North of England evidence based development project: guideline for angiotensin converting enzyme inhibitors in primary care management of adults with symptomatic heart failure

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This article provides recommendations—evidence based where possible—to guide general practitioners in their use of angiotensin converting enzyme inhibitors in adults with heart failure. The development group assumes that doctors will use their knowledge and judgment in applying the principles and recommendations given below in managing individual patients, since recommendations may not be appropriate for use in all circumstances. Doctors must take the decision to adopt any particular recommendation in the light of available resources and the circumstances of each patient. The statements accompanied by categories of evidence (cited as Ia, Ib, II, III, IV) and recommendations classified according to their strength (A, B, C, or D) are as described in our previous article (and in the box).[1] All recommendations are for general practitioners and apply to adult patients with heart failure attending general practice. This is a summary of the full guideline.[2]

Strength of recommendation

A—Directly based on category I evidence
B—Directly based on category II evidence or extrapolated recommendation from category I evidence
C—Directly based on category III evidence or extrapolated recommendation from category I or II evidence
D—Directly based on category IV evidence or extrapolated recommendation from category I, II or III evidence

Categories of evidence

Ia—Evidence from meta-analysis of randomised controlled trials
Ib—Evidence from at least one randomised controlled trial
IIa—Evidence from at least one controlled study without randomisation
IIb—Evidence from at least one other type of quasi-experimental study
III—Evidence from descriptive studies, such as comparative studies, correlation studies, and case-control studies
IV—Evidence from expert committee reports or opinions or clinical experience of respected authorities, or both

Summary points

Heart failure is a common condition in general practice and has a poor prognosis

Only 20-30% of these patients are currently prescribed an angiotensin converting enzyme inhibitor

All patients with symptomatic heart failure and evidence of impaired left ventricular function should be treated with an angiotensin converting enzyme inhibitor; so should patients with a recent myocardial infarction and evidence of left ventricular function

Left ventricular function should ideally be assessed by echocardiography or radionuclide measurements

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Symptomatic heart failure

Prevalence and incidence of symptomatic heart failure in adults

Statement: heart failure is a common chronic condition with a very poor prognosis (III)

With a list size of 2000 patients, a general practitioner will see about 20 patients with heart failure each year, 10 of whom will be new cases.[3] Reported prevalence rates range from 0.4% to 2%.[4–7] A general practitioner can expect about four admissions to hospital in patients with heart failure each year.[8] Half these patients will die within four years, and half of patients with severe heart failure will die within one year.[9]

Only 20-30% of patients assessed by their general practitioner as having heart failure are prescribed an angiotensin converting enzyme inhibitor.[4 10] Most patients who are investigated for heart failure have a

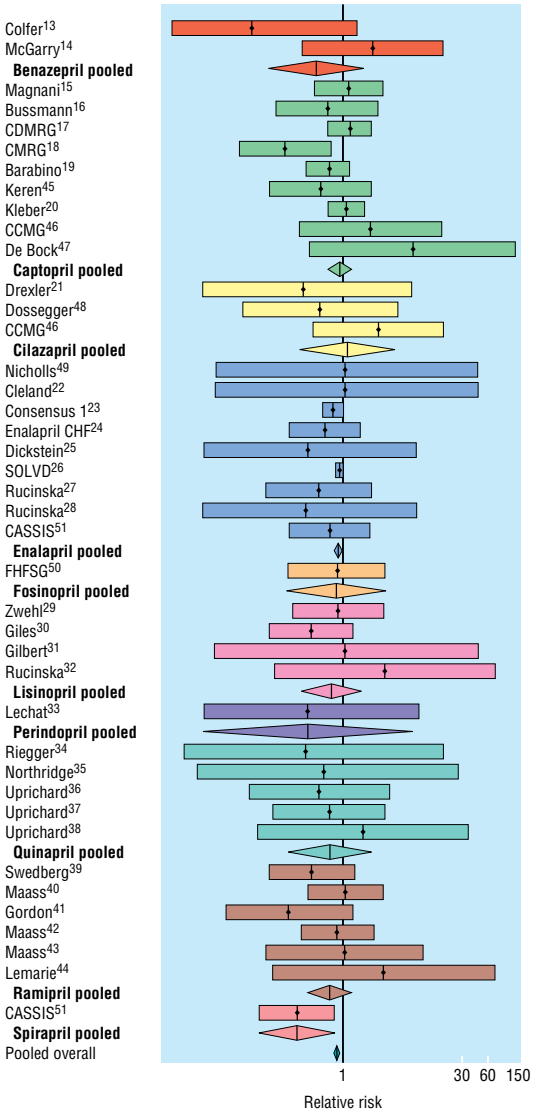

Fig 1 Relative risk (95% confidence interval) of mortality in placebo controlled trials of angiotensin converting enzyme inhibitors grouped in relation to drug. CDMRG=Captopril-Digoxin Multicentre Research Group; CMRG=Captopril Multicentre Research Group; CCMG=Cilazapril-Captopril Multicentre Group; Enalapril CHF=Enalapril Congestive Heart Failure Investigators; SOLVD=Study of Left Ventricular Disease Investigators; CASSIS=Czech and Slovak Spirapril Intervention Study Investigators; FHFSG=Fosinopril Heart Failure Study Group

chest *x* ray and electrocardiogram, but only about a third have echocardiography.[4–7] Diagnosis by clinical assessment has been estimated to be correct in about half of cases when confirmed by echocardiogram.[6–11]

Clinical effectiveness and cost effectiveness

Clinical effectiveness

Statement: angiotensin converting enzyme inhibitors are effective in treating heart failure. They reduce mortality in symptomatic patients who have a reported left ventricular ejection fraction of about 35% or less (Ia)

Garg and Yusuf reported a meta-analysis of 32 randomised trials comparing angiotensin converting enzyme inhibitors and placebo in patients with heart failure.[12] These trials were of at least eight weeks' duration and had total mortality, analysed in relation to intention to treat, as their outcome. Besides these 32 studies,[13–44] we identified a further seven studies (nine comparisons)[45–51] that met the criteria applied by Garg and Yusuf. The pooled relative risk of mortality, using a fixed effects model, was 0.83 (95% confidence interval 0.76 to 0.90) when taking an angiotensin converting enzyme inhibitor, with no evidence of heterogeneity of effect ($Q=34.71$, $df=40$, $P=0.71$) (fig 1).

