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SIMULATION MODELING AS AN AID TO DECISION-MAKING IN HEALTHCARE MANAGEMENT: THE ADJUVANT BREAST CANCER (ABC) TRIAL

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ABSTRACT

This paper presents simulation modeling as a decision support technique and suggests that it can be a useful for understanding problems related to health care, Randomized Clinical Trials in this case. The paper shows that simulation may not be regarded as a tool for deriving solutions to certain problems. In fact simulation is better suited for understanding the problem and enhancing systematic debate between the problem owners. The paper also demonstrates the usefulness of combining different software to provide a comprehensive tailor-made package (ABCSim). The example used is based on modeling a randomized clinical trial for Adjuvant Breast Cancer.

1 INTRODUCTION

This paper reports the usefulness of discrete event simulation modeling in exploring these issues. It focuses on the use of this form of simulation in supporting decision-making in a Randomized Clinical Trial (RCT). The objective of using simulation modeling is to help health economists identify the key factors active in the RCT through the development of a model of the healthcare related processes being studied by the RCT. This approach provides an opportunity to allow users to understand the role of these factors in the RCT. This research is carried out in the context of the Adjuvant Breast Cancer RCT.

The Adjuvant Breast Cancer (ABC) Trial is a national collaborative randomized clinical trial. The main objective of adjuvant therapy for early breast cancer is to prolong survival while maintaining a high quality of life (Early Breast Cancer Trialists' Collaborative Group 1992). The principle aim of the Trial is to assess the value of combining alternative forms of adjuvant therapy for early breast cancer. More formally, the Trial aims to assess the value of adding cytotoxic chemotherapy and/or ovarian suppression to prolonged adjuvant Tamoxifen in order to treat pre/perimenopausal women with early breast cancer, and cytotoxic chemotherapy to prolonged adjuvant Tamoxifen in order to treat post menopausal women with early breast cancer. To investigate the effect of additional treatment, clinicians have further specified treatment plans that are randomly selected based on initial treatment. For example, a pre/perimenopausal patient who has been initially treated with Tamoxifen and chemotherapy may be randomly selected to have subsequent treatment with ovarian suppression or nothing. The Trial aims to include four thousand pre/perimenopausal and two thousand postmenopausal women. The clinical end-points of the Trial are overall and relapse-free survival for five years.

A group of health economists have the task of evaluating the economic implications of the ABC Trial to determine the cost effectiveness of the various treatment combinations by comparing the additional resource use with the survival gains and quality of life effects. This is a difficult task as data collection for factors such as quality of life, for example, is very time consuming as it involves interviewing patients on the basis of questionnaires to determine how a particular treatment plan has affected their general health state. Pursuing the collection of data for the number of patients involved in the ABC Trial is almost impossible given the limited resources that the health economist group has available. Given that data collection is severely limited, some way of understanding which of the range of economic factors are the most critical in determining the effectiveness of the range of treatments involved in the Trial, and therefore what data must be collected, is essential for the evaluation to be practical.

The paper discusses the development of ABCSim, a simulation package developed with the purpose of

helping the health economist group overcome the practical difficulties of data collection, and also assisting them in better understanding the issues involved in adjuvant breast cancer treatment. The next section addresses the role of economic evaluation in the ABC Trial. The sections that follow address previous attempts to model economic factors in RCTs and the development, validation, and verification of ABCSim.

2 THE ROLE OF ECONOMIC EVALUATION IN THE ABC TRIAL

In the treatment of early breast cancer it is sometimes unclear whether the possible benefits of certain treatments will always outweigh the side effects that a patient might suffer. The current possible treatment alternatives are listed in Table 1 below:

Table 1: Randomization Options for the Adjuvant Breast Cancer Trial.

