Research Protocol

Development of Protocol for the Indian Council of Medical Research (ICMR) task force study to strengthen the implementation of National Programme for Prevention and Control of Non-Communicable Diseases (NP-NCD) in tribal population

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Abstract

Understanding the health culture of tribal community is important as health problems among tribal communities and their care is influenced by sociocultural factors, which will help in the implementation of health services. The conventional way of improving the access for the general populations may not suit the tribal populations owing to their distinct culture and owing to health systems factors as well. A stepwise process was followed for the development of a protocol to study to strengthen the implementation of National Programme for Prevention and Control of Non-Communicable Diseases. The study was planned to be carried out across six tribal districts of India. A detailed protocol was built around Implementation Research Logic Model, primarily as a method for planning, executing, reporting, and synthesizing the implementation.

Keywords: ICMR task force study, implementation, NP-NCD, protocol, strengthen

Introduction

The phenomenon of epidemiological transition over the last few hundred years has changed the disease pattern to a lower burden of communicable and nutrition-deficit diseases and a relatively higher burden of non-communicable

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diseases (NCDs) and injuries.[1] NCDs are accountable for 74% of all deaths globally and about 77% of such deaths occur in low- and middle-income countries (LMIC). The four groups, that is, cardiovascular diseases, cancers, chronic respiratory disorders, and diabetes, are responsible for more than 80% of all premature NCD deaths.[2] India too has reported a significant increase in the proportion of NCD deaths from 37.9% in 1990 to 61.8% in 2016.[3] The fifth round of the National Family Health Survey has documented that about 13.5% of women and 15.6% of men either had high blood sugar levels or were on anti-diabetic medication. Similarly, about 20.2% of women and 22.7% of men were either having elevated blood pressure or were on anti-hypertensive drugs.[4]

The NCDs have been found associated with modifiable risk factors, such as physical inactivity, unhealthy diet, and tobacco-alcohol use, and non-modifiable risk factors, which include age, sex, ethnicity, and heredity.[5] The presence of modifiable contributing factors renders these disorders preventable to some extent and targeted interventions can assist in fighting the NCD pandemic.

The Government of India (GOI) launched the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) in 2010, which envisaged providing promotive, curative, and supportive services with provisions for expanding the diseases covered under programme to chronic lung disease and geriatric disorders.[6] The programme was renamed National Programme for Prevention and Control of Non-Communicable Diseases (NP-NCD) in 2023, focussing on strengthening infrastructure, human resource development, health promotion, and awareness generation for prevention, early diagnosis, management, and referral to an appropriate level of healthcare facility.[7] Although the programme is well planned and designed, access and utilization by tribal population raises questions on its implementation value. The challenge of accessibility to health services and presence of traditional health seeking behavior among tribal communities need to be addressed.[8,9] Understanding the health culture of tribal community is important because health problems among tribal communities and their care are is influenced by socio cultural factors, which will help in the implementation of health services.[10] The conventional way of improving the access for the general populations may not suit the tribal populations owing to their distinct culture and owing to health systems factors as well.[11,12] Since the delivery of healthcare in tribal populations cannot be imagined without strengthening the existing primary care infrastructure, specifically designed targeted interventions (practical and sustainable) may be required to improve the health care access to the tribal populations. The current paper is a part of an ICMR task force study to strengthen the implementation of National Programme for Prevention and Control of Non-Communicable Diseases; the details of the paper are however limited to the development of the protocol for the conduct of the study.

Methodology

As a part of the national task force project, Indian council of Medical Research (ICMR), New Delhi, invited an open call for application, which included securing of concept note as a first step, followed by a submission of full proposal. Based on the merits of the proposal in the area of implementation research on Non communicable diseases in Tribal area, six researchers were invited to submit the full proposal.

Once the full proposals were received, an invitation for refinement for the development of a common protocol was sent to the investigators. This refinement was conducted through a 2-day workshop at the headquarters of the Indian Council of Medical Research (ICMR), New Delhi. Principal investigators from six participating sites, scientists from ICMR along with subject experts from Post Graduate Institute (PGI) Chandigarh, Karnataka Health Promotion Trust (KHPT), and All India Institute of Medical Sciences Jodhpur participated in the workshop.