In the studies of left ventricular function treatment trial, 2569 patients with overt but stabilised heart failure and a left ventricular ejection fraction of 35% or less were randomised to treatment with enalapril or placebo and were followed up for an average of 41 months.[26] The average benefit from angiotensin converting enzyme inhibitors in this trial was 2.44 months of extended life (calculated using Irwin's restricted mean based on original patient data).[52] Because trial data were analysed on an intention to treat basis, this estimate of benefit describes the effect of introducing routine treatment with angiotensin converting enzyme inhibitors for patients with clinical signs of heart failure and an ejection fraction of 35% or less. (Note that ejection fraction data should be regarded as semiquantitative. Low ejection fractions should be considered as a marker of important left ventricular dysfunction.)

Severity of heart failure

Statement: the beneficial effects of angiotensin converting enzyme inhibitors are shown for patients with a reported left ventricular ejection fraction of 35% or less (Ib): the greater the impairment, the greater the benefit (Ib)

The studies of left ventricular function treatment[26] and prevention[53] trials both show that the size of benefit is correlated with the ejection fraction: the lower the ejection fraction the greater the benefit. Stratified meta-analyses of placebo controlled trials support these conclusions. If studies are divided into two groups—one (the low risk group) with a normalised annual mortality of up to 15% over the intervention and control groups[13 15 17 19 20 22 25 26 28 29 31–38 41–47 49 50] and one (the high risk group) with a rate of more than 15%[14 16 18 21 23 24 27 30 39 40 51]—the relative risk of mortality in the low risk group is 0.88 (95% confidence interval 0.80 to 0.97) while that in the high risk group is 0.64 (0.51 to 0.81) (fig 2).

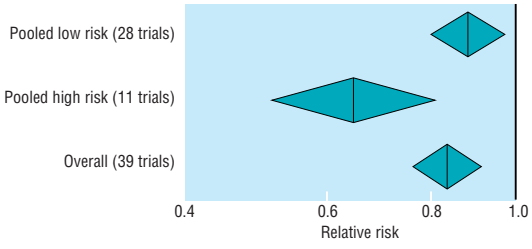

Fig 2 Relative risk of mortality from all causes in trials of angiotensin converting enzyme inhibitors compared with placebo in relation to underlying low and high mortality risk of trial subjects

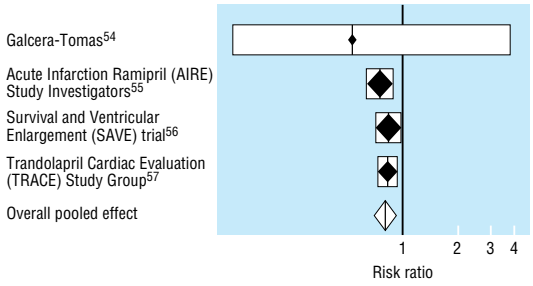

Fig 3 Risk ratio of survival after myocardial infarction in patients with evidence of left ventricular dysfunction

Heart failure and previous myocardial infarction

Statement: long term treatment trials in patients who have had myocardial infarction and have left ventricular dysfunction show that angiotensin converting enzyme inhibitors provide an important benefit (Ia)

Four trials, in which more than 6000 patients were randomised to treatment, examined the use of angiotensin converting enzyme inhibitors after myocardial infarction in patients with left ventricular dysfunction.[54–57] Planned follow up was up to 50 months. Meta-analysis of these trials, using a fixed effects model, suggests that angiotensin converting enzyme inhibition after myocardial infarction is beneficial (risk ratio 0.80; 0.74 to 0.88), with no evidence of variation between the estimates of effect provided by different trials ($Q = 1.01$; $df = 3$; $P = 0.80$) (fig 3). These findings are reinforced by the positive results from the studies of left ventricular function treatment (SOLVD) trial, in which 65% of the patients included had had a myocardial infarction.[26]

Quality of life

Statement: there is an improvement in symptoms and exercise tolerance when patients with symptomatic heart failure and a reported left ventricular ejection fraction of 35% or less are given an angiotensin converting enzyme inhibitor (Ia)

Statement: the value of the improvements in terms of general wellbeing of the patient is uncertain (Ia)

Narang et al reviewed 35 double blind placebo controlled trials in which the effects of angiotensin converting enzyme inhibitors and placebo were compared.[58] Altogether 3411 symptomatic patients were included. The ability to exercise for longer increased in 23 of 35 (66%) studies, while patients' symptoms improved in 25 of 33 (76%) studies. All nine trials with a study size more than 50, follow up of three to six months, and in which a treadmill exercise test was used showed improved exercise capacity and symptoms.

The single largest and most general assessment of patients' quality of life comes from a subsidiary analysis of the studies of left ventricular function treatment[26] and prevention[53] trials. In an analysis of patients enrolled in these treatment and prevention trials, Rogers found statistically significant improvements in self assessed dyspnoea and social functioning in those patients treated with angiotensin converting enzyme inhibitors, although these improvements did not persist for the full two years of follow up.[59] Another analysis of studies of left ventricular function data, using the observed frequency of dyspnoea, showed that a reduction in symptoms was achieved and maintained beyond two years in those treated with enalapril compared with those treated with placebo.[60]

Cost effectiveness

Statement: angiotensin converting enzyme inhibitors seem to be cost effective (III)

Trials consistently show a reduction in admissions to hospital for progressive heart disease in patients taking angiotensin converting enzyme inhibitors. It is unclear whether these are lasting reductions or simply reflect a "window in time" effect. More patients receiving angiotensin converting enzyme inhibitors completed the trial follow up period without their heart disease progressing, but all patients deteriorated in following years. The data do not suggest that more admissions to hospital for other reasons offset reduced admissions to hospital for heart failure; angiotensin converting enzyme inhibitors seem to reduce admission to hospital for other causes in patients with symptoms of heart failure. We cannot assume that rates of admission to hospital during trials will be matched in clinical practice. However, the admission rate in the control arm of the studies of left ventricular function treatment trial matches precisely the rate found in general practice in England.[3] On average, each general practitioner could expect to have four patients with heart failure admitted to hospital each year, and the

Recommendations: clinical and cost effectiveness

- All patients with symptomatic heart failure and evidence of impaired left ventricular function should be treated with an angiotensin converting enzyme inhibitor (A)
- Patients with recent myocardial infarction and evidence of left ventricular dysfunction should be treated with an angiotensin converting enzyme inhibitor (A)
- Treatment of heart failure with angiotensin converting enzyme inhibitors is cost effective (C)

Net cost and benefit per patient of treatment with angiotensin converting enzyme (ACE) inhibitors for heart failure

Assumptions about costs/benefits arising from addition of ACE inhibitors to current care*	Cost-benefit estimate	
	Optimistic	Conservative
ACE inhibitor £100/year or £340/year for 4 years	£400	£1400
Two GP visits or 2 outpatient visits needed to start treatment†	£20	£138
Reduced or no hospital admission ‡	–£471	£0
GP visits related to heart failure unchanged or 1 extra visit/year for 4 years§	£0	£48
Net cost range	–£206	£1578
Increased life expectancy (based on comparisons with placebo)[26]	0.203 years	0.203 years
Incremental cost effectiveness of ACE inhibitor ¶	Small cost saving and health gain	£7770/life year gained

