THE FUTURE OF ECONOMIC MODELLING - A CASE STUDY OF CHRONIC HEART FAILURE

WORK IN PROGRESS PREPARED FOR HESG, BIRMINGHAM JANUARY 1999

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Abstract

This paper presents work in progress with regard to a modelling exercise to calculate the costs and benefits of treatment options for heart failure. The focus of the paper is on the extent to which the model is of practical use to health service decision makers.

Comparisons are made between the academic economist's approach and the areas of greatest interest to decision makers - in this case shadow Primary Care Group members. The paper addresses issues such as the extent to which a generic model can be sufficiently flexible to incorporate local requirements. In addition, the 'academic' modelling process is contrasted with the approach required to support real world decision makers.

The information sources utilized by the model are described and an assessment is made of quality of such sources. The paper explores the extent to which a pragmatic approach designed to appeal to end users compromises the integrity of the economic modelling process and assesses how the concepts of scientific integrity and practical value to end users can be jointly incorporated into a general framework of good modelling practice.

1. The aim of an economic model

Health economic models are increasingly being developed to support decision making in a wide range of therapeutic areas. In order to construct an economic model it is necessary to identify:-

1. Every therapeutic pathway followed by patients
2. All resources used at each stage of every pathway
3. The transitional probabilities that link pathways together.

An economic model should be based on a detailed understanding of the therapeutic area being evaluated, and should incorporate many of the factors that influence real life clinical decision making. Such a model, by explicitly linking these factors, and permitting the formal comparison of costs will illuminate the process of clinical decision making, which is otherwise obscure. To achieve this aim for particular contracts (such as a particular region), such models should ideally be capable of incorporating real variations in costs, clinical practice, and epidemiology. Perhaps the most important application of such a model is the identification of the consequences of particular changes for the systems cost-effectiveness, though the modelling process would no doubt also be valuable to physicians in their different roles, and would enable discussion and debate of other issues besides cost-effectiveness. Finally, a model, sufficiently defined, would enable the identification of medium to long-term implications and effects of particular changes.

A range of data sources is available to support economic modelling. Analyses attached to randomised clinical trials may need to be adjusted to reflect mainstream clinical practice. Clinical trials evaluate the efficacy of therapy undertaken by specialists in an environment of clinical certainty. In contrast economic models focus on evaluating the effectiveness of a therapy in a real world characterised by clinical uncertainty, where prescription and consumption take place under less than perfect conditions. In the real world patients are less rigorously selected, less rigorously monitored and therapy becomes provided by generalists with less immediate access to specialist diagnostic equipment. Further, in the real world compliance becomes a major factor affecting the cost effectiveness of drug therapy. Alternative data sources include medical databases, or an expert panel to identify the effectiveness of competing therapeutic options. However, the use of non-randomised information sources needs to be undertaken with caution. Therapeutic effectiveness will be affected by a large number of confounding variables which interfere with the pure relationship between the provision of therapy and patient response that is isolated in the randomised

controlled clinical trial procedure. As such, the interpretational difficulties underlying such studies are inevitably greater than those encountered in clinical trials.

2. Modelling in chronic heart failure

Both purchasers and providers require practical guidance as to how to cope with their rapidly growing elderly population with its associated implication of a expanding prevalence of chronic heart failure within their populations. However a balance must be struck between the clinicians' need for simplicity and the model builders' need for realism. The necessary trade off is between a practically focused simple model and a more complicated model that is of limited practical value because it cannot be manipulated by the clinicians concerned.

This paper describes work in progress in developing such a model; it is based upon a comprehensive review of the literature and attempts to provide practical guidance to both purchasers and providers in improving the management of chronic heart failure.

Chronic heart failure represents a major cause of death, disability and reduced quality of life. Heart failure affects 0.4 - 2% of the general population and 8 - 10% of the elderly.[1] There is a high mortality, with 50-60% of patients dying within five years of diagnosis. The morbidity caused by heart failure is reflected in the workloads of both secondary and primary care with 120,000 hospital admissions per year representing 5% of all admissions to adult medical and geriatric wards and 14 general practitioner consultations per general medical inpatient stay. Healthcare utilisation increases with severity of heart failure. Consequently, the financial burden upon the National Health Service is considerable with £360 million a year being spent on the management of heart failure.[2] Treatment provision is also frequently unsatisfactory from the perspective of both the patient and the clinician with an average inpatient stay of approximately 14 days and rates of readmission ranging from 29% to 47% within 3 to 6 months of discharge. The North West of England exhibits one of the highest rates of chronic heart failure in the country. For example, Liverpool Health Authority spend approximately £21 million on coronary disease which represents approximately 7% of their annual budget.[3] The profound negative effect on quality of life resulting from chronic heart failure has also been well documented.[2]

The management of chronic heart failure is both complex and costly, and clinicians have access to a rapidly expanding therapeutic armoury in confronting this disease.[4] A significant body of clinical evidence indicates that beneficial therapeutic interventions for CHF are not currently

being fully exploited.[5] In addition even where drug therapy is prescribed many patients do not adhere to long term medication.[6] Such high rates of non-compliance are particularly important given the availability of interventions which have been proven to reduce morbidity, mortality and hospitalization rates. The provision of improved therapy at the primary care level could significantly reduce hospitalisation leading both to a reduction in resource consumption and an improvement in the morbidity and mortality experienced by patients.[7-8]

The limitations of our model are difficult to overcome with currently available data. Such limitations should not distract us from the main focus which is to explore the balance between a necessary scientific complexity underlying the modelling process and the needs for simplicity in model structure to assist clinical decision making in the real world. Optimal decision making in this and indeed any therapeutic area is facilitated by access to a model exhibiting an appropriate balance of scientific rigour and practical usefulness.