The common protocol was to use implementation research design to develop implementation strategies for strengthening the NCD-related continuum of care under NPCDCS among Scheduled Tribe populations, with a focus on hypertension, diabetes, and COPD.

Study sites

This study was planned to be completed in six districts located across the country [Figure 1]: Chamba district of Himachal Pradesh, northernmost part of India with a predominantly

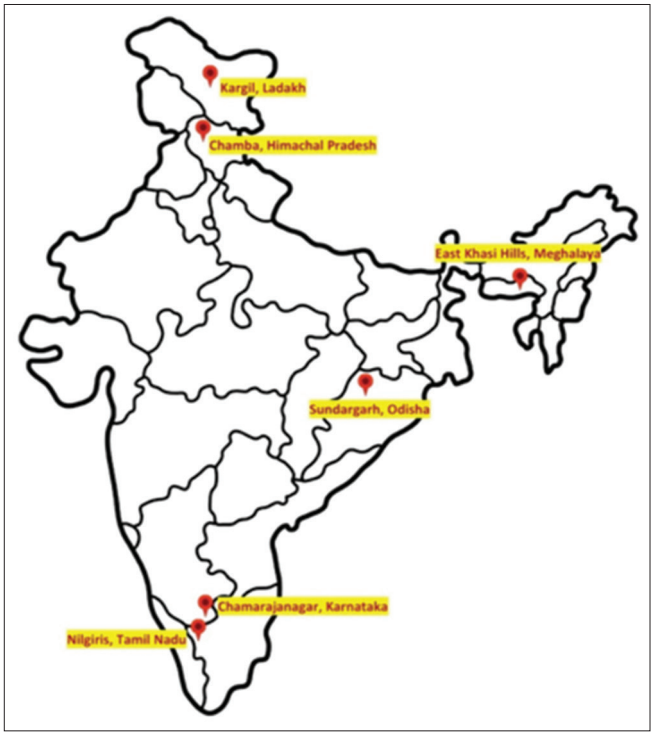

Figure 1: Study sites

transhumant agro-pastorlist (Gaddi) tribe, Kargil district in Ladakh, a union territory located in the extreme north of India and dominated by Puriga and Balti tribes of Tibetan origin. The tribal constitutes 86.9% of the total population. The region shares borders with Chamba district of Himachal Pradesh. In addition to these two districts from south, Chamarajanagar district is in Karnataka, with 11.8% tribal population comprising largely of Salogi and Nayaka tribes, and Nilgiri district in Tamil Nadu with tribes accounting for 4.46% of the population with 15 tribes recognized to be living here. From the north-east, East Khasi Hills district in Meghalaya with 80% of the total population, tribal predominates the Khasi tribals, who are agriculturists and the Sundargarh district in Odisha, with a tribal population constituting 50.7% of the district population, mainly Oraon, Munda, Kisan, Khadia, and Bhuyan.

The research components during the workshop were built around Implementation Research Logic Model, primarily as a method for planning, executing, reporting, and synthesizing the implementation. The deliberations of the workshop specified relationships between determinants of implementation, implementation strategies, the mechanisms of action resulting from the strategies, and the implementation and clinical outcomes to be affected.

The step was further broken down into (1) the need for identifying implementation strategies for the specific project that are related to implementation determinants (context-specific barriers and facilitators), (2) identifying specific mechanisms of action to change the context or the behaviors of those within the context, and (3) identifying proximal impacts of the strategy and its mechanisms, which then relate to the clinical outcomes if any. The causal pathway theory was largely explained in terms of the theory of change and the theory of action of the implementation strategies in a single model. A re-iterative method was used to refine and arrive at the final version.

Results

The summary of the protocol is provided in Figure 2. The protocol was divided into subsections using the standard format for protocol submission with subsections identified as objective, sample size, methods, and design.

Objectives

Objective 1 (Formative research): To assess the socio-demographic characteristics, disease burden, community perceptions, and healthcare access for hypertension, diabetes, and COPD among the tribal population, and to identify facilitators and barriers to care at the individual, household, community, and health system levels.

Objective 2 (Intervention Development and Implementation): To develop and implement strategies for strengthening the NCD-related continuum of care under NPCDCS, NHPM/AB, and other relevant programs, through community participation, multi-sectoral partnerships, and health system strengthening.