*Diagnosis costs excluded because of variation in tests performed or lack of adequate cost data and because costs may occur in any case as part of normal care.
†Cost per GP consultation data[65] and outpatient visit data[66]; no adequate data for costing additional blood tests.
‡Based on difference in studies on left ventricular disease (SOLVD) trial hospital admission in treatment and control groups,[26] an inpatient stay of 14.5 days,[5] and a cost of £125/inpatient day.[67]
§Patients visit their GP once a year in relation to heart failure; we assume a reduction in visits is implausible, but treatment delays disease progression.
¶ Survival gains were truncated in the SOLVD trial (4 years)[26]

studies of left ventricular function trial data show that angiotensin converting enzyme inhibitors might prevent (or delay) one of these hospital admissions. The annual cost of purchasing angiotensin converting enzyme inhibitors (at maintenance doses) ranges from £100 to £340 a year in relation to dosages reported in the *British National Formulary*.[61] However, whether these maintenance doses are always therapeutically equivalent to the doses in the trial is unclear.

The incremental cost for each patient taking angiotensin converting enzyme inhibitors in primary care may vary from a small cost saving to a net cost of nearly £1600 over four years (table). In terms of cost effectiveness, these drugs, when used to treat heart failure, probably fall in the approximate range £0-£10 000 per life year gained, given the range of assumptions listed and remaining uncertainties. The important variables are the cost of the angiotensin converting enzyme inhibitor and savings on the costs of a hospital inpatient stay. Exploring the influence of compliance with treatment on the estimates of cost effectiveness presented is not possible in this simple model. The trial data, analysed on an intention to treat basis, reflect compliance achieved in the studies of left ventricular function treatment trial. The degree to which these findings are generalisable to general practice in the United Kingdom is uncertain. Where non-compliance means stopping treatment, both costs and benefits are forgone and the cost effectiveness ratios are not altered appreciably. Substantial cross over to treatment with angiotensin converting enzyme inhibitors in the placebo group in the studies of left ventricular function trial may mean that the attributable benefits are underestimated.

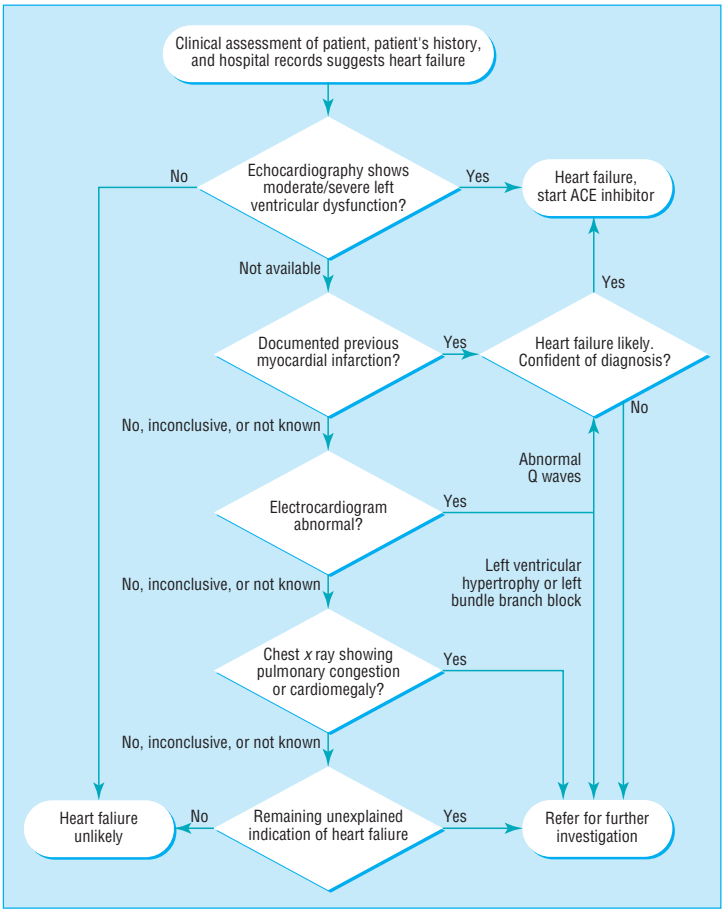

Fig 4 Algorithm for diagnosing suspected heart failure in primary care

Recommendations: diagnosis

- Left ventricular function should be evaluated in all patients with suspected heart failure who are being considered for treatment with angiotensin converting enzyme inhibitors in health districts with the facilities to perform echocardiography or radionuclide measurements (A)
- Where no facilities for measuring left ventricular function exist, all patients being considered for treatment with angiotensin converting enzyme inhibitors should be managed in line with the flow chart in fig 4 (D)

Diagnosis of heart failure

Statement: patients with heart failure who will benefit from treatment with angiotensin converting enzyme inhibitors are best identified by echocardiography (Ia)

Statement: there is some evidence that heart failure is misdiagnosed in general practice (III)

Statement: if echocardiography or radionuclide measurement is not available, patients with heart failure who are likely to benefit from treatment with angiotensin converting enzyme inhibitors have to be identified clinically (IV)

The best way of identifying patients with impaired left ventricular function is with echocardiography or radionuclide measurement. If these investigations are not available, the combination of a patient's past medical history, response to diuretics, chest *x* ray, and electrocardiogram can be used to identify the likelihood of heart failure, as set out in the flow chart in figure 4. The sensitivity and specificity of this flow chart are not known.[62]

Initiating and managing treatment

The range of angiotensin converting enzyme inhibitors that can be prescribed for treating heart failure and their dosages, cautions, contraindications, and side effects are described in section 2.5.5 of the *British National Formulary*.[61] All recommendations for treatment apply only in the absence of recognised cautions, contraindications, side effects, or interactions, as documented in the formulary.

