# THE EFFECTIVENESS OF SPECIFIC EPILEPSY SERVICES

## A West Midlands Health Technology Assessment Group Report

Authors: Catherine Meads, Peter Bradley and Amanda Burls

Department of Public Health & Epidemiology
University of Birmingham
Edgbaston
Birmingham
B15 2TT

Correspondence to: Catherine Meads
Department of Public Health & Epidemiology
University of Birmingham
Edgbaston
Birmingham
B15 2TT

ISBN No. 0704422735



May 2001

## About West Midlands Health Technology Assessment Group

The West Midlands Health Technology Assessment Group (HTAG) produce rapid systematic reviews about the effectiveness of healthcare interventions and technologies, in response to requests from West Midlands Health Authorities or the HTA programme. Reviews usually take 3-6 months and aim to give a timely and accurate analysis of the quality, strength and direction of the available evidence, generating an economic analysis (where possible a cost-utility analysis) of the intervention.
intervention.

## About InterTASC

West Midlands HTAG is a member of InterTASC which is a national collaboration with three other units who do rapid reviews: the Trent Working Group on Acute Purchasing; the Wessex Institute for Health Research and Development; York Centre for Reviews and Dissemination. The aim of InterTASC is to share the work on reviewing the effectiveness and cost-effectiveness of health care interventions in order to avoid unnecessary duplication and improve the peer reviewing and quality control of reports.

## Contributions of authors

Peter Bradley started the collection and collation of the evidence for this review, wrote the protocol and first draft of the report. Catherine Meads undertook the rest of the collection and collation of the evidence and finished the production of the report. Amanda Burls acted as editor of the review, gave advice about formulation of the question and overall process of the review and commented on the draft report.

## Conflict of interest

This work has been undertaken by people funded by the NHS. The authors have received no funding from any sponsor in this work.

## West Midlands Regional Evaluation Panel Recommendation:

The recommendation for the effectiveness of specific epilepsy services was:

**Specific Epilepsy Clinics – Not proven**
**Specialist Nurses - Supported**

It is reasonable to assume that if hospital admission can be prevented then mortality may fall also. However, although the trial results were consistent with such a fall the trial was not large enough to demonstrate a statistically significant reduction in death rates in high risk infants. The panel do not see any reason to change the current usage in high risk cases at tertiary centres.

## Anticipated expiry date: 2003

- This report was completed in May 2001
- The searches were completed in January 2001

There are no known clinical trials in progress of palivizumab in the general population for which the drug is indicated. However, there is a randomised controlled trial in progress evaluating the safety of palivizumab in children with a broad spectrum of congenital heart disease. A further trial of palivizumab in children with cystic fibrosis is also scheduled.

# Contents

## Tables



## Figures

# Appendices

## Summary


- Epilepsy is a disorder of the nervous system involving recurrent brief disturbances of brain function. Apart from migraine, epilepsy is the most common neurological condition, with a 2-5% lifetime population prevalence.

- Medical management of epilepsy involves hospital specialists and GPs. There has been great concern expressed over the current standard of epilepsy services in the UK in recent years. The most clinically effective model of outpatient and general practice care for patients with epilepsy in the UK is unknown.

- This report contains two systematic reviews on the relative clinical effectiveness and cost effectiveness of specialist epilepsy clinics compared to general neurology clinics and on specialist epilepsy nurses in primary, secondary or tertiary care compared to 'usual care'.

- Medline, Psychlit, Embase, Healthplan, BIDS ISI, The Cochrane Library and other databases were searched for relevant studies. The findings were one randomised controlled trial (RCT) and two other studies comparing epilepsy clinics to neurology outpatient clinics and three RCTs and a controlled study comparing specialist epilepsy nurses to 'usual care'.

- Epilepsy clinics - there was no evidence of improvement of seizure frequency or seizure severity when compared to neurology outpatient clinics. There was no information available on quality of life outcomes. Epilepsy clinics were found to be more expensive but no test of statistical significance was available.

- Epilepsy nurses- there was no evidence of improvement of seizure frequency or seizure severity when compared to 'usual care' but some evidence of decreased rates of depression. No effect on generic quality of life measurement was shown. Care by specialist nurses was found to be cheaper than 'usual care' but not significantly so.

- There was insufficient evidence to undertake a cost effectiveness analysis.

- A separate review compared specialist to generalist clinics or specialist nurses to 'usual care' for other chronic medical conditions. The 3 RCTs of specialist clinics found showed no clear benefits or differences in costs. Of the 5 RCTs of specialist nurses, three showed no differences on the main physical outcome measure and two had improved outcomes for the specialist nurse group. One had a lower point estimate of cost for the specialist nurse group.

- More research is needed to determine the most clinically effective model of service provision for people with epilepsy. Despite the lack of evidence, it should be borne in mind that present quality of care for people with epilepsy is generally poor and improvements need to be made.

# 1 Introduction

This report systematically reviews two aspects of specific epilepsy care provision.

1. The evidence on the relative clinical effectiveness and cost-effectiveness of specialist epilepsy clinics compared to general neurology outpatient clinics.
2. The evidence on the relative clinical effectiveness and cost-effectiveness of specialist epilepsy nurses in inpatient, outpatient or GP care compared to 'usual care' without a specialist epilepsy nurse.

These reviews were undertaken in order to assess the most effective model of care to improve medical outcomes for patients with epilepsy in the UK. It is acknowledged that these two models of care are not mutually exclusive. Tertiary epilepsy services have not been reviewed.

# 2 Background

Epilepsy is a disorder of the nervous system involving recurrent brief disturbances of brain function (seizures) that may manifest as impairment or loss of consciousness, abnormal behaviour, emotion, motor function or physical sensation.

A seizure is a single episode of disturbance. Seizures are classified as partial or generalised, of known or unknown cause and can vary from mild to severe.

Partial seizures affect a small area of the brain whereas generalised seizures affect both sides of the brain simultaneously.

Partial seizures can be simple partial seizures, complex partial seizures or partial seizures evolving to secondarily generalised seizures. Simple partial seizures cause no loss of consciousness whereas in complex partial seizures consciousness is impaired.

Generalised seizures may involve impairment of consciousness and motor manifestations are bilateral. Generalised seizures take several main forms:

- Tonic seizures cause a sudden increase in muscle tone, which often results in falling backwards.
- Atonic seizures (otherwise known as drop attacks) cause a sudden loss of muscle tone, often resulting in falling forwards.
- Clonic seizures are marked by alternate contraction and relaxation of muscle occurring in rapid succession.
- Myoclonic seizures have sudden brief shock-like contractions of muscles that may involve the whole body or are restricted to one area only.
- Absence seizures involve a very brief loss of consciousness. (Previously known as petit mal).
- Atypical absence seizures which last for a much longer time and may involve jerks or twitching of different parts of the body.
- Tonic-clonic seizures characterised by immediate loss of consciousness, then a tonic phase followed by a clonic phase, accompanied by laboured breathing, incontinence, tongue/mouth biting and skin colour changes. (Previously known as grand mal).

Approximately 60 % of patients have generalised tonic-clonic seizures, 3% simple partial seizures, 20% complex partial seizures, 12% mixed tonic-clonic seizures and 5% absence seizures and seizures of other types.[1] One person with epilepsy can have one or several different categories of seizures over time and epilepsy is not necessarily a life-long condition.

## 2.1 Causes of seizures

In adults, epilepsy usually results from damage to neurones in the cerebral cortex whereas in children most epilepsy is idiopathic (no apparent structural injury, probable genetic cause). Approximately 60% of all cases have no clearly identifiable cause of the neuronal damage, 15% are following a cerebrovascular accident and 6% are from cerebral tumours or are alcohol related.[1]

## 2.2 Social and psychological factors affecting people with epilepsy

Attitudes to epilepsy in society vary but some individuals with epilepsy still meet considerable prejudice in social life and employment. Up to the nineteenth century, seizures were considered to be a result of possession by the Devil. Well into the twentieth century epilepsy was regarded as a psychiatric illness.[2] Epileptic fits frighten people and therefore people with epilepsy tend to become stigmatised or rejected.[3] There are severe psychological consequences for the person with epilepsy resulting from chronic fear of seizures, their unpredictable occurrence, embarrassing nature and physical consequences:

- Individuals with epilepsy become constrained by their own or their carers' fears resulting in unnecessary overprotection and restriction of activities.[3]
- There is a higher rate of unemployment or underemployment in people with epilepsy compared to the general population.[4] Some jobs are not possible for those with epilepsy including the police, the armed services, pilots, fire and prison service.[5] Driving of motor vehicles is only permitted if a person has been seizure free during the day for one year or more or has experienced nocturnal seizures only for three years. Other restrictions also apply, particularly regarding heavy goods and public service vehicle licences.[5]
- Rates of depression, anxiety and poor self-esteem are increased in people with epilepsy compared to the general population.[4; 6] Suicide is more common in people with epilepsy than would be expected by chance.[3]
- Seizure related injuries range from minor cuts and bruises to major events such as car accidents, head injuries and serious burns.[7] In one study[4] 8% patients had had a burn or scald, 27% a head injury, 13% a dental injury and 35% reported some other injury within the previous year. Biting of the tongue during a seizure can occasionally cause slurred speech for several days afterwards.

# 3 Epidemiology

## 3.1 Incidence/Prevalence

Apart from migraine, epilepsy is the most common neurological condition. Data from the World Health Organisation suggests that as many as 1 in 20 people may have a seizure during their lives and that at least 1 in 200 people have epilepsy in the longer-term.[8]

In the U.K, the incidence of epilepsy is estimated at 50-70/100,000 per year, the prevalence of active epilepsy is 5-10/1,000 and the lifetime prevalence is 2-5% for the general population.[1] In the UK it is estimated that there are over 300,000 persons with active epilepsy and over a million with a history of seizures.[1; 9]

According to the GP Morbidity Survey 1991, the incidence and prevalence rise in young adulthood and old age. There are no great differences between the sexes.[10] (See Table 1)

**Table 1 - Incidence, prevalence and consultation rates per 10,000 person years**

| **Males: Age** | **0-4** | **05-14** | **15-24** | **25-44** | **45-64** | **65-74** | **75-84** | **>85** |
|---|---|---|---|---|---|---|---|---|
| **Incidence** | 10 | 13 | 19 | 9 | 10 | 16 | 18 | 12 |
| **Prevalence** | 15 | 25 | 45 | 36 | 40 | 38 | 46 | 30 |
| **Consultations** | 29 | 47 | 95 | 89 | 99 | 84 | 85 | 107 |
| | | | | | | | | |
| **Females: Age** | **0-4** | **05-14** | **15-24** | **25-44** | **45-64** | **65-74** | **75-84** | **>85** |
| **Incidence** | 15 | 12 | 15 | 11 | 8 | 16 | 16 | 14 |
| **Prevalence** | 18 | 24 | 45 | 38 | 36 | 43 | 40 | 35 |
| **Consultations** | 33 | 48 | 103 | 99 | 78 | 92 | 83 | 65 |
| | | | | | | | | |

In the West Midlands, with a total population of over 5 million people, (using 1997/98 ONS figures) there will be approximately 19,000 people with epilepsy and 43,000 GP consultations per year.

# 4 Outline of current service

Most care for people with epilepsy is undertaken by general practices. GPs are mostly involved in managing the chronic condition of epilepsy. Hospital specialists often lead the medical management of patients, by offering advice and support to GPs. Their contribution is particularly important at the time of diagnosis. The proportion of care received from general practice or secondary/tertiary care is dependent on many factors, including the level of GP expertise, locally determined patterns of care and levels of communication.