First stage treatment plan for individual pre/perimenopausal patients (not randomized)	Second Stage treatment options (randomized)
Tamoxifen Tamoxifen + Chemotherapy Tamoxifen + Ovarian Suppression	Yes Ovarian Suppression, Yes Chemotherapy Yes Ovarian Suppression, No Chemotherapy No Ovarian Suppression, Yes Chemotherapy No Ovarian Suppression, No Chemotherapy
First stage treatment plan for individual post 0menopausal patients (not randomized)	Second Stage treatment option for post menopausal (randomized)
Tamoxifen	Yes Chemotherapy
Tamoxifen	No Chemotherapy

Side effects include, among others, ovarian suppression may cause early menopausal symptoms that may be more severe or have more psychological consequences than would otherwise happen at a later age. Early menopausal symptoms are an adverse side effect of chemotherapy for pre-menopausal women. Chemotherapy may itself induce nausea and vomiting. The key to treatment selection is the balance between the effect of treatment on a patient's quality of life and any increased survival advantages associated with the additional adjuvant treatments. Economic evaluation aims to inform treatment selection by attempting to estimate the survival gains and quality of life effects with the additional resource costs. These costs are incurred in administering the additional treatments and in the management of the possible side effects resulting from these treatments. It is usual to represent a patient's state of health by combining the health state with a quality of life utility weight between zero and one; where zero is death and one is good health.

To evaluate the relative success of the different possible treatments for different cohorts of patients, hypotheses must be formed and tested. Data must be gathered on cost, quality of life and survival to determine the validity of a hypothesis. Cost and survival data may be taken from standard sources or from observation. Collection of data concerning quality of life is derived by patient questionnaire and interview. However, problems involved with data collection, such as limited data collection resources, the use of clinical staff to collect data (thereby removing them from their own work), the possible disturbing of the clinical process by interruptions for data collection, and the effect on data of people saying what they think the questioner wants to hear rather than what they might actually feel, add to the difficulties of collecting data on the quality of every patient's life both during and after treatment. Given these difficulties, it is clear that any data collection carried out in order to test hypotheses about quality of life must be carefully organized and well focused. We now review an attempt that used Markovian techniques to focus attention on the factors that appear to be influential in the assessment of treatments in a RCT.

3 A TRADITIONAL APPROACH: MARKOV MODELING OF ADJUVANT BREAST CANCER TREATMENT

In this section we review how economic factors in adjuvant treatment have been previously modeled using Markov modeling. We also discuss some of the shortcomings of this technique. Markov modeling alone has been chosen for discussion here, as there appears to be no evidence in the literature of alternative methods used for modeling the economic factors concerning Adjuvant Breast Cancer. This section concludes with a brief discussion of discrete event simulation which, we suggest, is possibly a better candidate for this type of modeling.

In the study performed by Hillner and Smith (1991), Markovian analysis was used to investigate the cost effectiveness of adjuvant chemotherapy in node-negative (a cancer type) women. It examined the use of chemotherapy at different levels of recurrence risk. The model used the following variables; risk of recurrence, efficacy of adjuvant therapy, duration of benefit from adjuvant therapy, and quality of life. The data used was based on the literature and expert opinion, all of which was presented explicitly to support appropriate interpretation of

data generated by the model. This modeling approach allowed different patient cohorts to be analyzed without a great deal of extra modification to the model. Experimentation was performed by running the model several times and varying the chemotherapy effect, age, probabilities of toxicity effects, and the probability of first recurrence. Markov modeling techniques appear to provide certain benefits. Among these are that patient pathways can be defined in some detail by the specification of health states and the routes between them. The cost-effectiveness of the intervention can be easily tested for different patient cohorts.

However, Markovian analysis has its drawbacks. Markov modeling can be accused of incompleteness, or an inability to model reality to a sufficiently close degree. For example, a fundamental limitation of Markov processes is that a fixed time period must be chosen. Patients can only change in health state at the end of each time period (in this case, a period of one year). The choice of a year represented a trade off between the accurate description of the length of certain health states with a relatively short duration, such as the toxicity health states, and the need to model the relatively long time horizon of patient survival. If a shorter time period had been chosen, then the total number of time periods needed to analyze each cohort of patients would have increased, requiring a longer model running time. Another possible problem of this approach is that only the path probabilities may be time independent. This particular restriction may have important implications when modeling adjuvant therapy for breast cancer where the disease free interval is thought to affect a woman's prognosis once a recurrence is experienced. For example, the longer a woman is recurrence free, the better will be her prognosis if she does suffer a recurrence. Also, it appears that patient history is important in determining the recurrence of cancer. The memory-less property of Markov models prevents the modeling of such decisions. The shortcomings of the Markovian approach were highlighted during initial discussions focused on developing a model of the ABC Trial. In the Trial, patients were seen to experience wide differences in the state of their health at various stages. It is difficult to determine what would be the smallest time period needed for Markovian analysis to balance model detail with model run time.

