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USING SIMULATION MODELLING TECHNIQUES TO FACILITATE THE MANAGEMENT OF THE WAITING LIST FOR LIVER TRANSPLANTATION - A PILOT STUDY

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Abstract

This paper reports upon the development of a discrete event simulation model which is being used to evaluate the clinical and economic impact of alternative decision criteria in the management of the waiting list for liver transplantation at one London transplantation centre. Using historical clinical and resource use data from patients referred for transplantation, the model is constructed to predict changes in the net length of survival (i.e. predicted survival with transplantation versus survival without transplantation) and resources used for individual patients according to the time at which transplantation actually occurred, and according to alternative times at which transplantation may have occurred had the waiting list been managed differently. Information on resources used over time with and without transplantation are being coupled with unit cost information from the hospital centre in order to obtain estimates of the costs of care received. The model is being been developed such that it will be possible to estimate, for a defined cohort of patients, the impact of changes in the timing of transplantation for the average net life expectancy, resources used and the overall cost effectiveness of the transplantation programme.

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Introduction

The technology of liver transplantation has never been the subject of a randomised controlled trial. However, there is a growing body of evidence to suggest that for certain groups of patients with end stage liver disease, liver transplantation can lead to a considerable improvement in health status.[1-6] To date, little evaluative research on liver transplantation has been undertaken. This is in contrast to other solid organ transplant procedures e.g. heart transplantation, which has been the subject of several major evaluative studies undertaken in the US, in the UK and in the Netherlands[7-9]. The most comprehensive study of the costs and benefits of liver transplantation thus far undertaken in a European setting concluded that liver transplantation significantly improves the long term survival of patients.[10] However, no evaluative study has yet attempted to consider the potential influence of a centre's liver transplantation selection criteria upon the long term survival of patients with end stage liver disease and the impact of such changes in survival in influencing the overall cost effectiveness of this technology.

Within the UK NHS liver transplantation is currently provided by seven Department of Health designated liver transplantation centres. In 1980, fewer than 50 liver transplants were performed throughout Europe.[11] However in 1996 over 600 liver transplants were performed in England and Wales alone.[12] The transplant waiting list has increased markedly during this period. However in recent years the supply of donor organs has remained relatively constant. This is in spite of the increased use of split livers in clinical practice and the use of livers from donors classified as marginal (e.g. non-heart beating donors and those over 60 years of age). Given this situation, there are not enough donor livers available to transplant all patients in need of a liver transplant[13] Every year, a substantial minority of patients on the transplant waiting list die before a donor liver becomes available. Given this life or death situation, it is imperative that the donor organs which do become available are used as efficiently as possible.

The United States has clear and explicit guidelines concerning prioritisation of patients on the waiting list for liver transplantation. The US system is co-

ordinated by UNOS, an organisation which supervises the procurement of all solid organs and the formulation of patient waiting lists, monitors the performance of surgeons and transplant centres and distributes donor organs amongst transplant centres. Once deemed to be a suitable candidate for transplantation, a patient is placed on the waiting list. Donor livers are allocated according to a point system which ranks candidates according to blood group compatibility, extent of medical urgency and amount of time on the waiting list. In addition, priority is given to potential recipients in the same locality or region as the harvesting site. In the UK, no explicit guidelines currently exist for prioritising patients on the waiting list for liver transplantation. The UK system is co-ordinated by UKTSSA (UK Transplant Support Services Authority). Each transplant centre has a geographical zone within which it is responsible for harvesting all donor livers. There is, in general, broad agreement amongst UK transplant centres that patients who are unlikely to survive for more than three days without a new liver should be given urgent priority. Such patients form the super urgent waiting list. Patients are ranked in order of the length of time spent on the super urgent waiting list and the blood group of the patient. Blood group identical patients take priority over blood group compatible ones. If there are no patients on the super urgent list for whom a liver graft is available, then the routine patients will be considered. The same criteria are used for routine patients as for super-urgent patients (i.e. length of time on the waiting list and blood group compatibility). Routine patients from the harvesting centre will have first call on the liver. If there is no suitable recipient then the donor liver will be offered to other transplant centres.

