CHAPTER 2:

METHODOLOGY AND DATA COLLECTION

2.1 TARGET STUDY POPULATION

Geographically, the country was divided into six zones mainly north, south, east, west, central and north-east zone. The target study population for National NCD Monitoring Survey (NNMS) – 2017-18 was the entire adult population between age 18-69 years and adolescent population aged 15-17 years which includes both gender, and those living in the urban and rural areas of the country.

2.2 SAMPLE SIZE AND DESIGN

2.2.1 Study design

The National NCD Monitoring Survey (NNMS) was a cross-sectional survey, conducted during the period 2017–18. Multistage cluster sampling design was adopted to cover an age range of 15-69 years. Since the information for NCD indicators was to be obtained separately for adults and adolescents as listed in the *table 1.1.2*, the required sample size was calculated independently for each of the target group of adult and adolescent population. Of the twenty-one indicators for NCDs, ten indicators are related to adults (Indicators 1-4, 6, 7, 9-11, 14), three indicators for adolescents (5, 8, 12), one indicator (13) for household level; and rest of the indicators (15-21) are associated with health system responses *(Table 1.1.2).* Out of the 21 indicators, eight indicators pertaining to adults; three indicators for adolescents, one indicator for household level and five indicators related to the response of national systems were estimated for the NNMS – 2017-18. The remaining would be ascertained from other reliable sources.

2.2.2 Determination of sample size

The target study population was divided into four subgroups (urban and rural, men and women) (2 x 2 = 4). Accordingly, the sample size determined for one subgroup was inflated four times to get the required sample size for the target population of adults and adolescents separately.

For sample size estimation of adults and adolescents, the prevalence of a few key NCD indicators was derived from IDSP-NCD risk factors survey (2008-09) report assuming no appreciable changes. These included tobacco and alcohol use, obesity, physical activity; among these, the expected prevalence of obesity was observed to be comparatively low among adults and adolescents. Hence, the prevalence of obesity was taken, to arrive at sample size estimates for the National NCD Monitoring Survey – 2017-18.

Prevalence of obesity (9% among adults and 6% in adolescents), the relative precision of 15% for adults and 50% for adolescents, a non-response rate of 15% and a design effect of 1.5, the required sample size for estimating the NCD indicators for four strata for the NNMS was calculated as 12000 adults (18-69 years) and 1700 adolescents (15-17 years). One adult was selected from each household, i.e. 12000 households were required for the survey.

The proportion of the adolescent population from Census 2011 is 10 to 15%. Assuming 12% of adolescents would be available in the selected households of 12000 for adults, the expected sample size for adolescents

to be recruited was 1440, assuming if one adolescent was selected from each household. However, we included all the adolescents who were available at the selected households to reach the required sample size.

The survey had fixed the same sampling frame for adult and adolescent. The selection of adult was restricted to only one for each household, using the KISH method developed in Computer-Assisted Personal Interviewing (CAPI). Considering that the prevalence of some indicators (like smoking and use of alcohol among females may be lower) at the subgroup level were lower than 7%, the sample size computed would be optimum for arriving at reliable estimates. Further not affecting the overall operational cost of the survey. This sample size was also considered to be adequate to capture sufficient number of diagnosed cases of hypertension/myocardial infarction/angina/stroke/diabetes among the targeted adult population i.e. proportion of those who received drug therapy and counselling.

As this was the first time in the country that urinary sodium was being estimated at national level, it was done in a subsample of 3000 adults (18-69 years), which was 25% of the overall sample size.

The health facility survey was also conducted simultaneously. According to the National NCD framework, the target set for availability with essential medicines and technologies is 80%. Based on this set 80% target and assuming 50% and 15% of relative precision, a sample size of 302 was estimated for the health facility survey. There were four strata – rural/urban and private/public facilities. Thus, a sample of 300 was considered for each strata totalling to 1200 in all the four strata (urban/rural and public and private). Even though the indicator was related to primary level health facilities, keeping in view with the NPCDCS strategy, the level of facilities was expanded to include community health centres (CHCs) and district hospitals (DHs). However, for private facilities only the primary care facilities were surveyed.

2.2.3 Allocation of sample size

The national representative sample size of 12000 households was equally allocated to both the urban and rural areas, i.e. 6000 households for each. The PSUs for rural area was a village or group of villages and it was Census Enumeration Block (CEB) or ward for the urban areas. By selecting a total of 600 PSUs (300 from urban and 300 from rural) and 20 households from each PSU, the desired number of samples of 12000 households was made available for national survey.

2.2.4 Sampling frame

The national level sampling frame of PSUs for rural and urban areas were prepared using the standard procedure. At first stage, a sampling frame of all the districts with geographic contiguity was prepared and divided into 60 groups of districts with more or less equal population size using the 2011 census data. Within each of the 60 groups, the PSUs (i.e. villages for rural and wards for urban) were arranged in an ascending and descending order alternatively (implicit stratification) based on female literacy rates and proportion of agriculture workers. Thereafter, the rural and urban PSUs listed within each district of 60 groups were separated for preparing the rural and urban frame of PSUs/wards (urban).

2.2.5 Selection of PSUs and households

The 300 PSUs from rural sampling frame and 300 wards from urban sampling frame were selected using probability proportional to population size (PPS) method. The PSUs were villages in rural areas and CEBs in urban areas.

In every village/CEB selected, a mapping and household listing operation was carried out. The census location map was used to identify all the boundaries of the selected sampling unit [village or CEB] correctly. Assistance from the local authorities was obtained for identifying those new boundaries for those sampling units, whose boundaries had changed (2011 census location map). A boundary map was prepared using standard mapping symbols in the provided forms.

The household listing involved preparing up-to-date national and layout sketch maps, assigning numbers to structures, recording addresses or the location of the structures and identifying residential structures in the selected villages.

