Methodological Issues with Decision Analysis as a Tool in Service Configuration and Redesign

Fiona Clement [1], Joanne Gray [1,2], Stirling Bryan [3] and Cam Donaldson [1]

1. Institute of Health and Society, Newcastle University
2. School of Health and Social Care, Teesside University
3. Department of Health Economics, University of Birmingham

A paper presented to the 2008 Joint meeting of the UK Health Economics Study Group (HESG) and Nordic HESG in Aberdeen, Scotland, 27-29 August 2008

Corresponding Author:

Dr. Fiona Clement

Institute of Health and Society

Newcastle University

21 Claremont Place

Newcastle Upon Tyne

NE2 4AA

Email: f.m.shrive@ncl.ac.uk

Word Count: 3772 words, 2 Boxes

Introduction

Increasingly, service design and configuration are being acknowledged as an important modifiable factor in achieving better health outcomes. The way a particular service is organized, including operating hours, location, team design, and care pathways, impacts the outcomes of the service.

In parallel, there is increasing demand for the economic evaluation of health care programmes before their potential adoption. As such, economic tools, such as decision analysis, are increasingly being used to evaluate various health care programmes. However, the methodological and practical issues of applying decision analysis tools to complex health system changes have not been examined.

Recently, the National Institute for Health Research (NIHR) programme grant competition focused specifically five priority areas including stroke (1). The aim of this competition was to fund research programmes developed to provide evidence to improve health outcomes in England through promotion of health, prevention of ill health, and optimal disease management (including safety and quality). One of the key components of this research competition was to integrate decision-makers and clinicians into the research programme. The challenge for the researchers is to focus the very broad national research objective into an operational, feasible research question of interest to decision-makers who operate at a local level. This creates tension between a national agency interested in funding research of national and international relevance and a need to produce policy-relevant research within a local context. One of the teams funded was a multidisciplinary research and decision-maker team in the North-East of England. The programme of research, entitled “Development and Evaluation of Hyperactue Services for Patients with Acute Stroke" (DASH), examines the organization of pre-hospital and acute stroke care (see Box 1 for details).

We aim to document, using an illustrative example of stroke services in North-East England, the difficulties of applying a decision analysis framework to the economic evaluation of service configuration. First, we provide a brief and simple overview of decision analysis as a tool for cost-effectiveness to introduce readers to the basic goals and requirements of decision modeling. We then introduce service configuration and introduce our example. In the following sections we discuss four hurdles to applying decision analysis in service reconfiguration research; identification of appropriate comparator and alternatives; quantification of outcomes; availability of data, and lastly, the impact of external factors. In each section, we outline what might be ideally required from a research perspective, even if taking a reasonably pragmatic view, before outlining our experience to date in the evaluation of hyper acute stroke service provision.

Decision analysis as a tool for cost-effectiveness

Decision analysis is a tool to aid the weighing of the costs against the benefits of a health care intervention (2). It provides a structured framework for comparing the alternative choices to each other. Decision analysis is a computer model simulation of what would happen if one alternative was chosen as opposed to another. It consists of three steps; 1) Identification of the current standard of care, 2) identification of feasible alternatives, and 3) obtaining data on relative efficacy of alternatives compared to the standard of care (2). Thus, the model is based on our current knowledge of clinical outcomes, costs and benefits. Our current standard of care provides the baseline to which all other alternatives are compared. In many cases, alternatives are compared in terms of cost per QALY gained in comparison to the current standard of care.

Service reconfiguration

Design and improvement of services require the coordination of a number of different subunits, with multiple effects across a number of services over long time spans. The particular service is one component of a much larger organization. Interaction between the service and the organization is evolving and heterogeneous. Service reconfiguration is crucially dependent on the context within which it is being implemented. Thus, heterogeneity of service provision exists both within and across organizational boundaries largely due to context and implementation.

Service reconfiguration can happen at a variety of levels. It compasses changes such as the implementation of a team pager shared among specialist physicians to major changes such as a hospital closure. The effects of these reconfigurations within the service are often understudied, if not unknown. Additionally, the impact of these changes will reverberate throughout the organization, although, again, the size of the ripples is for the most part unknown.

Stroke service configuration provides a rich example of the complexities of service reconfiguration. Research has shown that the two most effective interventions for improving stroke outcomes are the implementation of dedicated stroke units and treatment with a drug called thrombolysis among eligible patients (3). However, delivery of thrombolysis requires infrastructure to support its use. Specifically, the effects of thrombolysis are time-dependent with greater clinical benefit seen the earlier the drug is administered and a time limit for administration of 3 hours post symptom onset (4).

Thus, within a 3 hour time window, the patient must recognize they are experiencing a stroke, call emergency medical staff, arrive at the hospital, undergo assessment for clinical eligibility and finally be administered thrombolysis by a stroke specialist. Stroke services must be organized to achieve treatment within a quick timeframe. This includes components of the stroke service itself (i.e. expedited care pathways to assess eligibility), other components of the health care service (i.e. recognition of a stroke patient and expedited triage by the paramedics) and components of the broader context (i.e. education of the public about stroke symptom awareness). Thus, in order to increase treatment rates with thrombolysis, service reconfiguration within the organization is required at a variety of levels.

The modeling phase of the DASH project aims to identify the optimal in-hospital service configuration to achieve maximum thrombolysis treatment rates. Previous models calculated the cost per QALY of thrombolysis compared to standard care (no treatment), thus the cost and benefit of thrombolysis treatment is already established (3;5;6). Within this previous work, the important clinical and health outcomes have already been defined. Thus, to compare service configurations a model can be developed that focuses on the costs required to reconfigure a service to increase the treatment rate with each additional patient treated gaining an established benefit. Our model structure sought to compare the ability of different service configurations to achieve symptom onset to treatment times of less than 3 hours, the time frame required for thrombolysis administration (see Box 2 for more details).