In a review of the criteria for prioritisation of patients on the waiting list for transplantation of all solid organs, Jonasson,[14] argues that:

'Length of time on the waiting list is the least fair, most easily manipulated and most mindless of all methods of organ allocation' (p3392).

The reasoning behind this argument stems from the observation that as the period on the waiting list is extended, the health of the patient tends to deteriorate. Traditionally, such patients are given the highest priority on the basis that they have waited for the longest period of time and they may not otherwise survive. However, from the standpoint of cost effectiveness this policy may not

be optimal since such patients tend to have a lower rate of success than less severely ill patients who have been waiting for a shorter time period. In a study undertaken in the UK of patients undergoing liver transplantation,[15] it was found that patients who required intensive care at the time of transplantation (a proxy for the severity of illness) had only half the survival rate at 12 months of a group of patients who were well enough to be waiting at home (41% versus 83% 12 month survival respectively). In addition, the total costs of transplantation for the less severely ill patient group were only 43% of the total costs for the critically ill group.

In evaluating the cost effectiveness of the technology of liver transplantation, the majority of published studies to date have compared the actual costs and survival experience of patients with transplantation to their estimated shadow costs and survival (i.e. expected costs and survival in the absence of transplantation). Such studies have used prognostic indices based upon Cox's proportional hazards models to estimate shadow survival.[10] This evaluation approach is restrictive in that it considers only one specific selection strategy, namely that already used by the transplant centre, to estimate the extent to which liver transplantation increases survival beyond that expected in the absence of transplantation. This paper reports upon the development of a discrete event simulation model, a more informative modelling approach which is able to predict changes in the net length of survival (ie. predicted survival with transplantation versus survival in the absence of transplantation) and net costs (i.e. costs with transplantation versus costs in the absence of transplantation) for individual patients according to changes in the decision criteria for transplantation at a particular point in time i.e. by managing the waiting list for transplantation such that selected patients are moved up or down the list in accordance with their clinical condition. Such an approach can be used to indicate whether or not the patients who were transplanted could have survived longer if they had been transplanted earlier or later in the course of their disease and hence provides information to facilitate decision-making regarding alternative strategies for the management of the waiting list for a given cohort of patients.

The modelling approach in clinical situations

The technology of liver transplantation for the treatment of end stage liver disease represents a complex clinical situation which changes over time. This complexity is very difficult to model using standard decision trees which are unable to incorporate time into the modelling process. Since their introduction in the early 1980's, Markov processes have tended to become more popular in modelling complex clinical situations because of their ability to incorporate time when outcomes or events occur, or re-occur, over time.[16] Evaluation using Markov models assumes that the problem to be modelled can be fully described as a series of mutually exclusive and independent states, and any movement between states is controlled by a transition probability which determines the probability that an individual will move from one state to another state in any given time period. A limitation of such processes concerns their 'memory free' nature which means that they are unable to use previous information about how or when an individual has arrived in a particular state. As such, all individuals are treated homogeneously regardless of the possibility that they may have arrived in a particular state at different times and may have followed different paths through the other identified states. However, if the process is analysed using discrete event simulation modelling techniques, the constraint of path independence is removed and individuals are no longer treated homogenously.[17]

Discrete event simulation modelling

Simulation modelling can be defined as 'the process of designing a model of a real system and conducting experiments with this model for the purpose of either understanding the behaviour of the system or of evaluating alternative strategies for the operation of the system'.[18] Discrete event simulation (DES), is one form of simulation modelling that is particularly useful in modelling systems where resource usage is under scrutiny. DES represents the traditional approach to simulation. A major advantage of the use of a DES model in a clinical decision making context is that it provides a mechanism for participants to run a range of 'what if' type scenarios to determine the effects of changes in model parameters e.g. patient selection, ways in which treatment is administered and/or the timing of treatment. Unlike markov modelling, for example, DES allows patients to have individual attributes which influence their progression

through the system. In addition, events are not limited to particular time intervals, which enhances the flexibility of the model. Assumptions and flow logic can be changed relatively easily by amendments to the programme code.[19] Rather than following individuals or a cohort through the model by assigning proportions to different pathways, DES models the path of an individual by sampling probabilities from a distribution. This provides a better understanding of the process being modelled and is more realistic in its depiction of the actual decision making context. A further advantage is that it has been found to be easier to communicate to non-mathematicians because of the ability to use visual simulation as an integral part of the modelling process.[19,-21] It has successfully been applied previously to health care programmes where variation and uncertainty exists e.g. planning services for renal patients and out-patient services.[20-22]

DES allows sensitivity analysis to establish the robustness of assumptions and allows for statistical testing of differences in the costs and outcomes between simulated study and control populations.

