Final Technical Report

for

Research Project

Population based Seroprevalence Study of Melioidosis in Odisha

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2023.7.Ind

December 2024

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Disclaimer

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Project Report

POPULATION BASED SEROPREVALENCE STUDY OF MELIOIDOSIS IN ODISHA

Submitted to:
WHO-India Office, New Delhi
Submitted on:
28.12.2023

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Acknowledgment

I would like to express my heartfelt appreciation and gratitude to several individuals and organizations whose unwavering support and guidance have been instrumental in the successful completion of this project.

Firstly, I extend my sincere thanks to the World Health Organization and specifically to Dr. Mohammad Ahmad, National Professional Officer for Research, at the WHO Headquarters. Their continuous support and valuable guidance have significantly contributed to the success of this endeavor.

I am deeply thankful to Co-Principal Investigator Dr. Arvind Kumar Singh for their esteemed guidance and constant support throughout the project. I extend my gratitude to all the Co-Investigators Dr Abhisek Mishra, Dr Askoka Mahapatra and Dr Srujana Mohanty who had always been a source of encouragement and has been instrumental for this endeavour.

This project would have been incomplete without mentioning the cooperation and support of the Government of Odisha officials at the Directorate of Health Services at State and district health officials in Puri, Mayurbhanj, Keonjhar, Sambalpur, Kadhamal, Nabarangapur districts.

Lastly, I would like to sincerely thank all the study team & participants for their invaluable time and cooperation. Their active involvement has been crucial in gathering the necessary data and insights for this project., and this research would not have been possible without their participation.

List of Abbreviation

AIIMS: All India Institute of Medical Sciences

AIDS: Acquired Immunodeficiency Syndrome

CDM & PHO: Chief Districts Medical & Public Health Officer

CEB: Census enumeration block

CI: Confidence Interval

DALYs: Disability-Adjusted Life-Year

HIV: Human Immunodeficiency Virus

IEC: Institutional Ethics Committee

IHA: Indirect Haemagglutination Assay

NTD: Neglected Tropical Diseases

OR: Odds Ratio

PSU: Primary Sampling Unit

RCF: Relative Centrifugal Force

SOP: Standard Operating System

SPSS: Statistical Package of Social Sciences

TB: Tuberculosis

WHO: World Health Organization

YLL: Years of life lost

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Introduction

Melioidosis, caused by the environmental saprophyte *Burkholderia pseudomallei* has substantial impact on the health-care systems and economies of numerous low and middle-income countries around the world, with counties of South Asia contributing to 44% of the global burden of the disease [1,2]. The disease has gained increased attention in several parts of India over the past decade with nearly half of the reports from India have been reported during the last five years and over 70% of the cases reported during the previous decade [2]. Birnie and colleagues in 2015 estimated that the global burden of melioidosis was 4·6 million disability-adjusted life-year (DALY) or 84·3 per 100000 people. Years of life lost (YLL) accounted for 98·9% of the total DALYs, and years lived with disability accounted for 1·1%.[1] Melioidosis so far is not included in the WHO portfolio of neglected tropical diseases (NTD), and thus research in melioidosis substantially lags other NTDs with similar global diseases burden. Melioidosis included in the list of nationally notifiable diseases in hyper endemic countries like Thailand and Australia,3 and in country like India, published cases from hospital-based studies are the only source of information and is believed to be gross underrepresentation of the total burden of the disease [2].

Seroprevalence studies in the general population are deemed necessary for an estimate of melioidosis endemicity as well as to explore the associated risk factors. Asymptomatic seroconversion is the most common event following environmental exposure and measurement of the antibodies can provide important epidemiological information and has public health significance. In India, few coastal southern states and union territories like Karnataka, Tamil Nadu and Puducherry have undertaken community based and hospital based melioidosis seroprevalence studies [3-6]. The number of culture-confirmed melioidosis cases from each of the major teaching hospitals of these southern states 7 is almost similar to the number of cases reported by our hospital at AIIMS-B (average 20-25 cases per year)8 and hence we speculate high degree of environmental exposure to *Burkholderia pseudomallei* across Odisha and corresponding antibody titer- in residents of Odisha, which is primarily an agricultural state with a long coast line similar to the other southern states.

Novelty of present study: Melioidosis is not a nationally notifiable disease in India. There is a no published literature about melioidosis seroprevalence from Odisha. With steady increase in the number of cases in the last few years, estimating the seroprevalence of melioidosis in Odisha is long overdue from public health perspective. The results of seroprevalence studies may aid public health approaches, such as community education and reducing environmental exposure, and in reducing morbidity and mortality attributed to melioidosis.

Study Objectives:

1. To determine the age, sex and region stratified seroprevalence rate of B. pseudomallei (Melioidosis) in residents of Odisha in the age group of 5-60 years using Indirect Haemagglutination assay (IHA)

2. To determine risk factors for Melioidosis infection in Odisha state

Materials & Methods:

Study Design:

This was a Population-based cross-sectional study of seroprevalence against melioidosis in the state of Odisha. Seropositivity will be defined as an IHA titer ≥20.

Study Setting:

The proposed study was carried out in the state of Odisha. In order to have a representative estimate of the entire Odisha state, we selected two districts randomly from each of the three revenue divisions of Odisha, making a total of six districts in the state (Each revenue division of Odisha had ten districts). The revenue divisions of Odisha were distinct in terms of coastal line, occupation, topography, and climatic conditions. The study was conducted in both urban areas and rural areas.

Study Population:

The study was carried out among persons aged 5-60 years, residing in the six randomly selected districts (under three Divisions) of the state of Odisha, as aforementioned. Children below the age of 5 years and adults above 60 years were likely to have had less environmental exposure to B. pseudomallei because of fewer outdoor activities and were not included in the study. Eligibility to participate in the study was identified as per the following inclusion-exclusion criteria, after obtaining written informed consent. The study participation was voluntary, and written informed consent was obtained from participants (> 18 years) and parents of all the participants (10-18 years). Additional verbal assent was obtained from the study subject when the study subject was less than 18 years.

Inclusion criteria

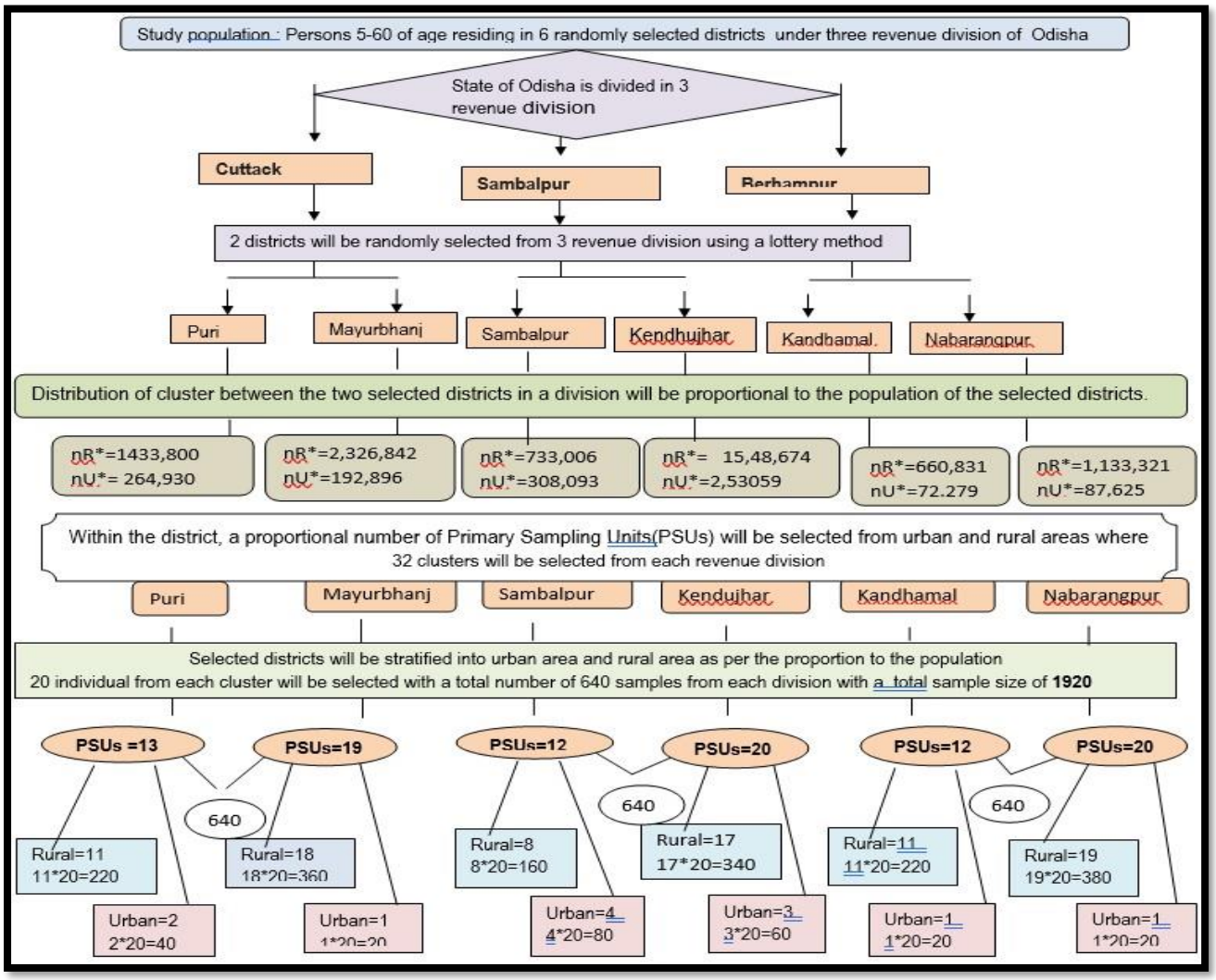
1. Residents of Odisha. The Standard definition of “resident” defined for the purposes of the National population register as a person who has resided in a local area for the past six months or more will be used.