The rural sample of households was selected in two stages: the selection of PSUs, which were villages were selected with PPS at the first stage, followed by the random selection of households within each PSUs at second stage using circular systematic sampling (done at the time of survey). In case, the village size was too big (>400 households) the village was segmented into multiple zones and two zones were selected by PPS for household listing. *(Figure 2.2.5.1a)*

In urban areas, a three-stage procedure was followed: In the first stage, wards were selected with PPS sampling. In the second stage, one CEB was selected randomly. In the final stage, the households were randomly selected within each CEB using the circular systematic sampling procedure at the time of the survey. *(Figure 2.2.5.1b)*

From each selected PSU, 20 households were selected after house listing. The procedure of house listing is described in detail in the *section 2.3, Field survey procedure.*

2.2.6 Selection of individual at household level

From each of the selected household, all adolescents in the age group of 15-17 years were included in the survey, if available; and one adult was selected from the age group 18-69 years using the KISH method.

The KISH method used was representative of all the age groups and gender. The grid assigned an equal probability of selection for each possible survey participant, thus addressing the selection bias. The probability of selection against the very young or very old was overcome by assigning numbers to each member of the household, based on their age. The age of an individual was recorded as completed age in years on the day of survey. The grid had a column for each household that was visited and a row for the number of eligible people within the household visited. All the eligible members of the household were labelled in order of increasing age, to give the youngest member a slightly greater chance of being chosen,

since it was difficult to track down younger adults at home. The KISH method [STEP wise approach to surveillance (STEPS)-WHO]** has been described in detail with an example in *annexure 01*.

The description of KISH methodology of selection of one individual at household level was provided as an alternative if the CAPI was not having a program or not being used due to any reason.

The three-level stratification and sampling frame in rural and urban areas are given in *Figure 2.2.5.1a and b*.

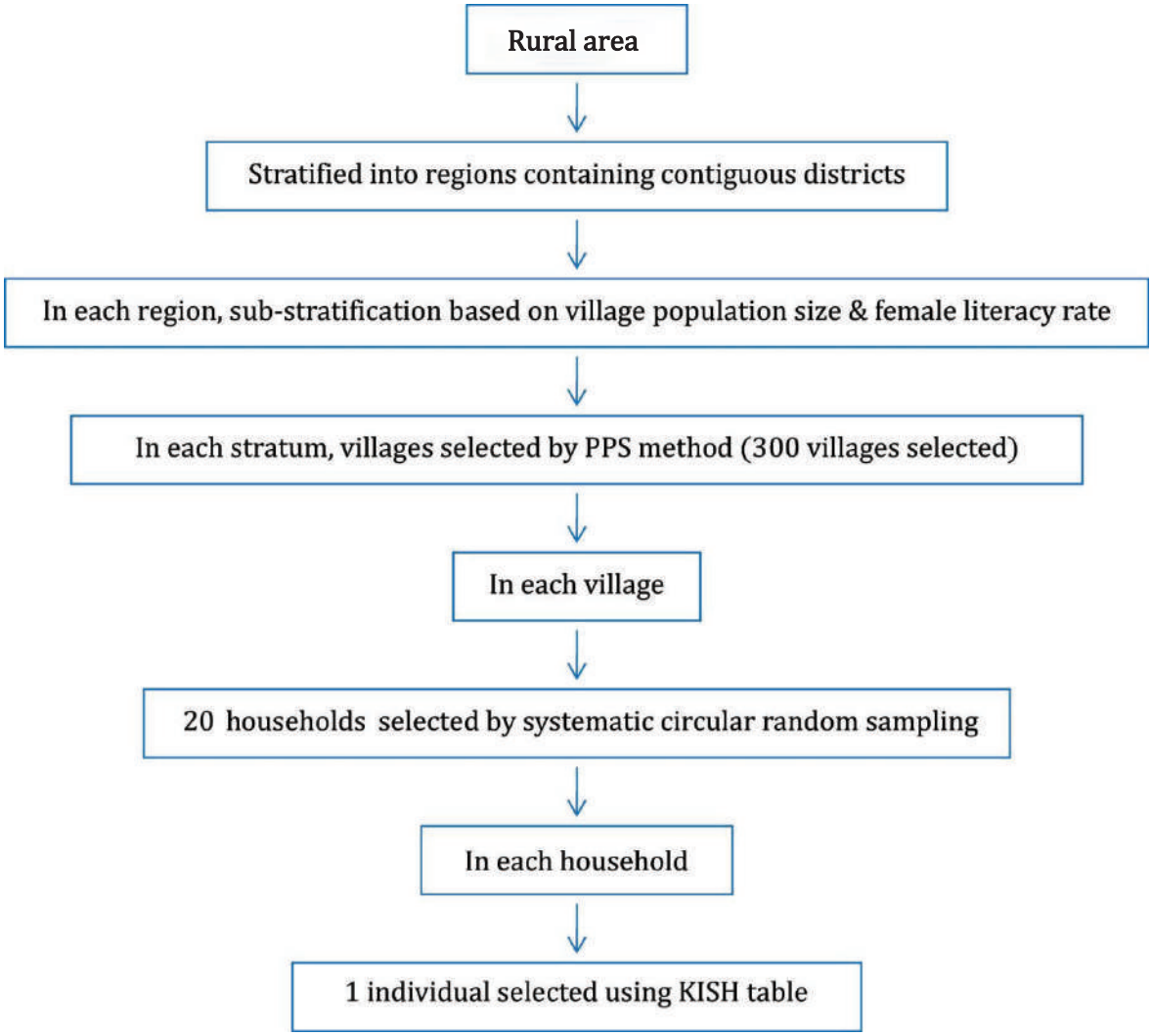


Figure 2.2.5.1a NNMS sampling design in rural areas

**Monitoring and surveillance of noncommunicable diseases, STEPwise approach to surveillance (STEPS) [Internet]. World Health Organization [cited 7 June 2018]. Available from: https://www.who.int/ncds/surveillance/steps/en/