Choice of drug

Statement: no clinically important differences between the effectiveness of the various angiotensin converting enzyme inhibitors have been reported, although most evidence is derived from randomised trials of enalapril (Ia)

From 39 trials (41 comparisons) there was no evidence of heterogeneity across studies, suggesting that the

Recommendation: choice of drug

- As there is no good evidence of clinically important differences in the effectiveness of available angiotensin converting enzyme inhibitors, patients should be treated with the cheapest drug that they can effectively use (B)

Recommendations: starting treatment

- All patients being considered for treatment with converting enzyme inhibition should have plasma/serum creatinine and electrolytes measured (D) and blood pressure measured (D)
- Patients should be considered for referral to hospital for assessment and supervised initiation of treatment if:
  - Plasma/serum sodium concentration is <135 mmol/l (D)
  - Plasma/serum creatinine concentration is >150 µmol/l (D)
  - Systolic blood pressure is below 100 mm Hg (D)
  - They require >80mg frusemide/day or equivalent (D)
  - They show symptoms of severe heart failure (D)
- Angiotensin converting enzyme inhibitors should be used with increasing caution as the patient's age increases (D)
- Angiotensin converting enzyme inhibitors should be used with caution in patients with severe peripheral vascular disease because of the possible association with atherosclerotic renal artery stenosis (D)
- Treatment with these drugs should be monitored (A)
- Drug dosages should be titrated upward over two to three weeks, aiming to reach the doses used in large scale clinical trials (A)

underlying drug effect was consistent across all contributing studies. Trials of enalapril provide greatest confidence in treatment effect for that drug.

Starting treatment

This section of the guideline is derived from the corresponding section in the Agency for Health Care Policy and Research guideline for the management of heart failure.[63]

Diuretic treatment and hyperkalaemia

When treatment is initiated, diuretic drugs should be withheld for a brief period (at least 24 hours) to allow any volume depletion to resolve. Hyperkalaemia (plasma/serum potassium concentration >5.5 mmol/l) is a potential problem when angiotensin converting enzyme inhibitors are used. Potassium sparing diuretic drugs (for example, spironolactone, amiloride, triamterene) should be stopped in all patients who are being started on angiotensin converting enzyme inhibitors, regardless of the serum potassium concentration. These drugs may be restarted if the patient remains hypokalaemic on full therapeutic doses of angiotensin converting enzyme inhibitors. In addition, potassium supplements should usually be withheld unless the patient has a low serum potassium concentration (<4.0 mmol/l). If potassium supplements are continued, serum potassium concentrations must be monitored every few days until they are stable because of the risk of renal failure.

Patients at risk of "first dose hypotension"

Patients who are at high risk of hypotension after the first dose of angiotensin converting enzyme inhibitors (severe left ventricular systolic dysfunction, initial systolic blood pressure <100 mm Hg, or serum sodium <135 mmol/l) should be considered for referral to hospital for assessment and supervised initiation of treatment. If this is not possible they should be given a small dose of a short acting agent and monitored closely for two hours.[64] The risk of hypotension increases with age.[65] If the test dose is tolerated, they should be started on a small dose of an inhibiting drug such as enalapril (2.5 mg twice daily) or captopril (12.5 mg three times daily). Patients who are not at high risk of hypotension after the first dose should be started on a small dosage of a drug such as enalapril (2.5 mg twice daily) or captopril (12.5 mg three times daily).

Monitoring treatment

Patients receiving angiotensin converting enzyme inhibitors should be monitored regularly. Before initiation of angiotensin converting enzyme inhibition they should have their blood pressure, renal function, and serum potassium measured. These measurements should be repeated one week after initiation of treatment and again one week after each significant increase in dosage. The guideline development group could find no basis for recommending one monitoring interval over another in long term treatment, and felt that monitoring at least once a year was appropriate. Treatment should be modified if the patient develops: *(a)* an increase in the serum creatinine concentration of 50 µmol/1 or more; *(b)* a serum potassium concentration of 5.5 mmol/l or more; or *(c)* symptomatic hypotension (a documented fall in blood pressure with dizziness or weakness).

Patients who develop renal insufficiency or hypotension should have their volume status reassessed. In patients who become hypovolaemic because of diuresis, the dose of any diuretic should be reduced and the angiotensin converting enzyme inhibitor drug may be tried again. These patients, though, should be considered for referral to a cardiologist, and all those who fail a second trial or who develop hyperkalaemia should not be retried on angiotensin converting enzyme inhibitors but referred to a specialist.

Side effects

Side effects of angiotensin converting enzyme inhibitor drugs and contraindications are covered in the *British National Formulary*.[61] Cough is common in patients taking these drugs, but it is also common in people with heart failure. Thus, patients who report cough while taking angiotensin converting enzyme inhibitors should be evaluated to see whether this results from pulmonary congestion before stopping treatment is considered.

Recommendations: monitoring, compliance, and education

- Doctors should ask regularly about any side effects of angiotensin converting enzyme inhibitors (D)
- Compliance with treatment is important and should be checked regularly, especially if symptom control is poor or drug dosage is about to be increased (D)
- Patients should be offered education about their treatment (D)

Compliance

Statement: compliance with treatment is important (IV). We identified no evidence on how compliance with treatment affects outcomes, but the guideline development group felt that the recommendation below reflected good clinical practice.

Patient education

Statement: education about his treatment is an important part of the management of any patient (IV)

Referral to a cardiologist

No evidence on referral to a cardiologist was identified by the group. The recommendations below are considered to reflect good clinical practice.

Recommendations: referral to a cardiologist

- Referral to a cardiologist is appropriate for:
  Patients in whom diagnostic doubt exists (D)
  Patients whose treatment should be initiated in hospital (see "Initiating and managing treatment") (D)
  Patients who present a problem in management (D)
- Patients' preferences should be taken into account in referral decisions (D)

Future research

In developing this guideline the group identified important issues that are not currently informed by research of a high quality. These include:
(1) Uniform requirements and standards of practice for identifying left ventricular dysfunction—for example, reporting echocardiography;
(2) Impact of access policies on assessing left ventricular dysfunction in primary care;
(3) Optimum strategy for initiating and monitoring treatment with angiotensin converting enzyme inhibitors in primary care;
(4) Good qualitative information on the impact of angiotensin converting enzyme inhibitors on quality of life in patients with heart failure;
(5) Influence of patient compliance on the effect of treatment with angiotensin converting enzyme inhibitors;
(6) Influence of patient education on the effect of treatment with angiotensin converting enzyme inhibitors;
(7) Carefully designed trials of the effect of starting treatment with angiotensin converting enzyme inhibitors in patients with or without left ventricular dysfunction immediately after myocardial infarction.

The project steering group comprises: Professor Michael Drummond, Centre for Health Economics, University of York; Professor Andrew Haines, Department of Primary Care and Population Sciences, University College London Medical School and Royal Free Hospital School of Medicine; Professor Ian Russell, Department of Health Sciences and Clinical Evaluation, University of York; Professor Tom Walley, Department of Pharmacology and Therapeutics, University of Liverpool.

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Conflict of interest: None.

Appendix

The guideline development group comprises the following members, in addition to the authors: Mr Joe Asghar, pharmaceutical adviser, Northumberland Health Authority; Mr Mark Campbell, prescribing unit manager, Regional Drug and Therapeutics Centre, University of Newcastle upon Tyne; Dr John Cleland, British Heart Foundation senior fellow, University of Glasgow; Dr John Harley, general practitioner, Stockton-on-Tees; Dr Barbara Holding, general practitioner, Seghill; Dr David Napier, general practitioner, Seaham; Dr Basil Penney, general practitioner, Darlington; Dr Wendy Ross, general practitioner, Newcastle upon Tyne; Dr Malcolm Thomas, general practitioner, Guidepost, Northumberland; Dr Barnaby Thwaites, consultant cardiologist, Ashington.