3. The case study

3.1 Background to the model

Chronic heart failure is not an area which has been extensively researched and as such it is important that the available evidence is fully exploited. However, the limitations of the evidence base must be taken into account. The development of the economic model requires each aspect of clinical decision making to be clearly distinguished. The costs incurred at each stage together with the transitional probabilities linking each stage were then combined to estimate the cost of each branch of the model. While we recognise that the actual cost of managing the individual patient will vary in relation to factors such as their age and co-morbidities, the analysis focuses on identifying an average cost per patient following each of the individual treatment paths indicated. The average cost of patient management could then be calculated by weighting the cost of each treatment path by its associated probabilities.

The model presented here analysed a 12-month treatment period within the career of ill-health experienced by CHD patients. The use of expensive diagnostic procedures may appear to be 'uneconomical' when viewed over a 12 month period, but the opposite perspective may arise when viewed from their contribution towards the lifetime health experience of the patient. Time-scale is therefore of particular importance in interpreting the results obtained in an economic model for patients who are suffering from chronic illnesses.

A range of models are currently available which examine the cost effectiveness of ace inhibitors in heart failure (van Hout, Hart). The comparative advantage of our model is that it incorporates more recent therapeutic developments, including beta blockers (carvedilol), into the treatment scenarios. In addition to examining pharmaceutical treatments, this model is geared to helping GPs make decisions about the incremental benefits and costs of various diagnostic techniques which may be available to them. The emphasis on appropriate investigation and treatment for people with suspected heart failure within the National Service Framework on Coronary Heart Disease (DoH) means that clinicians need practical support which enables them to improve care within the context of a fixed budget.

3.2 Designing the model to meet the needs of decision makers

The development of the model incorporated the views and aimed to meet the needs of local clinicians. A working group comprising a consultant cardiologist and five general practitioners considered their information needs in relation to the management of heart failure and this provided direction during the construction of the model. A range of factors that will cause efficacy (as measured in clinical trials) to vary from real world effectiveness. For example:-

- Patients are less rigorously selected, so that disease free individuals receive therapy and patients with disease are not given access to beneficial treatment
- Patients are less rigorously monitored and dose titration to obtain maximum therapeutic benefit may not occur. (This applies to both ace inhibitors and beta blockers for heart failure)
- Therapy is provided by non-specialists who may feel uncomfortable with the roll out of patient management from secondary to primary care
- There is likely to be less specialist equipment - hence, diagnosis is often on the basis of symptoms, rather than diagnostic tests such as echocardiography. Waiting times for services are likely to be longer in practice.
- Compliance may be lower than that observed in clinical trials

Often such problems are side-stepped in the modelling process; for example, the focus might be a cohort of patients with a confirmed diagnosis of heart failure followed over a number of years. This avoids the need to consider patients wrongly diagnosed with heart failure and issues of access to services. Although methodologically neater, this approach does not meet the real needs of the potential users of the model. Rather than an elegant model which estimated future benefits, but excluded patients without heart failure, the GPs requested a model which would

help inform decisions in the short term, to reflect the current context and not an idealised abstraction of it. One of the problems in the management of heart failure concerns the difficulty in diagnosing the disease based on symptoms alone. In the early stages of disease the presenting clinical features are commonly non specific and some of the important supporting evidence for the diagnosis (cardiac enlargement or the presence of a third heart sound) may be difficult to detect or may be masked by other diseases. In addition, coexisting conditions that cause symptoms similar to those of heart failure are more common in patients with pulmonary disease or in elderly patients. Such individuals are routinely encountered in primary care and make it impossible, on the basis of clinical evidence alone, to determine the extent to which heart failure may be causing the symptoms. The major problem with existing models, in terms of their practical value to general practitioners, is a failure to incorporate all patients presenting with heart failure symptoms. GPs are required to manage all heart failure patients and not simply those within tightly defined disease severity or age related categories.

Although the GPs saw clinical benefits that were sustained over time as important, their immediate concern was with obtaining a snapshot of current services and treatment options which reflects the annual budget constraints within which resource allocation decisions are made. In large scale trials diagnostic facilities such as echocardiography are readily available, but this is not the case locally. In the Liverpool area, waiting times for access to consultant cardiologist supervised echocardiography is six months and rising. Local GPs wanted a model which could help them make decisions about the benefits and costs associated with investing in direct access echo services, since any increase in referrals to the consultant cardiologist will result in longer waiting times for cardiology outpatients generally.

Arguments which were presented by clinicians in favour of an annual time frame included uncertainty in relation to technological and organisational change, and the gradual shift to generic drugs as ace inhibitors lose their patents and costs fall.

3.3 Structure of the model

The principal data sources of information on therapeutic effectiveness and clinical practice are outlined in Tables 1 and 2. Clinical trials are based on recruitment of patients with a diagnosis of heart failure normally confirmed by echocardiography. The situation in general practice is that most patients who have a 'diagnosis' of heart failure have not undergone echocardiography and many of these patients will have been incorrectly diagnosed. For the modelling exercise, we highlighted 4 groups of patients as outlined below:-

- symptomatic patients with heart failure, not diagnosed and treated
- symptomatic patients without heart failure, not diagnosed and treated
- symptomatic patients with heart failure, diagnosed and treated
- symptomatic patients without heart failure, wrongly diagnosed and treated as heart failure

The full model is specified in figures 1 to 4, given after the two tables; the above categories appear in the last three figures.