Objective 3 (Evaluation and Dissemination for Scaling-Up of Strategies): To assess the impact of the intervention on modifiable parameters and behaviors, disease control, out-of-pocket costs, community and health system perceptions, and program acceptability, and to examine the suitability, replicability, and sustainability of the intervention for the tribal population.

Sample size

For quantitative household survey: The required sample size was calculated according to the formula $n = Z^2_{1-\alpha/2}(1-P) / \varepsilon^2 P$.[13] By considering the prevalence of utilization of government healthcare service (P) of 23% (minimum of all sites were to be considered for all study sites), with 10% relative precision and 95% confidence interval, the sample size would be 2177.

By considering the design effect (DEFF) of 1.7, as cluster sampling was to be adopted, the sample size would be 3265. By considering 5% of the non-response rate, the sample size would be 3886.

Methods

We planned to use epidemiological methods of cross sectional study for the descriptive and explanatory questions through qualitative interviews (objective 1). From the results of objective 1, an implementation strategy was developed using quasi experimental study design (objective 2) and evaluation was designed using household survey and qualitative methods for objective 3. It was decided that from each district, four implementation units (PHC or upgraded PHC or CHC of population of about 20 to 30,000) will be taken with the criterion of highest concentration of the tribal population. Of the four units, two were allocated to the implementation research arm and the other two were allocated to the control arm. Three categories of healthcare facilities were planned to be identified: PHC villages, health sub-center villages, and villages having no facility. It was decided to further categorize into villages having road access and without access.

Study design

A multistage random sampling was used for selecting the households for the collection of the data on prevalence of the non-communicable diseases. For this purpose, villages/hamlets were categorized based on the availability of health facilities.

Data collection techniques: Both quantitative and qualitative research methods were implemented in the first phase of the study. Quantitative data pertaining to socio-economic, demographic details, healthcare seeking behavior, etc., were collected through pre-tested, interviewer-administered questionnaires. Qualitative methods (in-depth interviews, focus

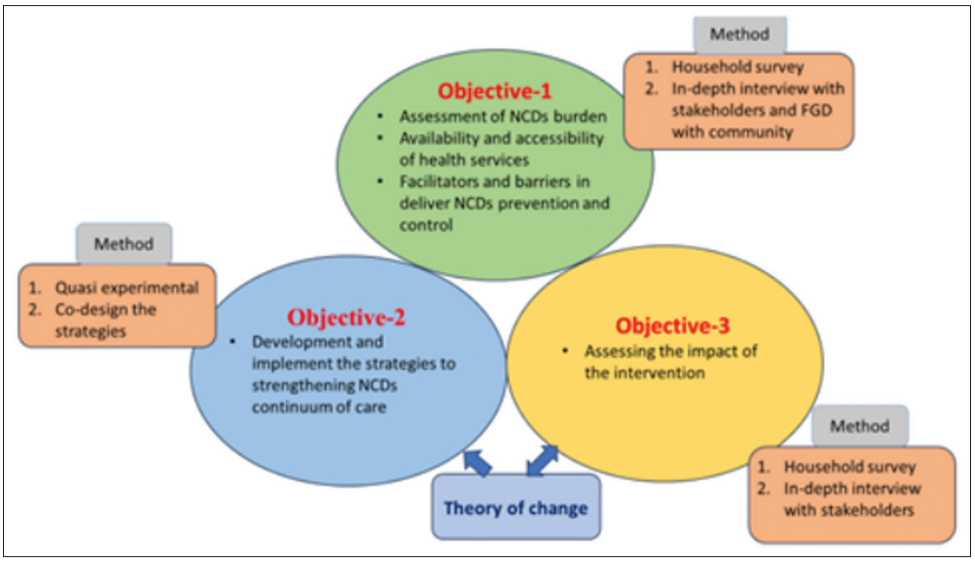

Figure 2: Objectives

group discussions, key-informant interviews, and case studies) with grounded theory approach were decided to be followed to understand the community's perspective about NCDs (perceived needs, barriers, and facilitators in accessing the healthcare services and their relevance) and in identifying the existing transport and communication channels and their utilization pattern among the tribal population. To understand the health system related factors, in-depth interviews were planned to be conducted with various health care providers with a specific focus on outreach of services, system's preparedness to meet the demands generated by the newer schemes (UHC, etc.), barriers, and facilitators (related to resources – financial as well human, infrastructure related issues, modes of communication/IEC, and health service delivery and behavior-related issues) for the provision of the services to the tribal communities. Healthcare policy makers/providers from different levels (state/district/sub-district/CHC/PHC) were decided to be the channels to under the health status of the district through in-depth interviews.