Usually, after a diagnosis or suspected diagnosis of epilepsy, a referral is made to a consultant neurologist, physician, psychiatrist or paediatrician. Usually patients are seen in outpatient clinics and returned to GP care once seizure control has been achieved. In a study by Thapar, 90% of patients with suspected epilepsy were referred from general practice to hospital where treatment was initiated.[2] The majority of patients were then discharged after 4 visits. Ninety percent of patients with epilepsy are not under hospital outpatient care at any one time.[2]

Some patients may require continuing hospital-based outpatient care for their epilepsy or for concomitant medical conditions. These include children, people with learning disabilities, people with intractable seizures and the homeless. Specialist medical help may also be required in certain situations, for example, if women become pregnant or are contemplating pregnancy or if people wish to reduce, stop or change their medication.

Rarely, inpatient care is used in epilepsy management e.g. for epilepsy surgery or inpatient assessment services. The numbers of patients requiring tertiary services represent a small percentage of the total number of patients requiring epilepsy care.

## 4.1 Standards of current service

There has been great concern expressed over the standard of epilepsy services in the UK in recent years in governmental reports, local audit reports and patient satisfaction questionnaires,[3; 11-19] which have generally described poor standards of care. The main problems described in the services are:

- varying access to services across the country
- a lack of systematic follow-up
- investigations not always used appropriately
- insufficient access to specialised investigations
- patients often seen in hospitals by non-neurologists
- inappropriate polypharmacy
- patients not complying with medication
- low levels of patient knowledge

British government policy on epilepsy care was set out in executive letter EL(95)120 in

1995.[20] The purpose of this letter was to improve the efficiency of delivery of epilepsy care in primary and secondary medical services, to ensure continuity of care throughout the patient's life, to plan services in accordance with patients' and their carers' wishes and to avoid discrimination against people with epilepsy in the NHS workplace.[20]

The National Association of Health Authorities and Trusts suggested that health gain (avoiding the morbidity and premature mortality that results from having epilepsy) could be achieved by improving the use of specialist skills; management of the primary/secondary care interface; proactive monitoring and staff education and development.[9] No evidence was provided to justify this health gain claim. Charitable organisations and government-funded reports have produced possible service specifications for epilepsy e.g. Epilepsy Task Force in 1995[21], the SIGN guidelines on epilepsy in 1997[22] and the CSAG report on services for patients with epilepsy in 1999.[23] However, these are based on expert opinion and surveys of patients and clinicians as well as the limited published evidence available. The UK Government Department of Health response to the CSAG reports[24] includes a commitment (through the National Institute for Clinical Excellence) to provide clear guidance on the clinical and cost effectiveness of health interventions. Although the reports mentioned above show that patients usually express a strong preference for specialist services, they do not clearly demonstrate that specialist service provision improves patients' epilepsy when compared to the current services available.

In the West Midlands there is a specialist epilepsy clinic, with a specialist epilepsy nurse-led liaison service, held at the Queen Elisabeth Psychiatric hospital in Birmingham. Provision of other specialist nurses in the West Midlands region is patchy. General neurology outpatient clinics that treat people with epilepsy are in most larger towns and cities in the region.

# 5 Outline of proposed service

As a result of the perceived deficiencies and suggestions to improve the quality of care offered to people with epilepsy, researchers and governmental reports have suggested two new models of service provision. These models are not mutually exclusive but have been reviewed separately for clarity.

1. Specialist epilepsy outpatient clinics (as opposed to general neurology or other outpatient clinics).[25-29] In this model of service provision, the care of people with epilepsy would be shared between GPs and hospital specialists. The hospital visits would involve attendance at a specialist clinic for epilepsy, rather than a general neurology or other outpatient clinic.

2. Nurse-based liaison services between primary and secondary care.[2; 12; 14; 30; 31] In this model of service provision, the care of people with epilepsy would be shared between GPs and hospital specialists and a nurse specifically trained in epilepsy management. The nurse could be based in general practice, the community or hospital.

Separate systematic reviews compare these two models with the present provision of service.

# 6 Aim of this review

**Systematic review 1**
To evaluate the existing evidence on whether specialist epilepsy clinics are more clinically effective and cost effective than general neurology outpatient clinics.

**Systematic review 2**
To evaluate the existing evidence on whether specialist epilepsy nurses in inpatient, outpatient or GP care are more clinically effective and cost effective than 'usual care' without a specialist nurse

# 7 Methods

## 7.1 Development of protocol

Protocols were developed with colleagues after a scoping review of the literature and extensive initial searches. (See Appendix 1).

## 7.2 Search strategy

The databases searched were those routinely used by the DES review team (see Appendix 1). The search strategy for Medline and Embase is shown in Appendix 2. For the other databases, the search term 'epilepsy' was used.

The names of epilepsy experts were found using the World Wide Web, the National Research Register, conference proceedings, The Cochrane Collaboration's e-mail conference on Effective Professional Practice and mailing list of its Review Group on Epilepsy. Many experts on epilepsy (over 100) were contacted to identify published or unpublished studies.

## 7.3 Inclusion and exclusion criteria

Two reviewers selected papers independently. All references selected by either researcher were obtained. Studies were only included if they met the following criteria:

Study design: Randomised controlled trial, controlled, cohort, case-control or matched study or audit.
Population: Anyone with any diagnosis of new or recurrent epilepsy except febrile convulsions.
Intervention 1. Specialist epilepsy clinic
Comparator 1. General neurology outpatient clinic
Intervention 2. Specialist epilepsy nurse
Comparator 2. Normal inpatient, outpatient or GP care without a specialist nurse

Outcomes: Studies were only included in either review if they reported results on one or more of: seizure frequency, seizure severity or quality of life. Objective outcomes were given preference over patient satisfaction outcomes. (Outcome measurement methods for epilepsy are given in Appendix 3.)

The exclusion criteria for both reviews were

- Studies with no results from intervention or comparison group, or
- Studies that did not distinguish between patients attending specialist and non-specialist care and hence gave results for both groups combined.
- Opinions of respected authorities and reports of expert committees.

## 7.4 Data collection and extraction strategy

Two reviewers independently extracted data from all relevant papers. A third reviewer was available to resolve any disagreements. Authors were contacted if there was missing or inconsistent data, to supply further information.

## 7.5 Quality assessment strategy

A Jadad score was used to assess the quality of RCTs.[32] For assessing the quality of other study types, a judgement was made on each study and each outcome within the study on the basis of the study design and the following factors:

- Whether the study matched the inclusion and exclusion criteria of the reviews.
- Whether the results match the conclusions.

## 7.6 Data synthesis and incremental cost utility analysis

There were insufficient studies in both systematic reviews to carry out a formal meta-analysis. There was no statistically significant difference in clinical effectiveness outcomes between intervention and comparison groups in either systematic review so an incremental cost-utility analysis was not carried out.

## 7.7 Economic analysis methods

Searches were made in Medline, Embase and NHS EED databases for any cost and quality of life data comparing epilepsy clinics to neurology out-patient clinics and specialist epilepsy nurses to ‘usual care’ not found during the clinical effectiveness searches. Both generic and patient centred outcomes were searched for. The search strategy is in Appendix 2.

Additional searches were made in the Cochrane Library, Medline, InterTASC databases and international HTA websites for systematic reviews of specialist versus generalist care for any chronic medical condition. This was undertaken in order to compare the results of the epilepsy systematic reviews to other medical conditions where specialist services are commonly provided. The search strategy is in Appendix 2.

The criteria used when assessing studies were:
Study design: Systematic reviews or randomised controlled trials.
Population: Any chronic medical condition in an adult population (n>1).
Intervention 1. Specialist clinic
Comparator 1. General medical outpatient clinic
Intervention 2. Specialist nurse
Comparator 2. Normal inpatient, outpatient or GP care without a specialist nurse
Outcomes: Any physical health outcomes or quality of life indices.

Exclusion criteria: Studies evaluating surgical or mental illnesses or on a geriatric population only. Studies reporting patient satisfaction outcomes only.

# 8 Results

## 8.1 Searches

The full results of the searches and details of clinical effectiveness studies found for both systematic reviews are shown in Appendix 4.

## 8.2 Systematic review 1. Results of specialist epilepsy clinics compared to general neurology outpatient clinics

Three studies were identified: one randomised controlled trial [33; 34], one matched study [35], and one audit.[36] Patient characteristics and study details are shown in

#### 8.2.1.1 Randomised controlled trial

This is reported as a book chapter[34] and an unpublished PhD thesis.[33] In the trial, 232 patients with epilepsy or possible epilepsy out of 296 cases referred to the University Hospital in Wales, were randomised to a specialist epilepsy clinic or a general neurology clinic and followed-up for one year. Of the 232 randomised patients, 130 were allocated to the epilepsy clinic and 102 to the neurology clinic. Follow up was for 3, 6 and 12 months and was carried out on 176 patients (160 for questionnaire assessments) who had had a seizure during the 12 month follow up. There are no details as to the number of patients followed up in each group. Results presented here are for 12 months only.

Fuller details of the trial are shown in Appendix 5.

#### 8.2.1.2 Matched study

This is reported in one journal article.[35] In this study, 32 adult patients attending a university hospital neurology outpatient clinic in the Netherlands were matched by seizure type and duration of epilepsy to the same number attending a specialist epilepsy clinic.

#### 8.2.1.3 Audit

This is reported in one journal article.[36] It was carried out at the same centres and by same investigators as the matched study mentioned above. The study compared 225 outpatients attending a specialist epilepsy centre to 120 attending a university hospital neurology outpatient clinic.

**Table 2 - Epilepsy clinic v neurology clinic patient and study details**

| Study Type | RCT | Matched | Audit |
|---|---|---|---|
| First Author | Morrow JI | Lammers MW | Wijsman DJ |
| Inclusion criteria | Epilepsy or possible epilepsy | Firm diagnosis, well defined seizures | Firm diagnosis, well defined seizures |
| Exclusion criteria | None stated | Progressive brain disorders, drug or seizure registration non-compliance, pseudoseizures, severe mental retardation | Progressive brain disorders, drug or seizure registration non-compliance, pseudoseizures, severe mental retardation |
| Outcome measures | Seizure control and frequency, AEDs, | Index of seizures, composite index of impairments | Index of seizures, composite index of impairments |
| Assessment used for seizures | Modified Cramer scales | Cramer scales | Cramer scales |
| Number with outcomes in specialist group | Unclear | 32 | 225 |
| Number with outcomes in comparison group | Unclear | 32 | 120 |
| Age distribution in two groups | No significant differences | Younger in epilepsy clinic group | No significant differences |
| Gender distribution in two groups | More males in epilepsy clinic | No significant differences | No significant differences |
| Jadad score | 2 | N/A | N/A |

### 8.2.2 Results of clinical effectiveness

Comparative results of the three studies are shown in Table 3. Only the RCT gives results on waiting times and false positive diagnosis rates for the two groups. These are given in Appendix 5.

#### 8.2.2.1 Randomised controlled trial

This trial showed that, in the specialist epilepsy clinic group, there were significant improvements in seizure frequency at 3 and 6 months but not at 12 months (as measured by a greater than 50% reduction in seizure frequency over baseline). Also self-reported seizure severity score was significantly improved in the epilepsy clinic group compared to the neurology clinic group at 3 months but not thereafter. However, in the epilepsy clinic group at 12 months, there were significant increases in the levels of advice and counselling and in patient satisfaction[34] when compared to the neurology clinic group.

Fuller details of the RCT results are shown in Appendix 5.

#### 8.2.2.2 Matched study

Complete seizure remission was achieved for significantly more patients at the neurology clinic than the epilepsy clinic but there were no significant differences in seizure activity index. Significantly more patients at the neurology clinic had a composite index of impairments of zero, indicating that they were seizure free and had no side effects of medication.