TABLE 1

DATA SOURCES FOR TREATMENT PATHWAY PROBABILITIES USED IN THE MODEL

PARAMETER	RANGE	BASE CASE	BASE CASE DATA SOURCE
Overall prevalence of CHF	0.3-2.0%	1%	McMurray93 [2]
% of patients symptomatic diagnosed CHF		60%	IMS database
% of non CHF pats. symptomatic		30%	IMS database
% age pop'n CHF symptoms	0.39-2.9%	1.2%	McMurray93 [2]
% pats seen by GP alone	19.7-25.6%	25.6%	Clarke94 [5]
% pats sent for an echo	21-60%	30%	Mair96 [3]
% pats seen by GP alone prescribed ACE	20-40%	30%	IMS database
% pats diagnosed by hospital consultant, prescribed ACE		72%	IMS database
% pats contra indicated (GP only)		4%	Mair 96 [3]
% pats who stop ACE (ADR)	8.9-20%	20%	Euro Soc of Cardiology,97 [9]
% pats who comply with ACE	70-83%	79%	Pfeffer et al 92 [10]
% pats given correct dose ACE		90%	Expert opinion
% pats contra indicated - carvedilol		20%	Expert opinion
% pats who stop carvedilol/beta(ADR)	3.6-8%	8%	Cohn 97 [11],Bristow96 [12]
% pats who comply with carvedilol	74-98%	98%	Krum 95 [13], Packer & Colucci 96 [14]
% pats with correct dose carvedilol	87-89%	89%	Packer & Bristow 96 [7]

TABLE 2

DATA SOURCES FOR MORTALITY AND MORBIDITY PROBABILITIES USED IN THE MODEL

PARAMETER	RANGE	BASE CASE	BASE CASE DATA SOURCE
Mortality CHF untreated	12%	12%	SOLVD trial [4]
Mortality CHF digoxin & diuretic		12%	Expert opinion
Reduction in Mortality CHF -from ACE (1Yr)	23-27%	23%	SOLVD [4]
Reduction in Mortality CHF -from carvedilol (1Yr) versus ACE alone	40-78%	48%	Doughty [14]
Hospitalisation CHF -digoxin & diuretic (1 Yr)		20%	local data
Reduction in Hospitalisation CHF -from ACE (1Yr)versus digoxin & diuretic		40%	SOLVD [4]
Reduction in Hospitalisation CHF -from carvedilol (1Yr)versus ACE alone		45%	Packer and Bristow 96 [7]

