Spatial Research Methodology Supplementing Cluster Randomized Controlled Trials: Learning from a Study of Community-Based Health Insurance Schemes in India

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Abstract
Most of the cluster randomized controlled trials (CRCTs) are conducted in a geographical area, but the present CRCT evaluation model does not capture "place" component. CRCTs reported without providing the information on spatio-temporal changes taking place at the experiment site, during the course of intervention, present only a part of the picture and also pose a great difficulty in finding out causal relationship between the intervention and outcome. We conclude that a complete evaluation model should have tools to capture people, place and time. Usually, "people" are captured using quantitative tools and "time" component is taken using different waves of data collection, "place" dimension needs to be integrated to make CRCT evaluation more comprehensive and effective. This research article reports the spatial methodological protocol followed in a project that assesses the impact of community-based health insurance schemes in rural India and demonstrates various advantages of incorporating spatial tools in the evaluation model. Results highlight the potential for applying this methodology in other studies.

1. Introduction

Development programs such as community-based health insurance (CBHI), target improvement of the quality of life across the area and therefore they usually operate at the groups of individuals, located in some geographical settings (White, 2009a). Cluster randomized controlled trials (CRCTs) are called gold standard for evaluating such group based programs (Isaakidis and Ioannidis, 2003). Studies indicate that about 80 per cent of all the data needed in studying the development program have an underlying geographical component (Williams, 1987 (cited in Carlos, 1996)) and (Franklin, 1992 (cited in Ball, 2009)). A closer examination of attributes encountered in CRCT evaluation (i.e. cluster, location, access, proximity, distance, catchment etc.) reveals underlying spatial characteristics. However, CRCT research has not demonstrated the significance of geographical attributes in designing, implementation and impact assessment. It is believed that trials report only a part of the picture when information on spatio-temporal changes at experiment site is not provided. This leads to greater difficulty in finding out causal relationship between the intervention and outcome. Deaton (2009) and White (2009b), have presented the importance of understanding external factors and context in the effective design, implementation and reporting of evaluation results. In order to overcome the aforementioned methodological gap, the Micro Insurance Academy is conducting three separate CRCT-based impact evaluations of CBHI schemes in two North Indian states of Bihar and Uttar Pradesh, in partnership with the Erasmus University, Rotterdam and University of Cologne, Cologne. The implementing partners in the states are three NGOs namely Nidan in Bihar and Shramik Bharti and BAIF in Uttar Pradesh. Each evaluation is structured as a CRCT, in which randomly selected members of a network of women's microfinance groups ("Self Help Groups" or SHGs) are offered an option to affiliate to a CBHI, which they design and manage themselves. Utilising spatial methodology along with quantitative and qualitative approaches, within the longitudinal timeframe of five years, the impact of each CBHI scheme on a range of indicators pertaining to the financial protection and healthcare access will be analysed. It is important to mention that the baseline survey is complete, and currently

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the project is set for the second wave of data collection and midterm evaluation. This research article presents the spatial methodological protocol that demonstrates the various advantages of incorporating spatial tools in designing and implementation of evaluation research.

1.1 Rationale

Given the complexities involved in assessing and understanding contexts of community-based health insurance and the methodological challenges pertaining to impact evaluation studies such as practical difficulty in creation of counterfactual, construction of sustainable implementation structure and development of standardized outcome indicators (Jutting, 2003, Carrin et al., 2005, Isaakidis and Ioannidis, 2009 and De et al., 2010), the paper attempts to delineate some of the advantages of spatial techniques. The methodology discussed in this paper will help to close these knowledge gaps in terms of providing innovative approach for creation of counterfactual and standardised outcome measures and to help in designing sustainable implementation structure. This will ultimately help in quickly initiating and scaling-up of the number of spatial methodology integrated CBHI trials.

2. Material and Methods

2.1 Objectives

The objectives of this research paper are:

- To demonstrate the utility of spatial methodology in optimal selection and demarcation of units of randomization.
- To demonstrate support provided by spatial datasets in establishing evidence based implementation structure.
- To devise methodology for creation of outcome indicators for capturing the impact of CBHI on healthcare access.