2. Participants 5-60 years age group

Exclusion criteria

1. People with history of bleeding disorder
2. People with HIV/AIDS, TB, on steroids or cancer chemotherapy
3. Sick people needing medical attention

Fig 1: Methodology flowchart



Sample size and sampling strategy:

Assuming a seropositivity of 29% from a population-based seroprevalence study along the west coast of south India, the desired sample size using nMaster 2.0 was estimated to be 632 (considering a confidence limit of 95%, absolute precision of 5%, and design effect of 2). To have an equal number of individuals in each cluster, the final sample size was taken as 640. Since different divisions might have varied prevalence of melioidosis, a sample size of 640 was taken for each of the three divisions. Thus, the total sample size was 1920.

A multistage cluster sampling strategy, like the National Family Health Survey, was followed to select the primary sampling units. Two districts from each of three divisions (total six districts in the state) were randomly selected using a lottery method. Selected districts were stratified into urban areas and rural areas as per the demarcation provided by the local bodies. In urban areas, Census enumeration block (CEB) was considered as a Primary Sampling Unit (PSU), whereas in rural areas, a census village was considered as a PSU. A PSU with a population

of less than 500 was pooled with the most adjacent PSU. Within the selected PSUs, 20 individuals were selected. Thus, 32 cluster-PSUs (640/20) were required to be selected from each division The distribution of clusters between the two selected districts in a division was proportional to the population of the selected districts. Within the district, a proportional number of PSUs were selected from urban and rural areas as per the urban-rural population distribution. The selection of PSUs was done randomly using a random number generator method. Selected districts are shown in Table 1 and Figure 1. The distribution of PSUs in each district is presented in Tables 2 and 3.

From each PSU, to determine the direction of households to start the data collection, the pencil spinning method was used after reaching the central place of the PSU. The nearest first household in the direction of the pencil was considered for further systemic sampling. The sampling interval was determined by dividing the number of households by the number of households to be selected (i.e., 20) and rounding it off to the nearest smaller whole number. The first household in the determined direction was selected randomly from a number between 1 and the sampling interval, and then from the first selected household, every Nth (N = sampling interval) household was selected until the required number of 20 households were selected. For example, if 93 households were present in the selected village, the sampling interval was 4 because 4 was the nearest smaller whole number to 93/20, i.e., 4.65. Thus, the first household was the fourth household in the direction of the pencil, and subsequently, houses were 8, 12, 16, 20, etc., until 20 participants were enrolled. One individual from the selected household was randomly selected using the Kish method.

Table 1: Division-wise list of districts and random

S.No	**Central Revenue Division (HQ: Cuttack)**	**Northern Revenue Division (HQ: Sambalpur)**	**Southern Revenue Division (HQ: Berhampur)**
1	Cuttack	Sambalpur *	Ganjam
2	Jagatsinghpur	Bargarh	Gajapati
3	Kendrapara	Jharsuguda	Kandhamal *
4	Jajpur	Debagarh	Boudh
5	Puri *	Balangir	Kalahandi
6	Khordha	Subarnapur	Nuapada
7	Nayagarh	Dhenkanal	Koraput
8	Balasore	Angul	Rayagada
9	Bhadrak	Kendujhar *	Nabarangpur *
10	Mayurbhanj *	Sundargarh	Malkangiri

*Selected district from each revenue division

Table 2: Distribution of PSUs in selected districts selection of district

Division	Name of the selected district	Total Population	Allocation of PSUs in each district *
Cuttack	Puri	16,98,730	13
	Mayurbhanj	25,19,738	19
Sambalpur	Sambalpur	10,41,099	12
	Kendhujhar	18,01,733	20
Berhampur	Kandhamal	7,33,110	12
	Nabarangpur	12,20,946	20

Figure 2: Map showing geographical location of selected districts in different divisions of Odisha

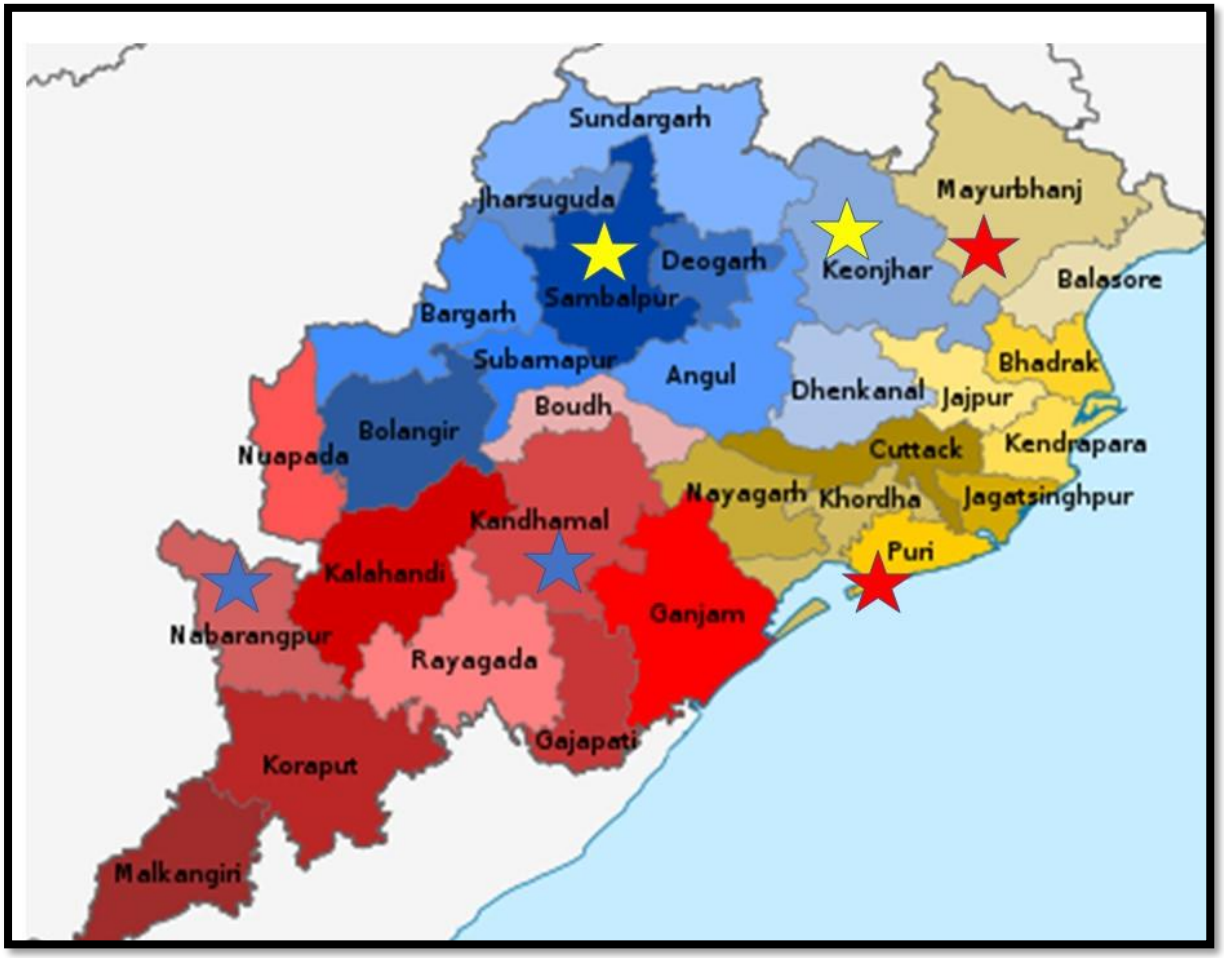


Table 3: Distribution of PSUs in urban and rural areas in randomly selected districts

Name of selected district	Allocation of PSUs in each district	Rural		Urban	
		Population	No. of allocated PSUs	Population	No. of allocated PSUs
Puri	13	14,33,800	11	2,64,930	2
Mayurbhanj	19	23,26,842	18	1,92,896	1
Sambalpur	12	7,33,006	8	3,08,093	4
Kendhujhar	20	15,48,674 2,53,059	17	2,53,059	3
Kandhamal	12	6,60,831	11	72,279	1
Nabarangapur	20	11,33,321	19	87,625	1

Field Implementation

Data collection: An official communication was held between the Principal & Co-Principal Investigators with Chief District Medical and Public Health Officers (CDM & PHOs). After the approval of an official letter from the CDM & PHOs of the District Hospital Headquarters, the study team went to the selected PSU (Annexure-III). After explanation of the study and obtaining written consent, all the participants were interviewed using a pre-designed and pre-tested questionnaire tool as attached (Annexure-I & II). Information related to their age, gender, socio-demography, annual income, education level, co-morbidities, occupation, smoking and alcohol consumption, possible activities leading to environmental exposure to the bacteria such as gardening, swimming, farming, fishing, housing conditions, lifestyle, and travel was obtained. The data was collected by trained field assistants in the local language. The content of the tool was further validated through a Pilot study conducted by the Kordha District. The inputs and suggestions from the Pilot were further customized to fit the local requirement**.**

Sample collection: About 5 ml of blood samples were collected by venipuncture from each participant in a serum separator tube, allowed to clot at room temperature for 30 minutes after collection, centrifuged at 1500 rpm Relative Centrifugal Force (RCF) for ten minutes to separate the serum, and stored locally below -20°C until they were shipped to the microbiology laboratory of AIIMS Bhubaneswar. The Guidance on regulations for the transport of infectious substances by WHO was followed. Serum samples were stored at -20°C until IHA is performed.

Performance of IHA

The serum samples were then analyzed for the presence of anti-*B. pseudomallei* antibodies using (IHA) test with the polysaccharide antigens. The polysaccharide antigens were prepared in our laboratory from clinical isolates of *B. pseudomallei*, as described by Peacock and Wuthiekanun. IHA was performed as per the standard procedure laid down by Mahidol University, as described below

Procedure Of Indirect Haemagglutination Assay (IHA) For Melioidosis

Preparation of antigen: Pooled antigens were separately prepared from two clinical *B. pseudomallei* isolates, originally isolated from patients with melioidosis.

