Epilepsy Management at Primary Health Level in rural China:

WHO/ILAE/IBE

A Global Campaign Against Epilepsy
Demonstration Project

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Foreword

Epilepsy is one of the most common neurological disorders, affecting about 50 million people in the world, 85% of whom live in resource-poor countries. Epilepsy imposes an enormous physical, psychological, social and economic burden on individuals, families and countries, especially due to misconceptions, fear and stigma. Many people with epilepsy suffer in silence, as they remain socially isolated for fear of possible hostile reactions of others not affected by epilepsy, and do not come forward for treatment.

Epilepsy is, however, one neurological disorder for which cost-effective treatments are available. Despite this about 60–90% of people with epilepsy in resource-poor countries do not receive appropriate treatment, or are inadequately treated due to deficiencies in health-care resources and delivery or more commonly social stigma.

As part of an epilepsy Demonstration Project (under the aegis of the Global Campaign Against Epilepsy), carried out in rural areas of six non-contiguous provinces of the People’s Republic of China, it was estimated that the number of people with epilepsy in China is almost 9 million with a treatment gap of 63%. The Demonstration Project was successful in implementing treatment and management of convulsive forms of epilepsy in rural areas of the country. Physicians with basic training were shown to be able to treat people with epilepsy. This cost-effective approach was successful in reducing the treatment gap by about 13%.

It is time now to scale up this model of epilepsy care so that more people in China and worldwide can benefit. It is hoped that this report will provide an opportunity to review the burden and resources available in the country and help develop a more effective and efficient strategy to scale up epilepsy care in China. Other resource-poor countries are also likely to find this report beneficial in addressing and improving care for people with epilepsy.

Dr Hans Troedsson, WHO Representative
WHO Country Office, China
Preface

The “Global Campaign Against Epilepsy – out of the shadows”, a joint initiative of the International Bureau for Epilepsy (IBE), the International League Against Epilepsy (ILAE), and the World Health Organization (WHO), has been gradually gathering momentum since its launch in 1997. In the first phase, it led to the organization of many awareness raising activities, such as regional conferences on “epilepsy as a public health priority” and the development of “regional declarations on epilepsy” around the world, which have endeavoured to encourage greater prioritization of epilepsy services. During its second phase, which was launched in 2001, the campaign moved from raising awareness to implementing demonstration projects. These projects have been set up to support health departments in identifying needs and promoting education, training, treatment, services, research and prevention, to reduce the treatment gap in epilepsy care on a national level.

It is evident that the collaboration between IBE, ILAE and WHO has given the campaign the opportunity to build a framework for concerted action on a global, regional and national level to raise awareness and reduce the treatment gap. This is a true joint venture, bringing together many experts all over the world, with one purpose – bringing epilepsy “out of the shadows”.

As part of the campaign and under the aegis of WHO and the Ministry of Health, People’s Republic of China, a Demonstration Project, “Epilepsy Management at a Primary Health Level”, was implemented in rural areas in six non-contiguous provinces of China. The Demonstration Project included two epidemiological surveys, a phenobarbital treatment intervention trial, and an educational programme. While the Department of Disease Control and the Department of International Cooperation of the Ministry of Health, China, were jointly responsible for the Demonstration Project, the Beijing Neurosurgical Institute was delegated the task of ensuring concerted action.

The epilepsy project in China is an example of successful partnerships: in the first place, the partnership between IBE, ILAE and WHO, but more importantly the partnership with China’s Ministry of Health, national chapters and members of IBE, ILAE and other scientific societies, WHO regional and country offices, other NGOs and WHO Collaborating Centres.

This report is based on the above project and documents the success achieved in reducing the epilepsy treatment gap in China by managing convulsive forms of epilepsy at a primary health-care level. As the success of any intervention is a consequence of it being sustainable in the long term, this report also presents the lessons derived for the development of an effective and sustainable framework for epilepsy care and scale-up in resource-poor settings. The current Demonstration Project and the intervention model described here have succeeded in the ultimate goal: to make epilepsy a national health priority in China.

Mike Glynn, President, IBE
Solomon L Moshé, President, ILAE
Benedetto Saraceno, Director, Department of Mental Health and Substance Abuse, WHO
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Demonstration projects on reducing the epilepsy treatment gap are amongst the most important projects within the framework of the International Bureau for Epilepsy (IBE)/International League Against Epilepsy (ILAE)/World Health Organization (WHO) Global Campaign Against Epilepsy. The Demonstration Project in the People’s Republic of China and its subsequent activities were achieved due to major collaborative efforts involving the WHO headquarters, regional and country offices, IBE/ILAE regional committees and national chapters/members and WHO Collaborating Centres.

Dr Benedetto Saraceno, WHO headquarters, Switzerland provided the vision and guidance for the entire project, while Dr Shekhar Saxena, WHO headquarters, Switzerland; Dr Giuliano Avanzini, Dr Jerome Engel Jr, Dr Solomon L Moshe, and Dr Edward H Reynolds of the ILAE; and Mr Mike Glynn and Mr Philip Lee of the IBE, provided their continuous support.

The work on this report was supervised and coordinated by Ms Hanneke M de Boer, Stichting Epilepsie Instellingen Nederland (SEIN), the Netherlands; Dr Tarun Dua, WHO headquarters, Switzerland; and Dr Josemir W Sander, University College London (UCL) Institute of Neurology, United Kingdom, and SEIN, the Netherlands.

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The Demonstration Project would not have been such a great success without the hard work of its principal investigators: Dr Wenzhi Wang and Dr Jianzhong Wu of the Beijing Neurosurgical Institute, Beijing; and co-investigators: Dr Desheng Wang, Harbin Medical University, Heilongjiang province; Dr Xiuying Dai, Ningxia Medical College, Ningxia Hui autonomous region; Dr Bin Yang, Jiaozuo People’s Hospital, Henan province; Dr Taiping Wang, Zhezhou County Hospital, Shanxi province; Dr Chenglin Yuan, Subei People’s Hospital, Yangzhou, Jiangsu province; Dr Zhen Hong and Dr Ding Ding of the Fudan University, Shanghai; Dr Guangyu Ma, Universal Love Hospital, Heilongjiang province; and Dr Patrick Kwan, Chinese University of Hong Kong, Hong Kong Special Administrative Region. Special thanks are due to local coordinators and leaders of “public health bureaus” in each of the participating provinces.

The contributions of all those mentioned above and the inputs from many unnamed people have been vital to “bring epilepsy out of the shadows in China”.
Abbreviations

CAAE ........................................................................... China Association Against Epilepsy
CFR ........................................................................ case fatality rate
CREST ..........................................................Collaborative Research on Epilepsy Stigma
DALY ...............................................................disability adjusted life years
EMPHL ..................................................Epilepsy Management at a Primary Health Level
GBD ........................................................................ global burden of disease
GCAE ......................................................Global Campaign Against Epilepsy
GNP ............................................................... gross national product
I$ ..............................................................................international dollar
ICBERG ..............................................International Community-based Epilepsy Research Group
IBE .............................................................................International Bureau for Epilepsy
ILAE ............................................................ International League Against Epilepsy
mhGAP ..................................................WHO mental health Gap Action Programme
PMR ...............................................................proportional mortality rate
SEIN .......................................................... Stichting Epilepsie Instellingen Nederland
SMR .............................................................standardized mortality ratio
SWOT ..........................................................strengths, weaknesses, opportunities and threats
US $ .........................................................................United States dollar
WHO .................................................................World Health Organization
¥ ........................................................................... Chinese Yuan Renminbi
YLD ............................................................... years lost due to disability
YLL ..............................................................years of life lost due to premature mortality
Executive summary

Epilepsy is the most common neurological disorder, affecting around 50 million people worldwide, 85% of whom live in resource-poor countries. It accounts for 0.5% of the world’s disease burden, which is the same as lung cancer among men or breast cancer among women. The disorder imposes a high economic burden on affected individuals, their carers and household members, and on the health services. Worldwide, mortality among people with epilepsy is two to three times higher than in the general population. It is known that with correct diagnosis and treatment up to 70% of epileptic seizures can be well controlled by antiepileptic medication without diminishing the quality of life of patients. However in resource-poor countries, almost 80% of people with epilepsy do not receive treatment or are inadequately treated due to deficiencies in health-care resources and delivery, and often, social stigma. The lifetime prevalence and active epilepsy prevalence in rural China were found to be 7.0/1000 and 4.6/1000, respectively; the treatment gap in those with active epilepsy was 63%.

People with epilepsy tend to have poor self-esteem, educational and occupational underachievement, and perceived, as well as enacted, stigma and discrimination. They are more likely to be under-employed or unemployed, and have lower rates of marriage and greater social isolation than the general population. Thus, reducing the burden of epilepsy is complicated and faces many barriers. Any management programme needs to bring about a change in cultural attitudes so that the stigma of epilepsy is reduced and more people come forward to receive treatment. In this context, the World Health Organization (WHO) in cooperation with the International League Against Epilepsy (ILAE) and the International Bureau for Epilepsy (IBE) launched the Global Campaign Against Epilepsy (GCAE) in 1997 in an attempt to bring epilepsy “out of the shadows” and to improve the acceptability, treatment, services and prevention of epilepsy worldwide.