An application in liver transplantation

The simulation model developed for this pilot study concentrates upon two main types of liver disease; alcoholic liver disease (ALD) and primary biliary cirrhosis (PBC). The reasons for choosing these two diseases are two-fold. Firstly, patients with these diseases represent the majority of liver transplants currently undertaken in the hospital centre at which this pilot study is being undertaken and, more generally, in the UK.[23] Secondly, several published and validated prognostic indices are available for these diseases which can be used to predict survival in the absence of transplantation given the values of the clinical variables specified.[24-26]

The pilot project involves several main elements:

1. The development of a simulation model reflecting the patterns of care received by patients referred for liver transplantation and the development of a subsidiary model reflecting the patterns of care received by patients receiving treatment (other than transplantation) for liver disease.

2. The identification and valuation of the resources used in the provision of liver transplantation and in the treatment of on-going liver disease identified in (1).
3. The development and/or application of prognostic models which predict survival in the absence of transplantation and post-transplant survival
4. The evaluation of the impact of alternative selection strategies for transplantation with respect to net survival, resource use and the cost effectiveness of the liver transplantation programme at the hospital centre.

Structural development of the model

The first stage of the project comprised the structural development of a simulation model for patients referred for transplantation. The model was developed in consultation with clinical colleagues at the hospital centre and CASM (the centre for applied simulation modelling) at Brunel University. The computer package SIMUL8 was chosen for the development of the simulation model, due to its relevance and versatility. SIMUL8 allows the development of a user interface. This enables the health economists to work with the model without the need for simulation expertise and gives the model more flexibility to accommodate changes based upon the requirements of the user. SIMUL8 also runs models effectively on low to mid range performance personal computers, and is low cost (the majority of simulation packages have the same or greater functionality than SIMUL8 but at a far greater cost).

The model has been developed such that it describes the movement of patients through a series of events which are assumed to happen at discrete points in time. The structure of the model reflects the pattern and timing of care received by patients entering the liver transplantation programme. The model structure is illustrated in Figure 1. All patients enter the model with end stage liver disease (ALD or PBC). Each patient is then assessed in order to determine their suitability for transplantation. If the patient is selected for transplantation then he/she joins the waiting list for transplantation. Patients are classified as either routine or super urgent listings. As indicated previously super urgent patients have priority for a donor liver over routine patients. During the candidacy phase (the period whilst the patient is waiting to receive a new organ) complication/s may occur which require in-patient admission/s. These complications may be fatal or they

may change the value of the clinical variables which predict estimated survival following transplantation. If a suitable donor organ becomes available, the patient is transplanted. If the patient survives the peri-operative period, he/she may survive for the follow up period. The patient may develop problems post transplant which require either one or a series of post transplant admissions to hospital. The patient may require re-transplantation (and hence loop back through the system to the assessment stage) or die at any time as a result of graft failure. Throughout the model, where appropriate, a distinction has been made between a general ward stay and a stay in the intensive care unit. The reason for separating out these two locations reflects the large differences in resource use and costs between them. Where a patient moves from the hospital ward to the intensive care unit in one hospital admission, this can be accounted for in the model by assuming a zero time interval between these two events. The programme samples selection criteria for listing, time spent waiting, patient survival and other decisions from probability distributions in order to simulate patient's routes through the system.

If the patient is rejected for transplantation, then control is passed to a subsidiary DES model which identifies the pattern of care for patients receiving treatment for their on-going liver disease. The model structure for such patients is illustrated in Figure 2. This model is far less complex than that for patients going forward for transplantation. Patients with liver disease require constant monitoring through regular out-patient visits and may develop complications which require in-patient admission/s. As in the transplantation model, a distinction has been made between a general ward stay and a stay in the intensive care unit.

