ORIGINAL ARTICLE

Opportunistic Research in Rural Areas through Community Health Worker Training: A Cost-effective method of Researching Medication Misuse in Rural India

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Abstract

Objective: To investigate a novel methodology, which was cost effective, to collect large amounts of data to further understand medication purchases and misuse in rural India. **Background: I**n India it is estimated that one third of expenditure of households is spent on health related expenses, and medication purchases make up a large proportion of these costs. **Methods:** This study explores the research approach that was conducted in 2012-13 by Layleaders enrolled in the Community Lay-Leaders' Health Certificate Program initiative by Christian Medical College (CMC), Vellore, India. **Results:** The methodology demonstrated a large data collection capacity, where 100 Layleaders participated and collected over 5000 surveys across 515 villages in North, Central and North East India **Conclusions:** Incorporating opportunistic research methods into community health worker training can be a cost effective way to collect meaningful and useful data in rural India. This study demonstrates a successful methodology that may be transferable to other rural areas and others conducting research training as part of community health worker training should consider such opportunistic research

Key Words

Rural Health; Medications; Cost-Effectiveness; Community Health; Disease Management

Introduction

Medication usage patterns Worldwide are influenced by factors such as poor medication availability, polypharmacy and unsafe utilization. In 2011, the WHO reported that globally more than a third of the world's population lacked access to essential medicines, (1). Furthermore, in developing countries, of those who had medication access, less than half adhered to the treatment schedule. Where medicines were accessible irrational prescribing and use is common place both in high and low-income countries. A data analysis study conducted across 97 countries reported that less than half of the patients received appropriate medication for common illnesses including pneumonia, malaria and childhood diarrhea, (2). This highlights the fact that the goal of rational prescription which aims at "patients receiving medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community" has yet to be achieved, (2,3).

In India it is estimated that one third of household expenditure is on health expenses, a large part of

which is medications, (2). Even in extremely poor and rural households, expenditure on out of pocket health expenses is around 5% of their monthly budgets, (2). Most poor Indians spend more on minor ailments than on diseases of a serious nature, (4). Various factors including over-the-counter availability, over supply, poor patient education and uninformed practitioners are presumed to all play a role, (5). Adding to the complexity is that India is the largest manufacturer and consumer of generic medicines, (6).

In order to combat this growing problem in India more data is needed from the rural communities, where most Indians reside. This research would also provide useful data to health care planners as they seek to address such problems. Drug utilization studies conducted at the level of healthcare facilities can provide data on prescribing and dispensing patterns. Other indicators of dangerous medication use include self-medication and non-adherence to prescribed regimens. Information about these factors is crucial to understand the applicability of health policies at household levels, and thus suggests the need for household surveys, (7). Household surveys can provide some of the most useful information, but are costly and time consuming. Moreover, the complicated planning and sampling methods involved in such surveys, especially in an Indian rural setting, may contribute to the scarcity of such household survey derived evidence, (8,9).

To generate data on this important problem in an affordable and timely manner this study describes a novel methodology of utilizing community health trainees (referred to as Layleaders), as part of their course, to gather data in diverse rural settings across India. These Layleaders were part of the 1 year distance education 'Community Lay-Leaders' Health Certificate Program (CLHTC) started as a 'Be a change agent' initiative by Christian Medical College (CMC), Vellore. It aims to equip the workers of NGOs who already live among the poor and are committed to their welfare, to handle preventive and basic curative care in remote Indian rural areas. A module of the CLHTC was training in research and survey methods that were used to gather data to explore medication usage patterns in communities across North, Central & North East India.

The results of surveys are not included and will be analyzed and published at a later date.

Aims & Objectives

This methodology paper aims to discuss a distinctive approach to gather large amounts of data at low cost through incidental collection as part of the CLHTC program. Objectives of this research project were to teach the practice and importance of field-based surveys and address the question of what is the nature, prevalence and impact (financial and side effects) of medication usage in India?

One of the CLHTC course objectives is to complete a basic field research project to gain experience with data collection to inform approaches to healthcare. In 2012-13 the Layleaders conducted household surveys to train on data collection and appropriate use of medications ('Medication usage study – IND-MEDUSE'). This research project sought to teach the practice and importance of field-based surveys and address the question of what is the nature, prevalence and impact (financial and side effects) of medication usage in India?