In coming to an understanding of the complexities inherent in treatment of Adjuvant Breast Cancer, we suggest that simulation modeling might better serve the needs of clinicians and those involved in the decision-making process. Simulation modeling, and its potential for enhancing systematic debate between those involved in complex healthcare issues such as breast cancer, is further described and discussed in the following section.

4 AN ALTERNATIVE APPROACH: SIMULATION MODELING AS A DECISION-SUPPORT TOOL

Traditional approaches to modeling, such as that described above, rely on the need to first collect data for the model. This data is then analyzed, and decisions are subsequently made. Such statistical modeling means that not only is there little transparency of the problem, but also that it deals only with the aggregate situation. As discussed earlier, the collection of data is not only complex but also expensive both in terms of time, effort and money. Although it would be possible to collect data on, for example, the effects of more prolonged chemotherapy on certain subjects, this raises particular problems. What, for example, are the increased costs in doing this? There is also the significant problem of collecting data which, by the time it is ready for analysis, may be out of date, or irrelevant, given the changing pace of not only medical technology but also healthcare advances in the field.

Simulation modeling, on the other hand, offers significant advantages in that making the model, and analyzing the problem with the aim of better understanding it, does not rely on the initial collection of data. As such, it offers considerable benefits for those involved in the decision-making process. Expert opinion is used to first establish the relationships which, in this study, concern the treatment and side effects of Adjuvant Breast Cancer and recurrences after treatment. Analysis can then be used to better understand what data does, in fact, need to be collected at a later stage. It also allows analysis and exploration of different decisions, and the impact of these decisions on future action. Simulation allows for discussions of 'better' solutions to the given probabilities, taking into account the previous history and or facts. It allows for identification of the key variables early in the process, and as such is a powerful tool to aid decision-making. The wide range of durations of health states suggests that a discrete event simulation approach is a more appropriate choice. Similarly, the fact that health state changes on the basis of patient history means that a modeling technique that can represent this is desirable. Again, discrete event simulation modeling appears to satisfy this requirement. Another factor in the choice of discrete event simulation modeling to support economic evaluation is the sophistication of software that exists to implement and experiment with such models. In the next section we discuss the method used to develop the simulation model of the economic factors relating to the treatment of adjuvant breast cancer and the package ABCSim.

5 THE ABCSIM PACKAGE

The ABC Trial is investigating the effectiveness of the various possible treatments (listed earlier in this paper) involved in the adjuvant treatment of breast cancer. The responsibility for this falls to a small group of health economists who will perform this task by collecting and analyzing data from the Trial. Limited resources, as is usual in public healthcare, means that it is vital to identify potential key factors in the Trial. Early identification of these factors will therefore help to ensure that data collection is effective and efficient; and thus cost-effective. To support the decision-making involved in identifying these key factors, ABCSim, a simulation package, was developed. This package contains a validated model of the economic factors identified in the Trial. A user-friendly interface was provided, designed to make data entry and the subsequent presentation of results readily accessible to the health economists who were to use it. In this section we review the development and validation of the model underpinning the ABCSim package and discuss various aspects of the user interface. A short discussion of the use of the package follows.