As part of this Campaign and under the auspices of WHO and the Ministry of Health of China, during 2000 to 2004, a Demonstration Project “Epilepsy Management at a Primary Health Level”, was carried out in rural areas of six non-contiguous provinces of the People’s Republic of China. This Project included two epidemiological surveys, conducted before and after a treatment intervention trial, and an educational programme in the target areas. The study results have been published in several international peer-reviewed journals as well as Chinese medical journals. This report presents the results of the project and derives lessons for the development of an effective and sustainable model and framework for epilepsy care and scale-up in resource-poor settings.

The first epidemiological survey (2000–2001) of around 55 000 people selected from random clusters found the lifetime prevalence and active epilepsy prevalence in rural China to be 7.0/1000 and 4.6/1000, respectively; the treatment gap in those with active epilepsy was 63%; and disease burden of epilepsy was 2.08 Disability Adjusted Life Years (DALY’s) per 1000 people. The standardized mortality ratio was 3.9, indicating that people with epilepsy are three to four times more likely to die prematurely than those in the general population. The results also suggested the possibility of high risk of mortality among young people (15–29 years) with epilepsy in China. In the subsequent intervention trial (2001–2004), trained primary care physicians treated over 2000 epilepsy patients with phenobarbital. After two years of treatment, 25% of patients were seizure free and a further 45% showed an improvement in their condition. Data from two counties that were analysed for the economic consequences of phenobarbital treatment showed that health system costs fell dramatically in both counties during the 12-month treatment period. An educational programme introduced after the first epidemiological survey, which ran in parallel with the intervention trial, was effective in making families and the general community aware that epilepsy is a treatable disorder. The second epidemiological survey conducted after the completion of the intervention and educational programme estimated the treatment gap of active epilepsy to be 50% – 13% lower than that of the first survey (63%) – confirming that this Demonstration Project was effective and feasible in rural China.

In order to improve epilepsy care in China, so that more people are benefited and there is sustainable development of policies and programmes, a model for epilepsy care was developed. The model aimed at first identifying management practices in terms of diagnosis,
treatment and follow-up of people with active (convulsive) forms of epilepsy in rural and semi-rural areas and then testing procedures and technical norms which would lead to the diagnosis, education, treatment and follow-up of people with active epilepsy at a primary health-care level.

The following issues were considered before and while implementing the model:

- initiating public education and advocacy activities
- estimating the size of the problem
- providing professional education including development of training materials
- developing a referral system
- choosing a suitable drug
- ensuring a regular drug supply
- encouraging stakeholder participation
- providing continued monitoring and evaluation
- providing supportive legislation.

While all of the above considerations must be taken into account in the design of an epilepsy care programme, any local issues should not be discounted.

The Demonstration Project and the model described in this report succeeded in the ultimate goal, i.e. to make epilepsy a national health priority in China. However, because the model will not spread on its own accord, proper planning is needed for a guided scale-up. Scaling up is much more than the mere incorporation of the innovation into a health programme and requires:

- enhanced political commitment – at first and at the highest level;
- assessment of needs and resources – by estimating prevalence, treatment and resource gap estimates to help highlight any gaps in the plan;
- development of a suitable policy and legislative infrastructure – to enable a supportive policy environment which can facilitate coordination of essential services and activities to ensure that treatment and care are delivered to those in need and fragmentation and inefficiency in the health system are prevented;
- identification of suitable interventions;
- delivery of the intervention package – including decisions on how best to deliver the chosen interventions at health facility, community, and household levels to ensure maximum impact;
- strengthening of human resources – by developing and upgrading human resources;
- mobilization of financial resources – so that dedicated resources are available;
- establishing a plan for monitoring and evaluation – for effective implementation;
- forming collaborative partnerships – by engaging multiple actors, interest groups and organizations.

The success of the project has already inspired the Chinese government to expand the project, and by the end of 2008 it integrated a further 79 counties in 15 provinces and treated 35,000 people with epilepsy. As a result of the Demonstration Project, epilepsy care is proposed to be included in the primary health-care system all over rural China during the next few years.

For China, a next step for sustainable scale-up would be engaging stakeholders. The WHO/ILAE/IBE Campaign’s involvement in the Demonstration Project in China has already helped establish a partnership that can be used for developing and implementing the scale-up plan. Commitment and partnerships between the government, health professionals, civil society, communities and families with support from the international community is, however, essential to improve epilepsy care and bring epilepsy “out of the shadows”.

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Epilepsy: A public health problem

The global problem
Epilepsy is the most common serious neurological disorder, affecting about 50 million people worldwide. Every year nearly two million people develop epilepsy. The disorder imposes a high economic burden on individuals with the condition, on their carers and family, and on the health services (1). The World Health Organization (WHO) estimates of disability adjusted life years (DALYs) suggest that epilepsy accounts for 0.5% of the world’s burden of disease, which is the same as lung cancer among men or breast cancer among women (2).

Epidemiological studies have consistently established that mortality among people with epilepsy is two to three times higher than in the general population. This has been shown in large population-based cohort incidence studies as well as in more selected populations (3).

In developed countries, sudden unexpected death in people with epilepsy has generally been reported to occur in conjunction with a generalized tonic–clonic seizure although the mechanism is unknown (4). In patients with chronic refractory epilepsy, sudden unexpected death may account for as much as 25–65% of all deaths (5).

The extent of this problem in resource-poor countries, however, is not known. Studies have shown that with correct diagnosis and treatment up to 70% of epileptic seizures can be well controlled by antiepileptic medication without diminishing the quality of life of the treated population. The outlook may, however, be less optimistic for the remaining 30%, whose seizures are chronic and intractable. In resource-poor countries, almost 80% of people with epilepsy do not receive treatment or are inadequately treated due to deficiencies in health-care resources and delivery, and often, social stigma (6).

Earlier studies highlighted a number of areas of particular concern for people with epilepsy, who tend to have poorer self-esteem than people without epilepsy (6). Potential sources of reduced self-esteem are parental overprotection and rejection, educational and occupational under-achievement, and perceived, as well as enacted, stigma and discrimination. Discrimination at the workplace and with respect to access to education is not unusual. Violations of human rights are often more subtle and include social ostracism, being overlooked for promotion at work, and denial of the right to participate in social activities taken for granted by others in the community. People with epilepsy are more likely to be under-employed or unemployed, have lower rates of marriage and greater social isolation than the general population.

Studies related to psychiatric and psychological outcomes of epilepsy have shown a high prevalence of psychiatric morbidity in nearly one third of people with epilepsy. Anxiety and depression are the two most common manifestations of psychopathology reported by people with epilepsy (7).

Social withdrawal and isolation are frequently the product of anxiety about the possible hostile reactions of others if a seizure should occur in a public place. Research also indicates that fear for their physical safety keeps many people with epilepsy isolated: more than one fifth of the people in one study said they were afraid to go out because of the possibility of seizures occurring that might lead to accidents; their most common coping strategy was therefore to stay at home (8). Problems in personal relationships are reflected in the lower rates of marriage and fertility among people with epilepsy compared to that in the general population.

WHO suggests that it would be appropriate to manage medical conditions requiring a low technological approach at a primary health-care level. This includes the management of convulsive forms of epilepsy. Convulsions are usually relatively easy to diagnose and the majority of people will respond to simple treatment schedules with drugs in the WHO Model List of Essential Medicines. Studies in resource-poor countries suggest that the use of older antiepileptic drugs in primary health-care settings represents cost-effective use of scarce health-care resources (7). Phenobarbital is the oldest and most widely used antiepileptic drug and several clinical trials have shown that it is efficacious for most types of seizures (9,10). It is on the WHO Model List of Essential Medicines and is recommended by WHO as a broad spectrum first-line drug for partial and generalized tonic–clonic seizures due to its efficacy.
good tolerability, reliable supply, affordable cost, broad spectrum of action and ease of use in resource-poor parts of the world (11, 12). In the WHO Western Pacific Region B, based on the Global Burden of Disease (GBD) regional classification system, to which the People’s Republic of China belongs, the annual patient cost of phenobarbital treatment per year was estimated at US$ 93; the cost per DALY averted was US$ 1534 (11).

Most cases of epilepsy can be treated successfully – up to 70% of people with epilepsy when provided with appropriate treatment can lead normal and productive lives. Unlike acute medical conditions, however, treatment is a long-term prospect and requires zealous adherence to prescribed regimens by the patients. Abrupt withdrawal of medication or the irregular use of antiepileptic drugs is often associated with serious consequences. Appropriate counselling and education of patients is therefore an important part of the management of the condition.