Material and Methods

The Layleaders were trained by Nurse Trainers at 15 regional centers across India to complete structured survey questionnaires. The Layleaders were from 15 areas around North, Central & North East India and so we anticipated that the compiled results would provide useful data to understand medication usage practice around India. Given both the paucity of data from rural areas, and the fact that about 70% of the Indian population lives in rural communities, (10), we anticipate that this methodology will provide important insights. The aim of this paper is to describe and discuss this novel methodology for gathering the data for this project. Ethics approval was obtained from the CMC Vellore Institution Review Board.

Study type: This was a multi-centric, multistage cross sectional study with face-to-face household surveys conducted over a six month period from Oct 2012 to March 2013. A structured questionnaire with a detailed data code book was used for survey data collection. The final survey had been piloted in three villages surrounding CMC, Vellore, India. The Layleaders attended the course contact sessions across 15 locations in India. The course included general survey skills training as well as supervision

from Nurse Trainers in delivery of the medication usage survey.

Sampling:
Selection of village and family units
The household units from the villages where the Layleaders served formed the sampling units. From the pre-allotted list of villages that each Layleader served, a village was selected by lot. Each Layleader surveyed every 3rd house in the selected village until 50 subjects, fitting the inclusion criteria, were interviewed. If a single village survey failed to yield 50 subjects, then the adjacent village was surveyed. Where households were unoccupied the next house was surveyed.

Selection of subject
In each of the selected households, the Layleader interviewed only those subjects that answered 'yes' to the question 'did anyone in this family have any health problems in the last 30 days?' If there was no one in that particular household then the next in row that met the sample criteria was pursued. If more than one person was accounted ill in a household, then all of those who had been unwell were included as subjects in the survey. If the subjects were minors, their parents or guardians were interviewed about the illness of their child.

For the purpose of this study, family unit/ household is defined as people living under the same roof, related by marriage/ blood/ adoption and formed a single unit in regards to household income and expenditure.

Inclusion criteria:
- All ages
- Acute (short, sudden onset) or chronic (prolonged) illness
- Visit to any practitioner or self-medication
- One or multiple visits for the same illness

Exclusion criteria
- Clinic visit for immunization
- Visits made for medication that are not intended for treatment of an illness (like oral contraceptives)

Questionnaire design:
The survey fields include details on demography, income, health seeking behavior, the prescriber type, medication prescribed and pre-existing illness. In total the questionnaire comprised of 32 questions that amounted to an average interview time of 30 to 40 minutes for each subject. The questionnaire and interview guidelines were iteratively developed by expert medical family practitioners and then adapted after field testing and piloting. The questionnaire was translated to Tamil and Hindi versions to accommodate for different languages used in the different areas where the Layleaders came from.

Data collection and Quality assurance: The Nurse Trainers underwent a rigorous 2 days training at CMC and they in turn trained and supervised the Layleaders who conducted the survey in their areas of work. The Nurse Trainers (research supervisors) were also actively involved in implementing the pilot study which facilitated them to resolve field related issues and provide suggested changes. The data collectors (Layleaders) were observed in the field and completed practice forms (not included in the study data).

Verbal consent and where possible written/ thumb print consent was obtained from the subjects before the interview.

Quality control measure included, 1) surveyor required to fill in checklist after every interview to ensure all fields were completed, 2) the questionnaire booklet contained quick reference guide and practice forms, and 3) every 10th survey was coloured and the data duplicated from the last form, this was sent to the field supervisor for assessment, corrections and clarifications.

Description of Data analysis: The data analysis will be undertaken in 2015 and be limited to basic univariate and bivariate statistical analysis to understand the demographic characteristics of the respondents, care seeking behaviour, medication misuse and cost. Parametric and Non-Parametric test based on normality assumption would be applied to understand the association between medication misuse and demographic characteristics of the respondents, health care provider and other exposure variables. Regression analysis will also be conducted to fit a model explaining the relationship between polypharmacy and other exposure variables and adjusting for clustering effect if any but the findings would be generalized to study sample only

Results

Data on the CLHTC Course: Four Master Trainers from CMC trained 40 Nurse Trainers who facilitated the contact program in 15 contact sub-centres. Over 3 years they have trained more than 500 Layleaders

to render basic health care to around 5000 villages, conducted school health programs in 1500 village schools, trained around 5000 community health workers (each trainee covers 10 villages and a minimum of 3 village schools), covering a population of 2,500,000. Summary of feedback from the Nurse Trainers and Layleaders