As is usual in the development of a simulation model, the initial phase consists of structuring the problem. This is followed by a cycle of conceptual model building, and then implementation of a computer model, and experimentation. Verification and validation occurs throughout this process (Paul and Balmer 1993; Pidd 1996 and 1998; Robinson 1994). Problem structuring in this ABCSim study involved regular meetings between a team of simulationists and the health economists involved in the Trial. Discussions focused on how modeling in general could be used to support the work of the health economists in this regard. The notion of a validated model concealed behind a user-friendly interface arose from these initial discussions, and subsequently formed the orientation for the development of the conceptual model. Conceptual modeling used an Activity Cycle Diagram (ACD) to capture the behavior of the system, although it could be argued that any other conceptual modeling technique could have been used (Taylor, et al. 1998). The basic structure of the economic factors was captured in terms of treatment pathways and health states. The model was divided into the selection of treatment (the randomization) and the modeling of cancer recurrence. The activities can be summarized in Table 2 below.

Table 2 : Activities in the Model

Branching activities	*Treatment*	*Remission and recurrences*
These are usually with zero durations and represent choice of treatment according to patient type (pre/perimenopausal or post menopausal) and different randomization options in addition to symptoms.	These activities represent the actual treatment durations. The ordering of activities depends on the treatment plan. Ordering is important, as the effects of possible treatments are not commutative.	After treatments, the patients have a remission period, and then either die or have a recurrence. The decision about what type of recurrence and length of remission depends on the patient's history through the model.

The admission activity has little purpose other than to mark the entry of patients into the system. The queues of the model are no more than an artifact of the modeling technique as there is no resource competition. The existence of the queues does however present the possibility of extending the model to analyze resource competition if the need arises in a later study. Translating the ACD model into a form suitable for execution on a computer involved the selection of an appropriate computer simulation tool. The selected tool was Simul8. This was chosen for a number of reasons. Firstly, because of its relative low cost in comparison to much of the other simulation software. Secondly, because it provided the basic simulation facilities required to accommodate the translated ACD model. Lastly, because it has facilities for building a user interface via a link to Visual Basic.

The queues and activities of the ACD mapped directly onto a Simul8 iconic representation (see Figure 1). The verification of the network structure was straightforward and resulted from a joint effort between the health economists and the simulationists. Additional detail was added to capture the relevant economic attributes active in the Trial and to generate appropriate output statistics. Table 3 summarizes the model's input factors and Table 4 summarizes the model output statistics. The model covers a wide range of input variables that can be split broadly into three distinct categories; incidences, costs, and quality of life. The incidence variables control patients' pathways through the model, whilst the cost variables are attributes linked to particular events or health states that the patient may pass through (as are the quality of life variables). Within the incidence category, the model variables may again be disaggregated to five further groups; age groups, toxicities, menopausal symptoms, relapses and death. In addition to the costs of administering the adjuvant treatments, costs need only be applied to three of the incidence groups; toxicities, menopausal symptoms and relapses. The required outputs statistics are average cost per patient, average quality adjusted life years (QALY's) per patient, average life year per patient per treatment arm, average differences between adjuvant and control patients, cost/utility ratio, and cost/life gained ratio.

As with any information system, its success or otherwise is in part due to a well-designed interface. Figure 2 shows the interface developed for the ABCSim package following data entry and analysis requirements. The health economists decided that experimentation should involve the comparison of test patient cohorts (alternative 1) with a control (alternative 2), allowing for changes to be made in the range of input factors for the test patient cohorts.