The treatment gap
In resource-poor settings, a lack of knowledge about epilepsy, inadequate medical resources and scarce supplies of antiepileptic drugs all work against the provision of appropriate treatment; in resource-poor countries almost 80% of people with epilepsy receive no treatment or are inadequately treated (13, 14). A large number of people with epilepsy are at risk of morbidity and mortality, mainly because of difficulties with the treatment infrastructure and in availability of suitable drugs (15).

In rural China, over half of the people with epilepsy have not been treated with standard antiepileptic treatment (1). While some patients receive no treatment at all for their condition, others are treated inappropriately with high-cost technologies that incur unnecessarily high expenses.

Given the recent advances in diagnostic and therapeutic tools it is surprising that over 50% of people with active epilepsy in the most populated country of the world do not receive treatment. This is probably due to local misperceptions about the nature of the disease. Because of stigma attached to the diagnosis of epilepsy, people are unlikely to admit that they have the condition and thus not get to know that adequate treatment exists (16).

The global response
In 1997, the WHO in cooperation with the International League Against Epilepsy (ILAE) and the International Bureau for Epilepsy (IBE) launched the Global Campaign Against Epilepsy (GCAE) in an attempt to bring epilepsy “out of the shadows” and to improve the treatment of people with epilepsy in resource-poor countries (17). The mission statement of the Campaign is “to improve the acceptability, treatment, services and prevention of epilepsy worldwide”.

The strategy of the Campaign includes two parallel and simultaneous tracks:
1. Raising general awareness and understanding of epilepsy, for example by organizing regional conferences on public health.
2. Supporting departments of health in identifying needs and promoting education, training, treatment, services, research and prevention nationally, by initiating Demonstration Projects.

The objectives of the Campaign are to:
• increase public and professional awareness of epilepsy as a universal and treatable brain disorder;
• raise epilepsy to a new plane of acceptability in the public domain;
• promote public and professional education about epilepsy;
• identify the needs of people with epilepsy at the national and regional levels;
• encourage governments and departments of health to address the needs of people with epilepsy including awareness, education, diagnosis, treatment, care, services and prevention.

Worldwide, Demonstration Projects have been set up to reduce the treatment gap and morbidity of people with epilepsy using community level interventions, train and educate health professionals, dispel stigma, identify potential for prevention and develop models of integration of epilepsy control into the health systems of participating countries (18).
**Epilepsy in the People’s Republic of China**

The People’s Republic of China (referred to as China in this report) is situated in the east of the Asian continent. It covers 9.6 million km² and is divided into 23 provinces, 5 autonomous regions and 4 municipalities. These divisions contain 335 districts, 2858 counties, 48,000 towns and 822,000 villages.

According to the national records, in 1998, China had a population of 1.25 billion people of 56 different ethnic groups. The urban population was 379 million (30.4%) and the rural population was 869 million (69.6%). The Chinese gross national product (GNP) was ¥7955 billion (US$ 980.2 billion with GNP/capita being US$ 780) in 1999; urban resident income was ¥5425 whilst rural resident net income was ¥2160 in 1998.

Since the adoption of policies leading to economic reform and opening to the outside world, the Chinese primary health-care system (the three-tier rural medical care system: county – town – village) has further developed its disease control activities and health campaigns. The system now provides comprehensive and sustainable health care to rural and semi-rural populations and covers the great majority of the population. In mainland China about 15,000 hospitals at the county level and above, and about 50,000 town hospitals play an important part in the rural medical care system. There are two million professional health workers (including western and Chinese physicians), averaging 1.6 per 1000 population. The medical care system is currently undergoing reforms with the result that health service coverage is expanding. This is part of the Chinese government’s great efforts in attaining the strategic goal of “health for all”.

Prior to 2000 there were few studies to investigate the prevalence of epilepsy in China and those that were conducted showed widely divergent values for the prevalence and incidence of epilepsy (10, 14).

The differences may be due to differing study objectives and methodologies or different economic levels or causes of epilepsy. The lifetime prevalence of epilepsy was reported between 3 and 5 per 1000 population, the incidence of epilepsy between 30 and 40 per 100,000 population per year, and epilepsy-related mortality between 3 and 7.9 per 100,000 population (10, 14).

In 1990, the GBD study estimated the DALYs experienced due to epilepsy as 0.81 per 1000 population (2).

In China, phenobarbital is widely available and its use is considered to be safe and practical. The Ministry of Health and the Chinese neurological community consider this drug to be the first option for treatment of epilepsy in rural areas of the country. In a previous feasibility study on the management of convulsive epilepsy in the community, conducted in four rural areas of China, primary care physicians, who received a short training in epilepsy, treated one group with phenobarbital while neurologists managed the other group. More than half the patients in each group became seizure free by the end of the study, and there were no withdrawals due to severe side effects. There was no statistical difference in the outcome between the two treatment groups (18, 19).

One of the greatest problems facing people with epilepsy is the stigma placed upon them by the community. Studies in China suggest that people with epilepsy are generally withdrawn from society; they feel isolated and are either overprotected or neglected. The attitudes towards people with epilepsy are often negative and most people would object to their children marrying or even playing with a person with epilepsy. About half the general population believes that people with epilepsy should not be employed. Some of these negative attitudes may arise because epilepsy is not seen as a medical condition but as a mental disorder, some even equating it to insanity (1).
As part of this Campaign, and under the auspices of WHO and the Ministry of Health of China, a Demonstration Project, “Epilepsy Management at a Primary Health Level” (EMPHL), was implemented in rural areas in six non-contiguous provinces of China. The Demonstration Project included two epidemiological surveys, a phenobarbital treatment intervention trial, and an educational programme.

**Aims of the project**

**Overall aims**

1. To generate procedures that will improve the identification and management of people with convulsive forms of epilepsy in rural and semi-rural areas of the country within the existing primary health-care system and with community participation.
2. To develop a model of epilepsy treatment at primary health level that can be applied nationwide.

**Specific aims**

1. To assess current management practices (identification, treatment, and follow-up) of patients with convulsive forms of epilepsy cases in rural and semi-rural areas of the country.
2. To estimate:
   - the prevalence of active forms of convulsive epilepsy
   - the scale of treatment gap via an active case finding methodology
   - changes the project may bring to these figures in the study area.
3. To ascertain the knowledge, attitudes and practice of epilepsy amongst health practitioners at the primary health level prior to the study and after they have undergone training for epilepsy.
4. To develop technical norms for the identification, education, treatment and follow-up of patients with epilepsy at a primary health-care level.
5. To carry out a feasibility study of the treatment of convulsive forms of epilepsy by primary health-care doctors, using phenobarbital.
6. To develop a programme for continuous professional education on epilepsy for primary health care.
7. To promote public awareness about epilepsy via an educational programme aimed at the community.
8. To develop local advocacy and support groups for people with epilepsy.
9. To reduce the economic and social burden of epilepsy in the study areas.

**Project organization**

The Department of Disease Control and the Department of International Cooperation of the Ministry of Health of China were responsible for the Demonstration Project and delegated the task of ensuring concerted action to the Beijing Neurosurgical Institute.

This project was carried out in Mulin and Dongning counties of Heilongjiang province, Wuzhong and Qingtongxia counties of Ningxia province, Wuzhi county of Henan province, Zezhou county of Shanxi province, Jinshan county in Shanghai Municipality and Hanjiang county of Jiangsu province. The setting of the Demonstration Project was at the primary health-care level as managed by local “public health bureaus”. The local neurologists of a medical university or general hospital and local public health bureaus were responsible for the local activities (Figure 1).
Each county has primary health-care facilities in place and about 20 primary health-care hospitals (town hospitals). An estimated 116 town hospitals were present in the seven counties. Each town has about 20-25 villages. Most villages have a clinic with one or two village doctors, with each village doctor having an average list size of about 1000 people. On average, a team of two town hospital doctors (senior primary health-care physicians – rural doctors) supervises the work of every 20–25 village doctors. The entire population in the study areas is covered by the primary health-care system and is the only modality of formal health delivery in the study areas. The town hospitals are responsible for management of patients with epilepsy, social intervention and education.

**Methodology and results**

**Overall plan**

A first epidemiological survey was carried out to obtain the latest and most reliable prevalence estimates for epilepsy in the area, which helped in the assessment of the disease burden of epilepsy in rural China, measured in DALYs. The efficacy of phenobarbital treatment was evaluated with a large community-based intervention trial; data from this prospective study were used to conduct a cost–outcome analysis of standard phenobarbital therapy. During the patient follow-up of this trial, deaths were noted and any premature mortality related to epilepsy analysed. After the completion of the intervention trial and the educational programme, the second prevalence and treatment gap survey of epilepsy was conducted to assess the effectiveness of the education and intervention programme into reducing the treatment gap. The definitions used for the purpose of this project are provided in Appendix I.

