

Chapter - 2 Methodology

2.1 Survey Design

The present survey adapted the same methodology (multistage cluster random sampling method) used in the National NCD Monitoring Survey (NNMS) – 2017 – 18 [5], with necessary modifications adopted for the unique cancer profile in the 12 PBCR covering areas in eight states of the NER

2.2 Study Population

The target population for the survey was defined as all residents aged 18 or above residing in their usual residence. The institutional population comprising those living in collective places like students' dormitories, hospitals, hotels, prisons, military barracks, etc., were included in the survey.

2.3 Sample size

The sample size for the survey was worked out to obtain reliable estimates for cancer risk factors related to adults in Population Based Cancer Registry (PBCR) covering areas. The sample size was estimated by considering the objectives of estimating the prevalence of behavioural risk factors for cancer and other NCDs (including tobacco use, alcohol consumption, and physical inactivity). The prevalence of tobacco use is 28.6% (GATS – 2), alcohol use is 17.1% at age >18 years (Magnitude of Substance abuse in India), and 54.5% are insufficiently engaged in physical activity (ICMR-INDIAB study). The proportion of the population burdened with NCDs and associated risk factors also vary across different parts of the country. The prevalence of alcohol use of 17% approximately and underlying assumptions of relative precision amounting to 15% of prevalence, design effect of 1.5, and non-response rate of 10% formed the basis for determining the sample size by gender in each state. The calculated sample size was estimated to be 23,040. The sample size was 2880 for those states with 100% coverage by the PBCR. For other PBCR areas, the sample size was adjusted according to coverage by PBCR as shown in the Table below:

Table 2.3.1 Sample size charting for the survey according to PBCR coverage area

Table 1: Sample size and number of PSU per study site									
SI No	Registry Name	State Name	State Total Population	State Total Population (Age 18+)	Total Population (Age 18+) covering PBCR by State wise	Total Population of Study site (as per census 2011)- (Age 18+)	% Of under PBCR covering area	Total sample size per Study Site (Approximately)	Total PSUs(48 HH per PSU)
	Sikkim - PBCR	Sikkim	610577	403569	403569	403569	100	2880	60
	Tripura - PBCR	Tripura	3673917	2444294	2444294	2444294	100	2880	60
	Mizoram - PBCR	Mizoram	1097206	674279	674279	674279	100	2880	60
	Manipur - PBCR	Manipur	2855794	1814488	1814488	1814488	100	2880	60
	Naharlagun - PBCR	Arunachal Pradesh (8 Districts)				434610	84.3	2400	50
	Pasighat - PBCR	Arunachal Pradesh (2 Districts)	13,83,727	792662	515541	80931	15.7	480	10
	Cachar - PBCR	Assam (Cachar District)				1073847	11.8	384	8
	Kamrup District and Kamrup Metropolitan - PBCR	Assam (2 Districts)	3,12,05,576	19109031	9087202	1862323	20.5	576	12
	Dibrugarh - Upper Assam PBCR	Assam (7 Districts)				4929169	54.2	1536	32
	Karimganj - PBCR	Assam (3 Districts)				1221863	13.4	384	8
	Meghalaya - PBCR	Meghalaya (4 Districts)	29,66,889	1580947	978370	978370	100.0	2880	60
	Nagaland - PBCR	Nagaland (2 Districts)	19,78,502	1156723	398456	398456	100.0	2880	60
								23040	480

2.4 Data Collection Tools

The study tools used for different levels included (i) Household (ii) Adult (iii) Adult with cancer and (iv) Health facility (PHC or urban equivalent, CHC/ District Hospital and private facilities). These instruments were adapted from the National NCD Monitoring Survey (NNMS) to suit survey objectives. Standard references were used to define the data variables [15,20,21].

2.5 Survey Period

The survey was conducted in a phased manner between November 2019 and April 2021. A fourteen months period was allocated to each implementing PBCR, which included delays due to the COVID 19 pandemic.

2.6 Governance of Survey

The survey implementation was under the supervision, coordination and monitoring of the Central Coordinating Agency (CCA) at ICMR - National Centre for Disease Informatics & Research (NCDIR), Bengaluru.

The CCA provided all technical and scientific assistance for the survey at all stages. It was responsible for overall coordination, monitoring, quality assurance, data maintenance, cleaning, analysis and report writing with the technical support from its partners. A team of experts were identified for survey supervision, monitoring and scientific guidance.

For the states of Arunachal Pradesh and Assam with multiple PBCRs, one of the PBCRs was selected as an implementing agency, with the other PBCRs' designated as 'collaborators'. A total of 9 implementing agencies and three collaborators were identified. The details have been provided in **Annexure 2**.

2.7 Quality Assurance and Training

The quality control measures were followed to standardise the survey at all stages and all levels of governance. This included preparing training materials, undertaking training, calibration and standardisation of equipment, data collection tools, field data collection and storage, handling blood samples and safe disposal mechanisms of the generated biomedical waste. A dashboard was created to monitor the live status of data collection and troubleshooting, or any queries or issues faced at the time of the field was solved through FAQ's and virtual calls.

All Principal Investigators (PI) and Co-Principal Investigators (Co-PI) from every PBCR were trained in all survey procedures as part of the CCA's two-day Training of Trainers program. A classroom-based training, demonstrations, hands-on and mock field drills were undertaken for the research team during the 3-day training program.

2.8 Data Management and Analysis

The field team used the handheld devices loaded with the software application for data collection and entered the field itself. Provision of keeping back up of data in SD cards in the handheld was also present. The data from the handheld devices were uploaded/ synced to the Central server at ICMR-NCDIR.

The data from all districts were compiled and cleaned, following which weighting procedures were followed for adjusting for sampling and population proportions and response rates. The detailed statistical analysis plan was prepared based on the identified indicators and subgroups. The data analysis was done using STATA 14.1 with prior developed analysis commands by complex survey analysis. The survey results have been presented by descriptive statistics with means and proportions with 95% confidence intervals (CIs) as a measure of precision on the estimated population parameters.

2.9 Ethical Considerations

The survey received ethical clearance from the Ethics review committee of the CCA, ICMR – NCDIR (NCDIR/IEC/2017/2). All participating PBCRs' also obtained approvals from their respective Ethics Committees. In addition, all participating centres informed the local authorities, citizen groups, community representatives and sought their support. During the COVID 19 pandemic, all instructions related to COVID 19 protocol were put in place from time to time and adhered to. All field staff and investigators with the necessary protective wear and instructed to follow COVID 19 appropriate behaviour.