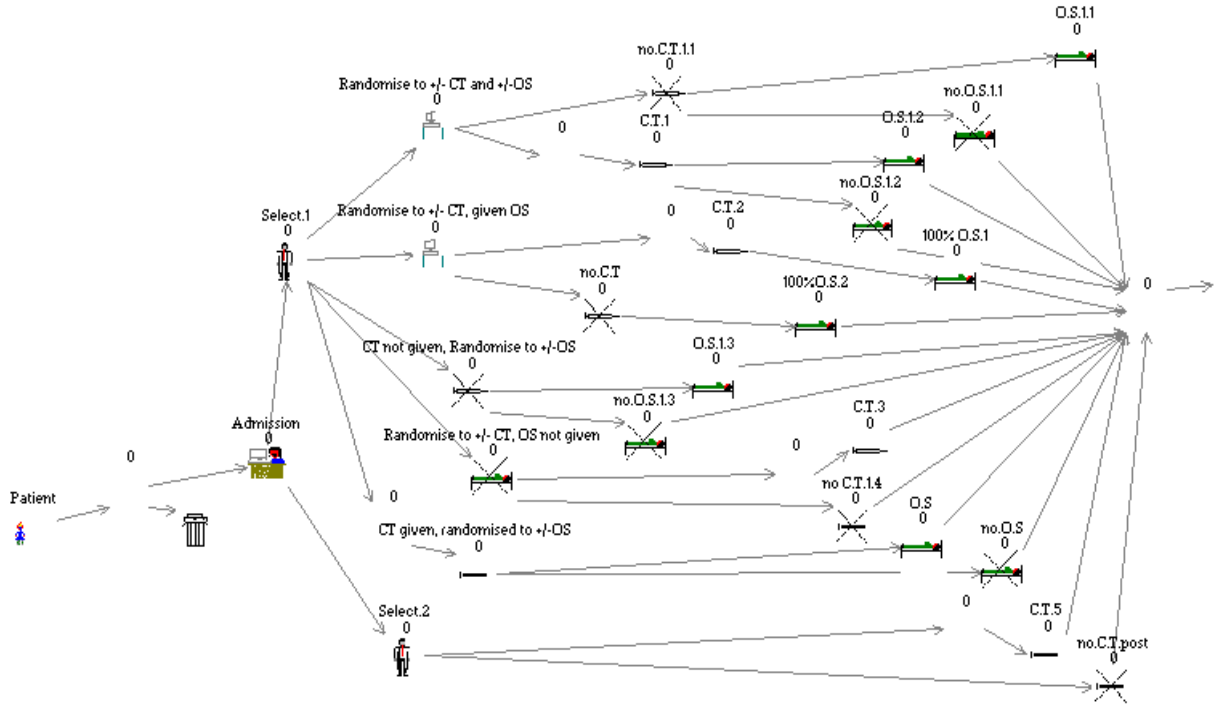

Figure 1: Simul8 Layout for ABC Trial (Treatment Phase)