Population of the model

In the second stage of the exercise, we commenced population of the models by defining two discrete cohorts. All patients with ALD or PBC who were accepted for the transplantation programme at the hospital centre and who had received a liver transplant during a nine year period commencing January 1989 and who were classified as routine listing were identified (n = 160). Routine patients make up the majority of patients transplanted at the hospital centre (85-90% of

transplants annually). We decided to focus solely upon routine patients for two main reasons. Firstly, due to the severity of their condition, super urgent patients are relatively inflexible in the timing of transplantation. Typically, such patients will die within three or four days if a donor liver is not made available to them. Secondly, super urgent patients generally receive very different patterns of care from routine patients, both in terms of the quantity and type of resources used and in terms of the timing of treatments administered.

A random sample of patients with ALD or PBC who were rejected for transplantation and who received treatment at the hospital centre for their on-going liver disease over a similar time period were also identified (n = 100). For the purposes of comparison, information was then extracted using a resource use information database and patient medical records on the timing and pattern of care received by each patient and key resources consumed. [The key elements of resource consumption identified are detailed in Tables 1a and 1b]. Once identified, these items were placed in a probabilistic format for inclusion into the discrete event simulation model. An illustration of the format of data for inclusion into the model is illustrated in Tables 2a and 2b. The resources identified are currently being valued using relevant unit cost estimates for the financial year 1997-1998. These estimates having been obtained from the Finance Department at the hospital centre.

Estimating survival probabilities

In the third stage of the project clinical data obtained from the Royal Free Hospital supplemented by information obtained from the UKTSSA database and clinical opinion is being used to identify the estimated probability of post transplantation survival and survival in the absence of transplantation based upon the clinical status of patients at defined time intervals following their inclusion on the transplant waiting list.

In order to estimate the probabilities of survival, serial data are required for the values of those clinical variables which are important in determining survival in the absence of transplantation and survival post transplantation. Ideally, these data are required at frequent time intervals for the entire period from the date of

entry on the waiting list until the point of transplantation for every patient in the study. Unfortunately, such data are only routinely recorded at the hospital centre at two distinct time periods: at the point of listing and immediately prior to transplantation. For the purposes of the modelling exercise, clinical opinion is therefore being used to forecast the changing values of key clinical variables during the intervening period. Similarly, where transplantation is assumed to occur at some fictitous time point beyond the actual time of transplantation for an individual patient, the changing values of key clinical variables up until that fictitous time point will be estimated and entered into the model. A key role of the sensitivity analysis will be to test the impact upon the results of variations (within a clinically plausible range) around the point estimates of the clinical variables specified within the model.

Survival in the absence of transplantation can be estimated using an appropriately applied prognostic model. There are several validated prognostic models available in the literature, all of which are based upon Cox regression techniques. In the case of patients with ALD, the Anand model will be used.[24] This model predicts survival in the absence of transplantation to a maximum of 4 years beyond the point of estimation. The model identifies the values of several key clinical variables: serum bilirubin, serum albumin, blood urea, ascites and spontaneous bacterial peritonitis as factors significantly predictive of survival. In the case of patients with PBC, the Royal Free[25] and Mayo model[26] will be used. The Royal Free model estimates survival in the absence of transplantation to a maximum of two years based upon the patient's age, serum bilirubin, serum albumin and ascites. The Mayo model estimates survival to a maximum of seven years based upon serum bilirubin, serum albumin, age, prothombin time and edema. A comparison of the comparability (or otherwise) of these two models for predicting survival in the absence of transplantation will be undertaken.

To the authors' knowledge, in the case of PBC, only one published prognostic index for estimating post transplant survival is available and in the case of ALD, no such model exists. Neuberger *et al*[27] developed a prognostic model using Cox's regression techniques to predict survival up to eight months post-transplant. Information from patients with PBC in three of the seven Department

of Health designated transplant centres in the UK was used. Preoperative information on serum urea, serum bilirubin, whether or not diuretic responsive ascites was present and year of transplant (before or after 1985) were found to be the variables which best predicted survival outcome. A validation of the post-transplant indices will be undertaken by comparing actual post transplant survival in the transplanted patient population used in the model with estimated survival based upon Neuberger *et al's* prognostic index.