#### 8.2.2.3 Audit

The specialist epilepsy centre patients had a wider diversity of seizure types. At this centre a greater diversity of drugs were prescribed. The mean seizure activity index was significantly higher at the epilepsy centre than the neurology clinic. The audit showed that there are very important differences in baseline characteristics and outcomes of treatment between patients attending an epilepsy clinic to those attending a neurology outpatient clinic.

Fuller details of the audit results are shown in Appendix 5.

**Table 3 - Epilepsy clinic v neurology clinic study results**

| Study Type | | RCT | Matched | Audit |
|---|---|---|---|---|
| First Author | | Morrow JI | Lammers MW | Wijsman DJ |
| Seizure frequency (>50% reduction from baseline) | specialist | 54%+ | - | - |
| | generalist | 42%+ | - | - |
| Complete seizure remission# | specialist | 54%+ | 18.8%* | 19.2%* |
| | generalist | 44%+ | 56.3%* | 43.3%* |
| Mean seizure severity score | specialist | 30+ | - | - |
| | generalist | 38+ | - | - |
| Composite index of impairments >100 | specialist | - | 9.4% | 10.7% |
| | generalist | - | 18.8% | 10.8% |
| Average number of AEDs | specialist | 1 | 1.8 | 2.0 |
| | generalist | 1 | 1.4 | 1.4 |

# complete remission for 3 months in those followed up
* $p<0.05$ + estimated from graph

### 8.2.3 Caveats of the studies

#### 8.2.3.1 Randomised controlled trial

There are several concerns with the internal and external validity of this RCT. A large number of patients were not randomised (60 patients out of a group of 292) and they differed significantly from the randomised group. The author was contacted about this but no satisfactory explanation was given. No patient numbers are given for those followed up in each group. Assessments of outcomes were not blinded, which made their interpretation open to bias. Also, some results were not easily explained, for example seizure control showed a statistically significant improvement in the specialist epilepsy clinic compared to the neurology clinic at six months, but this was lost by one year.[33]

#### 8.2.3.2 Matched study

This is a well planned comparative study. Patients were matched according to seizure type and duration of epilepsy, but unfortunately not matched to severity of epilepsy. The numbers were small and this study was not blinded. Therefore the results should be viewed with much caution.

#### 8.2.3.3 Audit

This study shows clearly that there is selection bias normally operating between patients attending the different clinics. Therefore, this study cannot show whether epilepsy clinics are more effective than neurology outpatient clinics.

## 8.3 Economic evidence

The RCT in the clinical effectiveness section above included a financial costing on epilepsy and neurology outpatient clinics. A record was kept of the number and type of staff normally in the clinics and the number of patients seen by them in a three-month period. Then, using the RCT patients, the number of visits by each patient and the number and type of investigations made were calculated.

**Table 4 - Epilepsy clinic RCT economic results**

| | Epilepsy clinic | Neurology clinic |
|---|---|---|
| Total staff costs | £33,000 | £41,507 |
| Number of all outpatient visits per year | 2,700 | 3,460 |
| Staff cost per out-patient visit | £12.23 | £11.99 |
| | | |
| Number of patients in RCT groups | 130 | 102 |
| Mean number of out-patient visits per RCT patient per year | 3.6 | 2.7 |
| Total cost of investigations on RCT patients in one year | £8131 | £6073 |
| Mean cost of investigations per RCT patient per year | £62.55 | £59.54 |
| Total mean clinic cost per patient per year | £106.57 | £91.91 |

Some of the costs were calculated on all clinic patients (staff costs per outpatient visit) and some just on the RCT patients (total cost of investigations) which means that there is a presumption that all clinic patients are similar. However, it was shown in the clinical effectiveness section that trial and non-trial patients differed. It is unclear how this would affect the results. No date or source is given on staff and investigation cost estimates but presumably they were from local sources shortly before 1993. Only point estimates of costs are given, without any distribution information, so it is impossible to calculate the statistical significance of the difference between the two costs.

Very little other economic evidence was found – see Appendix 6 for details.

## 8.4 Quality of life

The RCT,[33] included an assessment of 139 new patients attending both clinics, using the Nottingham Health Profile, the Hospital Anxiety and Depression Scale and questions of social and occupational functioning. These were independently, blindly mapped to the Rosser Index at start and at 12 months follow up. Unfortunately the results for patients attending the epilepsy clinic are not reported separately to those attending the neurology outpatient clinic.

There were numerous other studies found in the literature search that examined the quality of life of people with epilepsy. However, they did not differentiate between groups of patients attending specialist epilepsy clinics or neurology outpatient clinics so were not relevant to this review.

## 8.5 Systematic review 2. Results of specialist epilepsy nurses compared to 'usual care'

Five studies were identified: four randomised controlled trials (Ridsdale(1),[31; 37-42] Schull,[43] Warren[44], Ridsdale (2)[45]) and a controlled study (Mills[46; 47]). Details of these studies are shown in Table 5, Table 6 and Table 7.

### 8.5.1.1 Randomised Controlled Trials

Ridsdale et al (1) (and Scambler et al).
This trial is published in four journal articles by Ridsdale et al, dated between 1996 and 1999 and a conference abstract presented in 1998. A qualitative sub-group analysis of the same trial is published by Scambler et al in 1996 and by Ridsdale et al in 1999. In the trial, 251 from 283 eligible patients in 6 General Practices from the London area were randomised to nurse-run clinics or 'usual care' by General Practitioners. These were a self-selected sample that had returned a Hospital Anxiety and Depression Scale (HADS) and 'knowledge of epilepsy' questionnaire. Follow up was by re-administering the original questionnaire. There were no significant differences in baseline clinical characteristics between intervention and control groups. The sub-group analysis[42] interviewed 50 patients with epilepsy in remission or with low seizure frequency.

Ridsdale et al (2)
This trial is reported in one journal article. In the trial, from 159 patients newly referred to five local district hospitals for epilepsy, 128 met the inclusion criteria and 102 were randomised (because they returned the first questionnaire) to usual care or to two appointments with an epilepsy nurse specialist. Follow up was by questionnaire 3 months after the second nurse appointment for the intervention group. No details are given of follow up timing for the control group but presumably it was 6 months after the initial questionnaire. Baseline characteristics of the two groups were given but with no significance tests. The two groups do not appear to differ markedly.

Schull et al.
This is published as part of one journal article on clinical nurse care managers for patients with a variety of diseases. It was carried out in a public hospital in USA that provided primary, secondary and tertiary care to local residents. It compared 23 case-managed elective inpatients to 19 similar non-case managed patients. Case management was defined as organising and co-ordinating services and resources to meet an individual's healthcare needs and was carried out by a clinical nurse specialist. Cost control was a secondary objective. No baseline characteristics were given comparing the two randomised groups of patients.

## Table 5 - Epilepsy nurses - RCT and controlled study details

| | Ridsdale (1) | Ridsdale (2) | Schull | Warren | Mills |
|---|---|---|---|---|---|
| Patient definition | Aged over 15 Established diagnosis of epilepsy. Seizure within last 2 years or taking AEDs | Aged over 17. New diagnosis of epilepsy. 2 or more seizures at initial treatment with AEDs. Returned initial questionnaire | Epilepsy-related diagnoses (new onset, uncontrol-led or seizures related to intra-cranial lesions, drug toxicity or overdose) | Aged 16 or over. Diagnosis of epilepsy or possible epilepsy confirmed within 6-month follow up period. Attending out-patient service (new or follow up) | Aged 16 or over. Currently on AEDs for epilepsy |
| Exclusions | Other severe illness eg. cancer, active psychosis or severe depres-sion. Low IQ from learning disability or dementia. Failure to return initial questionnaire | Learning or language difficulties making it impossible to complete a questionnaire. Severe medical or psychological disease | Surgical procedures for evaluation or treatment of uncontrolled seizures | No epilepsy diagnosed during the 6mth follow up. Refusing, not attending or cancelling appointments. In another RCT or previous nurse specialist contact. Receiving a different treatment to that allocated. Lack of waiting room time, administrative error or clinic cancelled appointment. | None |
| Method of randomis-ation | Not stated | In blocks. Method not stated | Not stated | Computer generated block randomisation with sealed envelope | N/A |
| Power calculation | No | Yes | No | No | Yes |
| Method of data collection | Questionnaire survey (HADS and knowledge) | Questionnaire survey (advice provided, knowledge, HADs) | Hospital computerised information system and patient records | Postal questionnaire and data extraction from medical records (HADS, Impact of Epilepsy Scale) | Questionnaire completed by patient or carer |
| Blinding of outcome assessment | No | Not stated | Not stated | No | Not stated |
| Jadad score | 2 | 2 | 1 | 3 | N/A |
| Outcome measures | Depression, AED blood levels, knowledge of epilepsy, whether advice given, | Depression, anxiety, knowledge of epilepsy, whether advice given, patient satisfaction | Length of stay. Seizure related readmissions at 30 and 90 days, emergency department and ambulatory clinic visits, appointment compliance | Seizure frequency, AED side effects, injuries from seizures, epilepsy related service use, HADS, Impact of Epilepsy Scale, absence from work, knowledge of epilepsy, treatment compliance, clinic attendance, satisfaction with GP, outpatient clinic and nurse specialist, EUROQOL health status. | Primary outcomes – Frequency of seizures, use of AEDs, provision of information, use of care, attitudes to care. Secondary outcomes – preference of 1º or 2º based care, perceived effect of epilepsy and its treatment on everyday life. |
| Treatment | Primary care | Secondary care | Tertiary care. | Secondary care | Primary care |
| Nature of intervention | Nurse run clinic (? definition) | Specialist epilepsy nurse run clinic | Epilepsy nurse specialist case manager | Epilepsy nurse specialist case manager | Nurse run clinic plus liaison between and education of local health service. |
| Follow up | 6 months | 6 months | 90 days | 6 months | 1 year, 2 years |
| Intention to treat analysis | Yes | ?Yes | Probably yes | No | Yes |

Warren.
This trial is reported as a 175 page specialist report to a regional health authority. From 941 eligible patients, 268 were randomised to 'usual care' by doctors in the hospital outpatient clinic or a nurse-run clinic-based interventions in addition to 'usual care'. 34 patients were excluded as not having epilepsy during the 6-month follow up. Also, 20 epilepsy patients with learning disabilities were enrolled (consent given by carer). Randomisation took place prior to seeking patient's consent and full knowledge of eligibility. The nurse was responsible for improving clinical management, counselling and the record keeping. The nurse's main roles were patient education and co-ordination and monitoring of care. The study also considered the costs of the intervention for the NHS. There were no significant differences in baseline clinical characteristics between intervention and control groups but significantly more men and more employed in the intervention group.

#### 8.5.1.2 Controlled study

Mills et al.
This study is reported in two journal articles. Fourteen general practices were allocated to equal sized intervention or control groups by whether a specialist epilepsy nurse worked there or not. All GP practises had similar distributions of practice size, doctor-population ratio, patient socio-economic status and mean distance from hospital. The study population comprised all patients taking medication for epilepsy within these 14 practices. The questionnaire used was based on the Living with Epilepsy survey instrument. Although patient randomisation was not used in this study, selection bias of patients was minimised because intervention and control group allocation was by GP practice not by patient. Baseline characteristics in the two groups are similar except that significantly more in the control group had a seizure within the previous year.