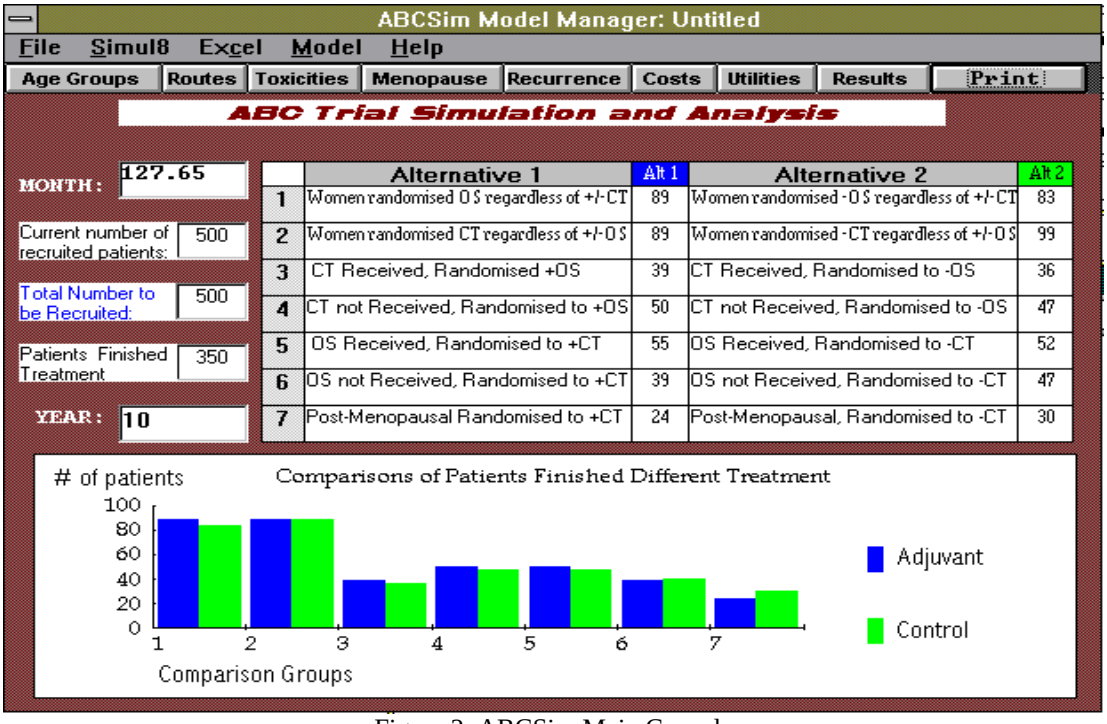

Figure 2: ABCSim Main Console

The main screen of the package facilitates the user to different sub-windows for entering the different input variables and viewing the different results. The major input factors are summarized in Table 3. An example of input sub-windows is shown in figure 3, which presents how the different cost variables can be inputted in a probabilistic form. Users are also able to examine results such as average cost, average life years gained, average quality of life, and average quality of life adjusted years (see Table 4). Figure 4 is an example of a results graph showing one of the output statistics, average QALY's per patient.

Table 3: Input Factors

Age	Treatment choice based on age of patient. There are four age groups.
Pathways	The different selections of treatments according to randomization and clinician decisions about different patients.
Toxicity	Side effects of chemotherapy. There are four levels of toxicity (none to severe).
Utilities	Quality of life utility range is between 0 and 1. Assigned to a patient based on the health state and the effects of treatments. Used as the basis for calculating QALY's.
Recurrences	Recurrences of cancer adjuvant treatment. The model provides input facilities for each recurrence in terms of duration and recurrence probabilities based on the current health state and history of the patient.
Cost	Cost is assigned for treatments, their related side effects, and recurrences.

Table 4: Output Factors

Generally the model results are collected at two points. The first one is when a patient dies or reaches 10 years in the model. The second one is at the end of the model, that is when every body dies.	
Average cost per patient per arm	Accumulated cost throughout the trial for each arm. The variability in cost comes from the fact that each patient may experience different side effects or symptoms.
Average QALY per patient per arm	The QALY's for each patient is calculated as on the basis of $u(s,e) * Y$ where u is the utility value which a function of the health state type, s, and the effect, e, and Y is the length of time that the patient stays in the same state and effect.
Average life year per patient per arm	This is the average years that patients live in the same comparison arm. This shows how long a patient may be expected to live after each combination of treatments
Average differences	Averages of costs, QALY's, and Life Years for control women are subtracted from averages, respectively, for adjuvant women.
Cost/utility ratio and cost/life gained ratio	After average differences are calculated, the ratio of cost difference to life year gained difference and ratio of cost to QALY's.

5.1 Verification and Validation

To date, the study has concentrated on collecting robust data for the validation of the incidences and cost variables categories. Verification of all three categories of input variables is now complete. The conceptual validation of the model is based on wide ranging discussion and consultation carried out during the formative stages of the project. Modeling alongside a large Randomized Controlled Trial (RCT) offered considerable benefits. Such a large pool of experts in the field of breast cancer, who were not only willing to discuss the model but were also able to provide advice on the structure of the model, was very valuable. This was supported by twice-yearly steering group meetings, which were used as the basis for general discussion, and individual physicians were visited independently for further consultations.

Inputs for the model were initially drawn from data derived from an ad hoc review of the literature supplemented by expert opinion. No strict constraints were placed on the reliability of the data so, for example, data was able to be collected from RCTs or an observational study. In addition, it was necessary to identify rough estimates of the overall expected effectiveness and costs of the different treatment options. The objective of the data collection was to ensure that the results calculated by the model, using disaggregated data, were significantly close to the results extrapolated from the literature. The dual results of the model, relating to the effectiveness of the various interventions, and the costs associated with patients in each of the relevant comparison groups, were validated separately. The remainder of this section provides a brief discussion about verification and validation techniques used in this exercise. The results of the validation of the simulation inputs for effectiveness are confined to the first 10 years following treatment, as few studies exist with longer follow up. Estimates of average life years alive from the point of treatment ranged from around 6.5 to 7 years for the postmenopausal non-CT comparison group to between 8.5 and 9 years for patients receiving all three adjuvant therapies. These results, whilst calculated in a different format to the results published in the overviews (Early Breast Cancer Triallists' Collaborative Group 1992; Hillner and Smith 1991), are sufficiently similar to the overview results to enhance confidence in the model, and its baseline inputs, for further investigation of the treatment area.