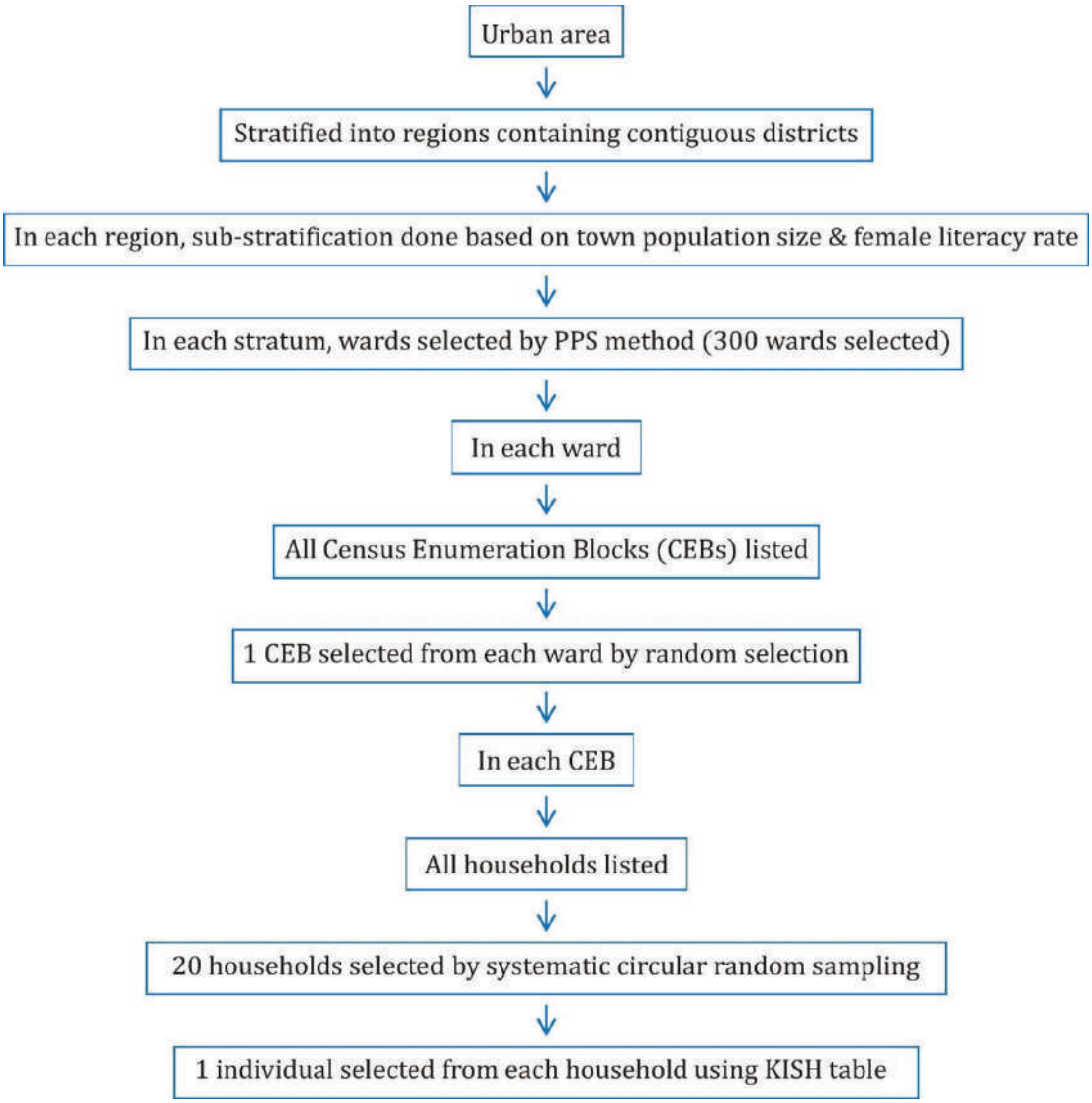


Figure 2.2.5.1b NNMS sampling design in urban areas

2.2.7 Sampling of health facility

Four types of health facilities (three public and one private) were identified for inclusion in the health facility survey based on the operational feasibility. A private primary health care facility was defined as one which has inpatient facility (not necessarily for NCDs) but has between 5-30 beds. A list of primary private health facilities in the nearby areas preferably within 5 or 10 Km range of selected PSUs was prepared. Specialized facilities like that of maternity, paediatric or orthopaedics were not included in the list. From the list of private health facilities, one each was selected randomly for health facility survey. For public primary care and secondary health care facilities (CHCs and DHs) survey, the facilities within the selected cluster were included (if 2 clusters fell in the same district, only one common DH was included).

2.3 FIELD SURVEY PROCEDURE

The field survey procedure included preparation of uniform guidelines and procedures, and the same were followed by the field teams while conducting the survey in the selected list of rural and urban PSUs.

Each survey team collected the name of PSU with state, district and block/sub-districts (with codes). Mapping and listing included preparation of a list of all households residing in the selected PSUs to ensure coverage of all households in the selected PSU. The prepared household listing information was used for selection of the 20 households as per the selected PSU. The same information was also utilized for developing sampling weights during analysis.

2.3.1 Locating the primary sampling units

The coordinator provided the listing team with a location map of the village and/or urban ward or block containing the selected PSU assigned to the team. The PSU was identified by a PSU number with three-digit PSU code and also the code corresponding to the census village. Upon arrival in the area, the team used the census location map to identify all the boundaries of the selected PSU. There were recognizable natural features such as streams or lakes, and other features such as roads or railroads. However, if the boundaries of the PSU had changed, the team obtained assistance from local authorities or people living in the vicinity to identify the boundaries.