Assessing the impact of alternative selection strategies

The final stage of the project concerns the evaluation of the impact of alternative selection strategies for transplantation. In order to do this effectively, the model requires data on the matching criteria for donor and recipient. The two main matching critera currently used throughout UK liver transplantation centres are the blood group compatibility and body weight of the donor and recipient [the body weight acting as an indicator of the size of the donated liver]. Any selection strategy employed in the model will be constrained by the need to ensure that all livers allocated are matched accordingly.

The selection strategies will be evaluated in terms of their impact upon health service resource use, estimated net life expectancy and the overall cost effectiveness of the liver transplantation programme at the hospital centre. The evaluation of the model will be carried out by thousands of iterations, resulting in an average estimated net life expectancy (predicted survival with transplantation minus predicted survival without transplantation), average net costs (average costs with transplantation minus average net costs in the absence of transplantation) and overall cost effectiveness of the transplantation programme for the cohort of patients given the values of the clinical variables specified at the time at which transplantation actually occurred. As the selection criteria are changed, the order and/or timing of transplantation for the cohort of patients will change. The impact of such changes upon the estimated net life expectancy, average net costs and overall cost effectiveness of the transplantation programme will be investigated.

Validation of the model

For validation, each of the two main component model outputs (costs and survival) and the total system model output (cost effectiveness) will be compared to the results obtained from the actual population/s observed. If the validation runs produce results that are sufficiently close to actual results then the model can be assumed to be predicting correctly.

Discussion

This paper has described the methodology which is being applied in a pilot study to evaluate the clinical and economic impact of alternative decision criteria for liver transplantation at one London centre. Although we have focused initially upon patients with ALD and PBC, it is possible that the model could be extended to take account of patients who receive liver transplants with other types of liver diseases. The structure of the model could also be developed at a national level by including data on the national supply of donor organs over time and the characteristics of patients at other transplant centres. Such an approach has already been adopted in the US where simulation modelling is currently being used to assess the impact upon survival of alternative liver allocation policies at a national level.[28] The approach may also be more generally applicable to facilitate the timing of other surgical interventions.

Although DES represents a potentially powerful tool for informing decisions about the timing of transplantation and other surgical interventions, it is important to recognise that the data requirements of such models are large and may, in some cases, prove to be a stumbling block to their useful application. Such models require detailed information, not only concerning the possible pathways followed by patients through the system and resources used, but also concerning the time periods between all resource impacting events. In order to predict the outcome of a procedure at different points in time, information is required upon the values of several different clinical variables at every time point to be considered. This information may be difficult to obtain, especially in instances where a retrospective data collection exercise is being undertaken. Alternatively, DES can be useful in highlighting important areas of data scarcity to help inform a prospective data collection process.

In summary, DES represents a data hungry and complicated modelling methodology. However, it does enable the modelling of complex and dynamic systems which are less easily modelled using other techniques. DES allows patients to have individual attributes which influence their progression through the system and it enables the impact of a range of hypothetical scenarios to be tested. As the number of liver transplants performed in the UK continue to increase, the calls for explicit guidelines for prioritising patients on the waiting list are likely to escalate in the future. DES may prove to be a powerful tool in assessing the impact of alternative selection strategies for transplantation. It may also prove to be useful in facilitating the timing of other surgical interventions and in health care decision-making more generally.

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APPENDIX

LIVER TX PATIENTS	Key elements of resource use
Assessment	Inpatient stays Outpatient visits Investigations and tests
Candidacy	Inpatient stays Outpatient visits Investigations and tests Drugs
Transplantation	Pre-operative hospital stay Pre-operative investigations and tests Pre-operative drugs Transplant operation Post-operative ICU stay Post-operative non-ICU hospital stay Post-operative investigations and tests Post-operative drugs
Post-transplant	Outpatient visits Inpatient stays Drugs Investigations and tests Re-transplant

LIVER DISEASE PATIENTS	Key elements of resource use
	Inpatient stays (ward) Inpatient stay (ICU Outpatient visits Investigations and tests Drugs

Table 2a: In-patient Assessment Admissions

Reason	%	L of Stay	Number of admission probabilities		
			1	2	3
Ltx assessment	100	10 days mean 3.2 days SD 9 days median 3-16 days range	100%	17%	3%

