2,5</sup>, such information from northeast India is largely lacking. The present communication reports on the seroprevalence of toxoplasmosis among apparently healthy individual in Assam of northeast India.

A total of 241 serum samples collected from apparently healthy individuals comprising different risk groups *viz.*, veterinarians, pet owners, agricultural workers, etc., individuals belonged to different religion from Kamrup district of Assam during 2004-05 were used in this study. Information regarding the age, sex, religion, occupation with regard to level of exposure to the animals, etc. was collected through a pre-designed questionnaire. The population was grouped according to their possible occupational exposure to

the livestock population. The serum samples were stored at -20°C until tested.

The level of antibody to *T. gondii* was measured by commercially available *Toxoplasma* ELISA Kit (Tulip Diagnostic Pvt. Ltd., Goa). In brief, the microplates absorbed with *Toxoplasma* antigen were incubated with test sera, alkaline phosphatase-conjugated anti-human IgG and tetramethyl benzidine (TMB) substrate sequentially. The reaction was stopped and read the microplates at 450 nm. Sera showing an ELISA value more than 1.00 OD were taken as positive for toxoplasmosis.

Although *Toxoplasma* infections are asymptomatic in most of the cases, they can cause congenital toxoplasmosis in infants and acute infections in immunosuppressed patients. The overall seropositivity of toxoplasmosis in this study was found to be 9.54% with 9.09% in male and 9.92% in female. The reported prevalence of antibody to *T. gondii* in human and animals ranged from 2% to 75% in Southeast Asian countries<sup>10, 11</sup>.

Although, the sample size was comparatively small, the seropositivity was found to be higher among Christians (16.66%) as compared to Hindus (9.86 %) and Muslims (7.79%). It is generally accepted that

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prevalence of any infection in human populations depends on geographic, climatic, hygienic, and socioeconomic conditions, as well as on the lifestyle of the population<sup>8</sup>. Further studies would be needed to elucidate epidemiological factor(s) relating to its seroprevalence among these groups.

Since livestock are known to be the major transmitters of the infection, the population under study was reclassified on the basis of the possibility of the access of these people to animal population (Table 1).

**Table 1. Seropositivity of toxoplasmosis among the various population groups exposed to animals**

Study Group	Samples tested	Positives No (%)
Veterinarians	78	8 (10.25)
Farmers	30	4 (13.33)
Pet Keepers	23	4 (17.39)
Dog owner	12	1 (8.33)
Cat owner	11	3 (27.27)
Others	110	7 (6.36)
Total	241	23 (9.54)

It has been reported that the level of seropositivity was higher amongst the population involved in frequent handling of the animals as against those that were not regularly exposed to the livestock<sup>7</sup>. Our study also revealed higher seropositivity against amongst the groups that were in regular contact with the animals, viz., veterinarians (10.25%), farmers (13.33%) and pet owners (17.39%) as against the other population that is not regularly exposed to the animals (6.36%). Hundred percent of the people who tested positive for toxoplasmosis was found to have handled one or other animals like cat, dog, cattle, sheep, goat, horse, etc. Shuhaiber and his co workers<sup>9</sup> found *T. gondii* infection among 14.2% veterinarians in Canada who were regularly exposed to cats.

Excepting the transplacental infection, the *Toxoplasma* is reported to be commonly transmitted either through contact with infected animals or exposure to contaminated soil or through ingestion of meat<sup>2,6</sup>. The level of exposure of the population to all

these predisposing factors is a major criterion for the prevalence of infection in that population. It is therefore imperative that the seroprevalence studies for the presence of toxoplasma infection in a population should be supplemented with a plethora of information regarding the socio cultural aspects, hygienic standards, climatic and geographical features related to the population under study to get a clearer epidemiological picture.

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*Letter to the Editor*

## Increasing Seropositivity of Leptospirosis in a Medical College in Ludhiana

*Dear Editor*

Leptospira are actively motile, delicate spirochaetes possessing a large number of closely wound spirals and characteristic hooked ends. They may be saprophytes or parasites. Leptospirosis, a zoonotic disease of worldwide prevalence, has a re-emerging pattern. In India, various workers have reported the disease from various parts of the country. Humans are infected when the water contaminated by the urine of carrier enters the body through cuts or abrasions on the skin or through the intact mucosa of the mouth, nose or conjunctiva. Clinical symptoms include fever, chills, headache, conjunctivitis, myalgia gastrointestinal complications and jaundice. Renal infection is a common sequel. Diagnosis can be made by demonstrating the Leptospira in the blood & urine of patient by dark ground illumination or by electron microscopy. Apart from this we can do culture, guinea pig inoculation or serological tests.

The present study was conducted from January 2003 to December 2006 in the department of Microbiology, Christian Medical College and Hospital, Ludhiana. All the blood/serum/plasma samples received in the laboratory from indoor and outdoor patients suspected of having leptospirosis were processed using immunochromatographic sandwich technique. It detects Leptospira specific IgM antibodies in the sample indicating current or recent leptospirosis. The broadly reactive genus specific antigen employed in the test allows the detection of Leptospira infection caused by a wide range of strains of different serovars. The isolation rate of the Leptospira has been mentioned in Table 1. Initially there is mild rise in the proportion of leptospirosis as it is 1.76% in the year 2003, 2.25% in 2004 and 12.10% in the year of 2005. But the proportion was found out to be 14.47% during 2006. The seropositivity has been reported to be 23.81% in hospitalized jaundiced patients in and around Kolkota<sup>2</sup>. In our study the overall positivity rate

is 7.11 % as we included all the patients in this study irrespective of their jaundice status. But the upsurge in the positivity rate from 1.76% (2003) to 14.47% (2006) over a short time period of 4 years is alarming. Further studies are required to confirm it.

