Rationale and design of a home-based care model of community care for epilepsy in low- and middle-income countries.

Background

Epilepsy affects 50 million people worldwide and 40 million of these live in low and middle income countries (LMICs).[1] Moreover, nearly 80% of those living in LMICs do not recieve the appropriate treatment and the level of care and support that they are supposed to receive.[1-4] The Global Burden of Diseases Study estimated that epilepsy accounted for 12,418 million disability-adjusted life years (DALYs) in 2015, thus ranked fifth in the list of neurological disorders causing disability and death on a global scale (GBD 2015 Neurological Collaborators Group, 2017).[5, 6] The DALYs associated with epilepsy are about equally divided between years lived with disability and premature mortality. The latter is a major issue inasmuch as mortality is increased 2-3 folds in people with epilepsy (PWE) in comparison to the general population.[7, 8] Premature mortality in PWE has not been amply studied largely on account of poor record keeping but the few studies that exist suggest that mortality may be increased 5-8 folds in PWE in LMICs.[9-11] Appropriate treatment is known to offset premature mortality associated with epilepsy.[12]

The 68th World Health Assembly adopted an unanimous resolution on epilepsy prevailing upon its member states to introduce and implement national programs for epilepsy care in order to reduce the gap in provision of care particularly in poor and remote regions and to integrate the provision of community-based epilepsy management in to primary care.[13] Furthermore, the WHO envisages epilepsy care as a joint responsibility between epilepsy specialists and primary care providers.[1] An international survey of 146 countries estimated that the main tasks of epilepsy specialists were to provide diagnostic and investigative services on a consultation basis, institute treatment changes and follow-up and provide education and counsel people with epilepsy. In most countries, primary care providers are delegated the tasks of case finding, referral to specialists, and then follow-up, monitor PWE to maintain them on drug therapy. In addition, the task of provision of information and education about epilepsy is one of the main responsibilities of primary care providers in LMICs. In comparison, the provision of information and counseling is not frequently the responsibility of

primary care providers, rather is undertaken by epilepsy specialists in high income countries.[1] This is perhaps on account of the limited number of epilepsy specialists in low income countries.[14]

The World Health Assembly resolution endevours to achieve a substantial reduction in the magnitude of the epilepsy treatment gap in LMICs by addressing some of the factors that pose barriers to health-seeking by PWE.[13] The barriers include components related to the supply side, e.g., the non-availability of epilepsy medicines on a regular basis, long distance to health care facilities and insufficient scale of expertise required to treat epilepsy, as well as those related to the demand side, e.g., cost of treatment, superstitions and beliefs regarding epilepsy, stigma, faith in traditional treatments and lack of faith in contemporary treatment.[15] Home-based care for epilepsy might possibly overcome some of these barriers by addressing factors such provision of regular supply of epilepsy medicines free of cost thus eliminating the “distance to health facility”factors as well as approaching stigma, false beliefs and self-management through provision of knowledge and guidance.

Regrettably, epilepsy management is not a key component of universal health coverage, nor is there a stand-alone national epilepsy care program in India. Ostensibly, the paucity of specialist care might be one of the reasons behind deficient standards of care for epilepsy in LMICs. For example, there are an estimated 8-12 million people with epilepsy in India.[16-18] Applying the yardstick of one neurologist for 100,000 people would mean a requirement of __ neurologists.[19, 20] In actual fact, a WHO survey of epilepsy care in 106 countries estimated a median of 0.07 neurologists/100,000 population in the SEARO region.[14] Hence, the number of neurologists required to care for people with epilepsy grossly falls short of the required number in many SEARO countries and LMICs. India appears to be ideally suited for testing a care model integrating specialist neurological expertise within the primary care infrastructure. There are about 2000-plus qualified neurologists, albeit insufficient by themselves to mantle the care of epilepsy in the country but sufficient to guide and counsel epilepsy care delivered by primary care providers. In addition, there is a vast resource of personnel and a well-developed infrastructure supporting primary care across the country.

We posed the research question, whether home-based care improves adherence to treatment, quality of life and seizure control in PWE residing in LMICs. Furthermore, in an attempt to answer this question, we test a model of community care for epilepsy in the form of a bundle comprising provision of essential epilepsy medicines and epilepsy self-management education delivered by primary care health providers.