Figure 1- Patient flow towards diagnostic strategies

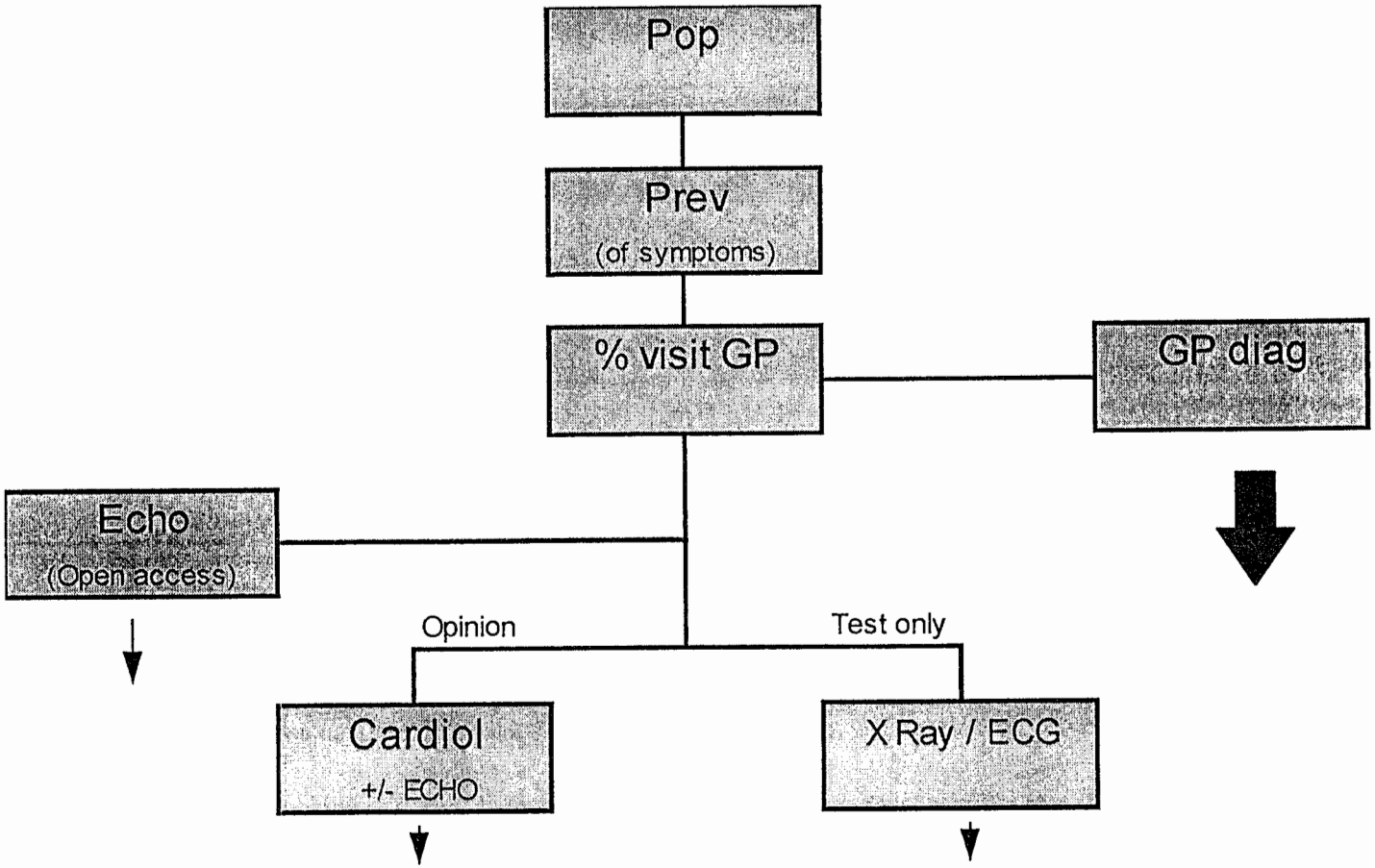


Figure 2 - Possible diagnoses

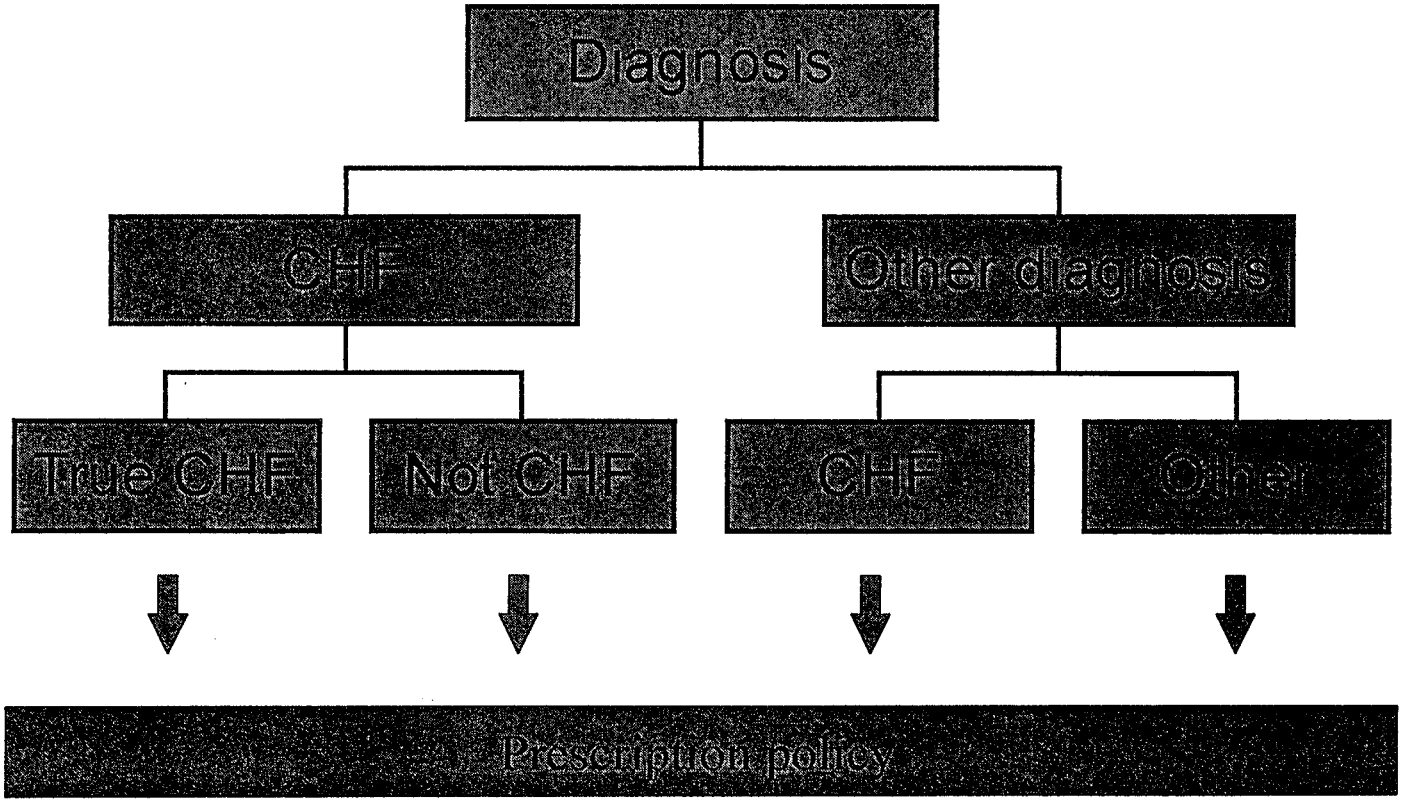