**Table 6 - Epilepsy nurses - RCT patient numbers**

| | Comparison | Number of patients randomised | Number followed up |
|---|---|---|---|
| Ridsdale (1) | Epilepsy nurse<br>GP | 127<br>124 | 100 (96-121)[#]<br>96 (95-114)[#] |
| Ridsdale (2) | Nurse specialist<br>Usual care | 54<br>48 | 47<br>43 |
| Schull | Case-managed<br>Non-case managed | 23<br>19 | ?23<br>?19 |
| Warren | Nurse specialist<br>Out-patient dept | 135<br>153 | 87 (64-85)[#]<br>120 (94-117)[#] |

[#] - Different numbers followed up for some outcomes

**Table 7 - Epilepsy nurses – controlled study (Mills) patient numbers**

| | Epilepsy nurse | GP |
|---|---|---|
| Initial number of patients | 278 | 296 |
| Number followed up at 1 year | 148 | 155 |
| Number followed up at 2 years | 120 | 120 |

### 8.5.2 Results of clinical effectiveness

Comparative results of the four RCTs and controlled study for any seizure frequency, seizure severity and quality of life outcomes are shown in Table 8. Much more detailed results, focusing on process of care outcomes, are in Appendix 7. None of the studies included details of waiting times or false positive diagnoses.

Ridsdale et al (1)
This trial showed no significant difference in rates of being seizure-free for the previous six months or the number of people depressed in the two groups. They report that the median depression score was significantly lower in the intervention group compared to controls but no scores were presented. In a sub group analysis of number of people with depression compared to presence or absence of seizures within the previous six months, the difference was only seen in the no recent seizure group (Relative risk 3.15, 95% confidence interval 1.15-8.60). All other outcomes related to the process of care.

Ridsdale et al (2)
This trial showed no significant differences in anxiety or depression or in time since last seizure between the two groups. All other outcomes related to the process of care.

Schull et al
This trial showed no difference in mean length of in-patient stay between case managed and non-case managed groups (6.97 v 6.79), no seizure related admissions at 30 days for either group but an increase in seizure related readmissions at 90 days in the non-case managed group. No significance tests were given.

Warren
This trial failed to find any significant improvement in medical or psychological outcomes for the specialist epilepsy nurse group compared to the hospital outpatient clinic. All other outcomes recorded relate to the process of care and the feelings of the patient.

**Table 8 - Epilepsy nurse versus 'usual care' results**

| | | Ridsdale (1) | Ridsdale (2) | Schull | Warren | Mills |
|---|---|---|---|---|---|---|
| Seizure frequency | | | | | | OR=1.02 |
| Time since last seizure (mths) | Specialist<br>Usual care | | 6.5 /47<br>4.9 /43 | | | |
| Seizure free for previous 6 mths | Specialist<br>Usual care | 67.4%/92<br>67.7%/96 | | | 30% /80<br>27% /111 | |
| Seizure related re-admission (90 days) | Specialist<br>Usual care | | | 0<br>3 | | |
| AED side effects | Specialist<br>Usual care | | | | 65% /81<br>71% /112 | OR=1.69 |
| Depression | Specialist<br>Usual care | 15.2% /92<br>19.8% /96 | 19% /47<br>19% /43 | | 18% /85<br>15% /117 | |

*p<0.05 OR = Odds ratio of epilepsy nurse compared to 'usual care'

Mills et al
The two-year results are presented in Table 8. At both 1 year and 2 year follow up there were no significant improvements in medical or psychological outcomes for the specialist epilepsy nurse group compared to care by GPs. Again, all other outcomes recorded relate to the process of care and the feelings of the patient.

### 8.5.3 Caveats of the studies

Ridsdale et al (1)
A questionnaire had to be completed by each person before inclusion into the study. Therefore the participants were a self-selected, probably more compliant group than those who did not fill out the questionnaire. The non-responders may also have been less affected by epilepsy. There was no comparison made between responders and non-responders. The study was not blinded to allocation of intervention or outcome assessment so results should be viewed with caution.

Ridsdale et al (2)
A questionnaire had to be completed by each person before inclusion into the study. Therefore the participants were a self-selected, probably more compliant group than those who did not fill out the questionnaire. The comparison between responders and non-responders showed that the non-responders were significantly younger. Three of the 12 dropouts during follow up developed severe illnesses that would have resulted in exclusion had they developed these illnesses before the start of the trial. As the trial was based on respondents to a questionnaire, it is probable that the results are only generalisable to more compliant patients with epilepsy.

Schull et al
There are only very sketchy details of this trial available and very few outcomes reported. It is impossible to know how well the trial was carried out. The small sample sizes mean that statistically significant results were very unlikely.

Warren
There are concerns about the external and internal validity of the study. Initially all patients not attending, cancelling or refusing appointments were excluded from the study. Patients were also excluded if they received a different intervention from that to which they had been randomly allocated. Patients who dropped out of the study were not followed up. Therefore the study results may only be generalisable to compliant patients over 16 who happen to not have had their clinic appointments cancelled or been subject to administrative error. The results may be biased and should be interpreted with caution.

Mills et al
This study was not randomised. There is no description of method of allocation of GP practices to epilepsy nurse or not. The questionnaire survey had a response rate of only 40.3% of all eligible adults at 2 years (non-responders were followed up three times). The response rate was very similar between intervention and control groups. Therefore the results may only be generalisable to more compliant GP patients.

## 8.6 Economic evidence

The Warren RCT[44] included in the clinical effectiveness section also carried out an economic analysis. A financial costing was made on the primary and secondary NHS service use and costs using data from the local NHS Trust finance department and annually published national data.[48] This calculated the number and type of staff used in both primary and secondary care, inpatient admissions and investigations performed for most of the trial participants over the 6 months that the RCT took place. All costs pertained to 1996/97.

**Table 9 - Epilepsy nurse (Warren) RCT economic results**

| | Epilepsy nurse | Usual care |
|---|---|---|
| Number of patients in RCT group | 83 | 116 |
| Mean GP consultations per patient | 0.9 | 1.8 |
| Primary health care mean cost per patient per year | £33 | £56 |
| Mean out-patient clinic doctor consultation per patient | 1.3 | 1.8 |
| Secondary health care mean cost per patient per year | £642 | £802 |
| Total mean NHS cost per patient per year | £674 | £858 |

The reduction per patient in total NHS costs of £184 per annum in the epilepsy nurse group was not statistically significant.

No other relevant economic studies were found.

## 8.7 Quality of life

In the Warren RCT,[44] patients from intervention and control groups were assessed at the six month follow up using the EUROQOL measure. This showed that there were very little differences between the two groups on both parts of the EUROQOL measure.

**Table 10 - Quality of life – Warren RCT**

| | Epilepsy nurse run clinic | Usual care in hospital out-patient department | |
|---|---|---|---|
| EUROQOL weighted health status (Mean +SD) | 0.72 (0.26) /85 | 0.69 (0.31) /117 | p=NS |
| EUROQOL self rated health status. (Mean +SD) | 62.1 (22.8) /85 | 65.2 (21.6) /117 | p=NS |

## 8.8 Other systematic reviews and RCTs on the benefits and costs of specialist clinics and specialist nurses

### 8.8.1 Specialist clinics – clinical effectiveness

One relevant systematic review was found.[49] This compared the efficacy of multidisciplinary team care programs to routine care in rheumatoid arthritis. However, of the four RCTs it reviewed, one presented no follow up results, one was dated 1974 and the remaining 2 RCTs had already been found during the searches. The RCT results are shown in Table 11. All three trials showed no significant differences between intervention and control groups for the main physical health measure.

**Table 11 - RCTs of specialist versus generalist outpatient clinics for chronic medical conditions**

| Author, date, type of study | Disease | Comparison | Number | Outcomes | Findings |
|---|---|---|---|---|---|
| Schned, 1995[50] | Rheumatoid arthritis | Team managed v. usual care | n=107 | Ritchie joint count | No significant differences |
| GRASSIC, 1994,[51] | Asthma | Integrated v conventional care | n=712 | FEV1 | No significant differences |
| Ahlmen, 1988,[52] | Rheumatoid arthritis | multi-disciplinary team v. regular care | n=59 | Ritchie joint count | No significant differences |

### 8.8.2 Specialist clinics – cost effectiveness

Two of the three RCTs listed above reported cost information. In Schned et al, the cost portion of the Health Assessment questionnaire was used to determine direct and indirect expenditures reported by the patient. In the GRASSIC study, costs to patients were assessed by patient completed questionnaire and to GPs from pre-existing government and health board information. The first trial showed no significant differences in cost between the two groups. The second study showed a slight cost saving for the integrated care group but no significance test is given.

### 8.8.3 Specialist nurses – clinical effectiveness

No systematic reviews were found. The five RCTs found are shown in Table 12. Two trials show improved health outcomes for the intervention group and three show no significant differences.

**Table 12 - RCTs of specialist nurses versus 'usual care' for chronic medical conditions**

| Author, date, type of study | Disease | Comparison | Number | Outcomes | Findings |
|---|---|---|---|---|---|
| Premaratne 1999,[53] | Asthma | Nurse specialist v GP care | n=780 | Quality of life | No significant difference |
| Jolly, 1998,[54] | MI, angina | Specialist liaison nurse v usual care | n=481 | Resting angina | No significant differences |
| Mulloy, 1995[55] | Asthma | Nurse education v usual out-patient care | n=33 | FEV1 | No significant differences |
| Weinberger, 1995,[56] | Non-insulin dependent diabetes mellitus | Nurse co-ordinated v primary care physician | n=275 | Glycosylated haemoglobin | Significantly lower in intervention group |
| McInnes, 1995,[57] | Hypertension | Independent nurse practitioner v outpatient clinic | n=540 | Proportion with adequate review of BP, ECG, serum creatinine | More adequate reviews in nurse pract-itioner group (significance test not given) |

### 8.8.4 Specialist nurses – cost effectiveness

Only one RCT listed above also reported costs. In McInnes et al costs were those attributable to medical, nursing and secretarial time, investigations, administration, patient travel and patient time. These were used to calculate a cost per adequate review. The total cost and the cost per adequate review were both less for the nurse practitioner group than the outpatient group but no test of significance was given.

# 9 Conclusions

There is no convincing evidence, from the RCTs or other studies reviewed, that specialist epilepsy clinics improve clinical effectiveness outcomes when compared to general outpatient neurology clinics or that specialist epilepsy nurses improve clinical effectiveness outcomes when compared to normal inpatient, outpatient or GP care.

This could be because the quality of information available is poor rather than because there is no effect of specialist treatment on these outcomes.

With specialist epilepsy clinics the information available is sparse and of limited quality. The single RCT available was poorly designed and reported. The patients who withdrew had much more severe epilepsy with more frequent seizures than those who remained within the RCT. Many more people withdrew from the neurology clinic arm of the trial, so even though seizure frequency was not given at baseline, the two groups were almost certainly not comparable. No numbers of patients followed up in each group are given. Therefore the results cannot be taken as proof that epilepsy clinics are no more effective than neurology outpatient clinics. Although providing interesting information, the other studies reviewed cannot provide evidence of increased effectiveness of epilepsy clinics because the casemix of patients attending epilepsy clinics and neurology outpatient clinics is different.

More research evidence is available on whether specialist epilepsy nurses improve outcomes relative to usual care in primary, secondary or tertiary health settings. None of the RCTs or the controlled study showed any significant differences between the two groups regarding seizure frequency or seizure severity. There was evidence that incidence of depression was decreased in the epilepsy nurse group in one study (Ridsdale (1)) but not in two others (Warren, Ridsdale (2)). There was good evidence that the process of care and/or patient satisfaction was improved in the epilepsy nurse groups compared to controls. However, there is an expectation that if the process of care is improved then clinical outcomes will improve. This was not shown.

The evidence on costs suggested that an epilepsy clinic is very slightly more expensive than a neurology outpatient clinic, but that employing an epilepsy nurse works out slightly cheaper in the long run because nurse consultation costs are cheaper than doctor consultation costs. The one RCT that compared quality of life outcomes[44] showed no difference between the epilepsy nurse and usual care groups at 6 months follow up.