Table 2b: Treatments and Investigations during Assessment Phase

Type of treatment/investigation	Unit cost (£)	Probability
Doppler ultrasound scan	64	0.78
CT - head	100	0.74
Lung function tests	250	0.74
Coeliac SMA with Lipiodol	384	0.67
CT-abdomen	100	0.67
Echocardiogram	250	0.63
X-ray	30	0.63
Bone density scan	50	0.56
Exercise ECG	20	0.52
Endoscopy (UGI)	270	0.41
Dental assessment	75	0.41
X-ray skeletal survey	30	0.37
Electroncephalogram	109	0.37
Dental treatment	395	0.30
CT - other	100	0.26
CT guided liver biopsy	160	0.26
CT-chest	100	0.19
Referral - other	100	0.19
Renal scan	50	0.15
Hepatic wedge pressures	200	0.11
ERCP	250	0.11
ECG	23	0.11
MRI - other	180	0.11
MUGA	160	0.11

Figure 1: Liver Transplant model

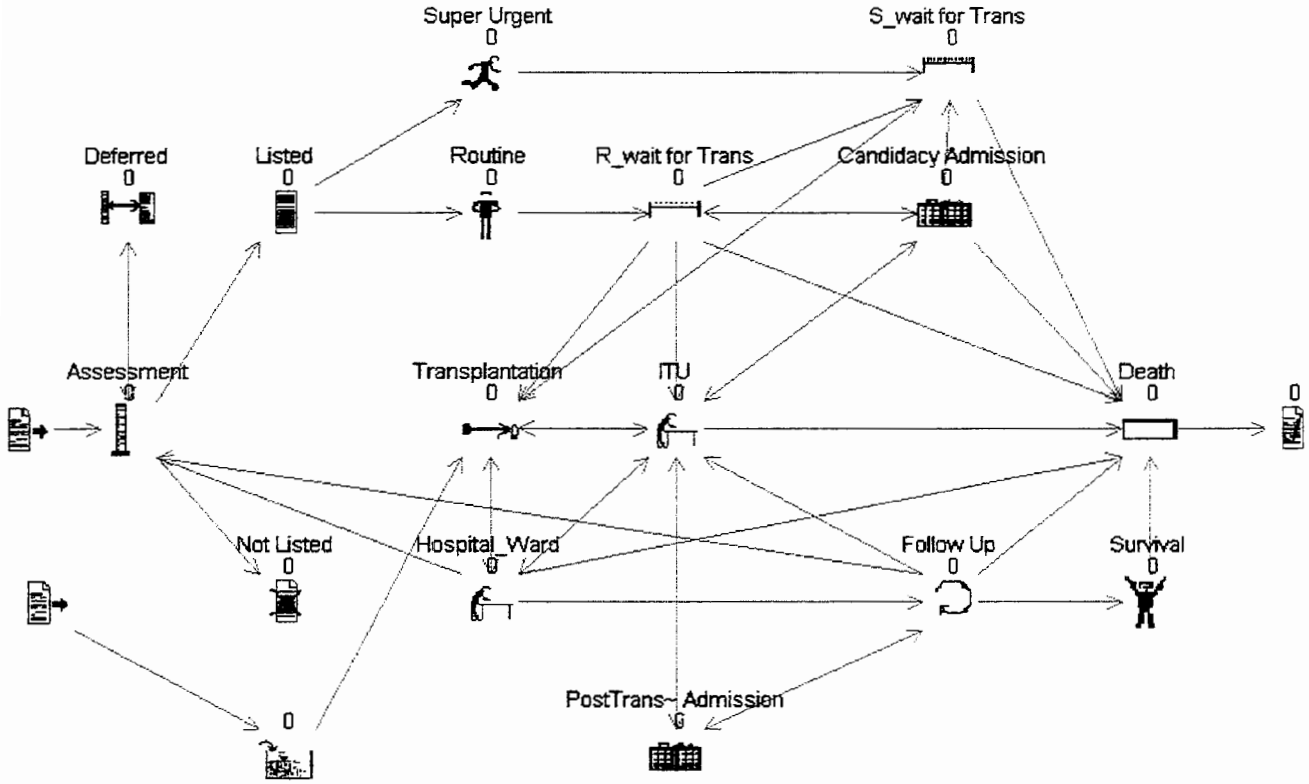

Figure 2: Liver Disease model