Figure 3 - Patient groups and prescription policy

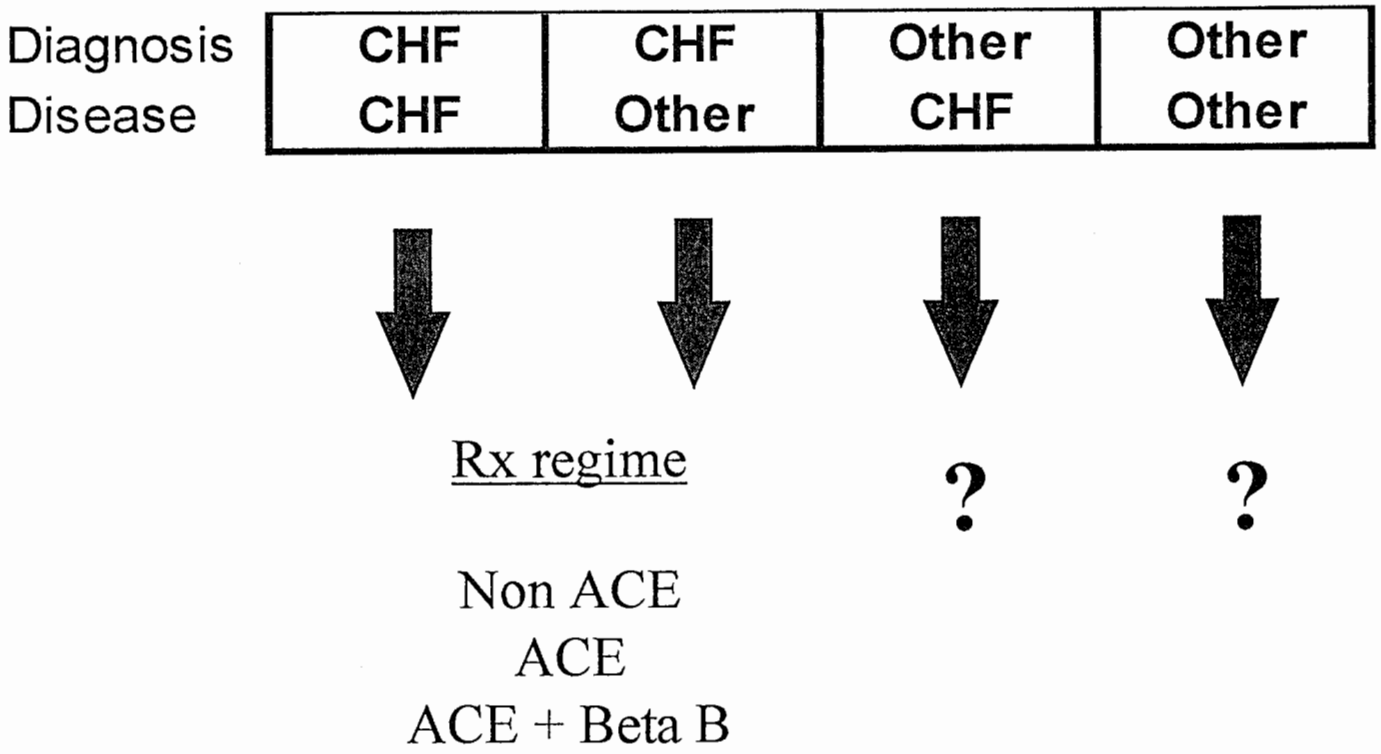
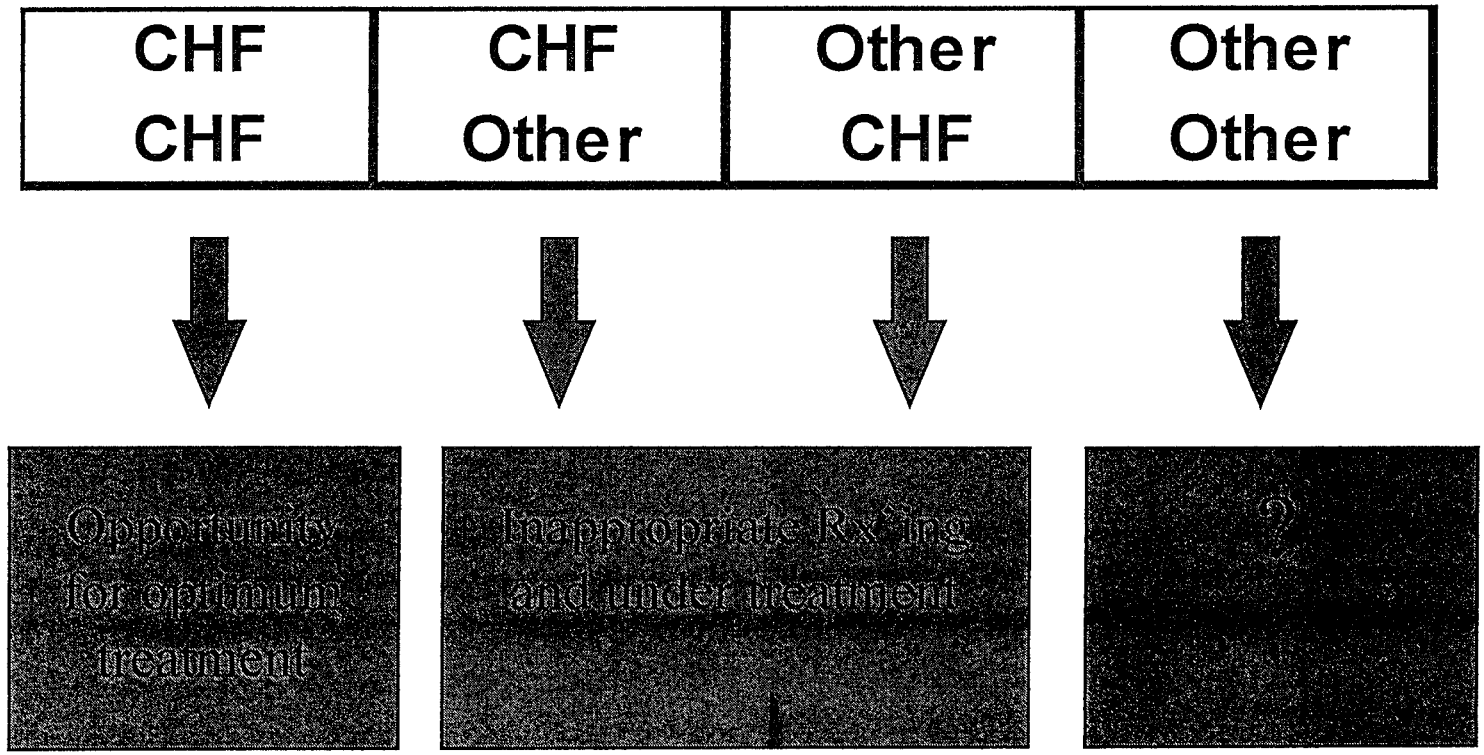