1. Each isolate (from the –80℃ freezer vial) were streaked directly onto separate Tryptone Soya Agar (TSA) plates to obtain single colonies. It was Incubated at 37℃ for 24-48 hours. purity was checked by visual inspection of colonies.
2. A sterile disposable loop was used, 5-6 colonies were touched and inoculated into 50ml volumes of Tryptone Soya broth (TSB) medium in 100 ml glass bottles.
3. Inoculated TSB were incubated loosely capped at 37℃ for 14 days, agitating the culture twice daily.
4. Each 14-day-old culture was again subcultured onto Macconkey agar plate to check for purity (If not pure, discarded).
5. Cultures were autoclaved at 121℃ for 15 minutes.
6. Then centrifuged at 4,000 rpm for 30 minutes, the supernatant was filtered out using a 0.2µ Millipore filter with a 10ml syringe, phenol was added (final concentration 0.5%), and stored at 4°C until use. [Antigen remains stable for 2 years].

Collection and storage of sheep red cells:

1. Under aseptic conditions, sheep blood was collected into an equal volume of sterile Alsever's solution. It was labelled with date and stored at 4°C for no longer than one month.
2. Just prior to use in an assay, cells were washed and suspended to give an initial working dilution of 10% washed cells. red cells volume was calculated of required and washed three times in PBS. if supernatant was still coloured after second wash, it was discarded. These were prepared fresh each time cells were to be sensitized.

a. 20 ml of Alsever's blood was Spin at 12,000 x g 10 min.
b. Clear Supernatant was removed (discarded, if, lysed).
c. Washed with 20 ml PBS. Mix (invert) and centrifuge as above (3 times).
d. From 3rd wash RBC pellet was used to make 10% solution in PBS (i.e., 2 ml blood cells in 18 ml PBS).

Determination of optimal bacterial antigen dilutions:

The optimal bacterial antigen dilution was established for each new batch of bacterial antigen.

l. **Preparation of positive control serum (to remove complement and non-specific sheep cell agglutinins):**

a. 300µl of positive control serum was inactivated in a closed Eppendorf tube for 30 minutes in 56°C water bath.

b. 900µl PBS-BSA was added and 300µl non-sensitized 10% sheep red blood cells and mixed thoroughly.

c. Incubated at room temperature for 1 hour, gently mixed every 15 minutes.

d. Centrifuged in micro-centrifuge for 3 minutes (13,000 rpm) and supernatant was retained, which represented a 1 in 5 dilution of serum. I was stored at 4°C for up to 24 hours or freeze at -80°C (good for up to 5 years).

II. Preparation of bacterial antigen dilution series and sensitization of red cells:

a. Each antigen was made 1/20 dilution in 3.0 ml of PBS (150µl antigen plus 2.85 ml PBS) as the starting tube.

b. 8 tubes for each antigen set a row of; final dilutions of antigen were made into a total volume of 1ml as follows.

Tube (5ml plain tubes)	1	2	3	4	5	6	7	8
Antigen (µl)	1000	500	333	250	200	167	143	0
Buffer (µl)	0	500	667	750	800	833	857	1000
Final dilution	1/20	1/40	1/60	1/80	1/100	1/120	1/140	0

c. 0.1ml of 10% washed sheep red cells in PBS was added to each tube, mixed thoroughly (inverted) and incubated at 37 °C for 1 hour, carefully mixed every 15 minutes.

d. Centrifuged for 5 minutes at 4,000 rpm and discarded supernatant (can pour off supernatant – has tight pellet).

e. Cells were washed 3 times in 2ml PBS, and then carefully removed all supernatant.

f. red cells were resuspended completely in 990µl PBS-BSA to give final concentration of 1% sensitized red cells. It was stored at 4°C until used in titration assay (within 24-48 hours).

III. Titration:

a. 2 x 96 U well microtitre plate was used, 50µl of PBS/BSA was added into all wells of columns 1 to 12.

b. 50µl of absorbed positive control serum was added to all wells in column 1.

c. A multi-channel pipette was used to made 1:2 dilutions from column 1 to 11 for each row, the final volume was discarded. The final dilution of serum should be 1:10 to 1:10,240 from column 1 to 11. Pipette up and down to mixed prior to transfer of 50 ul.

d. 25µl of red cells from each of the antigen dilution tubes was added into each well of the adjacent row from column 1 to 12 (see figure below, e.g.: 25µl of cells from antigen dilution 1:20 is added to each well of row A, 25µl of cells from antigen dilution 1:40 is added to each well of row B, etc). Note that red cells in rows A to G are sensitized whilst row H contains non-sensitized red cells.

e. The plate was gently taped on each of the 4 edges to mix thoroughly, covered with aluminium foil, and left on the bench at room temperature for 2 hours, then at 4°C overnight.

IV. Reading:

Negative wells (no red cell agglutination) had an intact button at the bottom of the well. Positive wells (red cell agglutination) demonstrated red cells settled as a fine carpet or appearing as a loose button with ragged or folded edges. The plates were read with a reading mirror for microtiter plate with transmitted light from below.

The titre recorded is the first clearly positive well; indeterminate results are recorded as equivocal and not used to define titre. There should be no agglutination in column 12 and row H.

Quality Assurance in the Study

Quality assurance measures with specimen collection, laboratory testing, training of survey staff, and data management were followed with emphasis on the following:

- Written standard operating procedures and protocols were prepared for the purpose of planning, training, project implementation, and data collection in fields and laboratory procedures.
- Training of trainers for laboratory testing, including exposure/training visits to Manipal, for hands-on training on the standardization of IHA.
- Training of field staff on standard procedures related to field implementation, including role plays and exercises covering phlebotomy, serum separation, shipment, and transportation of biological samples.
- Pilot community visit for filling out the questionnaire.
- Clearly defined responsibilities of the survey staff and professional coordination.
- Strong supervision by investigators and monitoring by WHO.

Ethical Approvals

The protocol was implemented after approval from the WHO-SEAR Ethics Committee, the institutional ethics committee (IEC) of AIIMS Bhubaneswar and State Research and Ethical Committee (Annex-IV).

Consent process: Informed written consent was taken from the participants (Annexure-II)). Upon visiting the participant's households, the study staff briefly explained the study to the potential participants. Further, the subject/parent information sheet was read to the subject/parent. For children under the age of 7 years, only parent/legal representative written consent was taken. For children 7-12 years old, the child's verbal assent, along with parent consent, was taken. For adolescents 12-17 years old, their written assent was taken along with parent consent.

Confidentiality: Confidentiality of the data collected was maintained. Identifying personal information was accessible only to the essential study staff, and the data was not used in any publications, reports, or media in a manner that could identify an individual participant.

Table 4: Study Timeline:

Activities	August-September 2023	September-November 2023	November-December 2023	December 2023
Preparatory activities and Capacity Building of staff, Training				
Sample, Data collection and transport of serum to AIIMS Bhubaneswar				
Sample testing and result interpretation				
Data analysis and dissemination of findings				

Data management and analysis:

Data Handling:

Data was collected using Epicollect5 software. All data was exported and cleaned in Microsoft Excel using Epicollect5 software. The data were analysed using SPSS (Statistical Package of Social Sciences) ver.22.0. After cleaning the pooled data sheet, the laboratory results were merged to create a final analysable database

Data Analysis

All data including the haemagglutination titers were entered in Microsoft excel and analyzed using SPSS version 22.0. All the categorical variables were summarised as frequency and percentages. Chi-square and Cochran Mantel-Haenszel model tests were performed to find the association of seropositivity with the socioeconomic status and various risk factors. The 95% confidence intervals (CIs) were estimated. All the statistical analyses were carried out at 5% level of significance and a p-value less than 0.05 was statistically significant.

Result:

The seroprevalence of the total sample (1920) using antibody titers > 1:20 was 20.9% (95% CI 19.0-22.7) (figure 4). The picture of the IHA plate is depicted in (Fig. 5). In addressing the challenges of total nonresponse among participants in the study a strategic method was implemented where in the nonresponsive individual were systematically replaced by the participants from the next household with the selected PSU (figure 3)

Demographic analysis of Study Individuals (n=1920)

The individuals in the age group of 31-40 constituted the highest proportion at 23.2%, followed closely by those in the 20 to 30 age range at 22.2%. In terms of gender, females represented the majority, constituting 63.3% of the population, while males accounted for 36.7%. The residence data indicated a predominantly rural population, with 87.5% residing in rural areas. The religious composition was predominantly Hindu, comprising 95.8%, with Muslims and Christians forming smaller percentages. Regarding caste, the highest percentage was observed among the Scheduled Tribes (ST) at 28.0%. Marital status revealed that 74.2% of the population was married. In educational status, the majority had completed schooling (67.4%). Homemakers constituted the majority at 37.3%, and in terms of income, the majority were within the income <100,000/year (60.9%) (Table 5)

