

**Title:** National snakebite project on capacity building of health system on prevention and management of snakebite envenoming including its complications in selected districts of Maharashtra and Odisha in India: a study protocol

### World Health Organization Trial Registration Data Set

Data Category	Information
Primary registry and trial identifying number	Clinical Trials Registry India no. CTRI/2021/11/038137
Date of registration in primary registry	18 November 2021
Secondary identifying numbers	NA
Source(s) of monetary or material support	Indian Council of Medical Research V. Ramalingaswami Bhawan, P.O. Box No. 4911 Ansari Nagar, New Delhi - 110029, India
Primary sponsor	Indian Council of Medical Research V. Ramalingaswami Bhawan, P.O. Box No. 4911 Ansari Nagar, New Delhi - 110029, India
Secondary sponsor(s)	NA
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Public title	Improving community awareness and capacity of healthcare providers for prevention and management of snakebite envenoming

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Scientific title	National snakebite project on capacity building of health system on prevention and management of snakebite envenoming including its complications in selected districts of Maharashtra and Odisha in India
Countries of recruitment	India
Health condition(s) or problem(s) studied	Snakebite Envenoming
Intervention(s)	<p>Community Intervention: Educational talks, IEC activities for increasing knowledge about snakes and snakebites and awareness regarding methods of preventing snakebites and early referral to health facilities. Engagement of local self-government institutions, teachers, Anganwadi, forest officials for promoting snakebite envenoming awareness among the community</p> <p>Health System Intervention: Periodic training of Medical Officers and other healthcare workers regarding implementation of the Standard Treatment Guidelines (2017) and notification of snakebite cases</p>
Key inclusion and exclusion criteria	<p>1. Focus Group Discussions Inclusion: Member of community above 18 years of age and willing to participate Exclusion: Healthcare providers</p> <p>2. Interview and training of Medical Officers (MO) and other Healthcare workers in the block All the Medical Officers and ASHA, ANM and MPW in the study blocks will be eligible</p> <p>3. Facility Survey All the Primary Health Centers, Rural Hospitals, Community Health Centers, Sub District Hospitals and District Hospitals in the selected blocks will be included. Sub centers will be excluded.</p>
Study type	<p>Type of study: Interventional Study Design: Exploratory study with Retrospective, Prospective, Cross Sectional and Qualitative component conducted in community and hospital setting.</p>
Date of first enrolment	Enrolment yet to begin
Target sample size	1. A total of 6 FGDs (3 males, 3 females) will be conducted in each block. Each FGD will be restricted to 8 to 16 participants. Overall, 24 FGDs will be

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	<p>conducted but the number of FGDs will vary according to the saturation of responses.</p> <p>2. Each block will have approximately 40 Medical Officers (MOs); so nearly 160 MOs will be trained during the study. Training will also be provided to outreach healthcare workers. Approximately 150 workers per block will be trained so a total of 600 workers will be trained in four blocks. Actual numbers will vary and the same MOs or healthcare workers may not be available throughout the study duration as there are frequent transfers in the health system.</p> <p>3. FGDs will be conducted in the study areas to evaluate the post-intervention community knowledge with similar methodology as described in point no. 1</p>
Recruitment status	Pending: participants are not being recruited or enrolled at any site
Primary outcome(s)	<p>Outcome Name: Case fatality rate</p> <p>Method of measurement: Prospective data collection at public health facilities in the block followed by comparison of collected data with retrospective data of the last two years before study initiation</p> <p>Time point: Two years from the start of the study</p>
Key secondary outcomes	<p>1. Outcome Name: Incidence of snakebite cases</p> <p>Method of measurement: Prospective data collection at public health facilities in the block followed by comparison of collected data with retrospective data of the last two years</p> <p>Time point: Two years from the start of the study</p> <p>2. Outcome Name: Incidence of complications due to snakebite envenoming</p> <p>Method of measurement: Prospective data collection at public health facilities in the block followed by comparison of collected data with retrospective data of the last two years</p> <p>Time point: Two years from the start of the study</p> <p>3. Outcome Name: Implementation of the Standard Treatment Guidelines, 2017 for the management of snakebite envenoming</p> <p>Method of measurement: Facility check surveys, periodic supervisory visits by Master trainers and subject experts</p> <p>Time point: 12 months in the study onwards</p>

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Ethics Review	<p>Ethics approval was obtained from the Institutional Ethics committee of ICMR- NIRRH (Ref. No. D/ICEC/Sci-194/209/2021) and ICMR-RMRCB (ICMR-RMRCB/IHEC-2021/79). The study is registered under the Clinical Trial Registry India, registration number - CTRI/2021/11/038137.</p> <p>Ethics committee contact –            Dr. Beena Joshi            NIRRH Ethics Committee for Clinical Studies            National Institute for Research in Reproductive and Child Health            J.M.Street, Parel. Mumbai 400 012            Tel.No.: Direct- 022-24192043 / 022-24192147            Board no.- 022-24192000            Email : <a href="mailto:nirrh.cliethics@gmail.com">nirrh.cliethics@gmail.com</a>, <a href="mailto:ieccr@nirrh.res.in">ieccr@nirrh.res.in</a></p>
Completion date	NA
Summary Results	NA
IPD sharing statement	The deidentified individual clinical trial participant-level data will not be shared. PI will have ultimate authority over datasets and access.

Data Set Source – World Health Organization Trial Registration Data Set (Version 1.3.1).  
<https://www.who.int/clinical-trials-registry-platform/network/who-data-set>. Accessed February 02, 2022.