Figure 4 - Patient groups and implications



3.4 Cost data used

Identifying NHS resource consumption related to chronic heart failure is difficult given the complexity and range of co-morbidities. However, any model focusing upon an illness of ageing will share this problem given the general morbidity experienced by such an elderly population. Evaluating such resource consumption requires a three stage analysis. Firstly, identify all resources consumed during the process of care provision. Secondly, measure the amount of each type of resource consumed. Thirdly, place a value on such resource consumption. The unit costs applied to resource consumption are derived from a range of sources, but each attempts to reflect the average cost (or prize) of such resources within the NHS. The amount of each type of resource consumed will depend on the pathway followed by each patient. Each stage of the patient pathway is associated with a defined level of resource consumption and a defined set of transitional probabilities of progressing to further stages of the overall pathway. Amounts of different resources contained by the entire set of patients suffering from chronic heart failure will depend on the therapeutic pathway followed by each individual patient.

Chronic heart failure is a common reason for primary care consultation with the rate of consultations rising rapidly with age (Morbidity statistics from general practice - fourth national study OPCS London HMSO 1995). The consultation rates are negligible in the under 45 age group, 107 for the 45-64 age group. 736 for the 65-74 age groups, 1894 for the 75-84 age group, and 3650 for the 85+ age group. In all age groups the consultation rate for males are greater than the consultation rate for females. These figures indicate that almost four out of ten of the most elderly members of our population will require a primary care consultation due to chronic heart failure

Cost data from a range of sources was used to populate the model. All costs are at 1998 price levels. Drug costs are taken directly from the Drug Tariff for the UK. Accuracy on drug costs is particularly important from the perspective of the study GPS, since increases in prescribing expenditure represent real additional commitments which must be found from savings elsewhere in the system. Local contract prices are used for hospital related costs. These reflect full costs including fixed costs and capital charges, based on average lengths of stay. Incorporating the full cost of hospital activity is in accordance with the notion that in the long run all costs are variable and this represents the long run opportunity cost of hospital bed occupancy. However, for the GPs concerned, the issue of hospital costs was less important since this resource may not be available to cover additional prescribing costs associated with

improved care. As outlined, the costs represent average speciality cost for cardiology. As actual costs will vary across patients, good modelling practice would suggest that individual cost estimates should be used where available and cost data presented with an indication of the likely variation around the mean. In this case, no individual patient cost data is available, but given that the perspective taken is that of primary care commissioning, it is considered reasonable to use 'market prices'.

The position is further complicated by the fact the Primary Care Group involved in the study is a minor user of the hospital and reduced bed occupancy for heart failure patients may mean that the resource is available for patients from other PCGs. The valuation of hospital resources in these circumstances is difficult. However, since the aim of the model is to provide information that is meaningful to our audience, contract prices are used. HESG members' views would be welcome on this issue.

The major cost drivers would appear to be the quality of the original diagnosis and the appropriateness of treatment provision. Estimates of resource consumption in our economic model are based primarily on a detailed literature review. This review is supported where necessary by analysis of patient databases (MediPlus).

3.5 Sensitivity Analysis

In economic modelling, sensitivity analysis is focused on those areas of greatest uncertainty or key variables in the model. Data sources are ideally randomised controlled trials (RCTs); 'expert opinion' may be seen as sub optimal, and the relevant variables, as prime candidates for sensitivity analysis. However, in practice, GPs were less than comfortable with some of the figures reported in peer reviewed publications. The reason given for this was that these studies did not reflect local circumstances, particularly in the case of RCTs, which were seen as not representative of reality. Additionally, costs of secondary care drug initiation and drug titration will be included in the sensitivity analysis to encompass as wide a range as possible of treatment scenarios.

Cardvedilol is a comparatively new drug with limited clinical data available concerning the impact of this drug in the UK context. As a consequence the likely take up rate of carvedilol will be varied over a wide range in the sensitivity analysis.