Figure 3: Sampling frame with the nonresponse participants

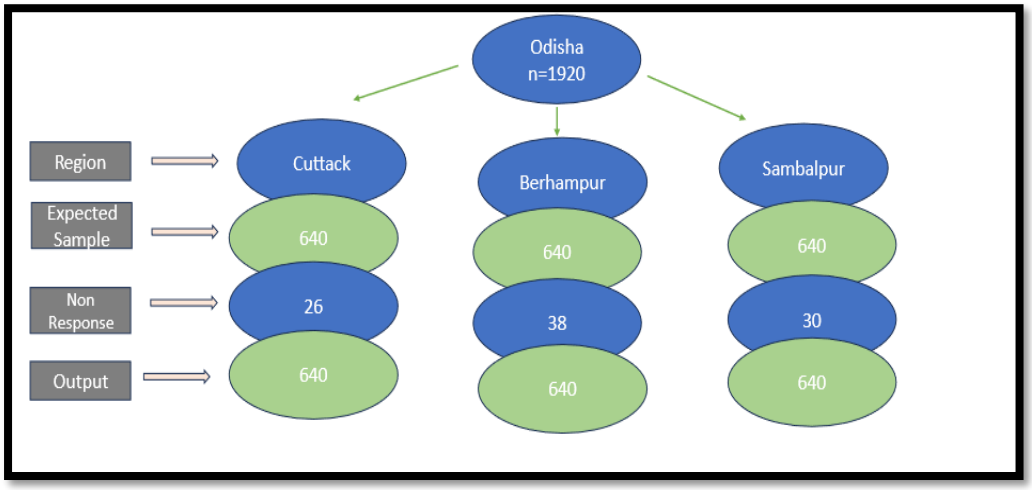
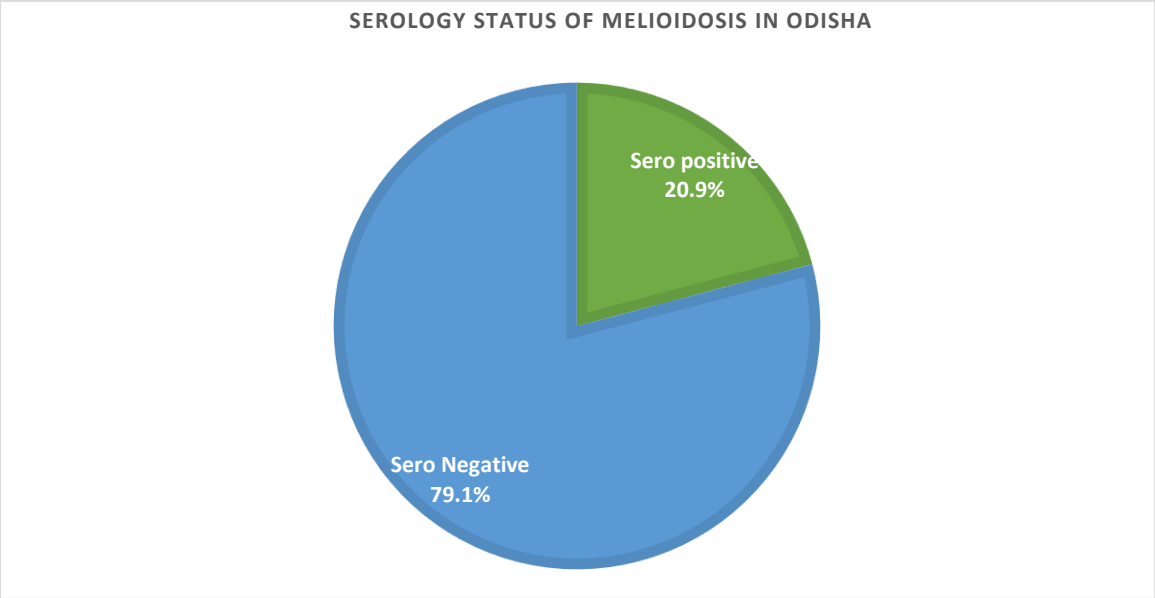
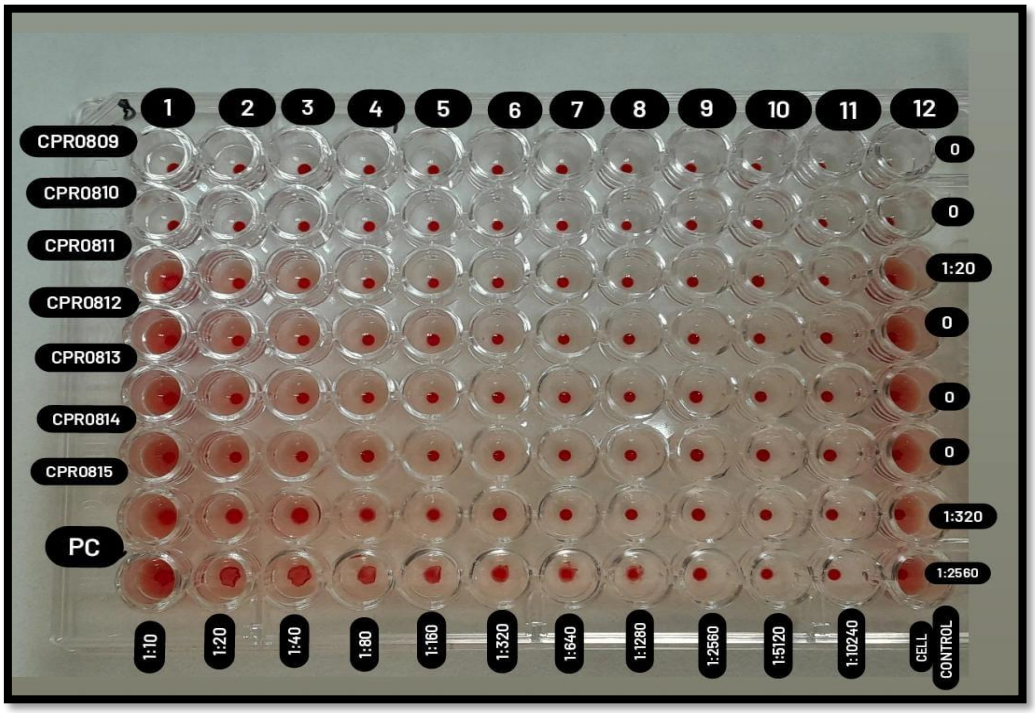


Figure 4: Seroprevalence of melioidosis in Odisha





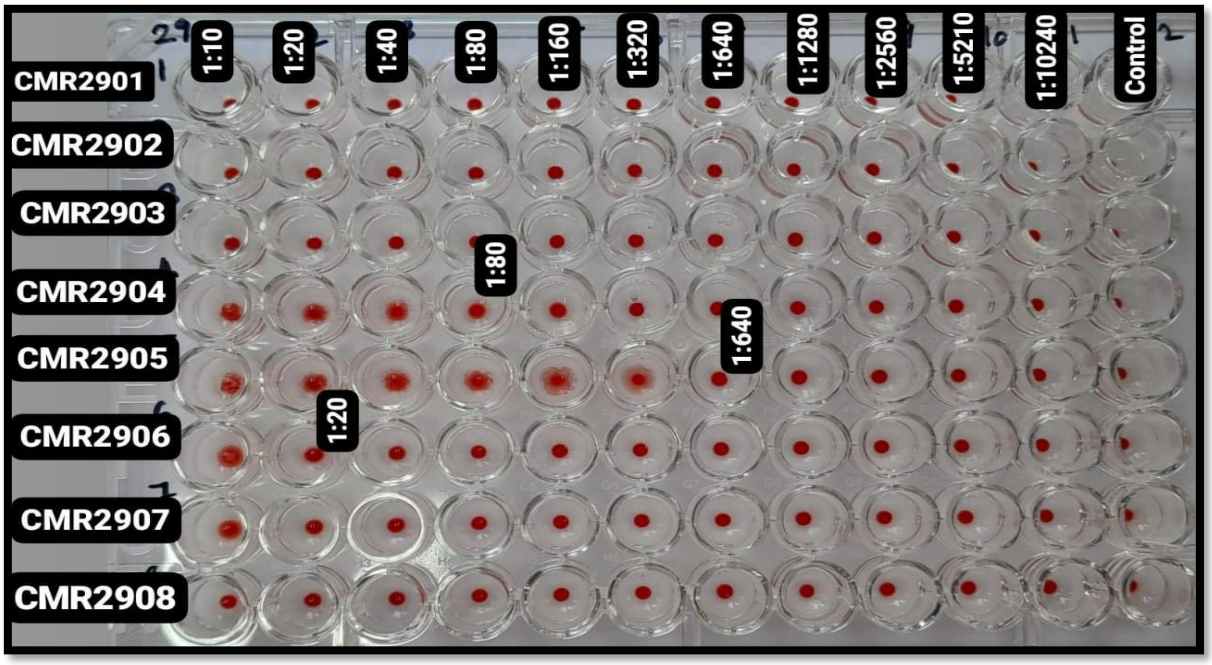
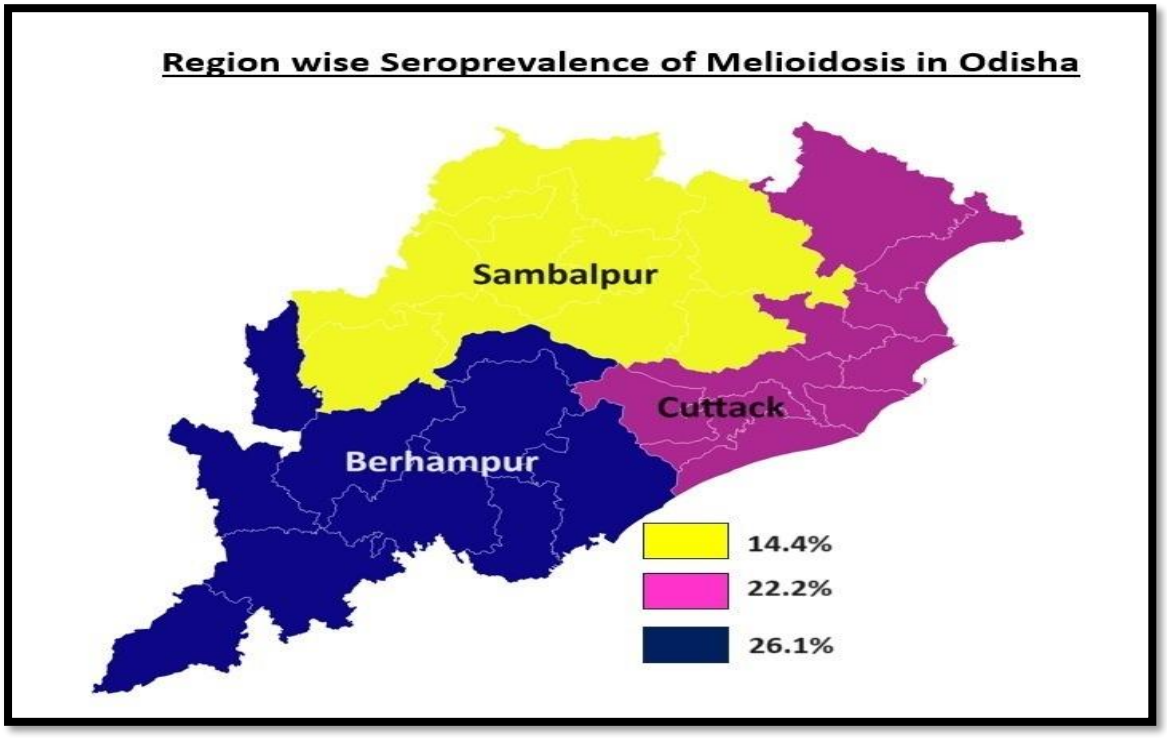


Fig 5. IHA plate with antibody titers, PC- Positive Control, CPR0809 -CPR0815 & CMR2901-CMR2908 are the test samples, 1:10-1:10240 are the Antibody titers.