Aims

Overall Aim: To develop and pilot test a model of community care for epilepsy in India.

Primary Aim: To determine if a home-based care intervention comprising health education emphasizing epilepsy self-management and provision of epilepsy medications is superior to usual clinic-based care in sustaining medication adherence in people with epilepsy in the community.

Secondary Aims: (i) To determine if home-based care is superior to usual clinic-based care in ensuring quality of life in people with epilepsy in the community.

(ii) To determine the impact of home-based care on seizure control in people with active epilepsy in the community.

(iii) To determine the cost-effectiveness of a home-based care plan over usual clinic-based care for managing epilepsy in the community in India.

(iv) To identify barriers in the implementation of a model of community care for people with active epilepsy in the community.

Our primary aim was focused on establishing a home-based care plan comprising health education emphasizing epilepsy self-management and provision of epilepsy medications was superior to usual clinic-based care in sustaining medication adherence in people with epilepsy in the community. We also sought to determine the impact of home-based care *vis-à-vis* usual clinic-

based care on the quality of life and seizure control in PWE in the community. A connected objective was to study the cost effectiveness of the home care plan. Finally, we pursued the identification of barriers to the implementation of the community care model of epilepsy care in India.

Setting of the trial

The community care was implemented on a pilot basis in the urban and peri-urban rural areas of Ludhiana district with an area of 3767 km^2. The estimated field-area population was 19,00,000 (2011 Census India).[21] Approximately, 80% of the population is literate and 30% is comprised of workers. The urban part of the district comprises of 75 municipal wards. The Government Health Department has divided the urban and peri-urban rural areas in to nine zones in order to facilitate immunization coverage (Fig. 1). We adopted the cluster sampling approach aiming for 2-3 clusters of 2000 population each in all nine zones.[22]