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Fifty years ago

The new NHS: Propaganda

The Government, continuing to ignore the overwhelming opposition to the National Health Service Act on the part of those who will work under it, are proceeding to waste the country's money in an attempt to secure co-operation by compulsion. By the use of films, posters and pamphlets they are preparing a huge publicity campaign to induce the public to bring pressure upon the medical profession. The trade unions, the Government's masters, are aiding and abetting this campaign. Some, at least, are using the strength of the organised workers as a means of influencing the decision of men and women who prefer to organize themselves on a voluntary basis.

(*Editorial*, 27 March 1948, p 605. See also editorial by Gordon Macpherson, 3 January 1998, p 6.)

Coping with loss

The dying child

Dora Black

This is the eighth in a series of 10 articles dealing with the different types of loss that doctors will meet in their practice

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The terminal phase of a life threatening illness may be defined as one where curative treatments are not applicable but palliation is given. There is evidence that children, even young ones, are usually aware that they are dying. They may pick up these cues from parents and hospital staff, who in one study gave significantly less time and attention to children who were terminally ill than to others.[1] They may not let anyone know that they know. Child and parents may maintain a "mutual pretence,"[2] and yet families who have an open communication fare better psychologically. The refusal of parents and medical carers to talk about issues of death and dying with children who have life threatening diseases impedes coping for the whole family.[3]

Parents appreciate staff openness and many years later remember vividly the method of imparting the bad news. Accurate information, delivered with skill and sympathy and updated regularly, lessens the parents' sense of helplessness and isolation and sets up a therapeutic alliance.[4]

Treatment setting

Children can be treated in a hospital ward, a hospice for children, or at home. Parents are more anxious, depressed, and defensive after death in hospital than at home, and when children die at home the long term outcome is better for the parents,[5] although the reactions of siblings have not been similarly studied.

Although children's hospices have been in existence for only a short time, they do have a specific role and can be helpful in providing respite care. When dying at home is not an option because of the complex medical and nursing needs of the child, or because of factors such as the needs of siblings or others, they can provide terminal care.[6]

More specialist units are developing home care teams so that children can receive much of their terminal care at home. Results of preliminary studies of such care are encouraging.[7 8]

ADRIANA DORSETT

Parents do not always admit the need for emotional support from within the family

Summary points

- Children with life threatening illness often know that they are dying but seldom have the opportunity to talk about it
- Children are usually less upset when they are cared for at home than in hospital and their long term outcome is better; children's hospices can provide specialist and respite care if it is needed
- Both parents and siblings are at risk for psychological disturbance when a child is dying; surviving children may need information, explanation and support
- When death occurs siblings and parents may be encouraged to view the body and attend the funeral
- Professionals benefit from training in communicating with parents and children faced with the death of a child

Effects on siblings

Siblings' understanding of illness seems to be related to age. Delays in understanding concepts, compared with healthy children, may be caused by avoidance of discussion of illness in families with sick children.[9]

Siblings of dying children have about double the risk of developing psychological disturbance; this seems to be related to demographic characteristics of the family, level of family functioning, and characteristics of the disease. Knowledge of illness is different in siblings of ill children than in siblings of healthy controls. Nevertheless, most siblings of sick children seem to be well adjusted and do not have a psychiatric disorder. Most studies have been cross sectional and have not looked at long term effects. Clinical experience leads one to try to offer preventive intervention counselling for all siblings of dying children.

Effects on parents

Mothers, more than fathers, are involved in nursing and caring for dying children and have therefore been more extensively studied. Several studies have found that mothers have an excess of depression.[10 11]

Mothers have reported a greater degree of difficulty with the problems of helplessness, loss of confidence in the ability to be a good parent, financial difficulties, being avoided by others, growing apart from their spouse, and fear of being unable to cope if the child should die than have fathers, who reported significantly greater difficulty with two problems—

feeling left out of the ill child's life and being worried that their spouse was too preoccupied with the dead child.[12] In a systematic eight year follow up study Lundin found more evidence of persisting tearfulness and grieving among parents who had lost a child than among widows and widowers, but the widows and widowers were more likely to continue to think about their dead partner and to express feelings of guilt.[13]

Attempts to keep secret from both patients and their siblings the fact that a child has a terminal illness often fail—and create more problems for the family

Parents may feel that they can never recover fully from the loss of a child. They may adjust to it, they may be able to resume their everyday activities, and they may even derive pleasure from life, but they feel they remain vulnerable.[14] For some parents, the new identity is a stronger one—they feel they have been "through the fire" and that nothing can affect them so profoundly again. The cost may be a reduction in their sensitivity to their other children or their partner, which may threaten the marriage or even disrupt it.

Effects on marriage, family, and coping

Marriages are stressed by the demands of treatment for serious illness and by the death of a child. Often the treating specialist hospital is at a distance and parents are separated as one accompanies the child and the other tries to keep the rest of the family going and earn a living. It is surprising therefore that most studies have not found an increase in divorce or separation, although marital distress is increased and this becomes worse as the disease worsens.[15] It seems that the stress of a serious and prolonged illness in a child is likely to make a poor marriage worse, but it may strengthen the relationship in an already close marriage, thus balancing the statistics.

A study of long term adjustment in families of children with cancer compared 38 families of a child who survived five years after treatment had ended with 13 families whose child had died. Five years after the death, the families of children who died scored at less adaptive levels of functioning on items measuring return to normal activities, zest for living, making plans for the future, recognising and accepting the family members' needs, admitting the need for emotional support from friends or family, and having placed the cancer in a less overwhelming perspective.[16]

Another study looked at the coping strategies of parents of children with cancer and found that they were not related to income or gender.[17] Parents who had a good relationship with the medical staff tended to use coping strategies such as denial, acceptance, or reliance on religion. The more highly educated parents tended to use information seeking as a coping strategy rather than the other strategies.

Death of a fetus or neonate

Miscarriages, induced termination of pregnancy, and stillbirths all provoke a grief reaction. It is likely that the degree of grief is directly related to the length of gestation and to whether it was a wanted child.[18] Ultrasound imaging of the fetus has resulted in earlier recognition of its humanity and may have increased the likelihood of a more severe grief reaction. Viewing the stillborn baby aids the resolution of grief, as does a proper burial or cremation ceremony. Most women who spontaneously miscarry or have a stillbirth or neonatal death feel that they are failing in their reproductive function, and would benefit from counselling.