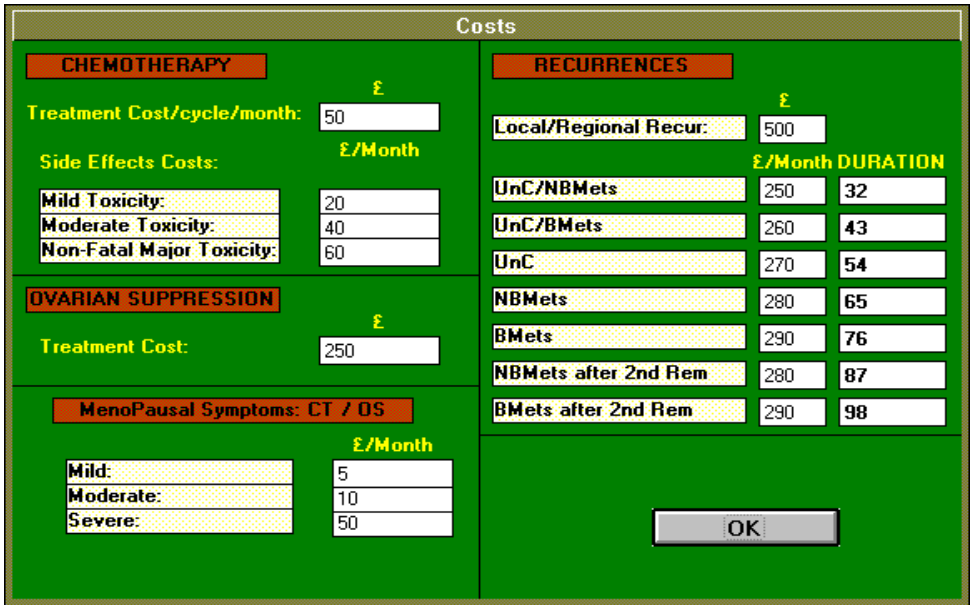

Figure 3: ABCSim Input Window for Costs and Recurrence Durations

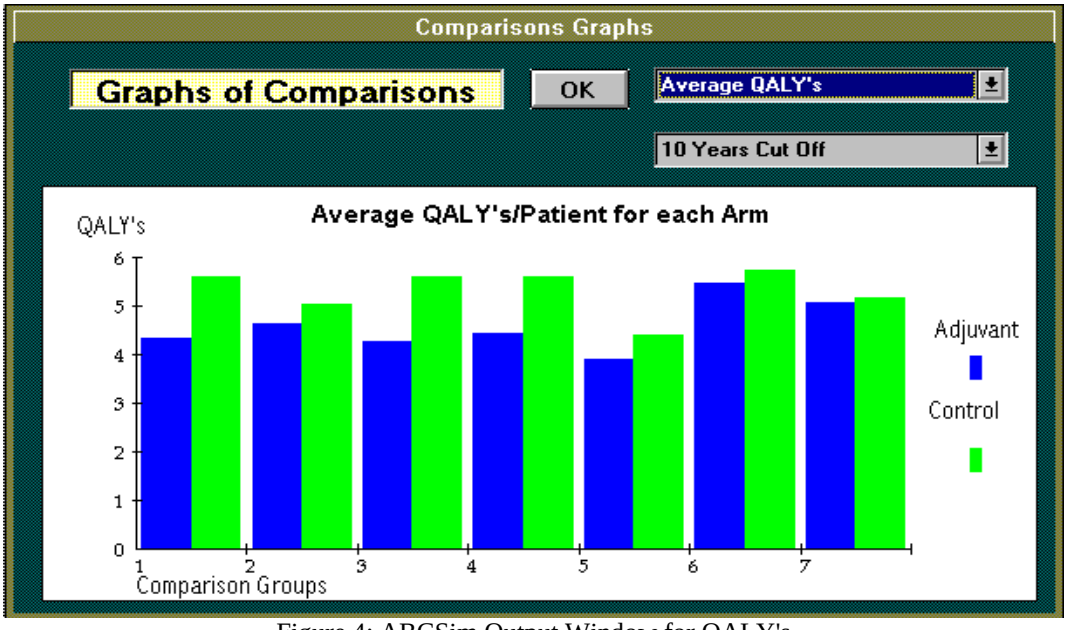

Figure 4: ABCSim Output Window for QALY's

6 CONCLUSIONS

The main objective of developing the ABCSim simulation model was to assist decision-makers in identifying the key variables of the ABC Trial, and to offer insights into which data to collect. The model is therefore used as a means of initial experimentation, and does not depend on real data in order to better understand the roles and interdependencies of factors within the model. The users, the health economists in this case, are assisted in their task in that they are able to change all the variables of the model with a view to investigating various aspects of the Trial. The model is as yet not at a stage of development where precise estimates of the specific values, such as additional cost of having adjuvant treatments, can be provided. Nevertheless, the model is currently able to give some relative measurements or tendencies of certain input combinations. For example, it is possible to know whether that the average QALY's with adjuvant therapy is relatively higher than with the control patients or vice versa given the input data. This highlights one of the key factors in economic evaluation, namely, whether or not the

introduction of a new treatment is justified; a decision that is based on comparing the cost and effect of the new and the old treatment. Simulation modeling allows for such discussion and evaluation.

Model use, mainly carried out by health economists, is conducted based on two basic steps for identifying the important variables in terms of sensitivity to model's outputs. The first step identifying the variables those have significant impact on final results. The second step is selecting and ordering such important variables based on significance of impact. Regarding the first step, sensitivity is measured by the percentage of change in Cost-Effectiveness from the base values that are usually defined by the users. Base values are results based on data already exist in the literature. To date there does not exist a methodology for deciding what a significant percentage is and it is usually agreed by the problem owners. One of the uses of the model is to act as a medium of discussion between the interested parties to define suitable significance levels. After deciding the important variables, the next step is to rank these variables to make it possible to delete the least important variables from the data collection accordingly. The ranking procedure, however, is more straightforward. It is actually based on Cost/Life-Years and Cost/QALY's ratios. The lower the ratio the higher the importance.