Before doing the listing, the panchayat leaders briefed to get an idea of the layout of the village, and the team toured the PSU to determine an efficient route of travel for listing all the structures. The PSUs were divided into sections (if possible) and a section could be a block of structures. This was useful to make a rough sketch map of the PSU indicating the boundaries of the sections, as well as the relative location of landmarks, public buildings - such as schools, temples, markets and main roads. This rough sketch served as guide for the team before they began the survey work.

2.3.2 Mapping and household listing

The objective of mapping and listing was to ensure that all households in the PSUs were included in the sampling frame. PSU boundaries were identified, location and layout maps were prepared, all structures within the area were numbered and a complete list of dwellings and households was prepared. *(Annexure 02)*. A household was defined as group of persons who lived together and shared same kitchen. All institutions, commercial establishments and hostels were excluded from the sampling frame.

The listing operation consisted of visiting each selected PSU/CEB, recording on listing forms a description of every structure together with the names of the heads of the households found in the structure and drawing a location map as well as the layout map of the structures in the PSUs.

2.4 SURVEY PREPARATION

2.4.1 Survey preparation and management

All study tools and procedures were pilot tested at four sites in collaboration with WHO-country office for India, All India Institute of Medical Sciences (AIIMS) New Delhi, AIIMS Jodhpur, AIIMS Bhubaneshwar and ICMR-NIE Chennai. Lessons learnt during piloting were incorporated in the form of changes in questionnaire wordings and changes in operational plan. Piloting also helped to revamp the field staff training plan.

In the absence of previous information on the urinary sodium excretion levels at population level, a pilot was also done to assess the validity of known equations (Kawasaki, Tanaka and INTERSALT) for estimation of urinary sodium excretion using both spot urine samples as well as 24-hr urine sample in the same individual.

The survey was implemented, coordinated and monitored by the central coordinating unit (CCU) at ICMR-National Centre for Disease Informatics & Research (NCDIR), Bengaluru. The technical working group (TWG) on National NCD Surveillance guided the overall conduct and supervised the survey in a timely manner. The country was divided into 10 contiguous zones each with approximately 60 survey clusters.

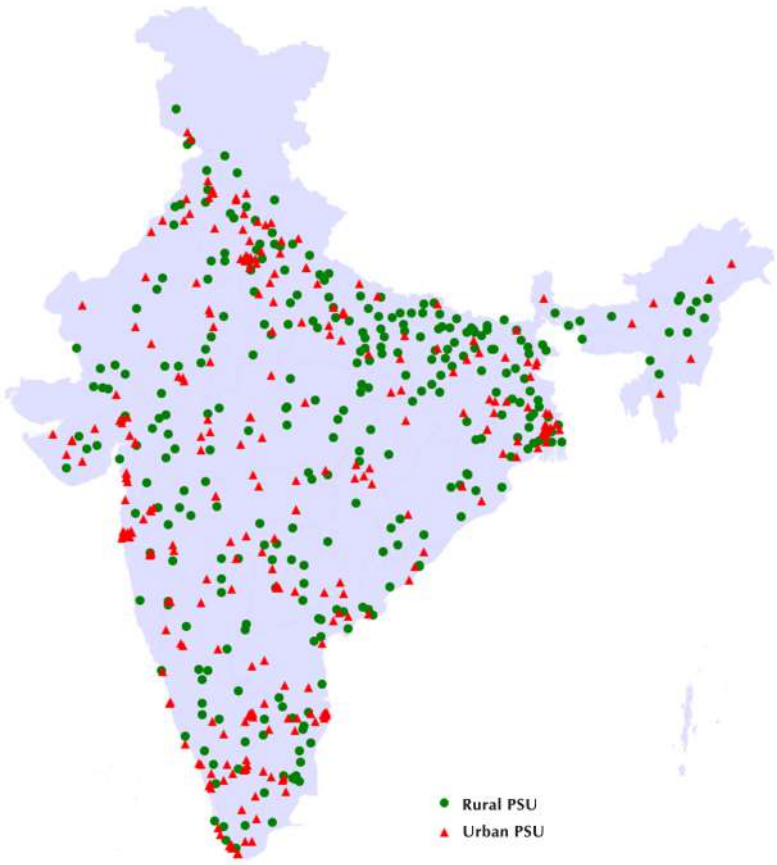


Figure 2.4.1.1a Geographical distribution of PSUs under NNMS - 2017-18

A total of 10 implementing agencies were identified by the CCU to carry out the survey, one for each zone *(Table 2.4.1.1)*. The team of each implementing agency was led by a Principal Investigator (PI) and at least one co-investigator with prior field survey experience. Agencies conducting the survey in more than one state, included one or more collaborating investigators in states outside their place to provide support for local language issues and facilitate logistics. The *figure 2.4.1.1a* depicts the coverage of PSUs, *figure 2.4.1.1b* shows the coverage of PSUs for urinary sample for sodium estimation and *figure 2.4.1.1c* depicts the coverage of health facilities for the NNMS – 2017–18.