The Institutional Ethics Committee of the Beijing Neurosurgical Institute scrutinized the protocol and gave their ethical approval for the study. All study subjects were asked to provide written informed consent (for children the consent was signed by their parent or guardian), after reading the study information leaflet. All aspects of the study were monitored and supervised by the international steering committee.

**Study areas and target population**

The Demonstration Project was implemented in rural areas in six non-contiguous provinces of China, with a population of 116 town hospitals. The study areas are covered by the primary health-care system and are the only modality of formal health delivery in the study areas. The town hospitals are responsible for management of patients with epilepsy, social intervention and education.

**Figure 1 Organization of the Demonstration Project**

Each county has primary health-care facilities in place and about 20 primary health-care hospitals (town hospitals). An estimated 116 town hospitals were present in the seven counties. Each town has about 20-25 villages. Most villages have a clinic with one or two village doctors, with each village doctor having an average list size of about 1000 people. On average, a team of two town hospital doctors (senior primary health-care physicians – rural doctors) supervises the work of every 20–25 village doctors. The entire population in the study areas is covered by the primary health-care system and is the only modality of formal health delivery in the study areas. The town hospitals are responsible for management of patients with epilepsy, social intervention and education.

**Methodology and results**

**Overall plan**

A first epidemiological survey was carried out to obtain the latest and most reliable prevalence estimates for epilepsy in the area, which helped in the assessment of the disease burden of epilepsy in rural China, measured in DALYs. The efficacy of phenobarbital treatment was evaluated with a large community-based intervention trial; data from this prospective study were used to conduct a cost–outcome analysis of standard phenobarbital therapy. During the patient follow-up of this trial, deaths were noted and any premature mortality related to epilepsy analysed. After the completion of the intervention trial and the educational programme, the second prevalence and treatment gap survey of epilepsy was conducted to assess the effectiveness of the education and intervention programme into reducing the treatment gap. The definitions used for the purpose of this project are provided in Appendix I.

The Institutional Ethics Committee of the Beijing Neurosurgical Institute scrutinized the protocol and gave their ethical approval for the study. All study subjects were asked to provide written informed consent (for children the consent was signed by their parent or guardian), after reading the study information leaflet. All aspects of the study were monitored and supervised by the international steering committee.

**Study areas and target population**

The Demonstration Project was implemented in rural areas in six non-contiguous provinces of China, with a population of 116 town hospitals. The study areas are covered by the primary health-care system and are the only modality of formal health delivery in the study areas. The town hospitals are responsible for management of patients with epilepsy, social intervention and education.
total population of over three million people. The study sites were: Mulin and Dongning counties in Hei longjiang province; Wuzhong and Qing tongxia counties in the Ningxia Hui autonomous region; Wuzhi county in Henan province; Zezhou county in Shanxi province; Hanjiang county in Jiangsu province; and Jinshan county in Shanghai municipality (Figure 2). The study areas were representative not only of the different geographical areas but also of the different economic levels in China.

First epidemiological survey

The prevalence of epilepsy and the treatment gap among 55,600 of the total population of 58,800 in 5 of the 6 project areas were assessed. The sixth area (Shanghai) was surveyed at a later date for logistical reasons. The screening questionnaire was based on the WHO screening questionnaires previously used in China and on the International Community-based Epilepsy Research Group (ICBERG) screening instrument (20) and validated at the Beijing Neurological Institute for specificity (78.5%) and sensitivity (100%). Participating physicians and health workers were trained to conduct the questionnaire using standardized techniques. On completion of the questionnaire a neurologist examined each person who had a positive response to any of the questions to determine the diagnosis.

The minimum lifetime prevalence of epilepsy, based on the number of people identified as having a definitive history of epilepsy, was 7.0/1000; and the prevalence of active epilepsy was 4.6/1000 (Table 1). Based on these, the estimated number of people with epilepsy in China was found to almost 9 million with approximately 6 million people having active epilepsy.

Of the 387 people identified with epilepsy, 158 did not receive any treatment (41%), 133 (35%) received irregular treatment, and only 96 (25%) received regular antiepileptic drug treatment in the week prior to the survey. A total of 257 patients had active epilepsy of which 161 (63%) did not receive any treatment in the week prior to the survey. The reason for the treatment gap is unclear, but it may be the result of the misperception of epilepsy in China. If epilepsy is not viewed as a manageable condition, it becomes stigmatized and people are unlikely to admit that they have epilepsy and thus will not seek treatment. This situation has been seen in many different cultures and is also evident in China (15).

Table 1. Prevalence of epilepsy in five study areas in rural China, 2000 survey

<table>
<thead>
<tr>
<th>Province</th>
<th>Lifetime epilepsy</th>
<th>Active epilepsy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cases identified</td>
<td>Prevalence (per 1000)</td>
</tr>
<tr>
<td>Heilongjiang</td>
<td>82</td>
<td>8.1</td>
</tr>
<tr>
<td>Henan</td>
<td>59</td>
<td>4.7</td>
</tr>
<tr>
<td>Jiangsu</td>
<td>87</td>
<td>7.8</td>
</tr>
<tr>
<td>Ningxia</td>
<td>99</td>
<td>8.5</td>
</tr>
<tr>
<td>Shanxi</td>
<td>60</td>
<td>5.8</td>
</tr>
<tr>
<td>Total</td>
<td>387</td>
<td>7.0</td>
</tr>
</tbody>
</table>

Figure 2. Map of China showing the intervention sites

Intervention trial of phenobarbital treatment

WHO suggests that medical disorders that require a low technological approach should be managed at the primary health-care level. This includes the
management of convulsive forms of epilepsy, which was the main focus of this study.

All primary-care physicians involved in the intervention and many local medical personnel received basic training in the diagnosis and management of epilepsy, and on the use of the screening questionnaire and study protocol.

Local primary-care physicians identified most of the patients with convulsive epilepsy from clinical attendance or previous health records. Some, however, were identified in the epidemiological survey, whereas others were referred by community leaders or self-referred as a result of a vigorous community awareness programme. Primary-care physicians made the initial diagnosis by using a specially designed questionnaire to screen possible cases of convulsive epilepsy; the diagnosis was then confirmed or refuted and a baseline seizure frequency was established by supervising neurologists. Diagnosis was based on the history and a witness’s account of a suspected convulsive seizure (Table 2).

Only patients who had at least two convulsive seizures in the past 12 months and had provided informed consent were included in the study. Patients under two years of age, or those with provoked seizures only, or those with certain medical conditions were excluded from the study. Of the 2455 patients recruited (Figure 3), most had received some kind of irregular treatment in the past, such as antiepileptic drugs, traditional Chinese medicine, acupuncture, or folk prescription. Patients entering the study were treated with phenobarbital monotherapy as the first option. The maintenance doses were those that controlled the seizures and were well tolerated. Patients attended their local clinic regularly for review of treatment and to receive further supplies of medication.

Rural physicians completed a follow-up form at each visit, recording the number of convulsive seizures and adverse events experienced by the patients. Neurologists visited each site to supervise the rural physicians and to check on patients whose seizures were not well controlled or who had severe adverse events.

The duration of follow-up ranged from one day to 32 months (median, 25 months). The probability of retention, a composite measure of efficacy and tolerability used as a measure of overall effectiveness, was 0.84 at one year and 0.76 at two years (Figure 4).

Table 2. Diagnostic criteria for a convulsive seizure

<table>
<thead>
<tr>
<th>Major criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of consciousness</td>
</tr>
<tr>
<td>Rigidity</td>
</tr>
<tr>
<td>Generalized convulsive movements</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minor criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bitten tongue or injury sustained in falling</td>
</tr>
<tr>
<td>Urinary incontinence</td>
</tr>
<tr>
<td>Post-seizure fatigue</td>
</tr>
<tr>
<td>Drowsiness</td>
</tr>
<tr>
<td>Headache or muscle aches</td>
</tr>
</tbody>
</table>

Positive diagnosis required at least two major criteria and two minor criteria.

Figure 3. Intervention trial flowchart
The percentage of patients who were seizure free for one month increased with time, and the average seizure frequency per month decreased (Figure 5).

Almost a quarter of patients withdrew from the study before its completion and a further 35 patients died. The most common reason for withdrawal was the subjective assumption of cure by the patient; only 1% of patients withdrew due to adverse events. Patients who withdrew from the study due to adverse events or lack of efficacy were offered treatment with alternative antiepileptic drugs. The frequency of all adverse events reduced with increased duration of follow-up (Table 3) This therapeutic intervention process confirmed that convulsions are relatively easy to identify even in primary-care settings, and that most people respond to simple drug treatment schedules.

**Educational programme**

After the first epidemiological survey was completed, an educational programme on epilepsy was introduced in the study areas via a number of media channels.