Figure 6: Distribution serology status against Melioidosis in Odisha



The seroprevalence data of melioidosis in Odisha was 20.9% (95% CI 19.0-22.7) for three revenue divisions, based on the seroprevalence of individuals in each region, revealing distinct levels of exposure or infection to melioidosis. The Berhampur region demonstrated the highest seroprevalence at 26.9% (CI 22.7-29.6) in the sampled population. The Cuttack region exhibited a seroprevalence rate of 14.3% (CI 11.7-17.3), suggesting a moderate prevalence within the sampled population. The Sambalpur region, with a rate of 22.1% (19.0-25.6), indicated a lower level of exposure compared to Cuttack (fig. 5).

Table 5. Socio-Demographic Characteristics of the participants (n = 1920)

Characteristics	Categories	Frequency (n%)
Age (in complete years)	5 to 10	83 (4.3)
	11 to 20	274 (14.3)
	21 to 30	427 (22.2)
	31 to 40	448 (23.3)
	41 to 50	351 (18.3)
	51 to 60	337 (17.6)
Gender	Male	705 (36.7)
	Female	1215 (63.3)
Residence	Urban	240 (12.5)
	Rural	1680 (87.5)
Religion	Hindu	1839 (95.8)
	Muslim	6 (0.3)
	Christian	75 (3.9)
Caste	General	385 (20.1)
	OBC	515 (26.8)
	SC	482 (25.1)
	ST	538 (28.0)
Marital Status	Married	1424 (74.2)
	Unmarried	413 (21.5)
	Divorce	8 (0.4)
	Widow	75 (3.9)
Schooling Status	No formally Schooling	378 (19.7)
	Completed Schooling	1294 (67.4)
	Currently going to School	248 (12.9)
Highest Educational Status	No formal Schooling	382 (19.9)
	Primary school completed	688 (35.8)
	Secondary school completed	251 (13.1)
	High school completed	429 (22.3)
	College/university completed	170 (8.9)
Main Work Status	Government employee	88 (4.6)
	Nongovernment employee	316 (16.5)
	Farming	454 (23.6)
	Homemaker	716 (37.3)
	Student	294 (15.3)
	Unemployed	52 (2.7)
Income	<100000	1169 (60.9)
	100001-300000	609 (31.7)
	>300000	142 (7.4)

Regarding age, the highest seroprevalence was observed in the 21 to 30 age group 23.2% (CI 19.2-27.4), followed closely by the 5 to 10 and 11 to 20 age groups. The older age groups,

from 31 to 60, showed lower seroprevalence rates, with the 41 to 50 age group having the lowest prevalence at 18.5% (CI 14.5-22.9). Gender-wise, females demonstrated a slightly higher seroprevalence 21.7% (19.4-.24.1), compared to males (19.4%) (CI 16.5-22.5). Region-specific analysis indicated substantial variability, with Berhampur exhibiting the highest seroprevalence at 26.1% (CI 22.7-29.6), followed by Cuttack at 22.2% (CI 19.0-25.6), and Sambalpur having the lowest seroprevalence at 14.4% (CI 11.7-17.3) (table 6).

Table 6. Age, gender and region stratified seroprevalence

Characteristics Categories		Total Samples (n%)	Total Positive (n)	Prevalence (95%CI)	Total Prevalence (95% CI)
Age (in complete years)	5 to 10	83 (4.3)	19	22.9 (14.3-33.4)	20.9 (19.0-22.7)
	11 to 20	274 (14.3)	61	22.3 (17.4-27.6)	
	21 to 30	427 (22.2)	99	23.2 (19.2-27.4)	
	31 to 40	448 (23.3)	88	19.6 (16.0-23.6)	
	41 to 50	351 (18.3)	65	18.5 (14.5-22.9)	
	51 to 60	337 (17.6)	69	20.5 (16.2-25.1)	
Gender	Male	705 (36.7)	137	19.4 (16.5-22.5)	
	Female	1215 (63.3)	264	21.7 (19.4-.24.1)	
Region	Cuttack	640 (33.3)	142	22.2 (19.0-25.6)	
	Sambalpur	640 (33.3)	92	14.4 (11.7-17.3)	
	Berhampur	640 (33.3)	167	26.1 (22.7-29.6)	

The association between seropositivity and various socio-demographic characteristics was examined in a cohort of 1920 individuals. Statistically significant associations were observed in residences, schooling status, highest educational status, and income. Specifically, individuals residing in urban areas, those with no formal schooling, and those with lower income levels were more likely to be seropositive. The association with residence highlighted potential urban-rural disparities, while educational and income disparities underscored socio-economic influences on seropositivity. The significant association between main work status and seropositivity indicated that individuals engaged in farming faced higher seropositivity risks (table 7).

Table 7: Serological status associated with Socio-demographic characteristic (n = 1920)

Characteristics	Seronegative	Seropositivity	P-Values

		n (%)	n (%)	
Age (in complete years)	5 to 10	64(77.1)	19(22.9)	0.619
	11 to 20	213(77.7)	61(22.3)	
	21 to 30	38(76.8)	99(23.2)	
	31 to 40	360(80.4)	88(19.6)	
	41 to 50	286(81.4)	65(18.5)	
	51 to 60	268(81.5)	69(20.5)	
Gender	Male	568 (80.6)	137(19.4)	0.233
	Female	951(78.3)	264(21.7)	
Residence	Urban	207(86.3)	33(13.8)	0.004
	Rural	1312(78.1)	368(21.9)	
Religion	Hindu	1461(79.4)	378(20.6)	0.180
	Muslim	5(83.3)	1(29.3)	
	Christian	53(70.7)	22(5.5)	
Caste	General	295(76.6)	90(23.4)	0.173
	OBC	423(82.1)	92(17.9)	
	SC	374(79.4)	108(20.6)	
	ST	427(79.1)	111(20.9)	
Marital Status	Married	1119(78.6)	305(21.4)	0.769
	Unmarried	334(80.9)	79(25.0)	
	Divorce	6(75.0)	2(0.5)	
	Widow	60(80.0)	15(20.0)	
Schooling Status	No formally Schooling	276(73.0)	102(27.0)	0.004
	Completed Schooling	1039(80.3)	255(19.7)	
	Currently going to School	204(82.3)	44(17.7)	
Highest Educational Status	No formal Schooling	283(74.1)	99(25.9)	0.020
	Primary school completed	540(78.5)	148(21.5)	
	Secondary school completed	200(79.7)	51(20.3)	
	High school completed	359(83.7)	70(16.3)	
	College/university completed	137(80.6)	33(19.4)	
Main Work Status	Government employee	74(84.1)	14(15.9)	0.039
	Nongovernment employee	266(84.2)	50(15.8)	
	Farming	343(75.6)	111(24.4)	
	Homemaker	555(77.9)	158(22.1)	
	Student	239(81.3)	55(18.7)	
	Unemployed	39(75.0)	13(25.0)	
Income	<100000	900(77.0)	269(23.0)	0.007
	100001-300000	496(81.4)	113(18.6)	
	>300000	123(86.6)	19(13.4)	

Assessment of risk factors associated with seropositivity in a high-risk population

The behavioural habits including smoking and alcohol intake. It was revealed that individuals who smoked exhibited a non-significant decrease in seropositivity with an odds ratio (OR) of 0.603, while alcohol intake was associated with a significant decrease in seropositivity, with an OR of 0.635. Drinking non-treated water was associated with a significantly higher odd of seropositivity. Activities near water bodies, activities involving soil, wearing footwear in the field, among co-morbidities, individuals with diabetes or hypertension, and travel history outside of the state did not show statistically significant associations with seropositivity. The analysis of engagement with cultivation approached significance, indicating a trend towards higher seropositivity in those engaged with cultivation. While this association fell just short of conventional significance (table 8).

Table 8. Risk factors associated with Seropositivity in high-risk population

Risk factors		Seronegative n (%)	Seropositivity n (%)	OR (95% CI)	P-Values
Behavioural habits					
Smoking	No	1439(78.8)	388(21.2)	Reference	0.093
	Yes	80(86.0)	13(14.0)	0.603(0.332-1.095)	
Alcohol intake	No	1304(78.2)	363(21.8)	Reference	0.014
	Yes	215(85.0)	38(15.0)	0.635 (0.441-0.914)	
Activities Near waterbodies	No	724(80.5)	175(19.5)	Reference	0.151
	Yes	795(77.9)	226(22.1)	1.176 (0.942-1.468)	
Activities involving Soil	No	1034(79.7)	263(20.3)	Reference	0.343
	Yes	138(76.7)	42(23.3)	1.118(0.886-1.412)	
Wear Foot wear in the field	Yes	708(80.3)	174(19.7)	0.878(0.703-1.096)	0.250
	No	877(78.1)	227(21.9)	Reference	
Travel History (Outside of state)	No	1489(79.2)	392(20.8)	Reference	0.734
	Yes	30(76.9)	9(23.1)	0.878(0.413-1.864)	
Co-morbidities	No	1492(79.1)	395(20.9)	Reference	0.700
Diabetes	Yes	27(81.8)	6(18.2)	0.839(0.334-2.047)	
Hypertension	No	1491(79.2)	392(20.8)	Reference	0.603
	Yes	28(75.7)	9(24.3)	1.223 (.572-2.612)	
Domestic Animal	No	749(78.3)	207(21.7)	Reference	0.410
	Yes	770(79.9)	194(20.1)	1.097(0.880-1.367)	
Engaged with Cultivation	No	1047(80.2)	258(19.8)	Reference	0.080
	Yes	472(76.7)	143(23.3)	1.229 (0.975-1.550)	
Drinking Water	Treated	159(85.0)	28(15.0)	Reference	0.036
	Non-treated	1360(78.5)	373(21.5)	1.557(1.026-2.365)	

Discussion:

India is recognized as an endemic country for melioidosis, a bacterial infection caused *by Burkholderia pseudomallei*, which has been successfully isolated from both soil and water sources [7,8,9]. This study contributes novel insights by focusing on a high-risk population comprised of homemaker and farmers, aiming to assess the extent of their exposure to *B. pseudomallei*. The overall seropositivity in the study population was noted at 20.9%, determined through the use of the indirect hemagglutination assay (IHA), a widely employed serological test in such studies since its inception in 1965 [10,11]. The study employed a cutoff titer of >1:20 to enhance test specificity, aligning with previous research from Southern India [12].