The protocol thus developed was designed as a quasi-experimental and implementation research and was planned to be carried out in three phases: (i) formative research (pre-implementation phase), (ii) intervention development and implementation, and (iii) evaluation and dissemination for scaling-up of strategies [Table 1]. The formative study was to be undertaken in all the four study units. Study was to be conducted among the tribal population and health system, specifically the primary healthcare system and other health care facilities. This phase of research was to be used to arrive at the prevalence of three noncommunicable diseases, that is, diabetes, hypertension, and COPD, and to assess the healthcare access to the tribal communities, to identify the bottlenecks, facilitators from both the people's and health system's perspective and to identify specific communication channels, and for identifying various stakeholders/partners that can take part in the intervention for improving healthcare access to the tribal population.

Statistical analysis: The quantitative and qualitative data were to be analyzed by SPSS and Atlas/ti (or any other), respectively. *Quantitative data*: The quantitative data were to be computerized and analyzed through SPSS. To summarize the quantitative data, descriptive statistics were to be used. To examine the associations between various dependent and independent variables multiple linear and logistic regressions were to be carried out.

Qualitative data: The qualitative data management and analysis was to be done with the help of Atlas/ti (Scientific Software Development, Berlin, Germany), a software package for qualitative data analysis. This computer-based software was to be employed for selecting relevant quotations from the text, coding, annotating, and comparing the quotations.

Discussion

The analyses of the utilization of health care in India are receiving increased attention because of the emergence of societal values and perceptions, specifically among marginalized and vulnerable populations like the tribal.

The delivery of healthcare to tribal populations is limited not only by the reduced presence of doctors, nurses, and healthcare professionals in tribal regions but also compounded due to difficulty in attracting and retaining skilled healthcare personnel in the primary healthcare set-up in the remote areas as well as imbalance in the distribution of healthcare professionals, with a concentration in urban areas.[14]

The GOI is inclined to increase delivery as well access to healthcare across all parts of the country including tribal areas and has launched programs like the NPCDCS to cater the needs of the general populace in a well-designed program mode. Policy makers and public health experts have opined (from time to time) on the need to revisit the program to further strengthen