Layleaders (data collectors): 84 of 150 Layleaders participated in any one of the 2 verbal feedback sessions organized and also submitted a written feedback form. Their feedback included:
- Layleaders vowed to use their flashcards to teach their communities about 'Useless Medicines'.
- Layleaders generally were able to gain access to families to complete the survey because they had rapport in the villages where they had worked.
- Many Layleaders used the opportunity to undertake screening (e.g. check BP & Anemia) and health education in those households surveyed.
- Some of the Layleaders have approached local Primary Health Centres for essential medicines and joined as medication providers in the National TB program.
- Some Layleaders have done advocacy and education with the local medical stores instructing them not to sell expired and sub-standard medications.
- Some Layleaders expressed a desire to be involved in similar surveys in future.
- Challenges identified: receiving truthful answers, inability to find tablet names (where tablets were loose in packets), and not enough time to adequately complete surveys.

Nurse Trainers (Supervisors):
37 out of 40 trainers participated in any 2 of the 3 verbal feedback sessions organized and submitted a written report. The Feedback included:
- The survey brought the Nurse Trainers and Layleaders much closer to each other.
- The data they collected and the stories they shared were teaching examples.
- Practicing the survey improved the quality of surveys.
- Pilot phase was most difficult – to get the Layleaders to understand was a challenge, but

they picked up fast once they did a few practice forms.
- Constant reminders were needed to get the Layleaders to send in the forms on time.
- Trouble-shooting when the Layleaders called from their fields was a major task but they enjoyed doing that.

Master Nurse Trainers (CMC):
4 trainers gave verbal feedback in 4 staff meetings, feedback included:
- Incomplete or illegible forms were a challenge.
- Clear guidelines formulated were helpful, still unexpected challenges rose from other quarters.
- Working with the initial forms with the research core group of doctors and epidemiologist was a great experience and learnt a lot about how to think through a problem and how to make and validate and fine tune questionnaires.
- Supervising the quality assurance of the whole project was a great responsibility and a good learning experience.

Discussion

Efforts to control irrational medication usage have included introducing essential medicines lists, drug monitoring systems, and adverse drug effect reporting systems. Education of health and medical staff at their training phase about rational prescribing, dispensing and consuming, can help in reaching the community about proper medication use, (11).

Medication misuse in India rates as one of India's biggest public health threats and issues. The novelty in this research method is that it utilizes an educational exercise, the CLHTC training course, to complete a very large multi-centric survey on this important issue. This paper shows that including practical research training as part of a community health worker training course can be used to cheaply gather interesting data from areas that are otherwise difficult to gather data from. At the same time, it can provide an excellent health worker training exercise.

Cost-effectiveness and coverage: The multi-centric survey was conducted across a large part of North, Central & North East India achieving a broad perspective of different villages. There were 15 distinct regions represented by the 15 training centres, and more than 515 villages included. The

representativeness across these villages is shown in that that no one village made up more than 1.3% of the total sample of 4800.

Collecting data from rural areas on an important issue such as medication misuse is very difficult. Typically, research involving large samples (5000 people) across multiple centres (15 centres) like this, could cost millions of dollars if conducted in an urban setting. Also, data collection in rural areas is also generally costly and time consuming to complete. However, using convenience sampling and integrating it with the certificate course allowed the completion of a large study, including rural areas, at low cost. Every level of training and manpower involved in the survey was rendered as part of the various levels of the CLHTC course. So interestingly, there was no budget for this study and the costs were absorbed under the course costs. If these expenses were separated out the overall cost would be less than one dollar (US) per participant.

Practical learning exercise: The practical approach of undertaking a survey as part of a real life research project is more effective than classroom teaching. The pedagogy of adult learning places value on real-life experiential learning, (12). When the educational experience is undertaken with close supervision and ongoing feedback it can be a powerful learning experience. The CMC team strongly supported the Nurse Trainers and Layleaders by mentorship, help with trouble shooting and field related problems.

The survey selected was closely related to the activities that the Layleaders would be undertaking back in their field. In this way the process of data collection is not a distraction but an important practice for the work they will be undertaking. The CLHTC course is unique in this way because the Layleaders have existing areas where they work and they can immediately apply their learning to their community health work.