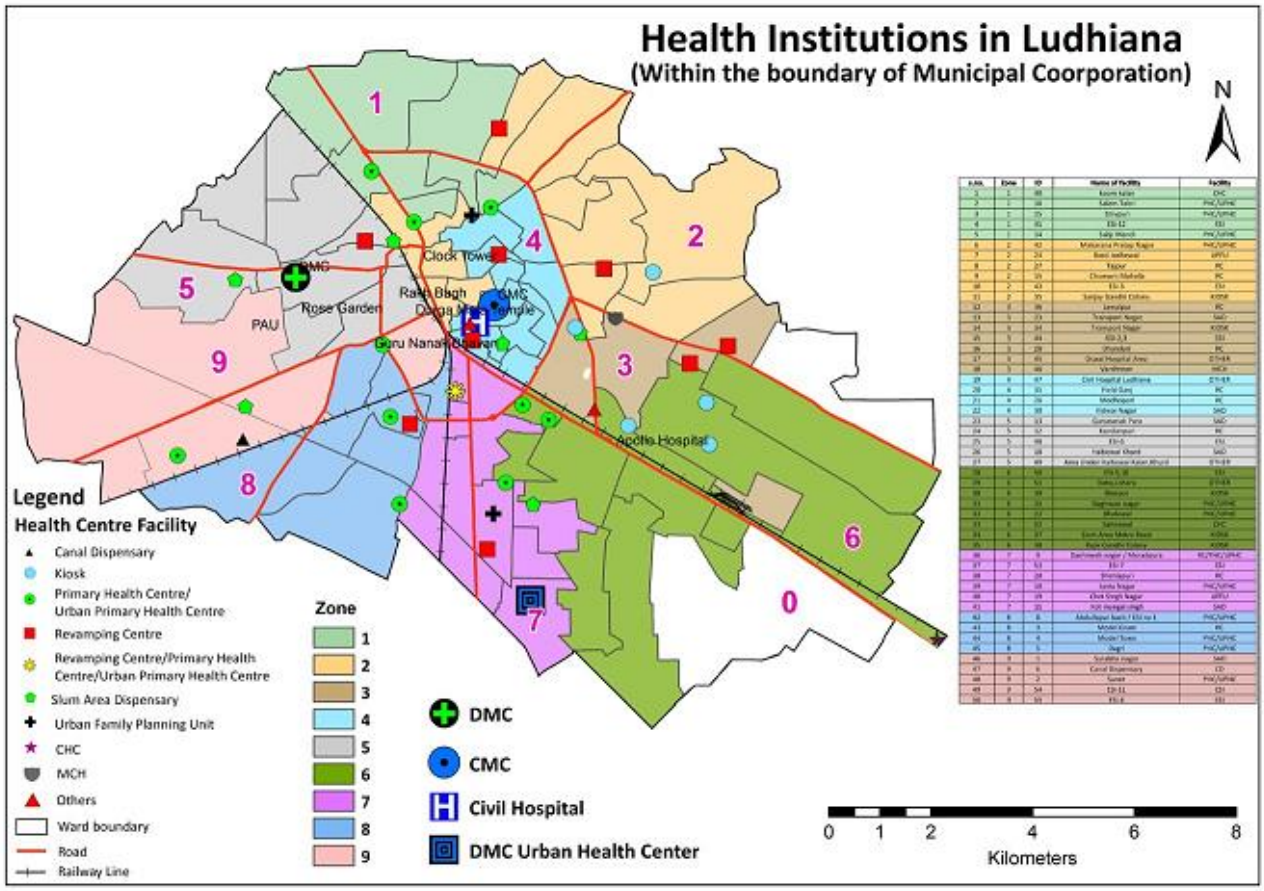

Fig. 1. Map of the study area with division in to nine immunization zones. The public health centres, district hospitals and tow private medical college hospitals are also mapped.

Screening for potential subjects

We opted to draw cases and controls from the community in order to include untreated, inappropriately treated and poorly-motivated PWE in addition, to those already on treatment. The 30-cluster sampling approach for evaluating vaccination coverage was used. This amounted to approximately 3 clusters per immunization zone (total 27 clusters). Precisely, the sampling frame comprised clusters from areas of lower socio-demographic index for which ASHA personnel were available and willing to assist the survey for epilepsy. A prevalence of epilepsy of 10 cases in 1000 population, to which an inflation rate of 50% was factored in order to account for locked households, refusal to participate in the screening process or to enroll in the trial.[23] Hence, it was decided to screen a minimum of 2000 population in each cluster.

Other than compliance of the ASHA personnel, the selection of clusters was random and undertaken prior to the survey. Study personnel accompanied by ASHA workers screened each cluster guided by detailed GIS maps with household numbers, superimposed on Google maps. Screening proceeded in an orderly fashion advancing to consecutive dwelling units along a street from a randomly chosen starting point and then to the adjoining street (Fig. 2). Inventories for locked households, supernumerary households including leased ones and tenants as well as of all family members in a given household were maintained. Locked household were revisited twice before excluding them from the survey.

The screening tool was selected following consideration of several questionnaires described in a recent systematic review of screening toolsfor epilepsy in the community.[24] The questionnaire was previously employed in Ecuador and its translated version was validated previously in the community currently being studied.[25, 26] Subjects were classified either as ′suspected cases of epilepsy′ or ′screened negative for epilepsy′ (Appendix, Table 1).

Trial recruitment and randomization

Suspected epilepsy cases following screening were invited for neurological assessments by two adult neurologists and paediatric neurologist with expertise in epilepsy evaluation and management. The suspected cases were investigated on a conservative basis with a minimum of a one-hour awake and sleep EEG and magnetic resonance imaging (MRI) if required in the judgment of the neurologist. All subjects above one month of age with active epilepsy were invited to enroll in the trial regardless of their treatment status (see operational definitions below). Febrile seizures, neonatal seizures, single seizures not fulfilling current operational criteria for epilepsy and acute symptomatic seizures associated with head injury, stroke and toxic, metabolic and acute infective conditions were excluded. Informed consent was obtained from all those willing to enroll. Finally, 10 confirmed subjects with active epilepsy were included in each cluster.

Each cluster was randomized according to either an interventional arm comprising a home-based care package (see below) delivered by study personnel or routine clinic-based care in the Government District Hospital.

Antiepileptic drug treatment plans were charted out by the study neurologists following neurological evaluations. In keeping with the pragmatic design, the choice of AED, its manner of initiation were left to the judgment of treating neurologist. Attempt was made to restrict the AED use to those on the state essential medication list.[27] However, two exceptions to the use of essential medications comprised of those subjects with active epilepsy who experienced seizure-freedom with alternative AEDs prior to enrollment and women with epilepsy in the reproductive age group in whom valproate was avoided. All AEDs were provided free of charge to subjects.