**Table 3. Adverse events experienced over different time periods with phenobarbital**

<table>
<thead>
<tr>
<th></th>
<th>1–3 months (n=2455)</th>
<th>7–12 months (n=2135)</th>
<th>19–24 months (n=1495)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drowsiness</td>
<td>667 (27)</td>
<td>287 (13)</td>
<td>120 (8)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>320 (14)</td>
<td>182 (9)</td>
<td>81 (5)</td>
</tr>
<tr>
<td>Headache</td>
<td>185 (8)</td>
<td>108 (5)</td>
<td>41 (3)</td>
</tr>
<tr>
<td>Ataxia</td>
<td>182 (7)</td>
<td>87 (4)</td>
<td>30 (2)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>154 (6)</td>
<td>94 (4)</td>
<td>31 (2)</td>
</tr>
<tr>
<td>Hyperactivity</td>
<td>51 (2)</td>
<td>37 (2)</td>
<td>13 (1)</td>
</tr>
<tr>
<td>Gastrointestinal complaints</td>
<td>347 (14)</td>
<td>192 (9)</td>
<td>55 (4)</td>
</tr>
<tr>
<td>Skin rash</td>
<td>81 (3)</td>
<td>34 (2)</td>
<td>13 (1)</td>
</tr>
<tr>
<td>Others</td>
<td>69 (3)</td>
<td>27 (1)</td>
<td>14 (1)</td>
</tr>
</tbody>
</table>

* If a patient presented with multiple reports of the same adverse event during a particular period, the event was recorded only once for that period.
Table 4. Educational activities about epilepsy for the general population, and patients and their families carried out during the intervention trial

<table>
<thead>
<tr>
<th>Province</th>
<th>No. of newspaper articles</th>
<th>No. of TV programmes</th>
<th>No. of copies of printed materials distributed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heilongjiang</td>
<td>18</td>
<td>12</td>
<td>2 600</td>
</tr>
<tr>
<td>Henan</td>
<td>2</td>
<td>3</td>
<td>35 000</td>
</tr>
<tr>
<td>Jiangsu</td>
<td>3</td>
<td>3</td>
<td>2 500</td>
</tr>
<tr>
<td>Ningxia</td>
<td>12</td>
<td>1</td>
<td>3 000</td>
</tr>
<tr>
<td>Shanghai</td>
<td>2</td>
<td>1</td>
<td>5 000</td>
</tr>
<tr>
<td>Shanxi</td>
<td>7</td>
<td>8</td>
<td>20 000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>44</strong></td>
<td><strong>28</strong></td>
<td><strong>68 100</strong></td>
</tr>
</tbody>
</table>

This aimed to increase awareness among the community that epilepsy is a treatable disorder (Table 4). Lectures and group discussions for patients and their families were arranged, and community leaders and local teachers were also presented with information about epilepsy, including its causes and treatment. People were encouraged by the media and community leaders to come for free diagnostic assessment and management where appropriate.

Second epidemiological survey

The second survey was carried out between September and December 2004, after the intervention trial and educational programme were completed. In order to avoid a reporting bias, different census units were studied in the second survey. Over 50 000 people were surveyed. The screening questionnaire and methodology used in 2004 were the same as that used in the 2000 survey.

The second survey showed a minimum lifetime prevalence rate of 6.2/1000, which is slightly lower than that of the previous survey. The prevalence of active epilepsy was 4.5/1000, similar to that found in the first survey (Table 5). In this survey, half the patients with active epilepsy had received antiepileptic treatment in the previous week. Thus, the treatment gap decreased significantly (by 13%) since the first survey. These results rendered further support to the Demonstration Project as an effective and feasible method of treatment for active epilepsy in rural China.

Disease burden of epilepsy by DALY measure

The GBD study measures the health status by the number of deaths and also by the impact of premature death and disability on a population. The single unit, DALY, combines the years of life lost due to premature mortality (YLL) and the years lost due to disability (YLD) to measure the overall “burden of disease” in the

Table 5. The prevalence of active epilepsy in the 2000 and 2004 surveys

<table>
<thead>
<tr>
<th>Province</th>
<th>2000 survey</th>
<th>2004 survey</th>
<th>2004 survey</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cases</td>
<td>Prevalence (per 1000)</td>
<td>Cases</td>
</tr>
<tr>
<td>Heilongjiang</td>
<td>49</td>
<td>4.8</td>
<td>57</td>
</tr>
<tr>
<td>Henan</td>
<td>43</td>
<td>3.5</td>
<td>29</td>
</tr>
<tr>
<td>Jiangsu</td>
<td>53</td>
<td>4.8</td>
<td>47</td>
</tr>
<tr>
<td>Ningxia</td>
<td>78</td>
<td>6.7</td>
<td>52</td>
</tr>
<tr>
<td>Shanxi</td>
<td>34</td>
<td>3.3</td>
<td>46</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>257</td>
<td>4.6</td>
<td>231</td>
</tr>
</tbody>
</table>
Epilepsy management in rural China

YLD was calculated based on prevalence data from the epidemiological survey. The average mortality due to epilepsy of 6 per 100,000 population (as reported in Chinese literature according to sex and age group in each of the study areas) was used for the calculation of YLL. The general formula and corresponding parameters of the GBD study were used to calculate the number of YLD and YLL per individual (2). The population of China in 2000 was used to adjust for the sex and age structures of the population of each study area (21).

Epilepsy caused 1.31–1.52 YLL per 1000 population in the six study areas in 2000. The YLD caused by epilepsy ranged from 0.46 to 1.01 per 1000 population. DALYs caused by epilepsy ranged from 1.83 to 2.48 per 1000 population. The estimates of overall YLL, YLD and DALY due to epilepsy in the Chinese rural population, by adjusting to sex and age structures of the population of China in 2000, were found to be 1.41 YLL and 0.67 YLD per 1000 population; the DALYs due to epilepsy were 2.07 per 1000 population (Table 6).

Table 6. YLL, YLD and DALY per 1000 population due to epilepsy in six study areas in China, by sex

<table>
<thead>
<tr>
<th>Area</th>
<th>YLL/1000</th>
<th>YLD/1000</th>
<th>DALY/1000</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
<td>Total</td>
</tr>
<tr>
<td>Heilongjiang</td>
<td>1.64</td>
<td>1.38</td>
<td>1.52</td>
</tr>
<tr>
<td>Henan</td>
<td>1.39</td>
<td>1.22</td>
<td>1.31</td>
</tr>
<tr>
<td>Jiangsu</td>
<td>1.51</td>
<td>1.19</td>
<td>1.35</td>
</tr>
<tr>
<td>Ningxia</td>
<td>1.53</td>
<td>1.42</td>
<td>1.47</td>
</tr>
<tr>
<td>Shanghai</td>
<td>1.57</td>
<td>1.22</td>
<td>1.39</td>
</tr>
<tr>
<td>Shanxi</td>
<td>1.49</td>
<td>1.29</td>
<td>1.39</td>
</tr>
<tr>
<td>Totala</td>
<td>1.52</td>
<td>1.30</td>
<td>1.41</td>
</tr>
</tbody>
</table>

* Sum of six study areas adjusted by the sex and age structure of the Chinese population in 2000.

The same information was then obtained for each subsequent three-month period. An economic burden questionnaire was also developed to establish the costs to patients in contact with other health-care services at different levels of the health system (23, 24).

After one year, the cost of running the primary-care level epilepsy Demonstration Project in rural Shanghai and Ningxia was calculated. The total one-year expenses per treated patient before the Demonstration Project were ¥1494.30 and ¥213.09 in rural Shanghai and Ningxia, respectively; this decreased to ¥91.52 and ¥45.90, respectively, during the Demonstration Project. These reductions in health system costs were statistically significant.

Cost–outcome analysis for the phenobarbital treatment trial

For the cost–outcome analysis two rural areas in Shanghai and Ningxia were chosen. These areas had different economic conditions and different health-care provisions. A total of 50 patients from rural Shanghai and 100 patients from rural Ningxia were randomly selected. The Demonstration Project was conducted in these areas and data prospectively collected for each study subject over a one-year period from the baseline assessment. Information on various health-care contacts associated with treatment and other health-care services were documented on regular visits during the trial. At the first visit, rural physicians asked the patients or their family members to list health-care contacts, access time and related medical expenses during the 12 months before treatment, which was used as the baseline data.
significant \( (P < 0.05; \text{Table 7}) \). In those continuing treatment, the seizure frequency among epilepsy patients decreased by about 60\% after one year of treatment.

From both the perspective of health-care service providers and patients, the results suggest that phenobarbital therapy is economically justifiable and worthwhile. The results demonstrate that the use of phenobarbital for the treatment of epilepsy has considerable appeal, especially in low-income regions, because in addition to clinical improvements the costs are also lower.

**Premature mortality in people with epilepsy**

People with epilepsy have an increased risk of premature death compared with the general population (3). However, the extent and nature of this risk has not been sufficiently examined, especially in resource-poor countries where there is often a large treatment gap with many patients not being treated (15,25). The EMPHL protocol used strict follow-up and management procedures, which made it possible to calculate proportional mortality rates (PMRs) and standardized mortality ratios (SMRs) to assess mortality among people with epilepsy.