Community benefits: The focuses of this survey for communities was appropriate because medication misuse, overuse and abuse are major problems in rural Indian communities. Contrary to the common held idea of health workers being only a 'medication dispensing node', trained health workers such as these Layleaders can play a more important role in limiting medication usage to those who truly need them. Engaging in the survey with community members had intrinsic value by providing an opportunity after completion of the survey to undertake health education about responsible medication usage.

Conclusion

Incorporating opportunistic research into community health worker training, when well designed with appropriate training and supervision, can be cheap and effective at characterizing important issues affecting rural areas. Such studies augment the chance for health workers to address their serving population and prove to be a valuable data source.

Recommendation

The sparse availability of data from the major rural population has always been a challenge, in addressing medication misuse on national level. This rendered the rural household vulnerable to tainted prescribing practices and deviated health seeking behaviours. Our study not only increases the basic knowledge build of the layleaders but also reveals their upcoming real life challenges and to address them at household level. So we recommend that others conducting research training as part of community health training should consider such opportunistic research projects. The topic should be carefully selected to be of relevance to the trainee's work, relevant to the community, well supported by the training institution, and feasible to undertake over the duration of the course.

Limitation of the study

The study does not provide data on prevalence of medication use as convenience sampling is employed. However, given the wide geographic coverage, it does give an indication of the medication usage behaviour across the country. Although the field areas for data collection were selected by using convenience sampling of where the Layleaders worked, the actual villages and households were selected randomly. This gives an indication of prevalence in that work area and limits bias resulting from the Layleaders' preferential selection of villages or households. Being an opportunistic research methodology, such randomization of selection was adapted to limit bias due to convenience sampling.

Guaranteeing the quality, accuracy and completeness of a survey conducted by many data collectors at 15 sites was challenging. However, extensive training; including field based practicing, close supervision, a simple tested survey and quality

control steps; including a supervisor review of every 10th survey and a checklist for each survey, maximized the quality of this research. This allowed correction of many mistakes and ensured that accurate and consistent data was gathered. Therefore, less than 4% of forms were inadequately filled and excluded from the analysis.

50 out of 150 Layleaders did not complete this component of the course, as they did not submit any completed survey forms but there was no indication of systematic bias. 27 of the candidates decided not to complete the course, and the remaining 13 did not respond to this requirement. Reasons given were they were too busy, the survey was too complicated, or they would do it later. Where booklets were submitted they took on average 6 months to be completed and returned. If completing the forms in a timely manner was part of the course assessment then the authors hypothesize that timeliness and response rate would have improved.

Relevance of the study

Our study involves a large sample, covering hard to reach rural population in India, and outlines an approach which can be utilised to generate data on issues of national importance. It introduces a novel method of acquiring sizeable household data from hard to reach populations in a cost effective manner, by including it as part of health workers training course.

Authors Contribution

NG – Conceived of, helped develop the concept and provided technical support to the project throughout, provided edits and corrections as manuscripts developed. JV – Co-led the research on the ground in India, worked with NG on operationalizing the concept, oversaw data collection and contributed to drafting manuscript. SB – Co-led the research on the ground in India, oversaw data collection and contributed to drafting manuscript. EV – Collected data, provided training for layleaders in the community and contributed to drafting the manuscript. SA – Collected and analysised the data, oversaw the data collection, and undertook data cleaning. BR – Advised on the development of the methods, trained the Layleaders in research and monitored quality control. NT –

Developed initial manuscript, gave feedback on the development of the concept, coordinated the input from the University of Melbourne.

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Tables

TABLE 1 SAMPLE FRAME AND RESPONSE PATTERNS

	Actual amount	Expected amount
Total Layleaders who submitted their survey booklets	100	150
Centres	14	15
Total Forms Collected	5007	7500
Invalid forms	207	250 (5% error rate)
Total Forms being analysed for the study	4800	5000
Total villages represented	515	
Total Layleaders who gave feedback on the survey	84	150
Total Nurse Trainers who gave feedback	37	40
Total Master Trainers who gave feedback	4	4
Total Cost of the Project	80,000 INR (1290USD) Less than 1$ per participant	50,000

Figures

FIGURE 1

Fig-1: Program Design

FIGURE 2