The available evidence shows no statistically significant differences in the main clinical effectiveness outcome measures in epilepsy. This means that we were unable to progress to an analysis of cost effectiveness.

Other randomised controlled trials of specialist versus generalist clinics or nurses show little or no benefit from specialist services.

Much more research needs to be undertaken on specialist epilepsy clinics and specialist epilepsy nurses if there is an expectation that these are to be ‘the best standard’ of health care delivery to people with epilepsy.

# Appendix 1 - Protocol used for the systematic review

**Do specialist epilepsy clinics offer advantages over general neurology clinics? (Protocol)**
**P.Bradley**
**Date last change to this document: 23.11.97**
Date of Review expected: 30.3.98

**Aim:** To investigate which is the most effective and economically appropriate model of out-patient care for patients with epilepsy.

**Objectives:** To conduct a systematic review of the effectiveness and cost-utility analysis of the clinical outcomes and quality of life for patients with epilepsy treated in general neurology out-patient clinics and specialist epilepsy clinics. Other specific interventions in out-patient epilepsy care and the assessment of the prevalence of unmet clinical need will also be considered if appropriate.

**Search Strategy for papers on effectiveness:**
Types of Evidence
Randomised controlled trials, controlled trials without randomisation, cohort and case controlled studies, multiple time series, dramatic results from uncontrolled experiments and opinions of respected authorities based on clinical evidence, descriptive studies or reports of expert committees will be considered.
Data sources
Data sources will include those advised by the DEC Health Technology Assessment Guidelines (See later).

**Search Strategy for data on costs:** Data on costs will include those advised by the DEC Health Technology Assessment Guidelines.

**Outcome measures:** The main outcomes which will be considered by the review are those which describe the patients' quality of life after clinic interventions. Often proxy measures are used in studies to assess these patient-centred outcomes. Therefore, the following outcomes will be considered; seizure frequency, appropriateness of medication prescribed, prevalence of drug monotherapy, appropriateness of serum level testing, waiting time for first out-patient clinic appointment, provision of information and advice by professionals to patients and carers, provision of services (e.g. Specialist Epilepsy Nurse, EEG, CT Scan, Video telemetry), patients' self perception of quality of life (including side-effects of medication), number of attendances at hospital clinic and General Practice, in-patient hospital stay, and social functioning.

**Data collection and analysis:** Data extraction will be performed by two reviewers, who will both check the data independently. Missing data will be obtained from the authors when possible. A cost-utility analysis and sensitivity analysis will be performed to investigate any heterogeneity in the results and to test the effect of including studies of lower methodological quality.

If possible, sub-group analyses will be performed to look at:
Age groups (children under 16, adults up to 64 years of age: adults aged 65 years or more)

Specific patient groups (e.g. patients with learning disabilities)
Epilepsy clinics in centres of excellence for neurology and those in district hospitals.

Information sources to be researched on effectiveness (as advised by DEC Health Technology Assessment guidelines)
Medline
Healthplan
GEARS
BIDS (Embase=Excerpta Medica)
CancerLit
York Register of economic assessments
Cochrane Database
Datastar/ WHO database
ECRI
Drugs and Therapeutic Bulletin
Effectiveness Healthcare Bulletin
Effectiveness Matters
Bandolier
Evidence Based Purchasing
National research register for ongoing research
Vignettes and expert panels from Standing Group on Health Technology Assessment
Product manufacturers e.g. drug companies
Experts in the field
References on papers already received

Information sources to be researched on costs (as advised by DEC Health Technology Assessments guidelines)
Local purchasers of health care
Local providers of health care
National Casemix Office
Published cost-effectiveness evaluations
Publications e.g. British National Formulary
Product manufacturers/ distributors
Experts
The literature

Additional sources of information
PsychLit database
World Wide Web sites
E-mail conferences on finding clinical trials

## Appendix 2 - Search Strategies used in the review

Search strategy run on all databases except GEARS OAD and Cochrane where "search" run.

No language restrictions.

MEDLINE 1966 - 1/98
Embase from start (?date) to 12/97

| No. | Records | Request |
|---|---|---|
| 1 | 38513 | explode "EPILEPSY"/ all subheadings |
| 2 | 45818 | EPILEP* |
| 3 | 37702 | #1 and #2 |
| 4 | 5931 | explode "PROGRAM-EVALUATION"/ all subheadings |
| 5 | 203393 | explode "DELIVERY-OF-HEALTH-CARE"/ all subheadings |
| 6 | 9 | #3 and #4 |
| 7 | 684 | #3 and #5 |
| 8 | 23451 | explode "AMBULATORY-CARE"/ all subheadings |
| 9 | 149 | #3 and #8 |
| 10 | 45818 | EPILEP* |
| 11 | 109327 | CENTRE* |
| 12 | 87 | EPILEP* near4 (CENTRE* in TI,AB) |
| 13 | 45818 | EPILEP* |
| 14 | 411850 | CENTER* |
| 15 | 110 | EPILEP* near4 (CENTER* in TI,AB) |
| 16 | 45818 | EPILEP* |
| 17 | 13346 | SPECIALIST* |
| 18 | 22 | EPILEP* near3 SPECIALIST* |
| 19 | 45818 | EPILEP* |
| 20 | 303181 | NURS* |
| 21 | 16 | EPILEP* near2 (NURS* in TI,AB) |
| 22 | 62195 | explode "OUTCOME-AND-PROCESS-ASSESSMENT-(HEALTH-CARE)"/ all subheadings |
| 23 | 614 | #22 and #3 |
| 24 | 31 | #7 and #23 |
| * 25 | 403 | #6 or #9 or #12 or #15 or #18 or #21 or #24 |

Medline on Ovid. 1966-Sept 1999. Clinical effectiveness search.

| | Search history | Results |
|---|---|---|
| 1 | Exp epilepsy/ or exp epilepsy, absence/ or exp epilepsy, complex partial/ or exp epilepsy, frontal lobe/ or exp epilepsy, generalised/ or exp epilepsy, myoclonic/ or exp epilepsy, partial/ or exp epilepsy, post-traumatic/ or exp epilepsy, rolandic/ or exp epilepsy, temporal lobe/ or exp epilepsy, tonic-clonic/ | 41637 |
| 2 | Randomized controlled trial.pt. | 116380 |
| 3 | Randomized controlled trials.sh. | 13086 |
| 4 | Random allocation.sh. | 38791 |
| 5 | Double blind method.sh. | 55762 |

| | | |
|---|---|---|
| 6 | Single blind method.sh. | 4360 |
| 7 | 2 or 3 or 4 or 5 or 6 | 165776 |
| 8 | Animal.sh. | 2890149 |
| 9 | Human.sh. | 6498300 |
| 10 | 8 not (8 and 9) | 2301242 |
| 11 | 7 not 10 | 157216 |
| 12 | 1 and 11 | 629 |
| 13 | Exp outpatient clinics, hospital/ or 'clinic'.mp. | 52326 |
| 14 | 12 and 13 | 6 |
| 15 | 1 and 13 | 440 |
| 16 | 'Special$'.mp. | 148553 |
| 17 | 15 and 16 | 48 |

Embase on Ovid. 1980 – Sept 1999. Clinical effectiveness search.

| | Search history | Results |
|---|---|---|
| 1 | Exp benign epilepsy of childhood/ or exp epilepsy/ or exp focal epilepsy/ or exp frontal lobe epilepsy/ or exp generalized epilepsy/ or exp grand mal epilepsy/ or exp intractable epilepsy/ or exp myoclonus epilepsy/ or exp photosensitive epilepsy/ or exp reflex epilepsy/ or exp rolandic epilepsy/ or exp 'seizure, epilepsy and convulsion'/ or exp traumatic epilepsy/ | 59272 |
| 2 | Exp randomized controlled trial/ | 38564 |
| 3 | Exp controlled study/ | 876347 |
| 4 | Randomised controlled trial$.tw. | 1423 |
| 5 | Exp randomization/ | 2432 |
| 6 | Exp Double blind procedure/ | 32260 |
| 7 | Exp single blind procedure/ | 2370 |
| 8 | 2 or 3 or 4 or 5 or 6 or 7 | 888017 |
| 9 | Limit 8 to human | 472963 |
| 10 | 1 and 9 | 4665 |
| 11 | Exp outpatient department/ or "##'Clinic$'.mp##"/ or "clinic$".mp. | 1318115 |
| 12 | 10 and 11 | 3908 |
| 13 | "special$'.mp. | 97300 |
| 14 | 12 and 13 | 87 |

Medline on Ovid. 1966-Sept 1999. Cost effectiveness search.

| | Search history | Results |
|---|---|---|
| 1 | Exp epilepsy/ or exp epilepsy, absence/ or exp epilepsy, complex partial/ or exp epilepsy, frontal lobe/ or exp epilepsy, generalised/ or exp epilepsy, myoclonic/ or exp epilepsy, partial/ or exp epilepsy, post-traumatic/ or exp epilepsy, rolandic/ or exp epilepsy, temporal lobe/ or exp epilepsy, tonic-clonic/ | 41637 |
| 2 | Exp Quality of life/ | 19294 |
| 3 | 1 and 2 | 241 |
| 4 | Limit 3 to human | 240 |
| 5 | Exp cost allocation/ or exp cost control/ or exp cost of illness/ or exp cost savings/ or exp cost sharing/ or exp cost-benefit analysis/ or exp 'costs and cost-analysis'/ or exp technology, high-cost/ | 58824 |
| 6 | 1 and 5 | 116 |

Embase on Ovid. 1980 – Sept 1999. Cost effectiveness search.

| | Search history | Results |
|---|---|---|
| 1 | Exp benign epilepsy of childhood/ or exp epilepsy/ or exp focal epilepsy/ or exp frontal lobe epilepsy/ or exp generalized epilepsy/ or exp grand mal epilepsy/ or exp intractable epilepsy/ or exp myoclonus epilepsy/ or exp photosensitive epilepsy/ or exp reflex epilepsy/ or exp rolandic epilepsy/ or exp 'seizure, epilepsy and convulsion'/ or exp traumatic epilepsy/ | 59272 |
| 2 | Exp cost/ or exp cost benefit analysis/ or exp cost control/ or exp cost effectiveness/ or exp drug cost/ or exp energy cost/ or exp health care cost/ or exp hospital cost/ or exp hospital running cost/ | 63172 |
| 3 | 1 and 2 | 440 |
| 4 | Exp outpatient department/ or "##'Clinic$'.mp##"/ or "clinic$".mp. | 1318115 |
| 5 | "special$'.mp. | 97300 |
| 6 | 3 and 4 and 5 | 12 |

Cochrane database - systematic reviews on specialist v generalist clinics or nurses

| | Search history | Results |
|---|---|---|
| 1 | Special* + outpatient + clinic* | 269 |
| 2 | Special* + nurs* | 619 |

Medline on Ovid 1993-7/2000. Systematic reviews and RCTs on specialist v generalist clinics or nurses

| | Search history | Result |
|---|---|---|
| 1 | "SPECIAL*".mp | 27155 |
| 2 | Exp nurse clinicians/ or exp nurse practitioners/ or "specialist nurse".mp. | 5166 |
| 3 | "OUT-PATIENT".mp. | 240491 |
| 4 | Exp outpatient clinics, hospital/ or "##'Outpatient*'.mp##"/ or "outpatient*".mp | 13945 |
| 5 | 3 or 4 | 250194 |
| 6 | Exp randomized controlled trials/ or "systematic review".mp. | 11852 |
| 7 | 1 and 5 and 6 | 24 |
| 8 | 2 and 6 | 10 |

# Appendix 3 - Outcome measures

The three main ways that the severity of epilepsy and treatment outcomes have been measured are seizure occurrence, seizure severity and global outcome scores.