Useful addresses

Stillbirth And Neonatal Death Society (SANDS), 28 Portland Place, London W1N 4DE (tel 0171 436 7940)

The Compassionate Friends, 53 North St, Bristol BS3 1EN (tel 01179 539 639)

Foundation for the Study of Infant Deaths (FSIDS), 14 Halkin St, London SW1X 7DP (tel 0171 235 0965)

Cruse-Bereavement Care, 126 Sheen Rd, Richmond, Surrey TW9 1UR (tel 0181 940 4818)

When a child dies in the womb, parents and siblings need information and support. Grief is a natural reaction

Many deaths in the first four weeks of life are related to congenital abnormalities in the infant, and parents need much support and informed advice, including genetic counselling, before they embark on further pregnancies.[19 20] The sudden infant death syndrome is the commonest cause of infant death between 4 and 52 weeks of age and causes high distress because of its suddenness, unexpectedness, and uncertain aetiology.[21]

One controlled study has shown that brief counselling can significantly reduce morbidity in parents after a perinatal death.[23] White and colleagues provide a useful source of advice.[24] The Stillbirth and Neonatal Death Society, The Compassionate Friends, and the Foundation for the Study of Infant Death offer volunteer counselling in many parts of Britain, as does Cruse Bereavement Care.

Helping the family of a dying child

The primary health care team may feel sidelined when a child has a terminal illness. These deaths are so rare, and the treatment of the life threatening illness that may have preceded the terminal phase may have been in the hands of specialists in a distant hospital, who may have maintained only formal and minimal contact with the general practitioner. One study found that family doctors rarely inquire about family functioning when a child is ill.[22] Caring for a dying child at home will inevitably involve family doctors more, and parents appreciate the interest expressed by their practitioner, even if he or she cannot cure their child.

The health visitor or practice nurse, or the general practitioners themselves, might find the time to pay a regular visit to the family or invite them to the surgery to review the functioning of each member of the family; attend to communication within the family, especially to the children; and check that all the social

Communicating religious beliefs about death of a sibling

When there is a belief in an afterlife, it is important that children understand that it is not the dead body that goes to heaven but that the parents believe that the dead child's soul is in heaven. Souls can only exist in a live person; when the body of that person dies, the soul flies off to heaven to live with God. Since the child's soul hasn't got a body to live in, she cannot return to earth.

benefits to which the family are entitled are being claimed. As death draws near, there needs to be an increase in the emotional care of the family, ensuring that the children have been informed of what is likely to happen and that there is a mobilisation of family and neighbourhood support. A review of the effects of bereavement on the different members of the family is helpful in calming the bereaved person's fears that his experiences betoken insanity. Siblings will usually benefit from being included in the funeral and viewing rituals, but they need proper preparation and explanation beforehand. They need to understand the permanence of death. Counsellors must respect the religious beliefs of the family and be prepared to discuss with parents how they can communicate with their surviving children (box).

Support for the family is needed whenever a child dies, and members of the primary care team are usually best placed to provide it

When a death during pregnancy occurs, parents in their distress may omit to let the siblings know what has happened. The children may have been told that mummy is having a baby—and then no baby appears. The family practitioner could check that the children know what has happened and why and that they know that it was not their fault.

The articles in this series are adapted from *Coping with Loss*, edited by Colin Murray Parkes, which will be published in July.

Drawing by 10 year old boy with a brain tumour. He described it as depicting him lying in bed and seeing himself suspended from the ceiling with the nurse manipulating him with the noose tied in a rope. His therapist worked with him on the feelings of helplessness engendered by his illness and the treatments for it. Note the accurate perception of the hospital bed

Continuing education for the primary care team

Although many general practitioners and their teams are comfortable in talking to adults about their impending death, they may feel less comfortable in talking with children. They may need more training in understanding the psychosocial aspects of children and death and the techniques of bereavement counselling. Some medical schools are tackling this problem with courses on communicating with children and on bereavement counselling,[25–29] and many training courses for general practitioners have at least one lecture on the subject. Cruse and other organisations run courses on bereavement counselling.

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Health needs assessment

Epidemiological issues in health needs assessment

Rhys Williams, John Wright

This is the second in a series of six articles describing approaches to and topics for health needs assessment, and how the results can be used effectively

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Summary points

Epidemiological methods can be used to describe health needs in terms of the distribution of specific diseases

Although incidence and prevalence do not necessarily equate with need, they are both important in describing the population burden of disease

Specific epidemiological studies can be expensive and time consuming. Existing information from previous studies can be used to inform local needs if criteria for generalisability are met

Routine sources of health information can suffer from inaccuracy and inappropriateness, but they can provide valuable descriptions of health and healthcare use in a defined population

The first article in this series explained the importance of health needs assessment in the context of planning and delivering health care to populations.[1] It mentioned the "epidemiological approach" to health needs assessment—the traditional public health approach of describing need in relation to specific health problems using estimates of the incidence, prevalence, and other surrogates of health impact derived from studies carried out locally or elsewhere. This approach has been extended to the consideration, alongside these measures, of the ways in which existing services are delivered and the effectiveness and cost effectiveness of interventions intended to meet the needs thus described (fig 1).[2] This is a logical extension as there is little point in estimating the burden of ill health (except for determining priorities for future research) if nothing can be done to reduce it.

Epidemiology has been defined as "the study of the distribution and determinants of health-related states or events in specific populations and the application of this study to control of health problems."[3] It tends, for the most part, to use the "medical model" of health need, viewing need in terms of the occurrence of specific diseases and health related states rather than client groups. Descriptive epidemiology (as opposed to analytical epidemiology—the investigation of the determinants of health related states or events) describes the occurrence of disease in terms of person, place, and time:

- Person—who the affected people are (in terms of their age, sex, occupation, socioeconomic group, etc);
- Place—where they are when they get diseases and in what way prevalence and incidence vary geographically (locally, regionally, nationally, or internationally);
- Time—when people get diseases, whether this varies by, for example, season; and how disease occurrence is changing over time.

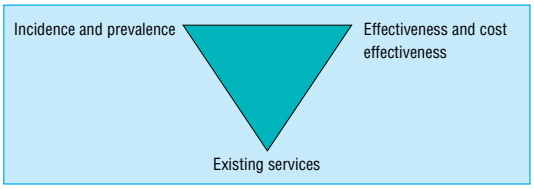


Fig 1 Components of health needs assessment. Modified from Stevens and Raftery[2]

Case definition

The usual starting point for any epidemiologically based needs assessment is the question, what is a case?

JANE SMITH

Epidemiologists place great importance on case definition; yet, for a thorough health needs assessment, simple case definitions usually need to be expanded to include valid measures of severity.