Definitions and operational criteria

Epilepsy: A condition characterized by recurrent (two or more) epileptic seizures, unprovoked by any immediate cause.[28, 29]

Active epilepsy: A condition characterized by two or more unprovoked seizures or having received appropriate treatment for the same in the preceding five years.[28]

Single seizure:One or more clinical seizure/s occurring within a 24 hour period regardless of whether provoked or unprovoked.

Acute symptomatic seizure/s:One or more clinical seizure/s occurring at the time of a systemic insult or in close temporal relationship with a documented brain insult.[30]

Febrile seizure/s: Clinical seizure/s after the age of one month in childhood associated with a febrile illness not caused by a central nervous system infection, without previous neonatal or other unprovoked seizures and not meeting criteria for acute symptomatic seizures.[31]

Appropriate treatment: Diagnosis and management of recurrent seizures (active epilepsy) and of the underlying cause according to established national standards (GEMIND).[32, 33]

Treatment gap: Proportion of people with active epilepsy who have not received appropriate treatment in the past one week.[32]

Interventional package and control procedures

The essential components of the interventional package comprised (1) delivery of AEDs, (2) education and counseling about epilepsy self-management and social functioning and (3) adherence monitoring, all delivered on a monthly basis by study personnel equivalently qualified as auxillary nurse midwifes (ANMs). During the first home visit, the study personnel explained the purpose, frequency and timings, and gave clear instructions regarding the names, dose and frequency of administration of AEDs that they would be dispensing. They also provided a seizure diary and prescription record to the subjects. During each monthly visit, they held discussions regarding epilepsy self-management, provided psychosocial education including schooling, marriage and employment, enquired about medication side-effects, verified seizure diaries and provided monthly stock of AEDs.

Records of the monthly visits were reviewed in bimonthly meetings with the study neurologists, who advised changes in the treatment plan according to seizure control status, side-effects and other circumstances as necessary. Any changes in treatment plan were implemented by unscheduled home visits.

Subjects in the control arm were asked to visit monthly clinics in the Government District Hospital

for physician check-up and procuring their AEDs.

Outcomes

Medication adherence was chosen to be the primary outcome and it was measured by pill counts and the use of vernacular-versions of the self-reporting medication-taking scale (SRMS) and brief medication questionnaire (BMQ).[34, 35] The pill counts and administration of the two questionnaires were undertaken on a monthly basis. The secondary outcome measures included quality of life as measured by the Personal Impact of Epilepsy (PIES) scale and time to first seizure (in days) after recruitment to the study.[35]

Instruments

The measurement of various outcome parameters were accomplished using the following tools:

<u>Measures of adherence</u>

i) Pill counts: Returned dosage units of each epilepsy medication at the time of monthly visits were subtracted from the number of units issued during the previous monthly visit to estimate non-adherence as a fraction of the number of issued units.

ii) Questionnaire-based measures: The SRMS and BMQ were translated to the vernacular language (Punjabi) by two multilingual translators not connected to the study team, followed by correspondence assessment by discussion between the two.[34, 35] The Punjabi version back-translated to English language and reviewed and compared with the original English version by two study team members. The translated versions were then administered to 15 PWE drawn from the out-patient clinic to verify linguistic comprehension and feasibility of the items. Finally, both scales were administered to

215 PWE (including 15 who self-admitted poor adherence) from the out-patient clinic in order to determine their reliability, validity and responsiveness in comparison to pill counts.

Quality of life

The Personal Impact of Epilepsy Scale (PIES) was chosen over other scales, e.g., Quality of Life in Epilepsy (QOLIE-89, -31, -10, -AD-48) because it could be administered to both PWE and their carers and hence, a single common scale for all subjects including adolescents, children and intellectually-challenged subjects could be applied.[36-41] The PIES was likewise translated to, and back-translated from vernacular language, examined for accuracy and validated in the same population of 215 PWE (including 15 who presented with drug-resistant epilepsy but later experience complete seizure control) from the out-patient clinic.