2.2 Study Setting

All the three trial sites were located at Northern India in the districts of Pratapgarh, Kanpur Dehat (in state of Uttar Pradesh) and Vaishali (in state of Bihar). Though all the three CRCTs follow the same methodological protocol, they differ in terms of location, size and distribution of trial participants. The experimental cohort comprised of 8933 participants distributed in 15 villages of Shivgarh block in Pratapgarh district, 7105 participants distributed in 42 villages of Rasulabad block in Kanpur Dehat district, and 7838 participants distributed in 34 villages of Mahua block in Vaishali district. Figure 1 depicts the location of experimental cohort in the blocks[1] of Rasulabad, Mahua and Shivgarh.

2.3 Tools, Techniques and Data Frame

Global Positioning System (GPS) and Healthcare provider (HCP) questionnaire were the tools utilized for the study. GPS helped in providing precise location of health facilities. The health facility maps procured from the office of chief medical officer were without any scale and incomplete as those were indicating only few Government health care facilities. GPS survey of all the health care facilities functioning in and around the project site was done in order get a real time picture of health care facilities working in the study area. HCP questionnaire captured supply side attributes (identification details, working timings, services offered, physical infrastructure, facility staff and fee/ charges) of all the available formal and informal healthcare providers working in and around the study area. ESRI[2] Arc map 9.3.1 GIS (Geographical Information System) software was used for synthesizing and analyzing datasets from different sources. Spatial research under the CBHI project introduced place component in the evaluation model as all the dataset collected under spatial research had geographical attributes (latitude and longitude coordinates). Spatial database frame was built incorporating primary and secondary, spatial and non-spatial datasets relating to configuration of villages, healthcare facilities/providers and physical access (road network).

2.4 Data Collection

The study incorporated three rounds of primary data collection of which the first wave of spatial survey (baseline) has been completed. Baseline survey included enlisting and GPS mapping of entire healthcare supply configuration (i.e. primary, secondary, tertiary) in and around experimental area. HCP tool was administered on each of the identified providers. A total of 3092 providers from government, private, charitable, local practitioners and others were mapped in all the three sites.

[1]A medium-sized Government of India administrative region
[2]Environmental System Research Institute