Table 1: Detailed Protocol

Objectives	Variables	Source	Methods
Community related			
1. To understand the demographic and socio-economic characteristics of- and modes of communication among the tribal population. a. Age/gender/educational/ occupational/religious/ethnic/ social networks/subscription to insurance b. Conflicts (internal/external)	• Gender/family size, age, education, occupation, income, religion, ethnicity, habitats and social networks • Living conditions – type of house, size, ownership, electricity, ventilation, cooking fuel (if LPG is used, its continuity and pattern of its use), kitchen, toilet/sanitation, source of water, wash practice-excreta disposal • Possession of ration card (BPL), Aadhaar • Health insurance (name the schemes) and health card • Existence of tribals and non-tribal/ethnic groups; relations between ethnic groups (internal conflicts) • External conflicts – armed conflict, animal interference, maoist/underground issues	• Head of Household (HOH/adult member • KI (key informant)	• QHS (Qualitative Household Survey) • IDI (Individual In depth interview)
c. Formal and informal processes of decision-making related to healthcare (hypertension, diabetes, and respiratory illnesses) issues (at household level and community level)	• Decision making regarding treatment of the family members, if he/she is ill • Community's role in decision making and care/ help provided by the community • Help seeking behavior in serious or chronic illnesses	• HOH/adult member • KI • Community	• QHS • IDI • Focussed group discussion (FGD)
d. Social structure – dynamics – Organizational capacity of the community to negotiate for better services (different community-level organization to deal with health/government amenities)	• Existence of social institutions, CBOs, gram sabhas, youth groups, self help groups (SHGs), ICDS (anganwadi), etc. • Role of VHSNCs, school management, gram kalyan samiti • Power relations, empowerment of these groups • Role in helping families in emergencies	• KI • Community • Members of VHSNCs	• IDI • FGD
e. Transport system that is available and physical distance to the health facilities-public and private (mapping)	• Availability of motorable-all season roads • Mode of public transport • Distance to PHC, HSC, private health facilities, non-govt. facilities etc., – time to reach. • Ambulance services – availability of 108 and other emergency services	• KI	• IDI
f. Existing communication channels available to these communities and their utilization pattern	• Viewership of TV, radio, means of getting to know the news (TV/radio/interpersonal/print media/)/mobile phones • Informal/traditional ways of communication • Community radio • Health-related information	• KI	• IDI
2. Assessment of the disease burden of these conditions through secondary data or through rapid surveys/assessment. a. Assessing the burden of hypertension, diabetes and COPD through rapid surveys/assessment and secondary data.	• Prevalence of hypertension, diabetes, and COPD (primary survey data and secondary data)	• Survey for hypertension, diabetes, and COPD • Record review	• Record review, NFHS, HIMS, DLHS and from local health facilities records, micro studies
b. Assessing the feasibility of estimating the prevalence of COPD through both questionnaire and spirometry methods at the Health and Wellness Center (HWC) level.	• Prevalence of COPD	• Survey for Hypertension, Diabetes, and COPD • Record review	• QHS
c. Estimating the awareness, treatment and control of these conditions (gaps in the continuum of care).	• Awareness of the condition/people under treatment/condition under control of those under treatment. Existence of conditions, awareness of their conditions	• Sample survey – FBG (Fasting blood glucose), Blood pressure, Height, Weight	• QHS

Contd...

Table 1: Contd...

Objectives	Variables	Source	Methods
Community related			
d. Treatment seeking behavior of known patients and calculating the costs (out-of-pocket, OoP)	• Treatment – sources of treatment, itinerary of treatments, frequency of visits, treatment details, costs (direct and indirect)	• Patients for hypertension, diabetes, and COPD	• Semi-structured interview (SSI)
e. Understanding the profile of the patients – risk/precipitating factors, etc., that are necessary for management	• FBG, BP levels, known risk factors – behavioral and metabolic	• Patients for hypertension, diabetes, and COPD	• Modified STEPwise approach to surveillance (STEPS) • SSI

its implementation with a focus on saturating the utilization. This is not just to address the geographical differentials but also difference in the primary health care settings across tribal India. The current study was part of the same process; an effort to identify a way forward in developing a protocol for strengthening implementation at the primary care level, which however is specific for the tribal population. It was realized that the utilization of healthcare services among tribal's can be viewed through determinants' models, considering access as a general concept summarizing a set of more specific dimensions, such as availability, affordability, accessibility, adequacy, and acceptability, all fundamental to delivery of primary care and as viewed by Fiedler (1981) and Anderson (1995).[15] The idea was to search for policy interventions to ameliorate the barriers and improve determinants. It was agreed that this can be attained through improving the primary healthcare services, including availability of health facilities, treatment, and quality of care. An access to healthcare becomes an issue once illness is recognized and treatment seeking is initiated.

Problems of accessibility, including long distances to the nearest government-based health facility, remote location of the habitation, lack of public and transport, etc., appear to continue as the major access barriers. Issues related to affordability in terms of treatment costs and loss of income, out-of-pocket expenses due to visits to healthcare facilities, costs of drugs, etc., may also play a major role. Moreover, poor knowledge about the existing government schemes adds up to the poor health care among the tribals. Adequacy and acceptability in terms of people's judgment of quality of care also play an important role. So, there is a need for an urgent implementation-based research program to scale up the existing program among the tribal populations all across the Indian subcontinent in better utilization of the existing government programs and schemes.

Conclusions

There is a need for an urgent implementation-based research program to scale up the existing healthcare program among the tribal populations all across the Indian subcontinent in better utilization of the existing government programs and schemes.

Ethics approval and consent to participate

The study was approved by the institution ethics committee, Dr. Rajendra Prasad Government Medical College vides letter no; HFW-H/DRPGMC/Ethics/2019/192 dated: 13:08:2019. The study did not include any study participants, and hence no consent was required.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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