Patients who are cases may possess relatively clear characteristics which separate them from those who are not cases. Examples are patients with the florid symptoms or signs of hypertension, asthma, or diabetes. However, in most conditions, including these three, individuals are encountered who are close to the borderline between normality and abnormality (fig 2). For these, internationally agreed criteria are required and are available.[4–6]

Such criteria may seem arbitrary but are, or at least should be, based on the probability of the future occurrence of specified outcomes known to be associated with the relevant condition. They may be based on physical signs or symptoms, or on physiological or biochemical characteristics which need to be measured by appropriate and standardised tests—for example, valid and repeatable questionnaires or physiological or biochemical tests. The criteria may change from time to time as further knowledge accrues but should not vary from place to place if estimates of incidence and prevalence are to be at all generalisable.

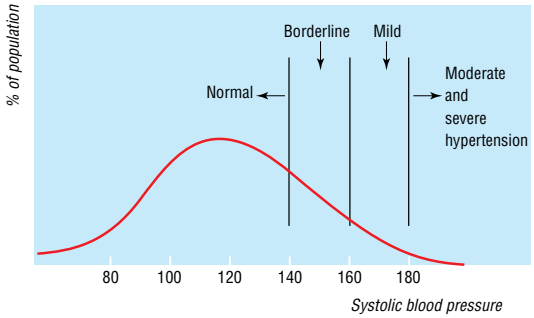


Fig 2 Classification of hypertension by systolic blood pressure shows the continuum from normal to abnormal

Incidence and prevalence

Incidence and prevalence are measures fundamental to the science of epidemiology. Both of these require the estimation of the numerator—the number of new cases observed (in the case of incidence) or the number of cases present in a population (in the case of prevalence)—and the estimation of the denominator (the number of people in the population at risk). Incidence is a rate (it has a time dimension) and prevalence is a proportion that is measured at a point in time but does not have a time dimension.

Neither prevalence nor incidence necessarily equates with need, but knowledge of incidence and prevalence is usually an essential starting point for the assessment of need. Prevalence increases if incidence (or the rate of relapse) increases. It also increases if the mortality (or remission) decreases. The relation between these variables is best summarised as the "prevalence pool" concept (fig 3). Only a part of this prevalence pool may be visible at any one time if any proportion of the existing cases of a disease remains unrecognised. Unrecognised cases may be those at an early stage of development or may be the least severe.

In health needs assessment it may be important to estimate both incidence and prevalence. Incidence is particularly important for diseases or conditions that are of short duration (such as many communicable diseases) or for those for which a substantial amount of the healthcare input occurs shortly after diagnosis (myocardial infarction, for example). Prevalence is particularly important when the duration of disease is long—for example, asthma, diabetes, or multiple sclerosis. Several types of incidence and prevalence may be used in needs assessment:

- Stratum specific estimates: for example, age specific—for those in a given age group;

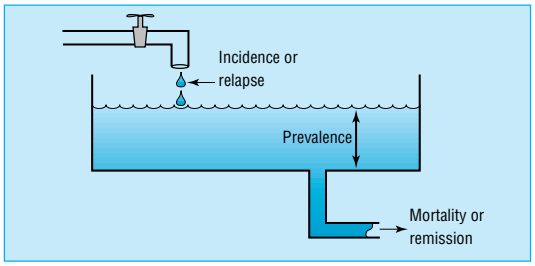


Fig 3 Prevalence pool

- Crude estimates: crudely calculated by summing the numerators over all strata (for example, all ages) and dividing by the denominator of the total population;
- Standardised estimates: taking into account that the populations being compared may differ in terms of age or another important attribute.

Standardised estimates may be derived by the direct or indirect method. In the direct method, the stratum specific estimates are taken from the population being standardised (this might be a town or locality) and applied to the stratum specific population figures of the standard population (that of the country, for example). The incidence or prevalence that would pertain in that population if those of the town or locality were applied to it can thus be calculated. In the indirect method, the process is reversed. The direct method is more usual and, in most cases, preferable. Using the indirect method is justified when the data items required for the direct method are not available and when small numbers in the stratum specific estimates in the population being standardised make them statistically unstable. The standardised mortality ratio is a ratio derived from the technique of indirect standardisation.

Generalisability

The NHS Management Executive set up the district health authority project in 1990 to support health authorities in their responsibility for assessing needs. This led to a series of reviews of healthcare needs assessment.[2] The aim of these reviews was to give practical guidance to purchasers on moving from a service led healthcare system to a needs led healthcare system. They provided an "off the shelf" guide to population needs for important health topics such as asthma and stroke.

Such general information, however, is often disregarded on the grounds that "it's not like that here." Standard epidemiological tools and guidance are extremely important. However, existing techniques are often crude, particularly when measuring morbidity. In the absence of dedicated research, evidence of morbidity is often derived from mortality data, and when research is available, extrapolation to different populations can disguise underlying variations.[7] Clearly, populations will differ in age, sex, socioeconomic and ethnic mix, and other attributes, or there may be other legitimate reasons for thinking that work carried out elsewhere is not applicable (use of an incorrect case definition, for example). Issues of generalisability can usually be divided into four broad areas:

- Case definitions—are they acceptable?
- The time since the study was carried out—is the information still timely?
- Is the study sound in other respects—methods of ascertainment (numerators) and demographic information (denominators)?
- Have the data been presented (or are they available) for the relevant strata of known confounders? (The term "confounders" is used here to encompass attributes which influence incidence or prevalence such as age, sex, and socioeconomic or ethnic group.)

Undertaking an epidemiological survey

Routine sources can provide only limited descriptions of disease; for more details, special surveys may be required. There are two main types of descriptive survey: prevalence (cross sectional) surveys and longitudinal surveys. These principles apply to all surveys, whether they are to describe disease or to provide patients' perspectives.

- Surveys cost time and money. It is important to ensure that the information wanted is not available from routine sources
- There should be a clear aim for the survey. What disease, or risk factor, is being measured? What is the case definition? What is the population of interest?
- Good planning is needed. Staff and resources will be needed to carry out the survey and produce a report
- Sample size for the survey must be calculated. This is usually a balance between the need for precision (more precise estimates of incidence and prevalence require larger samples) and the resources and time available
- Recruitment of the sample must be considered. A sampling frame must be chosen and from this the sample selected randomly, systematically, or purposefully
- The survey instrument (a symptom questionnaire, quality of life measure, physiological measurement, or laboratory test) should be valid, reliable, and repeatable
- Steps should be taken to ensure a high response rate. Questionnaires should be piloted

Diabetes is an example of a condition for which knowledge of incidence and prevalence in relation to confounders is essential if any valid estimate of need is to be made. In general practices that are known to have identified their diabetic patients comprehensively, the prevalence of diabetes shows a close and totally expected relation with the proportion of the practice list aged 65 years and over.[8] Thus, practices that are unsure of the completeness of their diabetes register can get some indication of how close they are to complete ascertainment by comparing their observed prevalence with that expected on the basis of this relation with age. However, this holds only if the practice population has a similar composition, in terms of ethnic origin, to the practices on which the initial observations have been made. Since it is known that the prevalence of diabetes varies between ethnic groups and, equally important, that the relation between prevalence and age is different in different ethnic groups, the ethnic composition of the practice needs to be taken into account.