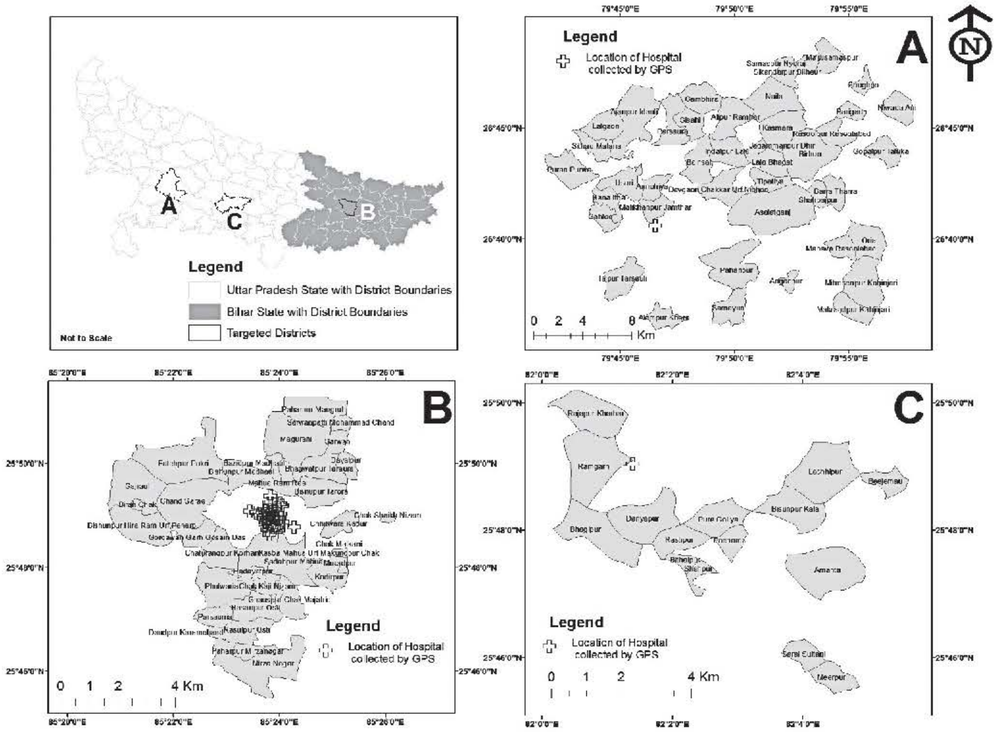

Figure 1: Location of the three trial sites & distribution of trial villages
CRCT villages in "A" Rasulabad block, district Kanpur Dehat, Uttar Pradesh,"B" Mahua block, district Vaishali, Bihar. "C" Shivgarh block, district Pratapgarh, Uttar Pradesh

2.5 Analysis

The primary aim of spatial methodology was to add place attributes in the evaluation model. Villages were set as a basic unit of analysis and spatial analysis was conducted utilizing GIS. Villages were given unique identification number utilizing census codes which was used as a primary key to join non spatial datasets relating to HCP survey and household records with spatial datasets. Baseline records of SHG members were combined with GIS maps of the project site in order to depict the spatial distribution of the trial population over villages. This spatial information helped in perceiving the patterns and relationships which were hidden when data was in the tabular form. Geoprocessing (i.e. proximity, overlay, spatial join etc.) tools gave opportunity for creation of new datasets from the base maps as villages were tagged as per the distance from the hospitals and condition of roads. After examining the distribution of each of the variables individually across the area, overlapping of multiple characteristics of interest was conducted using overlay and spatial addition functions.

3. Results and Discussion

This section discusses the utility of spatial datasets in three critical stages i.e. clustering, implementation and impact measurement of CRCTs.

3.1 Spatial Decisions in the Process of Clustering

Geographical assignment of unit of randomization becomes one of the crucial steps in the evaluations conducted under CRCT design. It was found that trials conducted at rural settings face special challenges in this regard, due to the remote rural locations, scattered population distribution and poor road network. Irrational clustering could lead to financial, logistical, and social difficulties (i.e. extra financial burden during the implementation, difficulty in logistics management of research and implementation teams, risk of study group contamination due to the proximity to control groups etc.); which could damage the sustainability of the scheme (CBHI). It was realised that assigning a set of villages into clusters is perhaps a simple task using statistical methods, but in practical terms it is a difficult and challenging exercise. For instance, when the initial clustering exercise conducted by utilizing conventional statistical method along with crude hardcopy maps, it was found to be inadequate at operational levels due to the irrational grouping of villages, i.e. far off villages or villages without any direct road network connectivity were grouped in together (see Figure 2. Image A.1). We have also found that geographical matching utilised in conventional clustering design needs to be improved, as it utilises crude out-dated maps while clustering for random assignment require latest locational details. Therefore, in the process of clustering, spatial matching in addition to statistical matching was added and cluster definitions were corrected. GIS maps explicitly addressed important implementation criteria i.e. communities must not be subdivided (non-divisibility of villages), clusters must be geographically compact (geographical contiguity); and the insurance scheme must have a roughly equal sized pool of potential members (equality of members).