### Seizure occurrence and frequency

This is the easiest outcome to measure and many people with epilepsy keep seizure diaries. Clinical studies of new anti-epileptic drugs (AEDs) commonly use seizure frequency as the only measure of efficacy.[58]

### Seizure severity

The main, well-developed method of outcome assessment of seizure severity is the Liverpool Seizure Severity Scale.[59] This has patient-based measures, using Likert scales, of the experience of seizures and their predictability. It was developed for used in AED trials.

### Combined seizure frequency and severity

This scale was developed for the USA Veteran's Administration by Cramer et al[60] in order to provide a means to evaluate AEDs in multicentre RCTs and is known as the Cramer Scales. It includes seizure frequency, seizure severity, neurotoxicity, systemic toxicity and behavioural toxicity and provides a composite score (also known as the composite index of impairments). In this scale a higher score indicates more problems. Neurotoxicity tests are for the presence of diplopia, dysarthria, ataxia, tremor, sedation, dizziness, headache and changes of mood and cognition. Systemic toxicity tests are for the presence of GI tract disturbances, hypersensitivity reactions, changes in hair texture and growth, impotence, blood, liver and kidney malfunction. Behavioural toxicity tests are for changes in motor/integrative skills, cognitions, memory and mood. The composite score is designed to reflect the total effect of seizures and drugs on the patient.

### Global outcome scores

The quality of life in patients with epilepsy is affected by seizures and their psychosocial consequences and also by the anti-epileptic drugs and their side effects. In order to evaluate quality of life, clinicians have either developed inventories specifically for epilepsy or used generic quality of life measures with or without extra items on epilepsy. Epilepsy specific inventories include the Epilepsy Surgery Inventory-55[61] which developed into the QOLIE (quality of life in epilepsy) inventory,[62; 63] the Liverpool Quality Of Life battery (LQOL) the SHE (subjective handicap of epilepsy) scale[64] and the Washington Psychosocial Seizure Inventory.[65; 66]

Generic measures of quality of life used include EUROQOL,[44] the Nottingham Health Profile (NHP)[33; 65; 67] and the Short Form Health Survey (SF-36).[4; 64] The EUROQOL measure is in two parts. The first (weighted health status) classifies health in five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each with three possible responses (no problem, some problem or extreme problem). The second part is self rated health status on a visual analogue scale (shown as a thermometer) where respondents mark how their health is on a scale of 0 (dead) to 100 (perfect health).

Generic measures of specific impairments include the Hospital Anxiety and Depression scale (HADS). This measure was originally developed as a screening tool for mood disorders in patients with psychiatric illnesses attending hospital out-patient clinics but is now widely used in psychological and psychiatric research. It measures anxiety and depression separately, with a higher score indicating more distress.

The purpose of any epilepsy treatment is to try to improve the quality of the lives of people with epilepsy. Traditionally, quality of life has been considered to be closely related to seizure frequency. However, several authors point out that this is not necessarily the case as the social and psychological consequences of epilepsy can lead to high levels of morbidity[58; 65; 68-70] (although this is often not the case when epilepsy is well controlled[67]).

# Appendix 4 - Full results of searches

**Table 13 - Clinical effectiveness search**

| Database | Years/date searched | Search strategy | Results | |
|---|---|---|---|---|
| | | | Total number of references | Number of included studies |
| Medline, Healthplan, GEARS, BIDS Embase | 1966-12/1997 or 1/1998 | See Appendix 2 | Unknown | 4 |
| | | | | |
| Medline | 1966-9/1999 | See Appendix 2 | 48 | 0 |
| Embase | 1980-9/1999 | See Appendix 2 | 87 | 1 |
| BIDS ISI | 1990-8/1999 | 'epilepsy'+'clinics' | 59 | 0 |
| Cochrane | 1999, issue 2 | 'epilepsy' and 'clinic*' | Unknown | 0 |
| DARE | 7/1999 | epilepsy | 22 | 0 |

Hand search of Seizure 1995-1999 – 0.
Hand search of Epilepsia 1999-2000 – 0.
Contact with experts – 1
Referenced in clinical effectiveness report – 1
Found during peer review - 1

**Table 14 - Details of clinical effectiveness studies found**

| Comparison | Type of study | Number of studies |
|---|---|---|
| Epilepsy clinics | RCT | 1 |
| | Case control | 1 |
| | Audit | 1 |
| Epilepsy nurses | RCT | 4 |
| | Controlled trial | 1 |

**Table 15 - Quality of life and cost/cost effectiveness/cost utility searches.**

| Database | Years/date searched | Search strategy | Results | |
|---|---|---|---|---|
| | | | Total number of references | Number of included studies |
| From clinical effectiveness search | 1966-1999 | Various | Unknown | 3 |
| | | | | |
| Medline | 1966-9/1999 | See Appendix 2 | 240+116 | 2 |
| Embase | 1980-9/1999 | See Appendix 2 | 440 | 0 |
| NHS EED | To 9/1999 | 'epilepsy' | 15 | 0 |

Hand search of Seizure 1995-1999 – 1.
Hand search of Epilepsia 1999-2000 – 0.
Referenced in another cost study – 1

**Table 16 - Systematic reviews and RCTs on specialist v generalist clinics or nurses**

| Database | Years/date searched | Search strategy | Results | |
|---|---|---|---|---|
| | | | Total number of references | Number of included studies |
| Cochrane library | 2000 issue 2 | See appendix 2 | 619 | 8 |
| Medline | 1993-July 2000 | See appendix 2 | 34 | 0 |

Searches of Wessex, Trent and York InterTASC databases, DARE, NHSEED, HTA, INAHTA, SBU, CACCHTA, NZHTA, DIMDI, DenmarkHTA (July 2000)– 0 studies.

# Appendix 5 - Further details of RCT and audit of specialist epilepsy clinic versus general neurology outpatient clinic

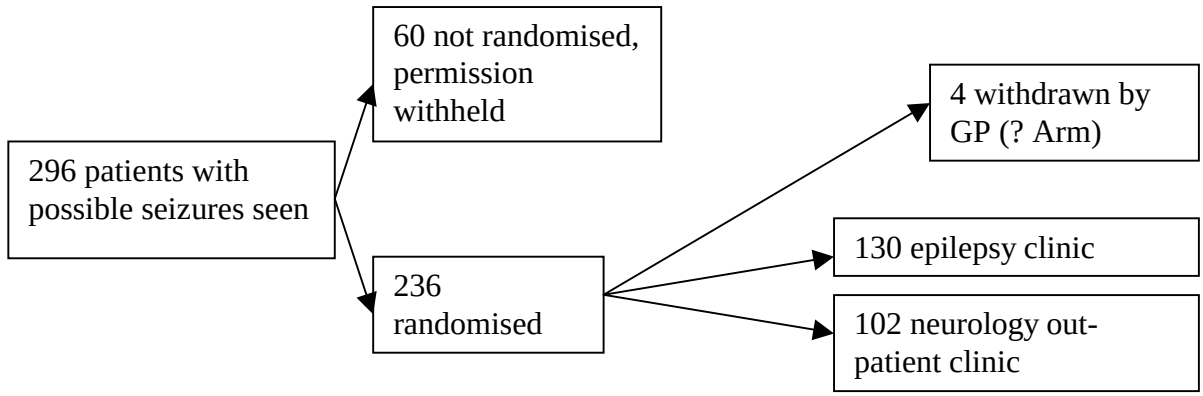
## 1. RCT of epilepsy clinic versus neurology outpatient clinic[33]

The trial design of this RCT is shown in Table 17 and Figure 1. There were large demographic differences between randomised and non-randomised groups (see Table 18) and also in numbers of patients in intervention and control groups (see Table 19).

**Table 17 - Epilepsy clinics - RCT Trial Design**

| Target patient definition | Exclusions | Treatment used | Randomisation method | Follow up period | Outcome measures |
|---|---|---|---|---|---|
| Newly referred patients with epilepsy or possible epilepsy | None stated. | Specialist epilepsy unit v neurology out-patient clinic in same city. Standard AEDs in both groups | Randomisation of referral letter by random numbers. (Consent from patient obtained after randomisation) | 3, 6 and 12 mths | Seizure control, seizure frequency, AEDs, concentrations and adverse effects, use of medical resources, number of investigations, amount of counselling and advice, NHP, HADS, social and occupational functioning. Satisfaction with GP and hospital services, financial costing. |

**Figure 1 - Flow diagram of epilepsy clinic RCT.**



Randomised versus non-randomised groups

There were 64 patients counted in the non-randomised group. The reason given for 60 new referrals being eligible but 'not randomised' was 'because permission was withheld' despite randomisation of referral letter before patient consent was sought. It is uncertain from the text whether exclusion was as a result of lack of permission from the patient, the local practitioners committee, the local ethics committee, the referring physician or the consultant to whom referred. A further 4 had been allocated to the neurology clinic but these were withdrawn by the GP after randomisation and have been counted in the non-randomised group. When demographic data were compared in the non-randomised and randomised groups they showed that there were significantly more patients with established epilepsy of known or possibly known cause in the non-randomised group compared to patients for diagnosis only in the randomised group. The non-randomised group were significantly more likely to have been referred by a hospital practitioner rather than a GP. The seizure history for the two groups is shown in Table 18. This shows that the epilepsy was much more severe in the non-randomised group. There were no significant differences in seizure types, AEDs or AED adverse effects between the two groups.

**Table 18 - Epilepsy clinics - RCT randomised v non-randomised groups**

| | Randomised group | | Non-randomised group | |
|---|---|---|---|---|
| | | 95% confidence intervals | | 95% confidence intervals |
| Mean number of seizures in previous 3 months | 16.75 | 14.75-18.75 | 45.5 | 34.8-56.2 |
| Median seizure frequency | 2 | - | 18 | - |
| Mean seizure score (Cramer) | 56.3 | 48.2-64.4 | 189.6 | 138.1-241.1 |

Epilepsy clinic versus neurology clinic

232 patients were randomised, 130 to the epilepsy clinic and 102 to the neurology clinic. There is no clear explanation in the text as to the discrepancy in numbers between the two clinics. The demographic characteristics of the two groups are similar and are shown in Table 19.

**Table 19 - Epilepsy clinics - RCT demographic characteristics**

| | Epilepsy clinic group | Neurology clinic group |
|---|---|---|
| Number of patients | 130 | 102 |
| % male | 44% | 33% |
| Mean age (range) | 32 (6-78) | 32 (8-74) |
| % for diagnosis | 38% | 31% |
| % with established epilepsy | 62% | 69% |
| Waiting time to be seen (wks) | 11 | 12 |
| Doubtful/unclassifiable seizures | 20% | 19.6% |

Follow up was at 3, 6 and 12 months. All patient case notes were reviewed. Follow up was

carried out only on those who had had at least one definite epileptic seizure during the follow up period (186 patients), as detailed in the hospital notes. Two patients died during the 12 months, two had moved away and a further six were lost to follow up. Therefore follow up was carried out on 176 patients. For questionnaire assessments, only 160 replies were obtained. There are no details as to the number of patients followed up in each group.

By 12 months only 46% of patients were still attending the neurology clinic and 68% still attending the epilepsy clinic. 40% of patients were seen on only one occasion in the Neurology clinic whereas 19% were seen only once in the epilepsy clinic.

## 2. Audit of epilepsy clinic compared to neurology clinic[36]

This audit showed that patients normally attending an epilepsy clinic have statistically significant differences in baseline characteristics and AEDs taken when compared to patients normally attending a neurology outpatient clinic. It suggested that those attending the epilepsy clinic normally have epilepsy that is harder to treat effectively. The comparison of the two clinics is shown in the table below.