A strong association emerged between seropositivity and exposure to alcohol intake and drinking water. corroborating findings in Bangladesh [13] and Thailand [14]. Additionally, individuals residing in rural areas and those in contact demonstrated significant associations with seropositivity, supporting observations from Thailand [14]. The relationship between age and seropositivity is unclear. We found higher seropositivity rates in the adult, aged between 21-40 years compared to older age groups which could reflect repeated exposure where as in Thailand, seropositivity rates increased with advancing age in children [15,16]. On the other hand, an inverse relationship between seroprevalence rate and advancing age was found in Australia [17]. The study concludes by highlighting the necessity for further research employing sensitive techniques and environmental sampling to accurately determine melioidosis seroprevalence and identify high-risk populations across different regions in India.

Conclusion:

In conclusion, this study contributes valuable insights into the complex interplay of demographic, socio-economic, behavioural, environmental and clinical risk factors in Melioidosis seropositivity. The observed associations emphasize the need for targeted public health interventions and further investigation into the specific risk factors identified. The observed seropositivity rates in high-risk groups ascertain the usefulness of IHA as a promising diagnostic tool for seroepidemiological surveys. This comprehensive analysis serves as a foundation for informed decision-making and the development of strategies to mitigate the impact of melioidosis in the high-risk population under study.

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Some images during data and sample collection

Some images during the field supervision by the WHO team


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ଜିଲ୍ଲା ମୁଖ୍ୟ ଚିକିତ୍ସାଳୟ
ସମ୍ବଲପୁର
DISTRICT HEADQUARTER HOSPITAL SAMBALPUR

Annexure-1

Data collection tool of "Population based Seroprevalence study of Melioidosis in Odisha"

Section 1: Identification I am going to first ask you a few questions about your background

1. District
   - Puri
   - Mayurbhanj
   - Sambalpur
   - Keonjhar
   - Kandhamal
   - Nabarangapur

2. Data recorded by
   - Soumya Ranjan Samal
   - Swagatika Senapati
   - Santosh Kumar Behera
   - Smrutirekha Mohanty
   - Other
3. Date of data collection
4. Inclusion Criteria:
   4a. Residency of Odisha?
   - Yes
   - No

   4b. How many members in your family?

   4c. How many members in your family under age of 5 to 60?
5. Exclusion Criteria:
   5a. Do you have any complication of bleeding disorder? (In past taken blood)
   - Yes
   - No

   5b. Dose you suffer from HIV/AIDS
   - Yes
   - No

   5c. Do you suffer from tuberculosis?
   - Yes
   - No

   5d. Are you currently taking any medication for Cancer?
   - Yes
   - No

   5e. Are you currently taking any therapeutic medicine or Steroids?
   (Prednisolone, Dexamethasone, Hydrocortisone....etc))
   - Yes
   - No

ϐf. Medically Sick (Are you taking any kind of medicine)

- Yes
- No

Add prescription Image:

6. I consent for the survey team to interview me/ my ward
   - YES
   - NO
7. I consent for providing the blood sample for the testing of Melioidosis.
   - YES
   - NO

Section 2: Background Information I am going to first ask you a few questions about your background

8. Unique ID:
9. What is your Name?
10. How old are you? (record age in complete years)
11. Gender
    - Male
    - Female
    - Other
12. Contact No:
13. Marital status
    - Married
    - Unmarried
    - Divorce
    - Widow
14. Have you ever attend school /currently going to school?
    - No formally Schooling
    - Completed Schooling
    - Currently going to School
15. What is the highest level of education you have completed?
    - No formal schooling
    - Less than primary school completed
    - Primary school completed
    - Less than secondary school completed
    - Secondary school completed
    - High school completed
    - College/university completed
    - Post graduate degree completed
    - Unable to Answer
    - Refused
16. Which of the following best describes your main work status?

- Student
- Homemaker
- Farming
- Agri Labour
- Other
- Unemployed

If other, Please Specify:

17. Complete Postal Address (House No & Landmark):
18. GPS Location:
19. Photo:

Section 3: Socio demographic Information

20. What is your current place of residence?

- Urban
- Rural

22. What is your religion?

- Hindu
- Muslim
- Christian
- Other

21. What is your Caste?

- General
- OBC
- SC
- ST

23. Name of the head of household?
24. What is the highest level of education of Head of Household, have completed?
    - No formal schooling
    - Less than primary school completed
    - Primary school completed
    - Less than secondary school completed
    - Secondary school completed
    - High school completed
    - College/university completed
    - Post graduate degree completed
    - Unable to Answer
    - Refused
25. Which of the following best describes your main work status?
    - Government employee
    - Nongovernment employee
    - Self-employed
    - Student
    - Homemaker
    - Farming
    - Agri Labour
    - Other

- Mud Worker
- unemployed

26 a. If other, please specify your Occupation

27. Does any member of this household own any agricultural land?

- Yes
- No

29. Does your household own any of the following animals:
    - Cows, bulls, buffaloes, or yaks
    - Camels
    - Horses, donkeys, or mules
    - Goats or sheep
    - Pigs
    - Chickens or ducks
    - None of the above
30. Does this household share a sleeping room with (this/these) animal(s)?
    - Yes
    - No
31. Does your household have a BPL or any equivalent card?
    - Yes
    - No
    - Don't Know
32. What is your annual income of family?
33. Whether any member of your household tested positive for COVID19, including any deceased person?
    - Yes
    - No
    - Don't Know
34. Whether any member of the household was hospitalized for treatment of COVID-19 infection?
    - Yes
    - No
    - Don't know

Section 4: Risk factors assessment

35. Travel History of family

19a. Does any of your family members ever visited outside thestate/ country in last 1 year?

- Yes
- No

19b. If yes, Which State

19c. For How Long, do you stay (In days)

19d. If yes, Which Country

19e. For How Long, do you stay (In days)

19f. What was the purpose of the visit?

- For study
- For work
- For tourism

36. Does your occupation involved water related activities
    - Yes

37. Do you use Footwear regularly while at home or in outside?
    - Yes
    - No
38. While at work in the field do you use footwear regularly?
    Yes /No

39 (a). Are you engaged in any water related activities?

- Swimming
- Fishing
- Gardening
- Pump House
- Sewage Plant
- Fetching Water
- Irrigation
- Other
- None
- Mud worker

39 (b). How long, you engaged in any water related activities? (In year)

39 (c). If No, in past, you engaged in any water related activities? (In year)

- Yes
- No

40. (a). Does your current work involve in soil?

- agricultural land digging
- manual soil transport (on head)
- Potter
- None

40 (b). How long, you engaged in any soil related activities? (In year)

40 (c). If No, in past, you engaged in any soil related activities? (In year)

- Yes
- No

41 a. Are you engaged in any kind of Cultivation?

- Yes
- No

41 (b). If yes, what type of farming involved in work?

- Rice
- Wheat
- Coconut
- Pulses
- Mixed cultivation
- Other
- Not Applicable

41 (c). If other (specify)

42. Do you continue to work in the field (Soil, Water & Mud) despite any injuries you may have?

- YES
- NO

44. Where is the water source located?

- IN OWN DWELLING
- IN OWN YARD/PLOT
- ELSEWHERE

45. What is the main source of drinking water?

- Piped into dwelling
- Piped to yard
- Public tap or standpipe
- Tube well or bore well

- Protected dug well
- Unprotected dug well
- Protected spring
- Unprotected spring
- Rainwater
- Tanker truck
- Cart with small tank
- Surface water
- Bottle water
- Community RO Plant

46. What does this household usually do to make the water safer to drink? Anything else?

- Boil
- Use alum
- Add bleach/chlorine tablets
- Strain through a cloth
- se water filter (ceramic/ sand/composite/etc)
- Use electronic purifier
- Use solar disinfection
- Let it stand and settle
- Other
- Don't know
- Non treated

46 (a). If Other (specify)

47. What is the main source of water for your household/ activity involved?

- Piped into dwelling
- Piped to yard
- Public tap or standpipe
- Tube well or bore well
- Protected dug well
- Unprotected dug well
- . Protected spring
- Unprotected spring
- Rainwater
- Tanker truck
- Cart with small tank
- Surface water
- Bottle water
- Community RO Plant

Thank you very much for all your responses so far. Now I would like to ask you some questions about your habits.

Section 5: Behavioural Habit

48 (a). Have you ever consumed alcohol in your life time?

- Yes
- No

49 . Do you currently intake alcohol?

- Yes
- No

49 (b). If yes then how often do you consume alcohol?

- Daily
- Weekly
- Monthly
- Less than monthly
- Occasionally

50. Have you ever smoked in the past?

- Yes
- No

51. Do you currently smoke

- Yes
- No

52 b). If yes then how often do you smoke?

- Daily
- Weekly
- Monthly
- Less than monthly
- Occasionally

53 Do you currently use tobacco in any form apart from smoking?

- YES
- NO

Thank you very much for all your responses so far. Now I would like to ask you some questions about your medical history.

Section 6: Medical History

Q.35 A. Have you ever been diagnosed by doctor or taking medication/under treatment for Diabetes?

- Yes
- No

Q.35 Ai. If yes, how long (Month) you have been diagnosed with diabetes?