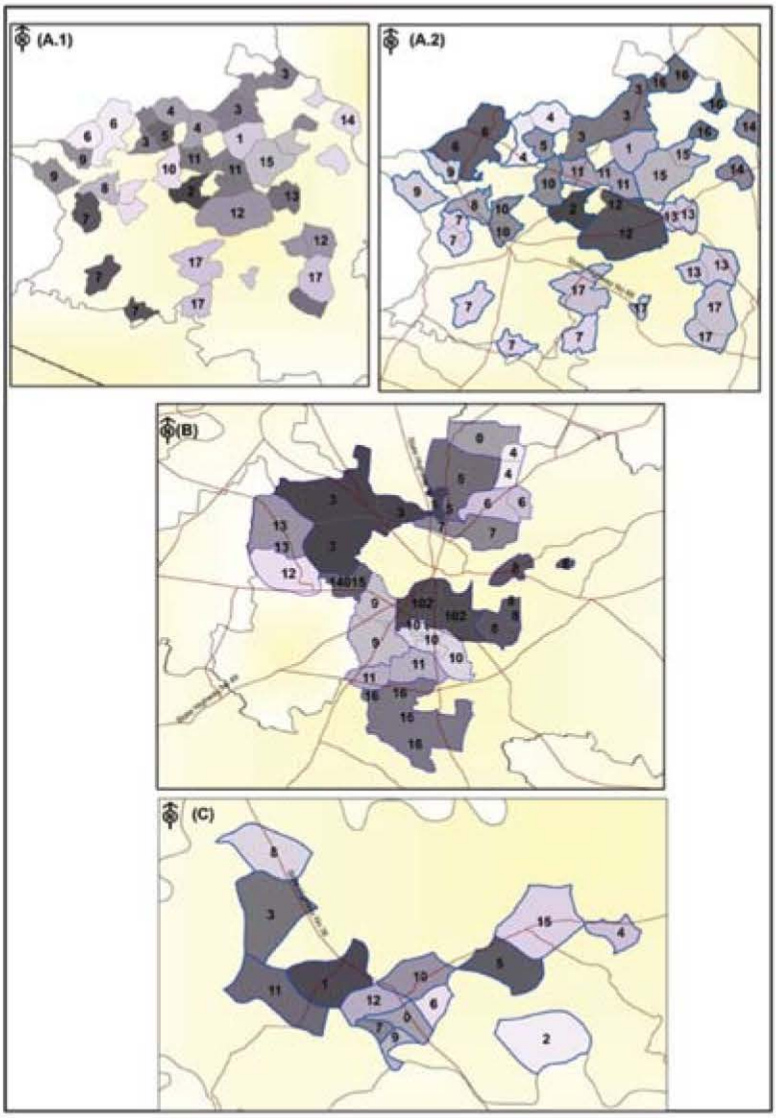

Figure 2: Geographically congruous clusters for random assignment."A.1" Cluster organization before consulting spatial data in Rasulabad site, "A.2" Final cluster organization at Rasulabad site (42 villages are organized into 17 clusters), "B" Final cluster organization at Mahua site (34 villages are organized into 15 clusters), "C" Final cluster organization at Shivgarh site (15 villages were called 15 clusters due to the adequate number of SHG members)

The final cluster distribution of each site evolved after spatial exercise can been seen in Figure 2 (see Image A.2, B & C). Once clustering was done, the next step was to balance clusters on the basis of urban area proximity as all the trials were of rural focus. Application of GIS enabled researchers to check the cluster proximity differential from urban centers. It is to be noted that these important hidden spatial facets are usually omitted from the evaluation model, due to non-availability of appropriate tools to capture and study such variables. However few researchers have pointed out the implications of cluster location in maintaining the data integrity and analysis in trials (Klar et al., 2007, Van et al., 2007)

3.2 Spatial Inputs in Program Intervention

The visual presentation of trial datasets utilizing GIS maps helped program managers (implementing people) in understanding the research structure i.e. distribution of samples, assignment of intervention and control groups in different waves in better way. This ultimately helped managers in preparation of stronger program implementation structure. Also, it was found that the implementation of step wedge impact assessment methodology, where the Phase-wise inclusion of treatment groups were involved (only $1/3^{rd}$ of clusters per phase and over three phases) requires precise information at micro level. Further spatial baseline survey helped in mapping the community settings, provider characteristics and physical accessibility of the target area, which helped in implementation of CBHI in better manner. For instance, important information about healthcare facilities, providers and physical proximity proved to be critical during the designing of the benefit package options such as inclusion of transportation cost in Kanpur site where secondary care health facilities were distantly located, inclusion of diagnostic facilities in Mahua site, where diagnostic services were available in the close proximity of target communities made the CBHI benefit package more relevant and attractive. Spatial information collected during different waves (Baseline, Midline and Endline survey) will also enable CRCT to examine infrastructural changes taking place in the experimental area i.e. opening, up-gradation or closing of hospitals, new road network, and development of business activities during the project time period (5 years).