**Table 20 - Audit comparison of epilepsy to neurology clinic**

| | Epilepsy centre | Neurology clinic | Significance |
|---|---|---|---|
| Median duration of epilepsy | 20 years | 10 years | p<0.001 |
| Seizure type – primary generalised tonic-clonic | 11.6% | 45.8% | p<0.001 |
| Seizure type – secondary generalised tonic-clonic | 16.4% | 9.2% | p=NS |
| Patients with more than one seizure type | 45.4% | 15.1% | p<0.001 |
| Monotherapy treatment | 62.5% | 28.0% | p<0.001 |
| Average number of AEDs | 2.0 | 1.4 | p=NG |
| Complete seizure remission | 19.2% | 43.3% | p<0.001 |
| Index of seizure score >100 | 16.4% | 13.3% | p=NS |
| Complete seizure control and no side effects of medication | 8.9% | 37.5% | p<0.001 |
| Composite index of impairments score >100 | 10.7% | 10.8% | p=NS |

# Appendix 6 - Economic evidence

## Epilepsy clinics - Other economic studies

There were numerous other studies found in literature search that examined the cost of treating epilepsy. However, most of them did not differentiate between the costs of specialist epilepsy clinics and neurology outpatient clinics, or the costs of epilepsy nurses compared to usual care. Therefore they were not relevant to this review.

There were only three relevant studies. The first was a cost-benefit analysis published in 1980.[71] It used a Markov model to estimate the decrease of epilepsy prevalence rate caused by having epilepsy clinics. Unfortunately, it based the clinical effectiveness transition probabilities from one functional level to another on the results of a dissertation published in Germany in 1967. The nature of this study is unknown. The approximate costs of epilepsy clinics were estimated from approximate staff salaries, buildings and technical costs over 30 years. The benefits were estimated from an average worker's salary in Germany in 1976 and the extra working capacity from increased functional levels of those with epilepsy and resulting decreased prevalence rate. The costs over a 30-year period were estimated to be DM 530 million whereas the benefits were valued at DM 574 million. Using the Markov model it was estimated that to attain benefit would take nearly 15 years of operation of the epilepsy clinics.

The second relevant study is an abstract of a cost study, based on 303 patients attending a specialist epilepsy outpatient clinic in Scotland in 1991.[72] It used computerised records of outpatient visits, inpatient admissions, investigations and treatments. The abstract does not mention the source of unit costs. It calculated that the direct hospital cost was £213 per person but indirect costs (social security etc) of £441 per person.

The third study is based on 745 patients attending a specialist epilepsy clinic in Hong Kong in 1996.[73] Direct, indirect and future costs were estimated 'by synthesising secondary and model data' and included outpatient visits, inpatient admissions and treatments. Costs of investigations were included within the other three categories. Subsidy was used as a proxy measure for inpatient costs, shadow market prices for outpatient costs and the purchasing price for AEDs. From 1992-1996 the overall direct costs for the 745 patients were US$982,800 which is approximately US$330 per patient per year. The overall indirect costs were US$1,320,700.

# Appendix 7 - Detailed results of RCTs and controlled study of epilepsy nurses compared to 'usual care'

## Ridsdale et al (1)[31; 37-39]

With regard to baseline characteristics, there were no significant differences between intervention and control groups on age, gender, epilepsy attacks, knowledge scores and depression status in the six months prior to the start of the RCT. In the sub group analysis, there was no differentiation in the results given between those who had had epilepsy nurse supervision and those with usual care by the GP. Therefore no results will be presented here.

The results shown in Table 21 suggest that the nurse was able to increase the detection of drug management changes, frequency of measurements of drug serum levels and level of advice given to patients. Despite the increased advice, there were no differences between the two groups on knowledge of epilepsy.

**Table 21 - Epilepsy nurses – Ridsdale (1) RCT results**

| | Epilepsy nurse run clinic | Usual care by GP | significance |
|---|---|---|---|
| AED levels checked within 6 months | 80/121 | 19/114 | p<0.01 |
| Advice given on driving | 84/119 | 52/113 | p<0.01 |
| Advice given on drug compliance | 95/119 | 29/113 | p<0.01 |
| Advice given on adverse drug effects | 86/119 | 18/113 | p<0.01 |
| Advice given on alcohol | 92/119 | 16/113 | p<0.01 |
| Advice given on self help groups | 79/119 | 6/113 | p<0.01 |
| Knowledge of epilepsy | | | p=NS |

## Schull et al[43]

There was no comparison of baseline characteristics. Some of the patients in the trial were admitted for seizure monitoring. Influencing length of stay was not considered possible for these patients because the occurrence of spontaneous seizures is not under nursing staff control. Where patients were admitted for other reasons, the length of stay was significantly less in the case managed group. No results of statistical significance tests were given.

**Table 22 - Epilepsy nurses – Schull RCT results**

| | Case managed | Non-case managed |
|---|---|---|
| Mean length of stay (days) | 6.96 | 6.79 |
| Mean length of stay for non-seizure monitoring patients | 5.60 | 7.57 |
| Seizure related readmissions at 30 days, | 0 | 0 |
| Seizure related readmissions at 90 days | 0 | 3 |
| seizure related emergency department visits, | 4 | 5 |
| ambulatory care clinic visits, | 3 | 5 |
| appointment compliance | 82 | 69 |

## Warren[44]

With regard to baseline characteristics, there were significantly more employed patients in the intervention group. Otherwise, there were no significant differences between intervention and control groups on age, gender, marital status, living circumstances, education, social class and a number of clinical characteristics including duration of epilepsy, time since last seizure and taking AEDs.

Most of the results were linked to the completion of a patient questionnaire. A high initial response rate (77%) was obtained. The response rate in the control group was 15% less than in the intervention group (control n=120, intervention n=87). However, data was not complete for all of the questions. Therefore, the actual number of responses for each question varied. (See Table 23)

**Table 23. Epilepsy nurses – Warren RCT results**

| | Epilepsy nurse run clinic | Usual care in hospital outpatient department | |
|---|---|---|---|
| Seizure free | 30% /80 | 27% /111 | p=NS |
| AED side effects | 65% /81 | 71% /112 | p=NS |
| Injuries from seizures | 29% /56 | 38% /81 | p=NS |
| GP consultations | 34% /83 | 47% /116 | p=NS |
| Out-patient clinic doctor consultation (Mean +SD) | 1.3 (0.6) /83 | 1.8 (0.8) /116 | P<0.01 |
| HADS anxious | 35% /85 | 33% /117 | p=NS |
| HADS depressed | 18% /85 | 15% /117 | p=NS |
| Impact of Epilepsy Score (Mean +SD) | 21.0 (6.9) /72 | 20.2 (6.3) /112 | p=NS |
| Absence from work % (for those in employment) | 65 % /31 | 67% /27 | p=NS |
| Patient knowledge of epilepsy (Medical knowledge) (Mean +SD) | 27.2 (3.7) /85 | 26.1 (3.8) /117 | p<0.05 |
| Treatment compliance | 54% /83 | 65% /114 | p=NS |
| Complete clinic attendance | 84% /84 | 92% /115 | p=NS |
| Patient satisfaction with GP | 52% /33 | 48% /60 | p=NS |
| Patient satisfaction with out-patient clinic doctors | 82% /78 | 80% /104 | p=NS |

This study suggested that a specialist epilepsy nurse improved patient outcomes in terms of increasing their knowledge about epilepsy and that such a service would be cost-effective by reducing consultations to GPs and attendances at hospital out-patients.[44] The benefits of decreased hospital and GP consultations were partially offset by increased consultations with general practice nurses. However, the study results failed to show any significant increase in improved medical or psychological outcomes for patients

### Ridsdale et al (2)[45]

The baseline characteristics of age, gender, months since last seizure, school leaving age, educational qualifications and questionnaire scores were presented. Statistical significance tests were not given but the two groups appear to be similar. The results from the patient completed HADs questionnaire are given in Table 24.

**Table 24. Epilepsy nurses – Ridsdale (2) RCT results**

| | Nurse specialist | Usual care |
|---|---|---|
| Cases of anxiety (score >8)<br>Anxiety score (median) | 15/47 (32%)<br>5.7 | 18/43 (42%)<br>6.0 |
| Cases of depression (score >8)<br>Depression score (median) | 9/47 (19%)<br>2.7 | 8/43 (19%)<br>3.7 |

The epilepsy nurse specialist group were significantly more likely to report that sufficient advice had been given on a wide range of subjects such as driving, epilepsy types and side effects of AEDs. There was no significant difference between the two groups in median knowledge of epilepsy scores.

### Controlled study – Mills et al[46; 47]

Non-responders to the initial patient questionnaire were followed up three times. For the final follow up, shortened versions of the questionnaire, which included the primary outcome measures, were sent by recorded delivery. The response rates to the questionnaire differed before and after one year's follow up. Results here are for respondents to both baseline and follow up surveys.

<u>Baseline and 1 year results</u>
There were significant baseline differences between the two groups. The control group had significantly more years of having epileptic attacks, were more likely to have had an epileptic attack in the last year and were more likely to have seen a GP or hospital doctor for their epilepsy within the past year. There were no differences on age, gender, employment, social class or presence of other long-term health problems. Both groups felt equally unhappy about life as a whole and stigmatised because of epilepsy before and at one year's follow up.

**Table 25 - Epilepsy nurses – Mills controlled trial results**

| | Nurse (/148) | Control (/155) | Significance |
|---|---|---|---|
| Had epilepsy attack in past year | 32.8% | 39.4% | p=NS |
| Had 1 or more epilepsy attack per month in past year | 16.8% | 20.5% | p=NS |
| Other long term health problems | 51.4% | 44.4% | p=NS |
| Injury as a result of epilepsy | 10.8% | 14.8% | p=NS |
| Monotherapy AED | 66.7% | 61.6% | p=NS |
| Reported side effects from AEDs in past month | 42.6% | 48.4% | p=NS |
| Feel well controlled by AEDs | 74.2% | 67.9% | p=NS |

Baseline and 2 year results

Again, there were significant baseline differences between the two groups. This time people in the control group had significantly more years free from epileptic attacks and were less likely to have had a seizure in the last year. They were also less likely to have seen a GP or hospital doctor for their epilepsy within the past year and to feel stigmatised about their epilepsy. At two years follow up, the only significant outcome measure result was that the intervention group were significantly less likely to feel that their GP knew enough about epilepsy. There was no significant difference between the two groups on the number of seizures in the last year, seizure induced injuries, hospital out-patient attendance, in-patient admission, AED monotherapy, side effects and compliance. At two years both groups felt equally unhappy about life as a whole and stigmatised because of their epilepsy.

# 10 References


1. Brown S, Betts T, Chadwick D, Hall B, Shorvon S, Wallace S. An epilepsy needs document. *Seizure* 1993;**2**:91-103.

2. Thapar AK. Care of patients with epilepsy in the community: will new initiatives address old problems? *British Journal of General Practice* 1996;**46**:37-42.

3. Betts T. Epilepsy services, what people need, what the want, what they get. *Acta Neurologica Scandinavica* 1992;**2**:95-100.

4. Baker G.A., Jacoby A, Buck D., Stalgis C., Monnet D. Quality of life of people with epilepsy: a European study. *Epilepsia* 1997;**38**:353-362.

5. British Epilepsy Association. Epilepsy Care: Making It Happen. A toolkit for today. 1999. Leeds, British Epilepsy Association.

6. Robertson M.M., Channon S., Baker J. Depressive symptomatology in a general hospital sample of outpatients with temporal lobe epilepsy: a controlled sample. *Epilepsia* 1994;**35**:771-777.