Q.35 Aii. Are you presently taking medication for Diabetes?

- yes
- No

Q. 35 Aiii. If Yes, Name of the treatment

Q. 35 B. Have you ever been diagnosed by doctor or taking medication/under treatment for Hypertension?

- Yes
- No

Q. 35 Bi.If Yes, how long (Month) you have been diagnosed with Hypertension?

Q. 35 Bii. Are you presently taking medication for Hypertension?

- yes
- No

Q. 35 Biii. If Yes, Name of the treatment

Q. 35 C. Have you ever been diagnosed by doctor or taking medication/under treatment for Asthma

- Daily
- Weekly
- Monthly
- Less than monthly
- Occasionally

50. Have you ever smoked in the past?

- Yes
- No

51. Do you currently smoke

- Yes
- No

52 b). If yes then how often do you smoke?

- Daily
- Weekly
- Monthly
- Less than monthly
- Occasionally

53 Do you currently use tobacco in any form apart from smoking?

- YES
- NO

Thank you very much for all your responses so far. Now I would like to ask you some questions about your medical history.

Section 6: Medical History

Q.35 A. Have you ever been diagnosed by doctor or taking medication/under treatment for Diabetes?

- Yes
- No

Q.35 Ai. If yes, how long (Month) you have been diagnosed with diabetes?

Q.35 Aii. Are you presently taking medication for Diabetes?

- yes
- No

Q. 35 Aiii. If Yes, Name of the treatment

Q. 35 B. Have you ever been diagnosed by doctor or taking medication/under treatment for Hypertension?

- Yes
- No

Q. 35 Bi.If Yes, how long (Month) you have been diagnosed with Hypertension?

Q. 35 Bii. Are you presently taking medication for Hypertension?

- yes
- No

Q. 35 Biii. If Yes, Name of the treatment

Q. 35 C. Have you ever been diagnosed by doctor or taking medication/under treatment for Asthma

- No

Q. 35 Hi. If Yes, Duration (Months)

Q.35 Hii. Are you presently taking medication for Liver related disease?

- Yes
- No

Q. 35 Hiii. If Yes, Name of the treatment

Annexure-II

Participant Informed Consent Form

Study Title: Population based Sero-prevalence Study of Melioidosis in Odisha

The content of the information sheet has been provided and carefully read by me / explained to me, in local language that I can understand, and I have fully understood the content. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and I am free to withdraw my participation at any time, without giving any reason, without my medical care or legal right being affected. The nature and purpose of the study and its potential risks/ benefits and expected duration of the study and other relevant details of the study have been explained to me in detail. I have been explained that the information obtained will be kept confidential and only investigators can have direct access to the records.

In case of any queries or questions I can contact Dr Bijayani Behera, Additional Professor, Dept of microbiology AIIMS Bhubaneswar

(Signature / left thumb impression) Date .....

Name of the participant: .....

Place .....

Name of witness: .....

Signature: ..... Date: .....

(Signature of witness is required if the respondent is illiterate. A witness should be literate and not related to Investigator)

Name of Interviewer: .....

Signature.....

Date: .....

Assent Form

(Age < 18 years)

I have read all the information and all my queries have been answered. I can contact site investigator at any point of time for further clarifications.

I agree to take part in the research.

Name of child _____ Signature of child: _____

Date: _____

OR

I do not wish to take part in the research and I have not signed the assent below.

_____

(Initialed by child/minor)

I have witnessed the accurate reading of the assent form to the child, and the child has opportunity to ask questions. I confirm that the child has given consent freely. **[In case of illiterate child]**

Name of witness (not a parent) _____

Signature of Witness _____ Date _____

The prospective participant has read or observed the exact form of acceptance form correctly, and the person has the opportunity to ask questions.

I confirm that the person has freely agreed

Name of Investigator _____

Signature of Investigator _____ Date _____

Annexure-III

All India Institute of Medical Sciences, Bhubaneswar -19
अखिल भारतीय आयुर्विज्ञान संस्थान, भुवनेश्वर
Department of Microbiology

Ref: AIIMS/BBSR/MB/BB/EMF/22-23 Date:20/11/2023

To
Chief District Medical and Public Health Officer, Kandhamal

Subject: Regarding Approval and extending support for data collection and sample collection for the WHO-AIIMS Bhubaneswar Collaborative project entitled "Population based seroprevalence study of melioidosis in Odisha"

Dear Ma'am/ Sir,

Greetings from AIIMS, Bhubaneswar.

We are happy to inform you that AIIMS Bhubaneswar (Department of Microbiology and the Department of Community Medicine & Family Medicine), in collaboration with World Health Organization is conducting a cross-sectional study to assess the seroprevalence and risk factors of Melioidosis in Odisha. We have received necessary approval from the State Research and Ethics Committee, the Directorate of Health Services, (Letter No 12913/MS-2-IV-02-2022 Dated 29/05/23) in addition to approval from ethics committee of AIIMS Bhubaneswar and WHO.

From three revenue divisions of Odisha, six districts, i.e., Puri, Mayurbhanj, Sambalpur, Keonjhar, Kandhamal & Nabarangapur are randomly selected. The selected villages (as per the micro-plan attached herewith) will be paid a visit by our dedicated survey team for collection of blood sample for the proposed seroprevalence study.

In this regard, we kindly request your support for the execution of this study in data and sample collection and provide a space in the laboratory for the centrifugation and sample storage for 15 days in the District Headquarter Hospital or nearest Community Health Centers. The study findings will significantly contribute to public health approaches, including community education and strategies for reducing environmental exposure, ultimately leading to decrease in morbidity attributed to melioidosis.

Looking forward for your necessary support and cooperation.

Thanking you & Regards

Bijayini Behera.
Dr Bijayini Behera
Additional Professor
Dept. of Microbiology, AIIMS, Bhubaneswar

Dr. Bijayini Behera
Additional Profes
Department of Microl
AIIMS, Bhubane

Enclosure:

1. Approval letter of State Research and Ethics Committee, the Directorate of Health Services, Odisha.
2. Tentative micro-plan for field visit of survey team.

Copy to: DPMU, Kandhamal District for kind information and necessary support

OFFICE OF THE CHIEF DISTRICT MEDICAL &PUBLIC HEALTH OFFICER
District Surveillance Unit (IDSP)
Email Id: dsusambalpur@gmail.com, Tel # 0663-2403644,

Letter No 1302 /IDSP Date 09.11.2023

To,

The DMO(MS)-cum-Superintendent, DHH, Sambalpur.
The ADUPHO, Urban Health, Sambalpur.
The Superintendent, SDH Kuchinda
The /Superintendent/ BPHOs of CHC Laida/ CHC Debeipali/ CHC Themra / CHC Jujomura.
The Hospital Manager/ Microbiologist DHH, Sambalpur

Sub: To extend necessary support to the WHO-AIIMS Bhubaneswar Collaborative project entitles **"Population based seroprevalence study on Melioidosis in Odisha".**
Ref: AIIMS/BBSR/MB/BB/EMF/22-223, Date: 06/11/2023 from Additional Professor, Dept. of Microbiology, AIIMS Bhubaneswar.

Dear Sir/ Madam,

With reference to subject cited above I am to inform you that AIIMS- Bhubaneswar is going to carry out a Serological Survey to access the sero prevalence and risk factors of Melioidosis in Odisha among various age groups including children, general population and health care worker from 14th Nov. to 16th Nov. 2023 in our district. Therefore you are requested for giving support to team for smooth collection of Data & Sample provide space in lab for centrifugation & storage of Sample. Date and Place are for cluster sample collection attached in "Annexure A" for your reference.

This is for favour of your information and necessary action.