3.3 Spatial Inputs in Impact Measurement – Access indicator

Accessibility is a major issue for both the stakeholders i.e., community and providers. The impact of geographical proximity on healthcare seeking behaviour has been reported by researcher (Jutting, 2003) working in the micro insurance impact evaluation. Our hypothesis posits that the financial protection gained by community due to the CBHI, will structure the healthcare demand which will in turn influence the healthcare supply configuration i.e. up- gradation or closing of existing health facilities, opening of new health facilities etc. Literature review indicates absence of studies on these aspects of CRCT evaluation. In the present study, spatial approach helped in capturing empirical datasets relating to road networks, healthcare supply configuration and non-spatial data on healthcare resources. Utilising geographical information system, all these independent attributes were integrated and access indicators, i.e. village wise healthcare index (VHSI) was developed. The calculation adopted in the development of index utilizes the concept of location based measurement of accessibility which deals with the spatial distribution of opportunities (health facilities) (Salze et al., 2010). As per methodology for creation of VHSI, Healthcare Supply Index *I* for each village can be represented as:

$$I_{ji} = f(S_j, d_{ji}, c_i)$$

Equation 1

Where distance to the nearest facility represents ***'d'***, road condition represents ***'c'*** and the service (inpatient care) received from that health facility represents ***'S'***, *i* represents a village and *j* represents the facility. Thus VHSI of a particular village is a function of distance as well as road condition to the secondary healthcare facility. Village- wise distance to the health facility and status of road network were studied using GIS based overlay and proximity functions. Each of the target village was tagged as per the distance to the nearest hospital and status of road network. Further, hospital availability score and road accessibility score were added to form a composite score and were reclassified into three categories i.e. low, medium and high. Figure 3 depicts the methodology adopted for computation of VHSI and the inter-site and intra-site distribution of this access indicator.

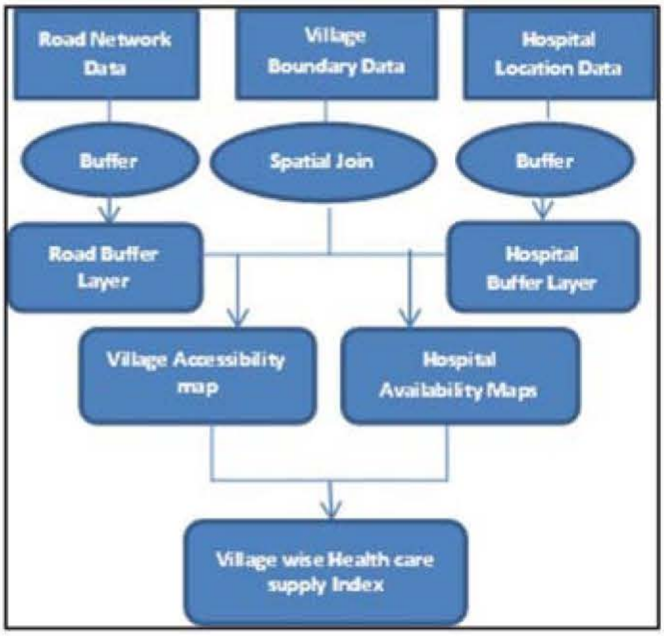

Figure 3: Flow chart on access indicator. Flow chart depicting methodology for development of access indicator.