Ancillary appraisals

Besides measurement of the outcomes, additional evaluations were conducted in order to fully document the impact of the intervention. These were accomplished by using translated versions of the Epilepsy Self-management Scale (ESMS), Kilifi Epilepsy Stigma Scale (KESS) and the Kilifi Epilepsy Beliefs and Attitudes Scales (KEBAS).[42-46] The translated versions were validated using protocols similar to those applied to scales for the outcome parameters discussed above.

Follow-up procedures

The duration of the trial was 18 months. Outcome assessment was undertaken by a study nurse who was blinded to the randomization status. The study nurse undertook pill-counts and recorded

outcome parameters on a study tablet that transmitted data to a central server. Pill counts were undertaken and, self-reported medication-taking scale and brief medication questionnaire were administered on a monthly basis (Fig. 3).[34, 35] The adverse effects profile questionnaire was administered once in 3 months, PIES once in 6 months and the Epilepsy self-management, Kilifi stigma and Kilifi Beliefs and Attitudes scales were administered in the beginning, mid-way and at the end of the trial.[36, 45, 46]

Sample size

Statistical analysis

Geo-spatial mapping

The justification for utilizing Geographic Information System (GIS) mapping was three-fold: (1) to map out households within each cluster selected for the community survey to identify PWE; (2) to determine geographic correlates including spatial clustering of the epilepsy cases identified in the community survey and (3) to aid in the analysis of factors associated with treatment-seeking behavior of the control group.

Economic analysis

A separate economic analysis of the intervention, based on governmental and societal perspectivesis underway. The analytic horizon will be for the trial period. The cost items will include service delivery costs as well as patient costs. Daily log books maintained online by all study personnel will be examined. In addition, a structured questionnaire will be prepared for collecting all costs related

to service delivery and patient cost. Service delivery cost will include training, time cost of service providers etc. Patient cost will include treatment cost as well as time costs of patients, accompanied persons, informal caregivers. Human capital approach will be used for calculating these costs. Both cost-effectiveness analysis in relation to a meaningful change in quality of life evaluated using PIES as a measure of effectiveness and cost-benefit analysis in comparison to costs of routine clinic-based care will be calculated.

Ethical considerations

The trial was approved by the institutional ethics committee. Informed consents were recorded from all subjects enrolled. The trial was registered with the Clinical Trials Registry of India (CTRI) (No.). A data sharing policy have been put up on the institutional website for research and development (Appendix 2).

Discussion

Future research questions

Conflict of Interest

Financial support

Appendix 1: English version of the screening questionnaire (adapted from Placencia et al, 1992; with permission) and its interpretation.

Q. 1. Have you ever had attacks of shaking of the arms or legs, which you could not control?

Q. 2. Have you ever had attacks in which you fall and become pale?

Both question 1 and 2 must be affirmative to render the subject positive.

Q. 3. Have you ever lost consciousness?

Q. 4. Have you ever had attacks in which you fall with loss of consciousness?

Q. 5. Have you ever had attacks in which you fall and bite your tongue?

Q. 6. Have you ever had attacks in which you fall and lose control of your bladder?

Q. 7. Have you ever had brief attacks of shaking or trembling in one arm or leg or in the face?

Q. 8. Have you ever had attacks in which you lose contact with the surroundings and experience abnormal smells?

Q. 9 Have you ever been told that you have or had epilepsy or epileptic fits?

Any question 3 to 9 if affirmative renders the subject positive.

Screening classification	**Q. 1 & 2**	**Q. 3-9**
Suspected epilepsy	BOTH affirmative	+ ANY affirmative
	ONE affirmative	+ ANY affirmative
	BOTH negative	+ ANY affirmative
Screened negative for epilepsy	BOTH negative	+ ALL negative
	ONE affirmative	+ ALL negative

Appendix 2: Data sharing policy

1. The study protocol in its final version as approved by the Institutional Ethics Committee will be posted on the host institutional research and development website from trial inception.
2. In addition, statistical analysis plan, project report submitted to the Indian Council of Medical Research, informed consent forms and analytic code will be made available at the institutional R&D website immediately after publication of results.
3. Anonymised individual subject data garnered during the trial will be available three months after publication in a password protected file on the host institutional research and development website.
4. Researchers who wish to access data including for individual level data meta-analysis should contact CIFE and proceed to make a formal proposal in a prescribed format. Permission will be granted after approval by the Indian Council of Medical Research and Institutional Ethics Committee.

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