Yours Faithfully

9.11.23

Chief District Medical & Public health Officer, Sambalpur

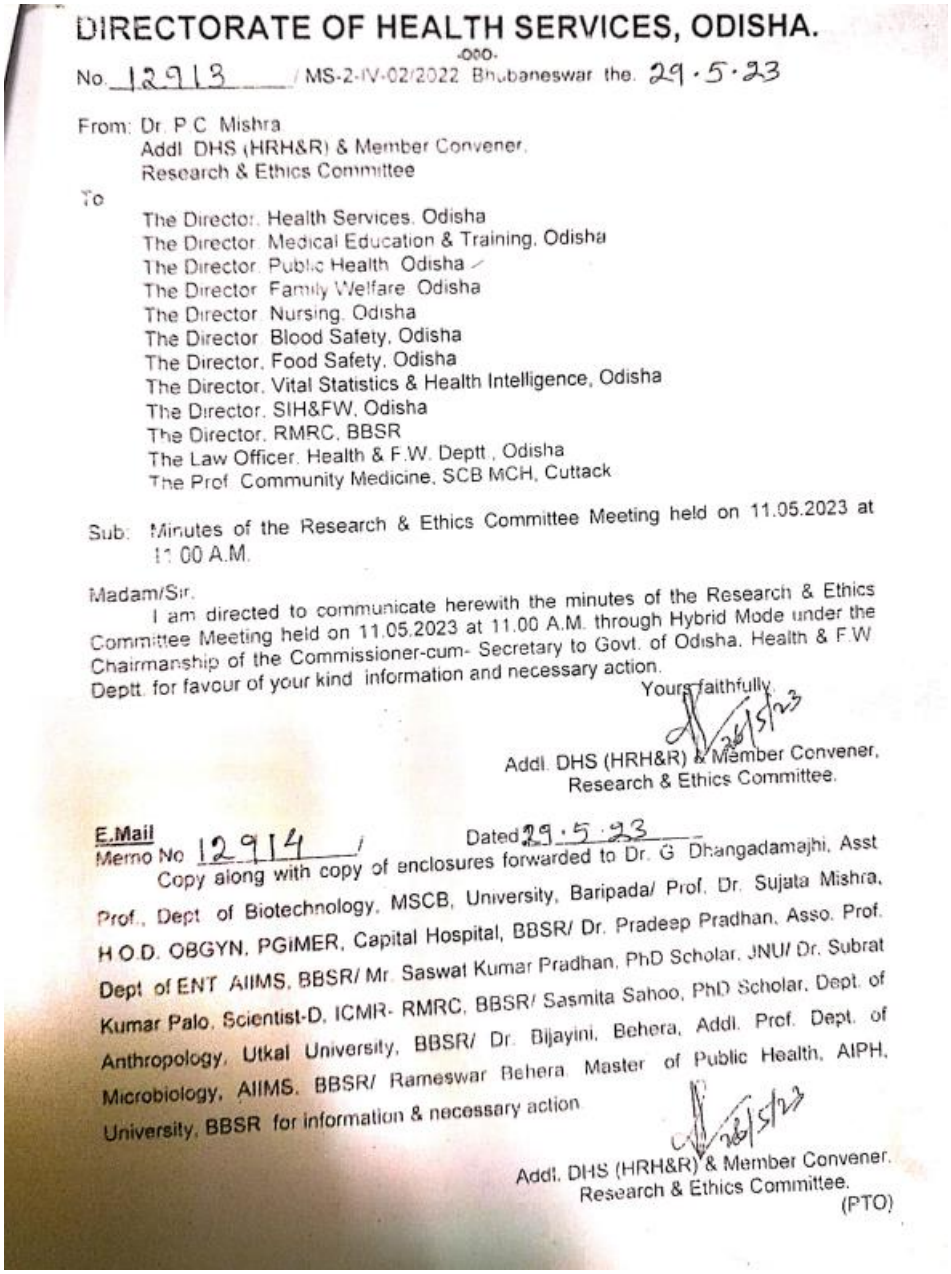
Memo No 1303 /IDSP Dated 09.11.2023

Copy forwaded to DPM, NHM Sambalpur for information and necessary action.
Copy submitted to DPH,Odisha for information.
Copy forwarded to AIIMS, Bhubaneswar for information & necessary action.

9.11.23

Chief District Medical and Public health Officer, Sambalpur

Annexure- IV



DIRECTORATE OF HEALTH SERVICES, ODISHA.

-000-

No. 12913 / MS-2-IV-02/2022 Bhubaneswar the. 29.5.23

From: Dr. P.C. Mishra
Addl. DHS (HRH&R) & Member Convener,
Research & Ethics Committee

To
The Director, Health Services, Odisha
The Director, Medical Education & Training, Odisha
The Director, Public Health, Odisha
The Director, Family Welfare, Odisha
The Director, Nursing, Odisha
The Director, Blood Safety, Odisha
The Director, Food Safety, Odisha
The Director, Vital Statistics & Health Intelligence, Odisha
The Director, SIH&FW, Odisha
The Director, RMRC, BBSR
The Law Officer, Health & F.W. Deptt., Odisha
The Prof. Community Medicine, SCB MCH, Cuttack

Sub: Minutes of the Research & Ethics Committee Meeting held on 11.05.2023 at 11.00 A.M.

Madam/Sir,

I am directed to communicate herewith the minutes of the Research & Ethics Committee Meeting held on 11.05.2023 at 11.00 A.M. through Hybrid Mode under the Chairmanship of the Commissioner-cum- Secretary to Govt. of Odisha, Health & F.W Deptt. for favour of your kind information and necessary action.

Yours faithfully,

26/5/23

Addl. DHS (HRH&R) & Member Convener,
Research & Ethics Committee.

E.Mail
Memo No. 12914 / Dated 29.5.23

Copy along with copy of enclosures forwarded to Dr. G. Dhangadamajhi, Asst Prof., Dept. of Biotechnology, MSCB, University, Baripada/ Prof. Dr. Sujata Mishra, H.O.D. OBGYN, PGIMER, Capital Hospital, BBSR/ Dr. Pradeep Pradhan, Asso. Prof. Dept. of ENT AIIMS, BBSR/ Mr. Saswat Kumar Pradhan, PhD Scholar, JNU/ Dr. Subrat Kumar Palo, Scientist-D, ICMR- RMRC, BBSR/ Sasmita Sahoo, PhD Scholar, Dept. of Anthropology, Utkal University, BBSR/ Dr. Bijayini, Behera, Addl. Prof. Dept. of Microbiology, AIIMS, BBSR/ Rameswar Behera, Master of Public Health, AIPH, University, BBSR for information & necessary action.

26/5/23

Addl. DHS (HRH&R) & Member Convener,
Research & Ethics Committee.

(PTO)

Memo No 12915 / Dated 29.5.23

Copy along with copy of enclosures forwarded to the Dean & Principal SCB Medical College, Cuttack/ Prof. & H.O.D. Community Medicine, SCB MCH, Cuttack/ Directors of Capital Hospital, Bhubaneswar and RGH, Rourkela/ All Chief District Medical & Public Health Officers of the State for information & necessary action.

26/5/23

Addl. DHS (HRH&R) & Member Convener,
Research & Ethics Committee.

Memo No 12916 / Dated 29.5.23

Copy along with copy of enclosures forwarded to the Special Secretary to Govt. of Odisha, Health & F.W. Deptt./ Special Secretary (MS)/ Special Secretary (PH) to Govt. in Health & F.W. Deptt. for kind information & necessary action.

26/5/23

Addl. DHS (HRH&R) & Member Convener,
Research & Ethics Committee.

Memo No 12917 / Dated 29.5.23

Copy along with copy of enclosures forwarded to the Mission Director, NHM, Odisha for kind information & necessary action.

26/5/23

Addl. DHS (HRH&R) & Member Convener,
Research & Ethics Committee.

Memo No 12918 / Dated 29.5.23

Copy along with copy of enclosures forwarded to Private Secretary to the Commissioner-cum- Secretary to Govt. of Odisha, Health & F.W. Deptt., for kind appraisal of the Commissioner-cum- Secretary, the Chairperson of Research & Ethics Committee.

26/5/23

Addl. DHS (HRH&R) & Member Convener,
Research & Ethics Committee.

Minutes of the Research & Ethics Committee Meeting held on 11.05.2023 at 11.00 A.M.

Venue- Through Hybrid Mode.

The Research & Ethics Committee Meeting was held on **11.05.2023 at 11.00.A.M** through virtual de under the Chairmanship of the Commissioner-cum- Secretary to Govt. of Odisha, Health & F.W. ptt.

The list of Members who joined in the meeting is attached at Annexure-I.

At the outset of the meeting, Additional Director (HRH & Research)-cum-Member Convener of esearch & Ethics Committee welcomed all the members and briefed the house on different proposals/study ports received. The representatives of different institutions who submitted the Research proposal/ study ports shared their topics through power point presentations followed by open discussions.

Sl. No	Research Proposals/ Dissemination Reports	Decision taken
01	Population structure of neglected malaria parasites(Plasmodium malariae and Plasmodium ovale) in Odisha and their impact on drug resistance - associated mutations in co-circulating P. falciparum/P.vivax. **Dr. G. Dhangadamajhi, Asst. Prof., Dept. of Biotechnology, MSCB, University, Baripada.**	• Approved • Study report should be shared with Health & F.W. Deptt., Govt. of Odisha • No portion of the study report should be published in any form or put into the Public domain without prior approval of the Govt.
02	WHO ACTION-III TRAIL: A multi-country, multi-center, three-arm, parallel group, double-blind, placebo-controlled, randomized trial of two doses of antenatal corticosteroids for women with a high probability of birth in the late preterm period in Hospital in low- resource countries to improve newborn outcomes. **Prof. Dr. Sujata Mishra, H.O.D. OBGYN, PGIMER, Capital Hospital, BBSR.**	• Approved • Study report should be shared with Health & F.W. Deptt., Govt. of Odisha • No portion of the report should be published in any form or put into the Public domain without prior approval of the Govt.
03	Screening of oral cancer using mobile phone-based (m-Health) versus Oral Visual Examination (OVE) In Rural Population in Odisha: A comparative study. **Dr. Pradeep Pradhan, Asso. Prof. Dept. of ENT, AIIMS, BBSR.**	• Approved only to go ahead for developing tool for competency assessment frame work. • Report should be shared with Health & F.W. Deptt., Govt. of Odisha • No portion of the report should be published in any form or put into the Public domain without prior approval of the Govt.
04	Immune status against SARS-CoV-2 among COVID-19 vaccinated adults In India: A health facility- based multicentric serial cross-sectional survey. **Dr. Subrat Kumar Palo, Scientist-D, ICMR- RMRC, BBSR.**	• Approved • Study report should be shared with Health & F.W. Deptt., Govt. of Odisha • No portion of the study report should be published in any form or put into the Public domain without prior approval of the Govt.
05	Study proposal "A Multi-centric, Prospective, Community - based Cohort Study to Estimate the Incidence of Dengue and Chikungunya Infection in India" Revised as Community	• Approved

	based Surveillance to estimate incidence and sero prevalence of Acute Febrile Illness with focus on Dengue and Chikungunya: A Prospective multicentric cohort Study. **Dr. Subrat Kumar Palo, Scientist-D, ICMR-RMRC, BBSR.**	• Study report should be shared with Health & F.W. Deptt., Govt. of Odisha • No portion of the study report should be published in any form or put into the Public domain without prior approval of the Govt.
06	Population based Seroprevalence study of Melioidosis in Odisha. **Dr. Bijayini, Behera, Addl. Prof. Dept. of Microbiology, AIIMS, BBSR.**	• Approved. • Study report should be shared with Health & F.W. Deptt., Govt. of Odisha • No. portion of the study report should be published in any form or put into the Public domain without prior approval of the Govt.
07	Community based Cross-sectional study on Risk assessment of diabetes among adults & understand patients experience living with diabetes in Ganjam district, Odisha. **Rameswar Behera, Master of Public Health, AIPH, University, BBSR.**	• Approved • Study report should be shared with Health & F.W. Deptt., Govt. of Odisha. • No portion of the study report should be published in any form or put into the Public domain without prior approval of the Govt.

The administrative approval is given to go ahead with the research project. Any logistic requirement, transpotatation and expenditure relating to Research shall be borne by the Researchers.

The meeting ended with vote of thanks to the chair and participants.

Commissioner-cum- Secretary, Health & F.W. Department,
Chairperson, Research & Ethics Committee

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