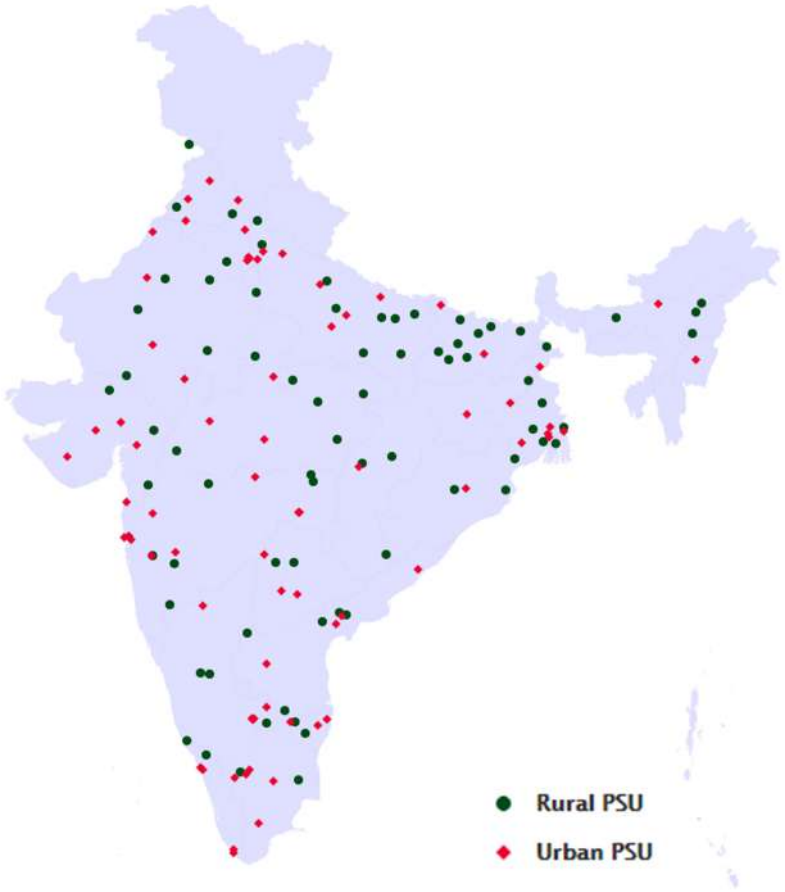


Figure 2.4.1.1b Geographical distribution of PSUs for urinary sample under NNMS - 2017-18

Table 2.4.1.1 List of survey implementing agencies, allotted states and number of PSUs covered for NNMS - 2017-18

Agency Name	List of allotted States	Urban	Rural	Total
All India Institute of Medical Sciences, New Delhi*	• Uttar Pradesh	29	46	75
National Centre for Disease Control, New Delhi	• Jammu & Kashmir • Himachal Pradesh • Punjab • Haryana • Chandigarh • Delhi NCR • Uttarakhand	33	19	52
All India Institute of Medical Sciences, Jodhpur	• Gujarat • Rajasthan	33	30	63
All India Institute of Medical Sciences, Bhopal	• Madhya Pradesh • Chhattisgarh • Jharkhand	26	35	61
Assam Medical College, Dibrugarh	• West Bengal • Sikkim • Assam • Nagaland • Mizoram • Manipur	31	38	69
All India Institute of Medical Sciences, Bhubaneshwar	• Orissa • Bihar	13	44	57
Byramjee Jeejeebhoy Medical College, Pune	• Maharashtra	41	23	64
ICMR-National Institute of Nutrition, Hyderabad	• Andhra Pradesh • Telangana	25	26	51
Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram	• Karnataka • Kerala	35	22	57
ICMR-National Institute of Epidemiology, Chennai	• Tamil Nadu	34	17	51
	Total	**300**	**300**	**600**

*Also acted as the reference laboratory for urinary Sodium, Potassium and Creatinine testing

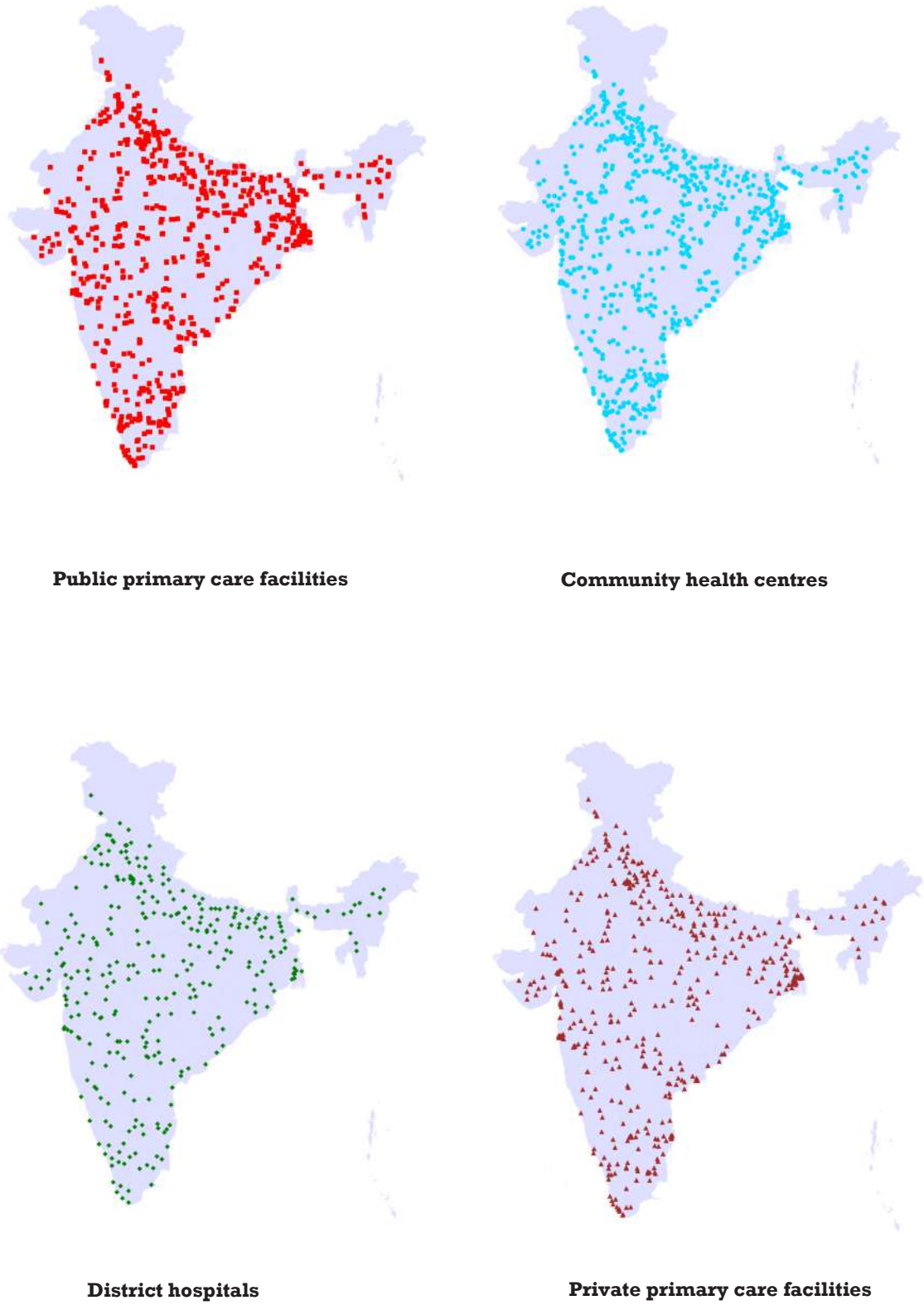


Figure 2.4.1.1c Geographical distribution of health facilities under NNMS – 2017-18