**Table-1: Seropositivity of leptospirosis in Christian Medical College, Ludhiana**

Year	No. of samples processed	Positivity No. (%)
2003	284	05 (01.76)
2004	355	08 (02.25)
2005	314	38 (12.10)
2006	228	33 (14.47)
Total	1181	84 (7.11)

The efforts of the physicians are needed to diagnose such patients and treat them in time as the mortality rises with onset of jaundice.

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## Notice

**The following decisions have been accepted in the AGB held on 8<sup>th</sup> March 2008 at Moulana Azad Medical College, New Delhi. These will be effective from 1<sup>st</sup> April 2008.**

### 1. Journal Advisory Committee:

A Journal Advisory Committee has been constituted with the following members: Dr. Deoki Nandan, Dr. Sandip Kumar Roy, Dr. Ranadeb Biswas, Dr. Farooq U. Ahmed, Dr. J. Ravi Kumar and Mrs. Shuva Kumari. The committee will function for the same period as of the Editorial Board of Indian Journal of Public Health. It has also been decided that henceforth, the newly elected Editorial Board in its first meeting or at the earliest will reconstitute the Journal Advisory Committee of not more than seven members with ratification from the Central Council. The tenure of the committee will be same of the Editorial Board.

### 2. Revised Subscription Rates:

Subscription rates of the journal has been revised and approved by the AGB. Revised rates are as follows:

#### Revised Annual (4 issues) Subscription Rates:

Subscription Category	In India	Foreign Countries	
		SAARC Countries	Other Countries
Individual	Rs. 600/- per year	\$ 50 per year	\$ 100 per year
Institutional	Rs. 2000/- per year	\$ 200 per year	\$ 300 per year

Minimum subscription should be for one year. Publishers / subscription agencies may have 10% discount.

Without subscription, individual or institution may have issues of the journal on request subject to availability. The rates are suggested as follows: For general issues - @ Rs. 200/- per copy for individual and @ Rs. 500/- per copy for Institution. For Special issues rates would be negotiable.

### 3. Revised Processing Costs/Reprint Charges:

For all publications in the IJPH, processing cost/reprint charge will be required except Editorial, Invited Articles, Conference Proceedings and Orations/Award Papers and Letter to the Editor.

#### Processing costs/reprint charges for 10 copies will be as follows:

Category of first author	Original Article / Review Article / Special Article etc (4 printed page)	Short Communication (2 printed page)
Member of IPHA	Rs. 1200/-	Rs. 800/-
Non-Member	Rs. 1500/-	Rs. 1000/-

The charges for each extra page beyond the recommended maximum size of article will be Rs. 500/-

For subsidised rate, membership proof of the first authors should be provided at the time of submission of the articles. Otherwise, charges will be demanded as non-members.

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#### 4. Revised Advertisement Rates:

No advertisement will be accepted for Back Cover. For other pages the revised rates are as follows:

2<sup>nd</sup>/3<sup>rd</sup> Inside Cover : Only Full Page: Black & White: Rs. 7000/-; Colour: Rs. 10000/-

Text Page: Only Black & White: Full Page: Rs. 5000/-; Half Page: Rs. 3000 /-

Full or part sponsorship of any issue of the Journal would be negotiable.

**Dr. Dilip Kumar Das**

Managing Editor  
IJPH

**Dr. Madhumita Dobe**

Secretary General  
IPHA

## Appeal to all Members of IPHA

### Greetings to all our Members from the headquarters

We wish to inform all the members of our Association that IPHA Bhavan at Kolkata is almost ready and is shortly going to function as the hub for future activities at the headquarters.

We were happy to organize the CC meeting on April 9th in the new Building. However all members present at the meeting realized that the new building lacks basic logistics like furniture etc. which are essential for carrying out activities in the premises.

We do not have ready funds to spend immediately for the building. So it was decided in the meeting that funds have to be raised to provide:

### 1. Furniture in-side the Building :

There are 8 rooms (including guestrooms) in the building which need furniture (like cots and beds, tables & chairs, cup-boards and other furnishings) The cost of furnishing each guest room is estimated to be about Rs. 25,000= 00.

2. The main seminar hall needs AV equipment (like LCD projector, Lap-top, OHP, and Audio-System), seating arrangements and wall and floor paneling. This may cost about Rs. 3.0 lakhs.

If our Association could acquire these things within the coming one year, then we could implement most of our future planned activities at and from\* the IPHA Bhaban. This can then be properly utilized and even start yielding revenue. The rooms can be let out for conferences and other teaching/training activities to promote public health. Our members visiting Kolkata can also then avail of the guesthouse facilities at the Bhavan, which is very close to the Kolkata Airport. We look forward to your visits at the headquarters.

So, we appeal to all members to actively participate in the IPHA Bhavan Development Campaign to raise funds from as many sources as possible through individual contributions and contributions from the district and State branches.

The names of the Donors who will donate Rs 25,000 and above will be inscribed in a Tablet on the wall of the room furnished with the donation.

To make a start and inspire others the AP Chapter, Hyderabad is donating Rs.25, 000.00 for furnishing one guest room. We earnestly solicit you to be the next esteemed donor.

**Dr. T.S.R. Sai**  
President

**Dr. Madhumita Dobe**  
Secretary General