During follow-up in the phenobarbital treatment trial, local primary-care physicians recorded demographic data and putative cause of death of any patient who died. Cause of death was attributed on clinical grounds and verbal autopsy (26). Specialists and the principal investigators in each study area gathered information about the cause of death through interviews with relatives or local village physicians. Death certificates were also used to confirm the cause of death.

The epilepsy case fatality rate (CFR) in mainland China was previously estimated as 0.7\% in hospitalized patients (27). In this study, the CFR was 1.4\%. The main cause of death was accidental or as a result of injury. In one third of patients, death was attributed to haemorrhagic or ischaemic stroke, whereas in two patients death was attributed to pneumonia. The age adjusted PMRs for injury (30\%), stroke (30\%), pneumonia (5\%), and myocardial infarction (6\%) were higher for the trial participants than for the 2004 Chinese general population (27). The adjusted PMR for neoplasm (15\%) was lower in the study population than in the general population. One patient death was attributed to “sudden unexpected death in epilepsy” after a negative postmortem examination, while the cause of death was not attributed in three patients because of lack of information.

The SMRs on the basis of age-specific and sex-specific mortality rates were calculated using the 2004 Chinese population estimates (28). The SMR for people with epilepsy was 3.9 and was higher among women than men. The overall SMR was just within the range reported from studies in developed countries (4) and was lower than those reported from prospective studies in developing countries. The SMR was raised in most age groups and was particularly high among young patients (age 15–29 years) (Figure 6).

The high SMR among young adults with epilepsy is a reflection of both the low mortality in the reference population and high mortality among epilepsy patients (29). These findings suggest that epilepsy could pose a potential threat to young people with the disorder in rural areas of China.

Figure 6. Age-specific SMRs of epilepsy in the study population in rural China, adjusted for 2004 Chinese population estimates (bars represent 95\% confidence intervals)
Table 7. Health-care contacts and access time for epilepsy patients treated in primary-care settings (rural Shanghai and Ningxia, China)

<table>
<thead>
<tr>
<th></th>
<th>Shanghai (n = 50)</th>
<th>Ningxia (n = 100)</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>One year follow up</td>
<td>Mean</td>
</tr>
<tr>
<td>Health-care contacts</td>
<td></td>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>Village health worker (visits)</td>
<td>0</td>
<td>0</td>
<td>13.56</td>
</tr>
<tr>
<td>Town hospital doctor (visits)</td>
<td>2.70</td>
<td>4.54</td>
<td>0.46</td>
</tr>
<tr>
<td>Neurologist (outpatient visits)</td>
<td>1.88</td>
<td>3.71</td>
<td>0.16</td>
</tr>
<tr>
<td>Hospital admission (days)</td>
<td>5.36</td>
<td>13.72</td>
<td>0</td>
</tr>
<tr>
<td>Health-care costs (in Yuan, 2004)</td>
<td></td>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>Village health worker</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Town hospital doctor</td>
<td>128.28</td>
<td>410.54</td>
<td>25.06</td>
</tr>
<tr>
<td>Neurologist</td>
<td>278.12</td>
<td>735.98</td>
<td>57.60</td>
</tr>
<tr>
<td>Hospital admission</td>
<td>965.40</td>
<td>2665.21</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>1371.80</td>
<td>2813.30</td>
<td>82.66</td>
</tr>
<tr>
<td>Access time (travel/waiting per visit)</td>
<td>0</td>
<td>0</td>
<td>11.62</td>
</tr>
<tr>
<td>Village health worker</td>
<td>28.30</td>
<td>46.33</td>
<td>20.70</td>
</tr>
<tr>
<td>Town hospital doctor</td>
<td>66.70</td>
<td>113.43</td>
<td>18.60</td>
</tr>
<tr>
<td>Hospital admission</td>
<td>75.84</td>
<td>168.23</td>
<td>0</td>
</tr>
<tr>
<td>Time costs (Yuan, 2004)</td>
<td>0</td>
<td>0</td>
<td>5.76</td>
</tr>
<tr>
<td>Village health worker</td>
<td>8.84</td>
<td>16.59</td>
<td>1.74</td>
</tr>
<tr>
<td>Town hospital doctor</td>
<td>16.99</td>
<td>35.40</td>
<td>1.36</td>
</tr>
<tr>
<td>Hospital admission</td>
<td>96.67</td>
<td>245.68</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>122.51</td>
<td>251.07</td>
<td>3.10</td>
</tr>
</tbody>
</table>
| Total health-care and time costs | 1493.30 | 3000.00 | 91.52 | 218.53 | 1402.79 | 545.82, 2259.76** | 213.09 | 858.33 | 158.83 | 2.07, 332.28*

* Average of 50 sampled cases in rural Shanghai and 100 sampled cases in rural Ningxia.

\* Patients were followed up by village health workers, and the costs were covered by the Demonstration Project.

\* P < 0.05, ** P < 0.001, Wilcoxon Signed Ranks test.
Discussion

Findings from the series of studies of the Demonstration Project have improved the understanding of care of epilepsy patients in China. The first survey added significantly to the epidemiologic understanding of epilepsy and showed that epilepsy was more common in China than previously thought. Lifetime prevalence was found to be 7.0/1000 compared with the previous estimate of 4.4/1000. Thus the estimated number of people with epilepsy in China is almost nine million. In addition, the survey identified a wide treatment gap of 63%.

Subsequent studies documented significant associated disability and increased mortality among patients with epilepsy compared with the general population. These studies provided important baseline data for the Demonstration Project so that the project’s effectiveness could be measured and the targeting of resources within the project improved. At the national level, data further confirmed that epilepsy should have a high priority in China. The high number of people with epilepsy and the high percentage of untreated epilepsy have encouraged policy-makers to make it a priority.

The intervention trial, where phenobarbital was used as the first treatment option, was successfully implemented within the existing health services in rural China and confirmed that in this setting the phenobarbital treatment protocol is feasible and that it has good efficacy and tolerability. Some adverse effects of phenobarbital, particularly neurotoxic effects including sedation, behavioural problems, impaired cognition and depressed mood, have been a concern in its clinical use. In this study, 27% of patients on phenobarbital initially experienced drowsiness, but such neurotoxic effects became less severe as time progressed and only 1% of patients had sufficiently severe adverse events to require withdrawal. Nonetheless, the cognitive effects of phenobarbital may have been underestimated, as formal psychometric testing was not carried out in this study. It will be important to address this issue in future studies.

To assess the wider impact of the intervention on public health, a sub-study on cost–outcome was conducted. It showed that phenobarbital treatment led to significant reductions in health system costs of epilepsy care, in parallel with improvement in seizure control.

In addition, based on the findings of the second survey conducted after the intervention trial, active epilepsy patients on treatment showed improvement in the demonstration areas. After the intervention, there was a significant reduction in the treatment gap, and a greater proportion of patients were taking antiepileptic medication regularly. Various factors could be responsible for the inadequate treatment of people with epilepsy, most importantly a lack of knowledge about the causes and treatment may influence health-seeking strategies and compliance. Thus, the reduction in treatment gap may, in part, be due to increased knowledge of epilepsy. Most people with epilepsy and their families in rural China are economically disadvantaged; and thus the provision of free phenobarbital, introduced throughout the study areas after the completion of the intervention trial, may also have contributed to the reduced treatment gap. The training of most primary-care physicians in the area also mitigated the lack of neurologists in rural areas.

Studies in China have shown the stigma that is attached to epilepsy and that people with epilepsy are generally withdrawn from society and feel isolated. Epilepsy is often not seen as a “normal” medical condition but as a mental disorder, with some even equating it with insanity. Therefore, to address this issue it is very important to promote public awareness about epilepsy and to educate the community. The Demonstration Project held education programmes using several different media to enhance the understanding of epilepsy in the general population. About 70% of patients with epilepsy, in the second survey, received educational books or attended counselling sessions. It is not known whether the benefit of the intervention trial will continue in the long term or whether it would, for example, reduce the increased premature mortality among people with epilepsy in the study areas. In areas where epilepsy has a large impact on individuals with epilepsy and their families, it remains to be determined whether this intervention has a positive effect. It will be important to conduct follow-up studies to assess the impact in the long term. Nonetheless, the project has already given hope and confidence to many people with epilepsy in rural China.