Official approvals were obtained from the MoHFW, Government of India. Health officials of selected states and districts were involved at all stages. CCU made all necessary official communications with principal secretaries of State health departments. They in turn, informed the concerned Chief Medical Officers/Chief

Medical and Health Officers/Civil Surgeons and district health officials for providing necessary support to the survey. An official letter by Principal Investigator (PI) of the State was also issued to the survey team for establishing their identity and obtaining local support. The team met community leaders before the survey and sought their concurrence. The survey team informed concerned village and ward authorities through issued official letters and documents.

2.4.2 Ethical approval

The survey received ethical clearance from the "Ethics review committee" of the CCU, ICMR-NCDIR. All other participating implementing agencies obtained approval from their respective institutional ethics committees.

The survey identified concerns that would require the highest level of ethical standards. These included:

1. Obtaining written informed consent from the study participants and in case of adolescents, their assent as well as their parents/guardian's consent was to be attained.
2. Concerns related to urine and blood sample collection and physical measurements especially weight and waist circumference.
3. Approvals and co-operation from the health officials and community leaders.
4. Maintaining data confidentiality and privacy.
5. Communicating health findings with the participants after the interview and referral to a nearby public health facility for further evaluation and management.

The CCU and each state implementing agency addressed to these concerns at every level.

Confidentiality

All the survey staff were trained in ethical procedures to protect confidentiality during data collection, no sharing of collected information and respondent referral. It was ensured that all the data collected through the hand-held devices were secured through a password-protected mechanism.

Informed consent

All the individual respondents were clearly explained and briefed about the survey objectives and details on the information to be captured as part of the survey. The participants were ensured regarding the confidentiality of the data collected and clarified that their participation was voluntary. Following their verbal consent to participate, a written informed consent was sought from each of the selected respondent. In case of an adolescent, the approvals and consent were obtained from their parents/guardians. An assent from the adolescent was obtained before data collection. Separate participant anthropometry and blood sugar reporting forms were used to obtain consent for the physical and biochemical measurements.

Protection of human participants

The survey teams were well trained in aseptic measures of sample collection and waste management. Highest level of standards during biochemical specimen collection was ensured by sterile aseptic procedures, to protect both the respondents and the survey staff. The risk of participation for all the

respondents was minimal, limited mostly to temporary discomfort associated with the finger prick blood collection process.

As a part of the survey, brief health promotion materials on NCDs and their associated risk factors were given to all the respondents following the interview. Those identified for referral were directed to the nearest public health care facility for further evaluation using a referral form/card. Every implementing agency maintained a recorded documentary of the referrals. Strict confidentiality towards circulation of results was maintained.

2.4.3 Training

The survey implementation was done under the supervision, coordination and monitoring of the CCU at ICMR-NCDIR, Bengaluru.

- **Training of Trainers (TOT)**: A four-day TOT was held for 2 investigators from each institution (total of about 20 investigators) which constituted the Principal Investigators (PIs)/Co-PIs/Collaborators from the Implementing agencies. The training was held between 26th July 2017 and 29th July 2017 in New Delhi.
- **Regional training of field teams**: Field teams underwent a five-day training including training in mapping and listing, data collection, measurement and data entry in handheld devices. It included a field visit and a pilot run of field work. The two investigators already trained were supported by the central team for the zonal trainings which were conducted for two institutions jointly (about 24 people). These were held in the respective zones. The trainings were conducted during August and September 2017.
- **Retraining:** Retraining of survey staff was conducted on survey methods and procedures after two months of the initiation of field activities. This was to refresh the knowledge of team members regarding survey methods, interview procedures and anthropometric measurements. This was also essential to clarify issues faced by them on the field.
- CCU conducted several sessions of online trainings with the staff of implementing agencies.

2.5 SURVEY INSTRUMENTS

2.5.1 Survey questionnaires

The NNMS 2017-18 used questionnaires at the household level, individual-adolescent, individual-adult, adult biochemical measurement, public primary care and secondary health care (CHCs and DHs) facilities and private health facility (primary care level). These instruments were adapted from WHO-STEPS and WHO-Service Availability and Readiness Assessment (SARA), WHO- Global School Student Health Survey (GSHS), Global Adult Tobacco Survey (GATS), Global Youth Tobacco Survey (GYTS) tools for Indian context and IDSP-NCD risk factor survey tools. The tools were pilot tested to suit the requirements of the National NCD monitoring framework.

Measurements

The household form captured details on housing type, type of toilet facility, source of drinking water, fuel used for cooking, type of cooking oil used and details on ration card.

The individual questionnaires for adults and adolescents included questions on socio-demographic factors and the following:

1. **Behavioural risk factors:** Through a face-to-face interview, questions and show cards were used to capture details for tobacco and alcohol use, details on diet and physical activity among adults and adolescents.
2. **Health seeking behaviours and management indicators (only adults)**: Participants were questioned about their history of raised blood pressure, raised blood glucose, raised cholesterol, history of CVDs including cerebrovascular accidents and details on cancer screening for cancer of breast, cervix and oral cavity.
3. **Physical measurements**: Height and weight were measured for both adults and adolescents, while waist circumference and blood pressure were measured only for adults.
4. **Biochemical analysis (only adults):** Fasting blood glucose (dry chemistry – strip method) and urinary sodium excretion in spot urine samples.
5. **Health system responses of public and private health facilities**: For availability of human resources, technologies, medicines and services being provided related to NCDs.

