Best practice: evidence from the clinical trials

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What is heart failure? is a question that can be addressed from the point of view of the doctor, the health service, and of the patient.

From the medical viewpoint, heart failure is where the heart is damaged to the extent that it is no longer an effective pump. There is a pronounced neurohormonal activation, and the affected patient is breathless, tired, and retains fluid and has a poor quality of life. Furthermore, as has been shown in several population based studies, patients have a reduced life expectancy, irrespective of the age at which they present. The Hillingdon heart failure study looked at incident heart failure in a west London population of 151 000 individuals. A total of 220 incident cases were identified and during a median follow-up of 42 months there were 126 deaths. The survival curve dropped rapidly, such that by three months a quarter of these patients had died. At six months only 70% survived and at 12 months this was down to 63% (fig 1). Survival among those patients who developed heart failure in the Framingham heart study between 1948 and 1988 was remarkably similar: two years after diagnosis half of the men had died.

From the point of view of the health service, heart failure represents a serious problem in that it poses a steadily rising burden on the secondary care sector: it accounts for 5% of acute medical admissions and around 10% of all medical bed days. These patients tend to have prolonged admissions and it is often difficult to discharge them home. Hospital discharge data from Scotland show that from 1983 to 1996 there was a steady increase in the number of discharges of patients with heart failure. In terms of cost, it has been shown that the National Health Service spends at least £400 million per year on the care of heart failure patients.

Heart failure is chiefly a problem of old age. In the Hillingdon heart failure study, the incidence of heart failure in young age groups was very low and only started to rise from the age of retirement. It is always around 75% higher in men than in women, reflecting the fact that coronary artery disease is by far the most common aetiology of heart failure in the western world. Population based studies show that the average age of the patient with heart failure is about 76 years, which is very much higher than the age of patients enrolled in clinical trials who have tended to be in their 50s and 60s; only very recently have patients in a older age groups been recruited into clinical trials. This clearly poses a problem in translating clinical trial data and results into routine clinical practice.

We also need to consider heart failure from the patient’s point of view. What most patients notice is that they are unable to undertake their usual activities; most are elderly and find they cannot play with their grandchildren, or do the things they hoped to do in their retirement. Many find they are socially isolated and unable to interact with their peers. They may be dependent on spouses for nursing care, and have a high need for emotional support. Often patients do not know they have heart failure and have very little insight into their condition: although this varies from one country to another it certainly appears to be a problem in the UK. Often patients are on multiple medications because of other problems of old age. It can be a real challenge to help these patients. Too often patients gradually deteriorate at home until they require readmission to hospital for stabilisation.

AIMS OF HEART FAILURE MANAGEMENT

In an ideal situation, the aims of heart failure management would be characterised by:

- evidence based care backed up by recent audit data
- multi-professional input
- seamless care between primary and secondary care sectors
- improved quality and length of life for patients
- reduced hospitalisation rates
- effective prevention of further deterioration
- affordability for the health service (and patient).

Such a situation is probably not true for any centre in the UK, but many are striving to get there. The conference proceedings published in this supplement to Heart aims to consider where we are with heart failure, to decide what is the current evidence base, what are the best practice models available, how can heart failure be diagnosed and prevented, and how much evidence is there that multidisciplinary working is a force for good. It concludes with a session on future directions in heart failure.

WHAT IS CURRENT BEST PRACTICE IN HEART FAILURE?

Heart failure is probably one of the most studied areas of clinical medicine, largely because there are many drugs that can be used to treat it. Consequently, there is no shortage of management guidelines for heart failure. The European Society of Cardiology recently produced new guidelines. Clinicians are often over focused on pharmacological treatment. However, this is only one small part of the whole management of the patient with heart failure; relatively little work has been done on assessing diagnostic methods, the delivery of care, and the effect of multi-professional intervention programmes.

Diagnosis

The European guidelines outline the modern approach to the diagnosis of suspected heart failure: they advocate looking for the presence of cardiac disease, which is where access to investigations such as ECG and chest x-ray, and the emerging role of natriuretic peptides, becomes important. It is likely that over the next five years the measurement of blood B type
natriuretic peptide (BNP) concentrations will become commonplace in primary care in order to triage patients for further investigations more efficiently.

If these tests are normal it is unlikely that the patient has heart failure. If, however, any of these are abnormal then it is necessary to go on to the key investigation of echocardiography. Access to echocardiography is one of the key markers of good diagnostic practice in heart failure. If heart failure is confirmed, it is vital to also assess the aetiology and severity of the syndrome, precipitating factors and the type of cardiac dysfunction in order to make a full diagnosis and to choose appropriate treatment. High quality diagnosis is absolutely essential, and is the foundation on which everything else is built.

Treatment options
In selecting the correct treatment it is important that patients also manage the condition as best they can. In other words they should feel empowered through being given full information about their condition and how it is being managed. Doctors are often quite poor at communicating information to patients. Written information should supplement verbal explanation, and dietary habits, drug counselling, exercise therapy, vaccinations, and travel are topics that should be covered. Although specific evidence that such communication improves the outcome for patients with heart failure and their carers may be lacking, intuitively clinicians realise that good communication is worthwhile.