Future research implications

A follow-up study to document long-term seizure control of patients included in the Demonstration Project would be of great value.
Project is being planned. It will assess the treatment status of the patients and factors associated with treatment withdrawal, as well as other aspects of outcome, including mortality and psychosocial aspects (e.g. quality of life scores, education, employment, marital status and their association with seizure control). In addition, the potential cognitive effects of phenobarbital should be systematically evaluated. In the absence of such effects, the way forward to reduce the treatment gap and the burden of epilepsy would be to introduce variations of this protocol, adapted to local needs and settings in other resource-poor countries.
Epilepsy management in rural China

The Demonstration Project in China helped develop a model for epilepsy care based on previous experiences in epilepsy management in primary-care settings with local issues and peculiarities. The model aims at first identifying management practices in terms of diagnosis, treatment and follow-up of people with convulsive forms of epilepsy in rural and semi-rural areas of the country and then testing procedures and technical norms which would lead to the identification, education, treatment and follow-up of such people at a primary health-care level.

Lessons learnt from the project indicate that a number of issues need to be taken into account when planning a model for the management of epilepsy in resource-poor settings. Some of them are unique to the environment for which they are developed whilst others are universal issues. These are discussed below and all of them have to be considered and dealt with appropriately within a model for it to succeed.

Public education and advocacy activities
A major problem identified in many resource-poor settings for the appropriate care of people with epilepsy is the enormous treatment gap. This, however, does not just involve the lack of provision of antiepileptic medication but also involves a diagnostic gap. The diagnostic gap is affected by local beliefs about the condition including the notion often held that epilepsy is not treatable by conventional means, thus leading to people with the condition not seeking medical attention. Awareness that epilepsy may be effectively treated needs to be increased at the community level and should be part of any intervention to increase its penetration and success. It is important that local beliefs and traditions are taken into account in setting up such interventions. In sites where indigenous forms of health delivery exist, incorporating practitioners of such traditions into a programme rather than antagonizing them would help in increasing its credibility.

Estimating the size of the problem
In this project, prior to the intervention in the target areas, an epidemiological estimation of the prevalence of active forms of convulsive epilepsy, as well as the scale of the treatment gap, was carried out via an active case-finding methodology. This allowed for a clear understanding of the scale of the problem in the targeted areas. Repeating the exercise in adjacent areas at the end of the intervention allowed for an estimation of any changes in the magnitude of the treatment gap as a result of the project. This is an important part of the process of measuring outcomes of any such projects and needs to be incorporated in any similar programme.

Professional education including development of training materials
As part of the model, the majority of primary and secondary health workers in the targeted areas underwent training in all aspects of diagnosis and management of epilepsy. This happened after an exercise was carried out to establish the knowledge, attitudes and practices related to epilepsy amongst these workers, which was used to fine-tune the education agenda. Establishing local practitioners for epilepsy management seems to be a critical step in the conception of the education programme and this will need to be incorporated in any similar future model. Continuing professional education on epilepsy for primary health-care workers is also critical and needs to be built into any model of epilepsy management. It would be of tremendous help if epilepsy is incorporated into the initial training prospectus of all health workers.

Developing a referral system
In this model, primary health-care workers initially identify people with suspected epileptic seizures, and the diagnosis and management of epilepsy is carried out by primary-care physicians under the supervision of local neurologists. Increasing the awareness of epilepsy in the community and the education of local teachers has facilitated patient referrals to the local health centre and helped dispel some of the myths associated with the condition. Critical end-points for referral to another level need to be developed taking into account local and environmental provisions and issues. An active referral network to and from the next level of health delivery needs to exist.

Choosing a suitable drug
Phenobarbital is often recommended as a first choice antiepileptic drug in resource-poor settings particularly in view of its affordability, despite concerns about potential problems with this drug. In this project, the
feasibility of primary health-care physicians treating convulsive forms of epilepsy using phenobarbital was ascertained. The drug was well tolerated and there were no reports of serious treatment side effects. Primary health-care physicians identified no major problems in prescribing and monitoring treatment with phenobarbital and treatment retention was satisfactory. Measuring the outcome of individual users is important to judge the success of the intervention at a clinical level. Pragmatic protocols for the management of the drug and tolerability issues need to be incorporated into the design of an intervention.

Regular drug supply
A major issue in resource-poor settings is ensuring a regular supply of antiepileptic drugs. It is imperative that arrangements are in place to ensure continuous supply of drugs to such settings and often measures to this end need to be arranged at the regional or national level. The involvement of public health policy-makers is therefore essential to put in place policies that will facilitate steady drug supplies. The current project had the full support of China’s Ministry of Health as well as the provincial public health authorities and mechanisms for the regular supply of antiepileptic drugs are now in place so that these are accessible and affordable to the end users.

Stakeholder participation
The involvement of users, family members and the community at large is important to maintain momentum that will facilitate the sustainability of the initiative. An intervention can only be judged in the long term by assessing its impact on the quality of life of the recipients and if they survive and thrive. Sustainability is, therefore, an obligation that needs to be built into any intervention, as its failure has critical repercussions on the lives of those it was set up to help. Maintaining the momentum also leads to continuous improvement of services, often driven by the recipient and the community. Meetings with local stakeholders and encouraging the creation of local advocacy and support groups for people with epilepsy, particularly with the involvement of end users, is an important part of this effort. Providing sustainability to an intervention is the only way to ensure that it reduces the economic and social burden that epilepsy imposes on people with the condition.

Continued evaluation
Measures to assess socioeconomic outcomes that are appropriate for the local community need to be developed and applied at certain points of the intervention and especially before scale-up, in order to ascertain its impact. A full evaluation of the programme should be carried out before any planned expansion and at certain end-points (annual or bi-annually cycles) after expansion. Continued monitoring of performance in terms of user numbers is required and so is the need to actively address any emerging issues.

Supportive legislation
The ultimate aim of any epilepsy intervention is to incorporate epilepsy health delivery into any existing or emerging national health programme. To enhance the chances of succeeding, supportive legislation needs to be in place and therefore a review of existing legislation or lack thereof needs to be encouraged and acted upon. The existence of a local lobby for epilepsy via advocacy and support groups may help in mobilizing the process required for change.
The current Demonstration Project and the model of epilepsy care described here succeeded in its ultimate goal, i.e. to make epilepsy a national health priority in China. While the issues discussed above must be taken into account in the design of an intervention, any local issue or idiosyncrasy should not be discounted, because the success of any programme lies in it being sustainable in the long term.

It is often presumed that once a pilot project demonstrates its innovation and effectiveness, the model will spread on its own. Spontaneous diffusion can start but for a large-scale impact, further expansion needs to be guided. Scaling up has become a central theme on the international public health agenda but practical guidance about it is limited. One definition of scaling up is “deliberate efforts to increase the impact of health service innovations successfully tested in pilot or experimental projects so as to benefit more people and to foster policy and programme development on a lasting basis” (30).

Innovation, which is very important for the success of any project, here refers to health service components or practices that are new or perceived as new in a particular programme context. Rather than a single medical therapy, clinical practice or programme component, these are a set of interventions, including the processes necessary to build sustainable implementation capacities. While a desired outcome of scaling up is the incorporation of the innovation into the existing health programme, scaling up is much more than routine programme implementation.

Scaling up involves the following tasks:

- identification of a set of interventions and strategies for health-service delivery, and planning of a sequence for adoption of these actions and of the pace at which interventions can be implemented and services expanded;
- consideration of obstacles that hinder the widespread implementation of the selected interventions, and the options that are available to deal with these obstacles;
- assessment of the total costs of scaling up and sustaining interventions in a range of scenarios that may be generalized;
- development and implementation of a system for monitoring and evaluation.

Figure 6. Framework for scaling up epilepsy care in China
The scale-up strategy proposed by the WHO mental health Gap Action Programme (mhGAP) is used here as the basis to develop a framework for scaling up epilepsy care in China (Figure 6).

**Enhance political commitment**
First and foremost, political commitment at the highest level is required for successful scale-up. For example, although China’s Ministry of Health was involved from the beginning in the initiation of the Demonstration Project on epilepsy, and did have some influence on the development of the protocol, actual commitment happened only by the end of the project, which is one of the project’s achievements. In 2007, the Director General of the Bureau of Disease Prevention and Control, Ministry of Health stated that work on epilepsy control, which started only in the past few years, has gradually become a priority. Until then the main focus of the Chinese government’s health policy had been infectious diseases, but now chronic noncommunicable conditions including epilepsy are also being paid attention to. The central government provided funds to treat epilepsy patients in rural areas as part of programme extension activities. Provincial governments have also been requested to provide more support to epilepsy care. The government has indicated that it would increase its coordination for epilepsy services.

Another prerequisite is to establish a core group of key stakeholders to guide the process. This group also provides technical assistance in the efforts to help utilize the innovation on a large scale. The Demonstration Project provided the opportunity to bring together the key stakeholders for epilepsy in the country, such as the Ministry of Health, Division of Noncommunicable Diseases Control, WHO Country Office, Neurosurgical Society of China, Beijing Neurosurgical Institute, China Association Against Epilepsy (CAAE) and local coordinators and leaders of public health bureaus in each of the participating provinces.