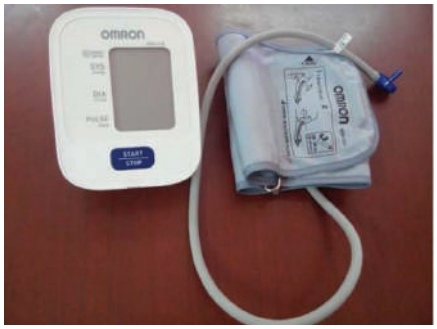
2.5.2 Physical measurements

The physical measurements included assessment of height, weight, waist circumference (WC) and blood pressure. The height *(Stadiometer, SECA 213, Seca Gmbh Co, Hamburg, Germany)*, weight (*Weighing machine, SECA 803, Seca Gmbh Co, Hamburg, Germany)* and WC *(Measuring tape, SECA 201, Seca Gmbh Co, Hamburg, Germany)* were measured using standard procedures to calculate BMI and central obesity. Blood pressure was measured after ensuring a rested phase of 10 minutes using standard automatic blood pressure machine *(OMROM HEM–7120, Omron corporation, Kyoto, Japan).* Second and third readings were obtained after 3 minutes resting interval between the readings. After discarding first reading, the mean of the second and third measurements of blood pressure were used for analysis.

Stadiometer

Weighing machine

Measuring tape



Automatic blood pressure machine

2.5.3 Biochemical estimation

The biochemical estimation was done only for adults and it included measurement of fasting blood glucose and the urinary sodium in spot urine samples. Bio-specimens were collected from adults through a camp-based approach and the participants were given appointment slips on a day prior to the camp along with instructions for fasting and for providing spot urine samples (in selected clusters only).

The estimation of fasting blood sugar (dry method) was done under aseptic conditions following all biosafety precautions of handling of bio-specimen and disposal of waste in the field. One place in the cluster was identified based on operational feasibility. All participants were called to that facility in a fasting state early in the morning. Date and time of their last meal were asked and noted in the camp activity sheet. Glucometer *(Gluco spark, Sensa core, Telangana, India)* based testing for fasting blood glucose was done after confirmation of fasting status.

Glucometer Lancet Holder Lancet Strip Box Control Solution

Equipment used to estimate capillary fasting blood glucose

Spot urine samples were collected from all the adult respondents who consented for this test in randomly selected 150 PSUs (75 Rural and 75 Urban PSUs) in a labelled sterile container which were stored appropriately, finally all samples were sent to the laboratory (Department of Biochemistry, C N Centre), AIIMS, New Delhi for analysing levels of Sodium (Na) excretion. The urinary Sodium and Potassium (K) levels were estimated on automated analyzer *(AU680 Chemistry analyzer, Beckman Coulter, CA, USA)* using indirect Ion Selective Electrode (ISE) method. Urinary Creatinine (Cr) levels were measured by Jaffe's method on Roche analyzer *(P800 Modular Analytics, Roche diagnostics, Mannheim, Germany)* using

commercially available kit *(Ref. 11875418-216, Roche diagnostics, Germany)*. The urinary sodium excretion (for sodium intake assessment) estimation in spot urine samples were done using the INTERSALT equation with Potassium.

INTERSALT equation with Potassium

Men: $23 \times (25.46 + [0.46 \times \text{spot Na (mmol/L)}] - [2.75 \times \text{spot Cr (mmol/L)}] - [0.13 \times \text{spot K(mmol/L)}] + [4.10 \times \text{BMI (Kg/m}^2)] + [0.26 \times \text{age (years)}])$

Women: $23 \times (5.07 + [0.34 \times \text{spot Na (mmol/L)}] - [2.16 \times \text{spot Cr (mmol/L)}] - [0.09 \times \text{spot K(mmol/L)}] + [2.39 \times \text{BMI (Kg/m}^2)] + [2.35 \times \text{age (years)}] - [0.03 \times \text{age}^2 \text{ (years)}])$

The calculated value in mmol/L was multiplied with a constant of 2.54 and divided by 1000 to arrive at the salt intake of population in grams.

2.5.4 Calibration (standardization) of equipments

The calibration of equipments was done by verifying measuring equipment against an accurate standard to determine any deviation and to correct any errors found. This was done periodically before start of every PSU. The calibration results were documented in log sheets and checked for any corrective actions. Each equipment had to be pre-coded and the code label had to be stuck at the back of the machine to help in documentation.

All the equipment used for the survey were checked for their working condition, damages, if all parts of the equipment were present and if the batteries were in place and carried charge. Before measuring the height, weight and WC of the study participants in the field, one of the technicians whose measurements were known (was measured during the field before start of every PSU) was used as a control, to confirm the correct functioning of the equipment. Other calibration checks performed have been described below:

Stadiometer calibrations were also done with the help of a new measuring tape. This was placed against the stadiometer and the markings of both were compared for accuracy.

Weighing machine calibrations were done with the help of known weights (pre-weighted sand bags of 250g, 500g, 1Kg, 1.5Kg, 2Kg, 5Kg etc.) or metal weights. Known weights were carried along with field kit.

Measuring tape was placed against a scale/ruler and/or a fresh/new tape and checked for accuracy of the readings.

Automatic blood pressure machines were calibrated by recording blood pressure for one field team member with the device to be checked. A new automated BP machine was used to re-check the BP of the same member and the values between them were compared for precision.

Glucometers were calibrated by comparing control solution values against the reference values provided by the manufacturer along with the kit.