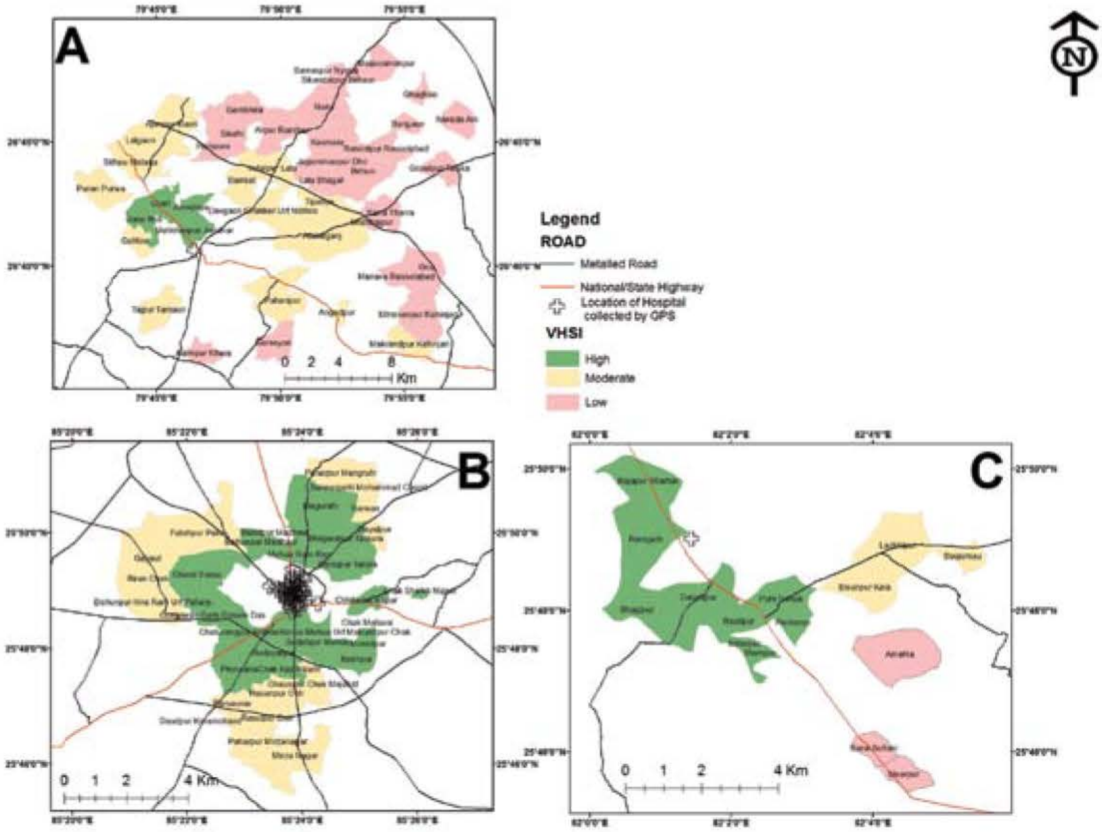

Figure 4: Site wise distribution of VHSI."A" Distribution of VHSI in Rasulabad block, district Kanpur dehat, Uttar Pradesh, "B" Distribution of VHSI in Mahua block, district Vaishali, Bihar. "C" Distribution of VHSI in Shivgarh block, district Pratapgarh, Uttar Pradesh

Table 1: Village-wise distribution of VHSI categories

VHSI	Percentage of villages		
	Rasulabad	**Shivgarh**	**Mahua**
High	10 (4)	67 (10)	56 (19)
Medium	33 (14)	25 (4)	44 (15)
Low	57 (24)	8 (1)	0

Comparisons between the three sites (Figure 4 - images A, B, C) indicate that Mahua and Shivagarh sites were better than Rasulabad site in terms of availability of hospitals and approach roads to access health facilities (see table 1). Importantly more than 55 % target villages in Mahua (19 villages out of 34) and Shivgarh (10 villages out of 15) sites were under high VHSI scores while only 10 % (4 villages out of 42) villages of Rasulabad site were found to be under high VHSI category. VHSI helped in illustrating the fact that even though intervention at all the sites was same, all the sites will report differential impact as all of them are quite different in terms of health facility accessibility status.

4. Conclusion

This paper clearly illustrates the fact that since CRCTs are conducted in the geographical space, incorporation of spatial data will surely strengthen the CRCT design and implementation. There is a definite methodological as well as implementation support by spatial research in the field of scientific CRCTs. We conclude that a complete evaluation model should have tools to capture people, place and time. Usually, "people" are captured using quantitative tools and "time" component is taken using different waves of data collection, and "place" dimension needs to be integrated to make CRCT evaluation more comprehensive and effective. Results highlight the potential for applying this methodology in other studies.

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