Although no convincing relation has been found between prevalence of diabetes and socioeconomic group, relations have been found between outcomes of diabetes and socioeconomic status: worse outcomes in the more disadvantaged groups are worse. For this reason, any estimate of need ("the ability to benefit from care"[2]) for diabetes services must take socioeconomic status into account.

If the four aspects described above are satisfied then there is no reason why information from other localities cannot be applied to the local situation. To do so, with all reasonable care, can save precious resources which might otherwise be squandered in carrying out yet another health needs assessment on a given health problem merely because of a misplaced enthusiasm for locally derived data.

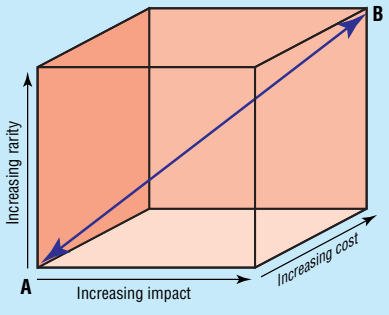
Small populations

"Locality based health needs assessment"—needs assessment dealing with populations smaller than district health authorities or their equivalents—has the advantage of allowing knowledge of the local scene to be used in planning local services. The use of local data, to the exclusion of data available from elsewhere, needs to be carefully considered. Apart from the cost implications of repeating locally what may have been done perfectly well elsewhere and can be extrapolated, statistical considerations need to be taken into account when assessing the frequency of relatively rare events. Even diseases that are common enough to be regarded as major public health problems (for example, carcinoma of the cervix) occur relatively infrequently in small populations.

Three important issues need to be taken into account when deciding the minimum size of the population on which a needs assessment should be based: the frequency of occurrence (incidence, prevalence, or both); the impact of the condition on those who have it; and the cost implications of treatment.

For a rare condition with a high impact on patients and carers and with high treatment costs (childhood leukaemia, for example) a relatively large population needs to be studied for needs assessment to be worth while. The extent of need for common, low impact, low cost conditions can be assessed on smaller populations. For a single practice it would be unwise to assess need for conditions with a prevalence of less than 1%. So whereas a needs assessment for childhood leukaemia would be of limited value for a population of under one million, a needs assessment for mild depression could be based on the population served by a four doctor practice.

The NHS, in common with many other organisations, devotes more care and resources to collecting data than it does to using the data it collects. Routine reports of information are not as comprehensive in Britain as in some countries (such as Scandinavian countries) but they do exist, and it is surprising how infrequently they are used or even known about (box).



A (common) - low cost, low impact - can use a small population
B (rare) - high cost, high impact - need a large population

Fig 4 Attributes of a health problem that influence the size of the population for needs assessment

National sources of health information in the United Kingdom

Population:
- Census data can be used to describe populations at a district or electoral ward level by age, sex, ethnic group, or socioeconomic status
- Census information on variables such as unemployment and overcrowding can be used to produce indices of deprivation for electoral wards (Jarman index, Townsend score)

Mortality:
- National registration of deaths and causes of death provide comprehensive (though not always accurate) information on mortality
- Perinatal and infant mortality "rates" (they are not rates but proportions) are used for comparisons of the quality of health care
- Standardised mortality rates are used to compare local information on total mortality or mortality from specific causes

Morbidity:
- National and local registers provide data of variable accuracy. Registers exist for cancers (type of cancer, treatment, and survival); drug addiction; congenital abnormalities; specific diseases (such as diabetes and stroke)
- Communicable disease notification provides a source of information for local surveillance
- The Royal College of General Practitioners collects morbidity data from sample practices around Britain
- Prescribing data can be a valuable surrogate marker of morbidity
- Insurance companies can be an important source of health information in countries with systems based largely on insurance

Health care:
- Hospital activity data can provide information on hospital admissions, diagnoses, length of stay, operations performed, and patients' characteristics
- Clinical indicators such as the health service indicators, can provide information on the comparative performance of hospitals and health authorities

Example of an epidemiological health needs assessment[9]

Objective: To assess whether the use of health services by people with coronary heart disease reflected need.

Setting: Health authority with a population of 530 000.

Methods: The prevalence of angina was determined by a validated postal questionnaire. Routine health data were collected on standardised mortality ratios; admission rates for coronary heart disease; and operation rates for angiography, angioplasty, and coronary heart disease. Census data were used to calculate Townsend scores to describe deprivation for electoral wards. Prevalence of angina and use of services were then compared with deprivation scores for each ward.

Results: Angina and mortality from heart disease was more common in wards with high deprivation scores. Treatment by revascularisation procedures was more common in more affluent wards.

Conclusion: The use of revascularisation services was not commensurate with need. Steps should be taken to ensure that health care is targeted at those who most need it.

These articles have been adapted from *Health Needs Assessment in Practice*, edited by John Wright, which will be published in July.

Unfortunately, "Murphy's law of information" plays a part at this stage: "The information we have is not what we want. The information we want is not what we need. The information we need is too expensive to collect." Despite that pessimistic view, routinely available data can be used, even if this entails some compromise in terms of precision. Used with survey information, routinely collected data can provide a powerful assessment of health needs and use of services (box).

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Innovations

An unusual use of a stethoscope

The patient awaiting operation was 94, well oriented, and fit for his age. At his preoperative anaesthetic assessment the only significant finding was deafness and I had to shout at the top of my voice for any communication, so it took a long time to explain matters to him. It suddenly struck me. "Why not try using a stethoscope in his ears?" I did and to my surprise I had only to whisper. It amused the whole ward, but it was a solution to my problem. I used this trick to wake him up from the anaesthetic and also asked the recovery nurses to try the same method. It was strange to see a patient in the recovery room with a stethoscope round his neck.

Others might find this unusual use of a stethoscope helpful.

Bela Vadodaria, *specialist registrar in anaesthetics, High Wycombe*

We welcome articles up to 600 words on topics such as *A memorable patient, A paper that changed my practice, My most unfortunate mistake,* or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk. Permission is needed from the patient or a relative if an identifiable patient is referred to. We also welcome contributions for "Endpieces," consisting of quotations of up to 80 words (but most are considerably shorter) from any source, ancient or modern, which have appealed to the reader.