**Assess needs and resources**
A situation analysis provides a thorough understanding of the needs related to epilepsy care and availability of local resources. The prevalence estimates carried out in the six provinces showed that epilepsy was more common in China than previously thought. Data collected during the course of the Demonstration Project also documented increased mortality and significant disability associated with the disorder among patients with epilepsy compared with the general population. In addition, the survey identified a wide treatment gap. These studies provided important baseline data, even though it is not nationally representative.

Another component of the situation analysis is to identify human, financial and material resources existing within the health systems at the national, provincial, county and municipality levels. The above information needs to be synthesized to highlight the gaps that must be addressed before scaling up epilepsy care. A SWOT analysis to identify strengths, weaknesses, opportunities, and threats, is a useful approach for this task.

**Facilitate and develop a supportive policy and legislative infrastructure**
A supportive policy environment aids the process of scaling up as it can facilitate coordination of essential services and activities to ensure that treatment and care are delivered to those in need and that fragmentation and inefficiency in the health system are prevented.

The Peking University Press recently published the “Green Book on Epilepsy Prevention and Control”, compiled by CAAE. The book aims to: provide a tool to promote an atmosphere of understanding and help people with epilepsy in China; serve as a report for the government and administration to stipulate further policies and regulations; and, present information to experts and scholars to demonstrate their past efforts and encourage future endeavours.

**Identify interventions for scale-up**
The model of epilepsy care, based on the evidence provided by the Demonstration Project, has certain attributes that enhance the possibility of its successful scale-up. The model includes a set of simple interventions – including amongst others, medical treatment with phenobarbital as the first choice of drug, and professional and public education – which are relevant as well as easy to implement; and are compatible with the practices of China’s national health programme.

As a next step to identify the strengths and challenges for sustainable scale-up, stakeholders (from top-level policy-makers to managers, neurologists, other health service providers and communities) should be engaged...
in a participatory process of retrospective review. Since the Ministry of Health officials are most familiar with the programme aims and established practices, their involvement is crucial. Integrating research (including capacity building in research) and evaluation into the scale-up process facilitates large-scale impact. It is important that there is agreement among stakeholders concerning the purpose of research and that research is not isolated from the programme context.

Most importantly, the key features of the model that were essential for its success need to be identified so that the processes can be streamlined and more readily replicated during scale-up. The challenges that emerged during the implementation of the Demonstration Project also need to be identified. A workshop or technical meeting bringing together a wide range of stakeholders may provide an opportunity to ascertain and discuss the lessons learnt and shape the way forward.

Some of the key issues that emerged from the Demonstration Project include:

- **Accessibility.** There should be “universal access” to treatment, i.e. all those who need it would have access to it.
- **Sustainability and adherence to treatment.** Since epilepsy is a chronic disorder for which lifelong treatment may be required, the intervention programme needs to be sustainable, and ways to improve adherence to treatment should be implemented. This may require extensive patient education, as demonstrated by the finding that the patient perception of “cure” was the most common reason for treatment withdrawal. This was because many patients, on becoming seizure-free after treatment, assumed that their epilepsy was cured and therefore discontinued treatment on their own volition.
- **Focus on women.** There is a need to meet the needs of women with epilepsy, with particular focus on issues such as contraception, fertility and potential fetal malformation after in utero exposure to phenobarbital.

**Deliver the intervention package**

Decisions on how to best deliver the chosen interventions at the health facility, community and household levels are critical to ensure maximum impact. It is essential that epilepsy care be integrated into the existing primary health-care system. Key considerations include: identifying and outlining the responsibility for implementation of interventions at different levels of the health system; integration into existing services; strengthening of health systems; improving links between communities and the health system; and developing strategies to reach populations with special needs.

**Strengthen human resources**

Developing and upgrading human resources is a primary challenge in scaling up. In extending epilepsy care to all of rural China, continuous training and retraining within the government programme on epilepsy, is essential to maintaining the quality of epilepsy care at a constant level. Key actions for strengthening human resources include:

- appropriate pre-service and in-service training of different cadres of health professionals with curricula that are needs-based and fit the purpose;
- improvement of access to information and knowledge resources;
- development of supportive supervision;
- development of simplified diagnostic and treatment tools.

**Mobilize financial resources**

Scaling up does not necessarily require massive external funding. Nevertheless, because scaling up is not a routine process, dedicated resources are necessary. Before mobilizing resources, the necessary first steps include an assessment of accurate costing to allow the establishment of realistic budgets and to estimate resource gaps. For sustainability, it is necessary to minimize the marginal costs of strengthening services for epilepsy care by building on existing strategies and plans. For continued operation, it is essential that scaling up becomes part of the regular service delivery.

**Establish a plan for monitoring and evaluation**

The phrase “what gets measured gets done” summarizes the importance of monitoring and evaluation for the planning and implementation of the programme. The scope of monitoring and evaluation reflects the scope of the implementation plan. The process should incorporate the selection of indicators and identification of tools and methods for measurement. It is important to decide which indicators to measure and for what
Epilepsy management in rural China

Outcomes

The Demonstration Project was successful in implementing treatment and management of convulsive forms of epilepsy in rural areas of China. Physicians with basic training were able to treat people with epilepsy using phenobarbital as the first option. Thus, this cost-effective approach can make a difference to the treatment gap in epilepsy; in this study it was reduced by about 13%.

The success of the project has led to many publications in international, as well as Chinese, medical journals (Appendix II). The project’s success also inspired the Chinese government to expand it. By the end of 2008, it included 79 counties in 15 provinces in China, and over 35 000 people with epilepsy were treated by trained town clinic physicians, following the Demonstration Project’s protocol. Furthermore, 1838 physicians from county hospitals were (re)trained by the end of June 2009. During 2010, 6 to 8 new counties in different provinces will be included.

To improve epilepsy care in China, so that more people benefit, and policies and programmes are developed sustainably, the proposed model for epilepsy care needs to be scaled up. Scaling up is a social, political and institutional process that needs to engage multiple actors, interest groups and organizations. Much more effort is, however, required to change policy, practice and service delivery systems. Commitment and partnerships between the government, health professionals, civil society, communities and families – with support from the international community – are essential for scaling up epilepsy care and decreasing the burden. Opportunities for scale-up exist in the country and concerted efforts need to be made in this direction.

Form collaborative partnerships

No individual or organization can succeed alone and scaling up requires the establishment of productive partnerships. The involvement of the WHO/ILAE/IBE/GCAE in the Demonstration Project from the beginning helped establish partnerships, such as with SEIN (Stichting Epilepsie Instellingen Nederland – a WHO Collaborating Centre for Research, Training and Treatment in Epilepsy), that can be involved in developing and implementing the scale-up. SEIN has also entered into an agreement for research on two projects in collaboration with the CAAE involving two more WHO Collaborating Centres in China (Beijing Neurosurgical Institute and Fudan University Hospital in Shanghai) and one in the United Kingdom (University College London). These two projects, outlined below, are funded by the Ministry of Health and SEIN:

- Long-term follow-up as well as status and survival assessment of all patients included in the original study (approximately 2400 people).
- Estimation of the neuro-cognitive impact of treatment with phenobarbital in drug naive patients with epilepsy particularly on memory and learning skills.

Other project partners include the Division of Public Health, University of Liverpool, United Kingdom (a WHO Collaborating Centre); Division of Neurosciences of the same university; and the School of Public Health, University of Texas, United States of America, through the CREST (Collaborative Research on Epilepsy Stigma) Project. This project involved ethnographic studies to explore prevailing beliefs and attitudes to epilepsy in China and Viet Nam (33).
Appendices

Appendix I: Definitions

Active epilepsy. Any person who has two or more unprovoked seizures in the 12 months immediately preceding identification is considered to have active epilepsy.

Appropriate treatment. Includes diagnosis and management of underlying causes, and management of recurrent seizures according to national standards, using antiepileptic drugs and surgery where feasible.

Case fatality rate (CFR). Number of deaths during follow-up divided by the number in the study cohort.

Disability adjusted life year (DALY). An indicator of the time lived with a disability (years lived with disability, YLD) plus the time lost due to premature mortality (years of life lost, YLL).

Lifetime prevalence of epilepsy. The number of people with epileptic seizures any time before the survey date divided by the surveyed target population size.

Proportional mortality rate (PMR): Proportion of deaths due to a specific cause in the population under study.

Standardized mortality ratio (SMR): The ratio of the observed number of deaths in the target epilepsy population to those expected.

Treatment gap. The difference between the number of people with active epilepsy and the number whose seizures are being appropriately treated in a given population at a given point in time, expressed as a percentage.

Untreated epilepsy. Any person with active epilepsy who had not received appropriate antiepileptic drug treatment in the week preceding identification is considered to have untreated epilepsy.

Appendix II: Publications from the Demonstration Project

The following publications originated from the Demonstration Project:


References


Epilepsy Management at Primary Health Level in rural China:

WHO/ILAE/IBE
A Global Campaign Against Epilepsy Demonstration Project

WHO China Office 2009