Guidelines, of course, can only provide guidance as to what should be done—they do not answer every clinical question that may arise. The pharmacological basis for the treatment of heart failure caused by left ventricular dysfunction—by far the most common cause of heart failure—is well founded on trials of drugs such as angiotensin converting enzyme (ACE) inhibitors, diuretics, and β blockers. There is also strong evidence for the use of aldosterone blockers such as spironolactone. The evidence for angiotensin 1 (AT1) receptor blockers such as valsartan, cardiac glycosides, and various other agents such as nitrates/hydralazine, positive inotropes, anticoagulants, antiarrhythmics, and oxygen are less good, but still reasonably strong. For most of these interventions there are data from at least two randomised controlled trials. There are some complex issues in elderly patients, not least because patients may require a bewildering array of agents in order to tackle a number of comorbidities.

But drug treatment is not the end of the story. Many patients ask whether they can have a heart transplant or some other surgical intervention such as coronary artery bypass grafting or percutaneous transluminal coronary angioplasty; while ventricular assist devices and implantable cardiac defibrillators may offer further options. It is often difficult to know where these measures fit into the management of heart failure, not least because the level of evidence for their use is limited. This will change in the coming years and will undoubtedly be covered in future guidelines.

Organisation of care
“Programmes” of care may offer a more sophisticated approach to the management of a patient with heart failure. Increasingly, cardiologists managing heart failure patients are signed up to management that encompasses:

- a team approach
- optimising medical care within guidelines
- discharge planning
- vigilant follow up, particularly in the first 10 days
- early attention to signs and symptoms of deterioration
- a flexible diuretic regimen

- increased access to health care
- intensive education and counselling, with attention to behavioural strategies and barriers to compliance.

Clearly, nurse led care is a very important means of adopting this approach to heart failure management, and one for which there is an increasingly strong evidence base. Yet this is one area that appears to have been overlooked in the latest European guidelines, which contain only one acknowledgement that “nurses can play an important role in innovative forms of care”. It is to be hoped this will be rectified in future editions of the guidelines. In the UK, the National Institute for Clinical Excellence (NICE) has commissioned guidelines for the management of patients with chronic heart failure. The publication date is set for early 2003.

CONCLUSION
It is clear that the evidence base for the management of heart failure is very secure and expanding. Most of the trial evidence relates to drug treatment rather than to other very important areas; it is to be hoped that this will change over the coming years. The sad fact is that it takes years for clinical trials to be conducted and published and for most patients to benefit from their findings. Clinicians know this from experience with ACE inhibitors, where it is only now that most patients with heart failure in the UK are given these drugs, yet still in many cases at inadequate doses. There is some evidence to suggest that the evidence regarding β blockade is being implemented as a routine, at least in specialist centres.

Knowledge is not usually the limiting factor in implementation. The point of this conference was not simply to provide delegates with a firmer knowledge of what heart failure management should entail, but to encourage delegates to incorporate this knowledge into everyday practice to the benefit of patients. The National Service Framework for coronary heart disease has been a powerful force for good for heart failure patients in that it has focused thinking on a small number of targets. It should, if it works, improve effectiveness, equity and efficiency of health care delivery.

It may seem rather obvious to say that the organisation of health care should facilitate rather than obstruct, yet too often the health service is more concerned with the way that things have been run in the past than in considering better ways of organising care. There are many reasons why it is difficult to engineer change in a complex organisation such as the NHS, but it is to be hoped that this conference proceedings will provide readers with a starting point.

References

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REFERENCES
QUESTION AND ANSWER SESSION

**Question:** Could you comment on some of the logistical difficulties in organising heart failure care, for instance echocardiography services in primary care?

**Professor Cowie:** I think there are so many areas within heart failure in which it is important to improve quality: this goes all the way from diagnosis (where echocardiography is key), right the way through to palliative care at the end of life. But it is important to be realistic and to realise that we have a limited amount of energy and resource. Let me share my experience of organising care in my previous post in Aberdeen—a teaching district general hospital covering a population of over 500,000. Initially we set up a nurse led heart failure service, which enabled us to educate the patients and follow them up more closely. It also helped us to initiate β-blockade for about 300–400 patients with heart failure. Moving on to diagnosis, we had two very large primary care trusts that had echocardiographic facilities. Of course, it is not just access to echocardiography that is required—the scan has to be interpreted, which is where the hospital service became involved. These were the target areas that we identified as points to tackle, but there are many other areas that require work to be done.

**Question:** The problem is who is going to do the echo? If you take a technician out of the district general hospital where they are desperately short of them already, and put one in primary care, this is a very difficult problem to address. Perhaps Professor Hobbs would like to comment.

**Professor Richard Hobbs:** There is an undersupply of many skilled people in the NHS.

**Question:** If we could rely on a simple blood test such as BNP taking over from echocardiography that would make life a lot easier. Do you think that is going to happen?

**Professor Cowie:** I do, but then I am an enthusiast for BNP. I think the studies that have been conducted (and there is one ongoing at the moment in the UK) show that if a patient’s BNP is normal and their ECG is also normal, then it is highly unlikely that they have heart failure as a cause of breathlessness. I think that is a very simple and much cheaper option to be used in primary care. Now that the assay methods are so much simpler and can be done in 15 minutes in the GP’s practice it then becomes possible to use it in clinical practice.