7. Hartshorn J.C. Importance of health and family variables related to quality of life in individuals with uncontrolled seizures. *Journal of Neuroscience Nursing* 1994;**26**:288-297.

8. French J. The long-term therapeutic management of epilepsy. *Annals of Internal Medicine* 1994;**120**:411-422.

9. National Association for Health Authorities and Trusts. Contracting for Quality Epilepsy Services. The Epilepsy Task Force. Update No. 12. 1995. Birmingham, National Association for Health Authorities and Trusts.

10. OPCS. Morbidity Statistics from General Practice. OPCS. 1991. London, HMSO.

11. Cooper G.L., Huitson A. An audit of the management of patients with epilepsy in thirty general practices. *Journal of General Practitioners* 1986;**36**:204-206.

12. Jacoby A. A general practice audit of the process of care for people with epilepsy. *Journal of General Practitioners* 1996;**46**:595-599.

13. Chappell B. Epilepsy: patient views on their condition and treatment. *Seizure* 1992;**1**:103-109.

14. Taylor M.P. Epilepsy in a Doncaster practice: audit and change over eight years. *Journal of the Royal College of General Practitioners* 1987;**37**:116-119.

15. Jain P., Patterson V.H., Morrow J.I. What people with epilepsy want from a hospital clinic. *Seizure* 1993;**2**:75-78.

16. Tobias E.S., Brodie A.F., Brodie M.J. An outcome audit at the epilepsy clinic: results from 1000 consecutive referrals. *Seizure* 1994;**3**:37-43.

17. Redhead K., Tasker P., Suchak K., et al. Audit of the care of patients with epilepsy in general practice. *British Journal of General Practice* 1996;**46**:731-734.

18. Carson N.E. Epilepsy: A disease audit. *Family Practice* 1985;**2**:235-237.

19. Lloyd Jones A. Medical audit of the care of patients with epilepsy in one group practice. *Journal of the Royal College of General Practitioners* 1980;**30**:396-400.

20. NHS Executive. Letter. EL (95) 120. 1996. Leeds, NHS.

21. Epilepsy Task Force. Specification for epilepsy services. 1995. London, Epilepsy Task Force.

22. Scottish Intercollegiate Guidelines Network. Diagnosis and Management of Epilepsy in Adults. 21. 1997. Edinburgh, Scottish Intercollegiate Guidelines Network.

23. Clinical Standards Advisory Group. Services for Patients with Epilepsy. 1999. London, HMSO.

24. Department of Health. Department of Health response to reports on pain, outpatients, depression and epilepsy by the Clinical Standards Advisory Group. 2000. London, Department of Health.

25. Morrow J.I. Specialised Epilepsy clinics-the pros and cons. *Seizure* 1993;**2**:267-268.

26. DHSS. Report of the working group on services for people with epilepsy. Report to the department of health and social security, the department of education and science and the welsh office. London, HMSO.

27. Upton D., Thompson P.J., Duncan J.S. Patient satisfaction with specialized epilepsy assessment and treatment. *Seizure* 1996;**5**:195-198.

28. Espir M., McCarthy M., Shorvon S. Survey of specialized hospital services for adults in the NE Thames region of the UK. *Neuroepidemiology* 1987;**6**:94-100.

29. Lesser R.P. The role of epilepsy centers in delivering care to patients with intractable epilepsy. *Neurology* 1994;**44**:1347-1352.

30. Betts T, Smith K. New departures in epilepsy care: an epilepsy liaison service. *Seizure* 1994;**3**:301-308.

31. Ridsdale L., Robins D., Fitzgerald A., Jeffery S., McGee L. Epilepsy monitoring and advice recorded: general practitioners' views, current practice and patients' preferences. *British Journal of General Practice* 1996;**46**:11-14.

32. Jadad A., Moore R., Carroll D. Assessing the quality of reports of randomised clinical trials: is blinding necessary? *Controlled Clinical Trials* 1996;**17**:1-12.

33. Morrow J.I. The clinical, social and psychological problems of patients with epilepsy. 1993. University of Wales, Cardiff.

34. Morrow J.I. An assessment of an epilepsy clinic. In: Chadwick D, ed. *Quality of life and quality of care in epilepsy*. London: Royal Society of Medicine, 1990;96-105.

35. Lammers M.W., Wijsman D.J., Hekster Y.A., et al. Epilepsy treatment in the Netherlands. Comparison of matched groups of two medical centres. *Acta Neurologica Scandinavica* 1994;**89**:415-420.

36. Wijsman D.J., Lammers M.W., Hekster Y.A., et al. Epilepsy treatment in the Netherlands: comparison of two medical centres. *Acta Neurologica Scandinavica* 1993;**87**:438-442.

37. Ridsdale L., Kwan I., Cryer C. The effect of a special nurse on patients' knowledge of epilepsy and their emotional state. *British Journal of General Practice* 1999;**49**:285-289.

38. Ridsdale L., Robins D., Cryer C., Williams H. Feasability and effects of nurse run clinics for patients with epilepsy in general practice: randomised controlled trial. *British Medical Journal* 1997;**314**:120-122.

39. Ridsdale L., Robins D., Fitzgerald A., Jeffery S., McGee L. Epilepsy in general practice: patients' psychological symptoms and their perception of stigma. *British Journal of General Practice* 1996;**46**:365-366.

40. Ridsdale L. What factors predicts knowledge of epilepsy? The effects of a epilepsy nurse input. 1998. Dublin, 15th WONCA World Conference. Irish College of General Practitioners. 6-18-1998.

41. Ridsdale L., Morgan M., O'Connor C. Promoting self-care in epilepsy: the views of patients on the advice they had received from specialists, family doctors and an epilepsy nurse. *Patient Education and Counseling* 1999;37:43-47

42. Scambler A., Scambler G., Ridsdale L., Robins D. Towards an evaluation of the effectiveness of an epilepsy nurse in primary care. *Seizure* 1996;**5**:255-258.

43. Schull D.E., Tosch P., Wood M. Clinical nurse specialists as collaborative care managers. *Nursing Management* 1992;**23**:30-33.

44. Warren E. An evaluation of a nurse specialist/case manager intervention in the management of epilepsy. RF13. 1998. Walton Centre, Liverpool., North West Regional Health Authority.

45. Ridsdale L., Kwan I., Cryer C., Epilepsy Care Evaluation Group. Newly diagnosed epilepsy: can nurse specialists help? A randomised controlled trial. *Epilepsia* 2000;**41**:1014-1019.

46. Mills N., Bachmann M.O., Harvey I., Hine I., McGowan M. Effect of a primary care based epilepsy specialist nurse service on quality of care from the patients' perspective: quasi-experimental evaluation. *Seizure* 1999;**8**:1-7.

47. Mills N., Bachmann M.O., Campbell R., Hine I., McGowan M. Effect of a primary care based epilepsy specialist nurse service on quality of care from the patients' perspective: results at two years follow up. *Seizure* 1999;**8**:291-296.

48. Netten A. and Dennett J. Unit costs of health and social care. 1997. Canterbury, PRSSU, University of Kent.

49. Vliet Vlieland TP, Hazes JM. Efficacy of multidisciplinary team care programs in rheumatoid arthritis. *Seminars in Arthritis and Rheumatism* 1997;**27**:110-122.

50. Schned ES, Doyle AT, Glickstein SL, et al. Team managed outpatient care for early onset chronic inflammatory arthritis. *Journal of Rheumatology* 1995;**22**:1141-1148.

51. Drummond N, Abdalla M, Buckingham JK, et al. Integrated care for asthma: a clinical, social and economic evaluation. Grampian Asthma Study of Integrated Care (GRASSIC). *British Medical Journal* 1994;**308**:559-564.

52. Ahlmen M, Sullivan M, Bjelle A. Team versus non-team outpatient care in rheumatoid arthritis. *Arthritis and Rheumatism* 1988;**31**:471-479.

53. Premaratne UN, Sterne JA, Marks GB, Webb JR, Azima H, Burney PG. Clustered randomised trial of an intervention to improve the management of asthma:Greenwich asthma study. *British Medical Journal* 1999;**318**:1251-1255.

54. Jolly K, Bradley F, Sharp S, Smith H, Mant D. Follow up care in general practice of patients with myocardial infarction or angina pectoris:initial results of the SHIP trial. *Family Practice* 1998;**15**:548-555.

55. Mulloy E, Donaghy D, Quigley C, McNicholas WT. A one-year prospective audit of an asthma education programme in an out-patient setting. *Irish Medical Journal* 1996;**89**:226-228.

56. Weinberger M, Kirkman MS, Samsa GP, et al. A nurse-coordinated intervention for primary care patients with non-insulin dependent diabetes mellitus: impact on glycaemic control and health related quality of life. *Journal of General Internal Medicine* 1995;**10**:59-66.

57. McInnes GT, McGhee SM. Delivery of care for hypertension. *Journal of Human Hypertension* 1995;**9**:429-433.

58. Smith D., Chadwick D, Baker G., Davis G, Dewey M. Seizure severity and quality of life. *Epilepsia* 1993;**34**:S35

59. Smith D., Baker G.A., Jacoby A, Chadwick DW. The contribution of the measurement of seizure severity to quality of life research. *Quality of Life Research* 1995;**4** :143-158.

60. Cramer J.A., Smith D.B., Mattson R.H., Escueta A.V., Collins J.F. A method of quantification for the evaluation of anti-epileptic drug therapy. *Neurology* 1983;**33**:26-37.

61. McLaughlan R.S., Rose K.J., Derry P.A., Bonnar C., Blume W.T., Girvin J.P. Health -related quality of life and seizure control in temporal lobe epilepsy. *Annals of Neurology* 1997;**41**:482-489.

62. Wildrick D., Parker-Fisher S., Morales A. Quality of life in children with well controlled epilepsy. *Journal of Neuroscience Nursing* 1996;**28**:192-198.

63. Breier J.I., Fuchs K.L., Brookshire B.L., et al. Quality of life perception in patients with epilepsy or pseudoseizures. *Archives of Neurology* 1998;**55**:660-665.

64. O'Donoghue M.F., Goodridge D.M., Redhead K., Sander J.W., Duncan J.S. Assessing the psychosocial consequences of epilepsy: a community based study. *British Journal of General Practice* 1999;**49**:211-214.

65. Baker G.A., Smith D.F., Dewey M, Jacoby A, Chadwick DW. The initial development of a health-related quality of life model as an outcome measure in epilepsy. *Epilepsy Research* 1993;**16**:65-81.

66. Kugoh T. Quality of life in adult patients with epilepsy. *Epilepsia* 1996;**37**:37-40.

67. Jacoby A. Epilepsy and the quality of everyday life: Findings from a study of people with well controlled epilepsy. *Social Science and Medicine* 1992;**34**:657-666.

68. Meador K.M. Research use of the new quality of life in epilepsy inventory. *Epilepsia* 1993;**34**:S34-S38

69. Beran R.G., Pachlatko C. Report of the international league against epilepsy commision on economic aspects of epilepsy. *Epilepsia* 1996;**37**:506-508.

70. Donker G.A., Foets M., Spreeuwenberg P. Epilepsy patients: health status and medical consumption. *Journal of Neurology* 1997;**244**:365-379.

71. Kriedel T. Cost benefit analysis of epilepsy clinics. *Social Science and Medicine* 1980;**14C**:35-39.

72. Davidson D.L., Swingler R.J., Moulding F. The cost of epilepsy in patients attending an out-patient clinic. *Seizure* 1992;**1**:P12-13.(Abstract)

73. Mak W., Fong J.K., Cheung R.T., Ho S.L. Cost of epilepsy in Hong Kong: experience from a regional hospital. *Seizure* 1999;**8**:456-464.