3.6 Initial results

The model demonstrates that prescribing ace inhibitors for patients with a diagnosis of heart failure confirmed by an echocardiogram is cost effective, compared to prescribing ace inhibitors on the basis of symptoms alone. This is because hospital admissions are reduced as a consequence of improved care. The large number of false positive diagnoses of heart failure with associated ongoing pharmacotherapy costs would be reduced as a consequence of improved diagnostic techniques, but increased detection rates mean overall drug costs would rise. With GP requested echocardiography increasing from 30% to 60%, deaths fall from 133 per annum to 132 and hospital admissions from 246 to 242 per annum. Costs for drugs are £52,446 under the 30% scenario and £53,763 under the 60% scenario, with hospital costs £786,108 and £704,042 respectively for these scenarios.

This modelling process coincides with the need to provide more pragmatic frameworks for decision making for those at the sharp end in the NHS. The limitations of the model include a one year time horizon, the use of average prices presented without confidence intervals and a reliance on 'expert opinion' to provide key parameters. The model does not capture the time lags associated with referrals to cardiology which mean either delays in treatment for at least 6 months, or all symptomatic patients being prescribed ace inhibitors including those patients who do not have heart failure. To accommodate such factors would require greater model complexity and a balance needs to be struck between the costs and benefits that would arise from such additional complexity.

4. Issues raised by the model

4.1. The requirements of good modelling practice

Buxton, et al[19] emphasizes five aspects of good modelling practice:-

1. keep it simple.
2. ensure transparency.
3. be explicit about data quality.
4. perform an adequate sensitivity analysis to cope with major areas of uncertainty
5. compare your work with that of others in a similar area to ensure consistency and reliability.

The quality of the clinical evidence underlying an economic model is crucial. The development of an economic model inevitably highlights areas in which further research is required to improve crucial elements of the modelling system. In this respect developing an economic

model for CHF rapidly leads to disenchantment with the current emphasis being placed upon evidence based medicine. In many crucial aspects of the model evidence is either unavailable, inconclusive or contradictory inevitably requiring assumptions to be made in certain areas. Such assumptions ought to be transparent, objective, and based on independent and high quality expert opinion. Such opinion will inevitably be required for areas where empirical data have yet to be generated, while transparency in model construction enables the quality and appropriateness of assumptions to be challenged and where necessary altered in the light of contradictory evidence. As the therapeutic understanding of the disease improves it is inevitable that the structure of the model will also change. Given the importance of transparency and openness, economic models should be available to independent academics for validation and replication. As well as having implications for the design and development of models this has implications for the documentation that it is reasonable to expect to be produced in support of models.

Finally, models need to be reviewed; openness at every stage is necessary, to ensure that the underlying assumptions are reasonable, in the view of outside colleagues, or 'face validity'. The developers of high quality economic models should have sufficient faith in their work to allow peer review and replication by colleagues who wish to examine their models. If the structure of the model and its underlying assumptions are sufficiently rigorous then the modellers have nothing to fear from such an open and transparent process.

4.2 The incorporation of different qualities of evidence

Any economic model must be based upon a valid clinical algorithm. While randomised clinical trials provide high quality evidence of efficacy, the real world focus of clinical practice requires extension of such evidence into effectiveness and cost effectiveness. Models invariably combine data of varying quality and almost inevitably require expert opinion to be incorporated into some part of the decision tree. Any economic model must take into account the quality of the evidence on which the model is based, as poor underlying data cannot be overcome by high quality design or sophisticated methodology. The aim of economic modelling is to ensure that the model is sufficiently robust, reliable and scientific, and does justice to the quality of the underlying information.

It follows that the starting point of any model is to undertake a comprehensive review of the existing literature; this ensures that all of the available evidence has been incorporated. In cases where evidence is either non-existent or contradictory then expert opinion is required to

achieve a consensus. The aim is to ensure that the assumptions of the model reflect as far as possible the weight of the available evidence. Inevitably such comprehensiveness implies that evidence of significantly different quality (from large scale randomised trials to small scale observational studies) is incorporated into the dataset underpinning the model. In our modelling the hierarchy of evidence was utilised to ensure that the highest possible quality of evidence was built into the model wherever this was available.

Maynard and Cookson[20] four guiding principals that will improve the quality and relevance of data obtained from clinical trials:-

1. Use appropriate outcome measures (for example increase length and quality of life).
2. Use longer follow-ups to reduce the need for extrapolation into uncharted territory.
3. Use appropriate comparators. (Comparison with current gold standard rather than placebo).
4. Employ surrogate outcome measures only when there are good reasons and evidence to support the assumption of a link between intermediate and final outcomes.

The aim of the randomised clinical trial methodology is to minimise bias. However, the information is generated in a highly selective patient group and in a very relatively specific clinical atmosphere. Obviously, observational studies are non-randomised and hence are susceptible to underlying bias. However, they do observe clinical behaviour and practice and hence have the benefit of incorporating a range of real world factors held constant in randomised studies.

4.3 The incorporation of expert opinion

Modelling usually requires the combination of underlying evidence of different qualities to operationalise and inform the model framework. In such circumstances it is important to specify a 'hierarchy' of evidence sources with evidence from a lower source on the hierarchy only being accepted if higher quality evidence sources are unavailable. In cases where high quality evidence is available from randomised control trials then such evidence should be used. Where such evidence is not available then observational studies or other studies of a non-randomised nature should be incorporated into the evidence base underlying the model. The process will continue until certain links in the evidence base underlying the model are simply non-existent at which time it is necessary to fall back upon 'expert opinion'. This inevitably introduces the possibility of bias into the analysis and should only be used as a last resort and

with extreme caution. Unlocking expert opinion in an unbiased and scientific manner is perhaps the greatest challenge facing economic modelling.