If any extreme deviations were noted with measured values against the standard, the equipments were replaced with another. This information was intimated to concerned study implementing authority for repair or replacement of the equipment.

2.6 DATA COLLECTION

The team at implementing agency was led by a principal investigator with prior field survey experience and at least one co-investigator. Some agencies also co-opted a collaborator investigator in States outside their own place to provide logistics, language and local coordination facilitation.

The teams were trained for all survey related work like house numbering/mapping, data entry on handheld device, interview tool use, equipment handling, equipment calibration, laboratory procedures and sample handling etc. In every team amongst the three MSWs recruited for the survey, the most competent one was designated as the team leader; at least one of the MSW was a female, who interviewed and conducted anthropometry of female respondents. The overview of data collection has been presented in *figure 2.6.1.*

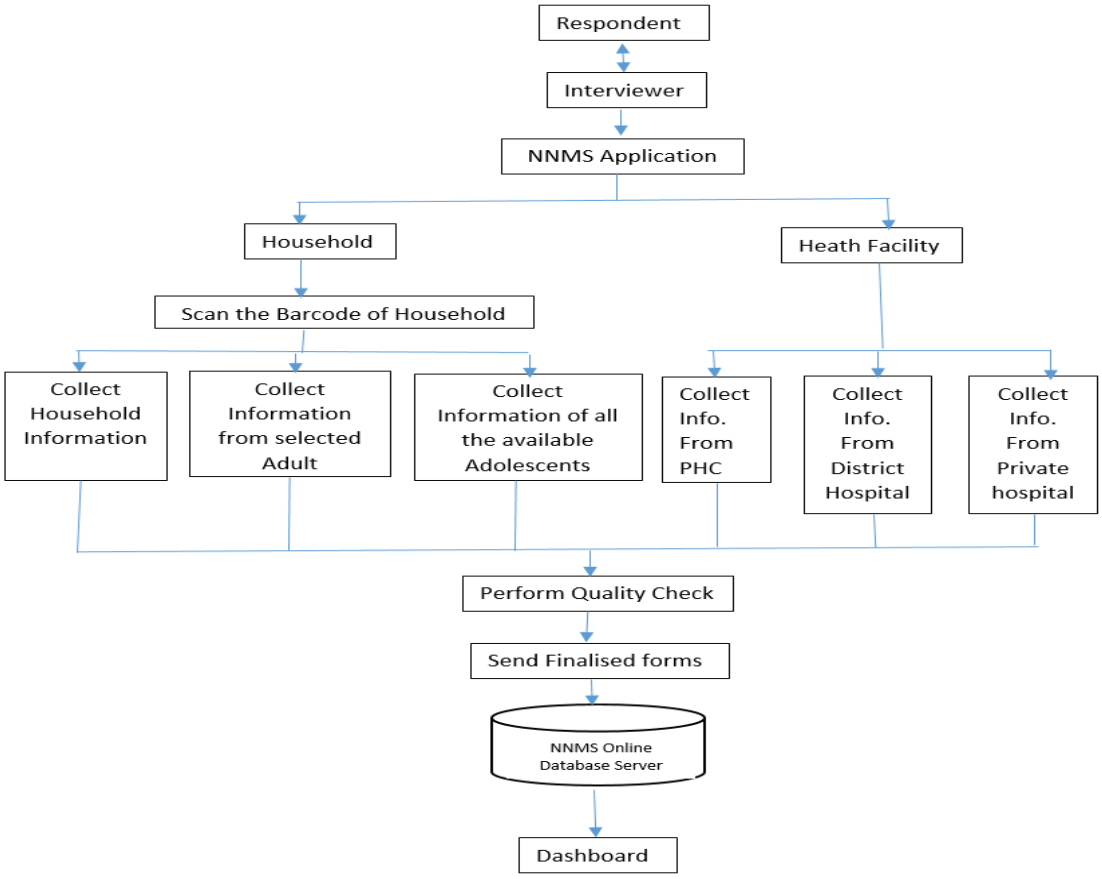


Figure 2.6.1 Data collection flowchart

2.7 QUALITY ASSURANCE MEASURES

Standards of quality control were achieved at various levels of the survey. All the study tools were reviewed and pre-tested in the field following expert group inputs. The household and individual level instruments were translated into local languages namely Hindi, Tamil, Telugu, Malayalam, Kannada, Marathi, Assamese, Gujarati, Bengali, Odia, Punjabi and all the translations were validated.

Each survey institution appointed one co-coordinator and one of its own faculty/scientist investigators to assure quality control. The quality assurance mechanisms followed were training, calibration and standardization of equipment and data collection tools, field data collection, recording and storage of data, handling of blood and urinary samples and their safe disposal and communication and counselling to the survey participants. Central coordinating unit was responsible for coordinating overall supervision, monitoring, data cleaning, data analysis and report writing with the technical support from its partners. Some of the quality assurance mechanisms followed have been listed in *table 2.7.1* below:

Table 2.7.1 Key quality assurance mechanisms followed

Standardization of manuals	• Survey questionnaires, field survey operational and training manuals • Laboratory biochemistry testing protocol & manual • Equipment manual • Quality assurance and monitoring manual • PDA and data management manual
Standardization of study tools	• Reviewed by experts - Study tools used: WHO-STEPS NCD risk factor survey instrument, WHO-GSHS tool, GATS, GYTS, IDSP-NCD risk factor survey and WHO-SARA tool • Review of questionnaires - National level group of experts • Pilot testing of questionnaires
Standardization of equipment	• Identified standard instruments for use across sites • Central purchase of equipments • Accuracy checks for equipments • Maintenance of calibration logs of equipments
Supervisory visits	• By the PI's • By NNMS Core group members • By TWG Members • WHO India Office
Field level quality checks	• Daily calibration checks of equipments • Field supervision form - completion of data collection, transmission, storage and safety of all equipments • Safe disposal of blood & urinary samples