One of the significant benefits of model is that is has permitted a greater understanding of the problems associated with adjuvant treatments of breast cancer. Developing and using the model allowed for better communication between the stakeholders, and also provided them with a sense of ownership and confidence in the model. Such interaction is central to the subsequent ABC Trial, and demonstrates that simulation modeling can usefully aid discussion and decision-making. The ABC Trial is still underway, and so it is too early to show absolute results. However, we are confident that the subsequent data collection will not only be appropriate and cost-effective, but that we have identified the key factors necessary for this to be carried out as efficiently as possible.

Another benefit that may be realized is that involving the stakeholders at all stages of the modeling process is. Not only does it facilitate communication but it also makes the resulting models both visible and accessible to all concerned, regardless of simulation expertise. Another aspect of such modeling relates to the perception of models in complex domains such as healthcare. It is important that they are seen as vehicles for more closely understanding the systems being modeled rather than techniques for finding solutions to those problems. A final aspect is the significance of using the model to look at the sensitivity of areas of the system. This is enabled by varying the values of parameters in the model and examining the impact on the outputs of the model. This work has led to more collaboration on other projects, and an increasing interest from outside healthcare bodies. Our work in this area has highlighted two significant advantages with this approach. First, as the model was being developed, the health economists found out more about their problem domain and this stimulated useful debate in the process. Second, such development and debate enabled the inclusion of still further complexity into the model, and thus enabled the stakeholders to form a richer picture of the issues concerning the treatment of breast cancer. As such, it makes a useful contribution to decision-making with regard to adjuvant breast cancer in a healthcare sector that is increasingly concerned with balancing the difficult demands of increasing sophistication and expectations with the financial constraints imposed.

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