Expert opinion should only be used in situations where there is a clear lack of other sources of evidence or where such evidence is unreliable, conflicting or insufficient to cover the requirement of the study. It is important that a validated approach, such as a variant of the Delphi approach, should be employed. In outline, Delphi is a family of methods, in which an expert group is facilitated to deal with a complex problem, identifying a group consensus in a manner that maximises the value of the information generated and minimises potential bias. However, to be of value the Delphi technique must be applied with the same objectivity required in any other research.[21]

The initial stage of the process requires the design of a questionnaire which is distributed to the expert group. The individual responses are collated and grouped before being fed back to individual respondents. At this stage respondents have the opportunity to change their individual responses in the light of the collective group response. 'Consensus' is then achieved through the exploration of disagreement and the reinforcement of agreement. The level of narrowing of opinion that is required to achieve consensus however has not been discussed in great detail and is still open to interpretation.

One problem generated by the Delphi technique is to provide a clear definition of what constitutes 'consensus'. The arbitrary definition of consensus based upon a post-hoc rationalisation of the data, again enables bias to be introduced into the analysis. Ideally the definition of consensus should be determined in advance of the commencement of the study. The process should follow a structure similar to the one below:

1. Development of initial questionnaire
2. Piloting of the questionnaire
3. Selection of appropriate and independent experts for the Delphi study
4. Distribution of questionnaire to experts
5. Summary of responses with each participant receiving their own responses and an analysis comparing each response with the group
6. Respondents have the opportunity to alter their responses
7. The process is repeated until 'consensus' is reached among the Delphi panel

Despite its relative validity a range of potential biases may be built into the Delphi technique. The selection of baseline data (e.g. choice of literature to be circulated to the experts) can bias the consensus view unless the advanced information is as objective and comprehensive as possible. Another possible source of bias results from the choice of experts and it is important that an explicit selection criteria underlying this choice is specified. In particular it is important that the members of the Delphi panel are independent and have expertise that is relevant to the population being analysed by the economic model; they must also be representative of the broad spectrum of clinical opinion, and not one section of it.

Further, too often, an 'expert' is automatically equated with a 'specialist'. However, the majority of chronic heart failures are treated entirely in primary care without reference to specialist advice. Only in the case where the economic model is focused only on the severe or complex forms of CHF will the specialists become the appropriate experts. Cardiologists only come into contact with the 'tip of the iceberg' of patients with CHF. By supporting the majority of patients without recourse to specialist advice primary care physicians ensure cardiologists encounter a very thin slice of reality with regard to the optimum treatment of CHF. Basing system wide recommendations on this thin slice of reality may run the risk of significantly distorting the treatment patterns of the majority of patients suffering from comparatively mild CHF. They see the patients that are most severe and fail to see the patients that are adequately supported at the primary care level. The vast majority of treatments are initiated empirically and where such empirism is successful such patients do not come to the attention of cardiologists.

4.4 The use of sensitivity analysis

Uncertainty arises from a number of sources in economic modelling. It can arise in relation to the variable quality of the underlying data or in relation to the quality and appropriateness of the assumptions and methodology used to inform the modelling process. The reliability of the model depends on its robustness in relation to reasonable variations in the crucial cost drivers underlying the model. The incorporation of comprehensive sensitivity analysis represents a crucial component of any economic model. Although the model has been based on the best available evidence, in such a comprehensive model it is inevitable that sources of evidence of different quality will be combined. Some sources of evidence are very powerful (e.g. a meta-analysis of randomised control trials) whereas other sources are less robust (e.g. expert but unproven clinical opinion). A sensitivity analysis is required to identify the impact of variations in factors that are more likely to be derived from less powerful sources of evidence.

Inevitably such cost drivers tend to occur at an early stage in the economic model where patients are being broadly divided into different treatment paths. As such any sensitivity analysis should concentrate on evaluating the impact of variations in assumptions at this early stage, given that even a significant cost variation is unlikely to affect the overall structure of results if its affects only a small minority of patients.

5. Conclusion

At this stage a definitive conclusion would be inappropriate since we are still at the early stages of the development of the model. However, a number of general conclusions may be made. Firstly, the development of the model demonstrates the feasibility and value in practice of developing an economic model in support of clinical decision making for chronic heart failure. The economic model has specifically been developed to inform and support the practical decision making of clinicians in this therapeutic area, as well as to describe the area to economists. For example, prior to implementing a change in clinical management the model will enable clinicians to identify the potential costs and benefits that would arise from such a change. Armed with such information they will be in a better position to assess the extent to which the implementation of the proposed change improves their ability to maximise the quality and quantity of health care to their patient population. The persuasive power of any clinical algorithm will be significantly enhanced in cases where its potential resource implications have been analysed prior to its implementation. Secondly, the development of an economic model requires enormous detail concerning the structure of services provided to patients at each stage of the clinical algorithm. Such a process in itself provides a useful check on the quality of the evidence underlying clinical decision making in each therapeutic area. The development of an economic model raises the issue to the clinician of the quality of the evidence underlying current decision making.

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