Hurdles for decision analysis in service reconfiguration

In conducting our research, we have identified four main hurdles to the application of “traditional” decision analysis for economic evaluation. In each section we outline the approach used in decision analysis when applied in drug evaluation then highlight the challenges of using this approach in the context of service configuration.

1. Identification of appropriate comparator and alternatives

Decision analysis requires identification of the current standard of care. All alternatives should be compared to care currently offered (2). In decision analysis comparing different drugs, the current standard of care is often easily identifiable; what drug at what dose are patients currently treated with? In the context of service reconfiguration the current standard is less clearly defined. Current service configuration varies geographically. Often there is no accepted standard service configuration nationally or internationally. Service configurations tend to be highly context specific and heterogeneous with large variation from hospital to hospital. The appropriate baseline comparator is deeply embedded within the context of the local health care system infrastructure. This is often influenced by the political, social and geographic elements of the environment within which health care operates.

The heterogeneity of service configuration makes identification and categorization of the appropriate alternatives equally difficult. Identification of manageable, realistic changes varies with context. The service reconfiguration alternatives feasible in one health care system may be inappropriate and unachievable in another health care context.

Returning to the example of stroke service where there are large variations both within country and internationally, the standard of care equally varies (7). Some geographic areas have no established stroke service, others have established models of patient transfer to one centralized stroke service, while yet others have developed telemedicine models of care delivery. Indeed, even within the fairly small geographic area of North East England there are hospitals without a stroke service, hospitals operating a modified telemedicine model and yet another acting as a centralized hub with patients redirected away from their local hospital to the centralized stroke unit. Across hospitals there are large variations in care pathways for patients with acute stroke and marked difference in the skills and competencies of those delivering the service. Choosing the relevant baseline comparator from the currently established service configurations is challenging and in the end, may need to reflect the local standard of care limiting the generalisability of any model.

Identifying feasible alternatives also may require a local lens. In areas where population dispersion rules out any service configuration requiring patient transport, the model need not include alternatives involving patient transfer. The more relevant comparator may be service configurations incorporating telemedicine models. Again, the model becomes context specific limiting the generalisability and comparability of the resulting cost-effectiveness information.

2. Quantifying outcomes

In decision analysis patients are moved between clinical states based on the likelihood (probability) of those states. In drug evaluation, the likelihood of different clinical states in the patient population currently receiving standard care is used and then the relative risk of the outcome with the new drug is applied to the observed probabilities. In the context of service reconfiguration, identifying and quantifying the outcomes is challenging. The overall effectiveness of a particular service reconfiguration may be more than the sum of the intervention parts. To return to our example of thrombolysis, the effectiveness of the intervention is likely greater than simply the improved health outcome of those patients receiving thrombolysis. Other stroke patients may benefit from increased awareness of stroke symptoms among medical professionals, more streamlined care pathways, dedicated stoke units, and other service improvements required to optimally operate a thrombolysis service.

In addition to the improved health outcomes experienced by patients, there may be important untraditional benefits due to the service reconfiguration. This may include things like improved learning opportunities for staff, improved job satisfaction, improved communication between staff members within and across departments and a variety of other more recently acknowledged factors that impact health outcomes. Quantifying these outcomes, particularly within a QALY framework, is challenging.

Even more challenging is identifying and quantifying the knock-on effects of any service reconfiguration. Specific health service programmes are one element of a complex healthcare system that includes a variety of components; people, organizations and service. Changes to one element of the complex system are likely to affect other elements of the system. However, the result of the initial change is generally unknown. Thus, the real impact on health, within and across the particular service, is difficult to quantify.

3. Availability of applicable data

An assumption inherent to decision analysis modeling is that the resulting differences in cost and outcomes between treatment alternatives are due to the treatment choice itself. To ensure the differences are due to treatment choice rather than a confounding factor, the model ideally should use data from high quality randomized controlled trials (RCT) comparing the alternative treatment choices to the current standard of care. Often in the case of new drugs, a RCT is completed comparing the current standard of care to a novel drug which instigates the economic evaluation. Thus, efficacy evidence is often available to inform the decision analysis model.

In service reconfiguration there is limited availability of good-quality, applicable data. Efficacy estimates, resulting from RCTs, of various service reconfigurations in comparison to the current configuration are simply not available. Not only is there a scarcity of RCT data, but also there is a lack of high quality data using any other well-established research design. Without RCT data, input values are limited to results from before and after studies, observational data and evaluation data. These types of data have inherent bias and thus the naïve application of a decision model may not accurately reflect the benefit or harms attributable to the service configuration.

Again, using our stroke service reconfiguration project as an example, we undertook a systematic review to identify published studies reporting outcomes of service reconfigurations. Of the 5069 citations screened, 213 articles were included in the full text screen. Of those, 69 studies reported some type of data regarding thrombolysis use in their service setting (8). However, none of the studies are RCTs and all are limited to post-reconfiguration data reporting. In addition, no standardized reporting was used across studies with some studies reporting the number of patients thrombolysed without reporting the total eligible population such that no risk or rate of thrombolysis could be calculated. With both the pre-reconfiguration and post-reconfiguration outcomes missing in the existing published literature, the decision analysis model must be put together using a “piecemeal” approach using the best data available and acknowledge the potential bias in the model as a result of this approach.

4. External factors

The aspects that are valued within service configuration changes are broader than health. A variety of political, contextual and societal forces are involved in service configuration changes. Decision analysis struggles to capture fully the effects of these other factors.

In addition, these conditions can change quickly and can have significant ramifications for the organization at both a macro and micro level. External events, such as economic recession or a sudden government windfall, may impact on health care funding. The resulting funding changes will trickle down through all aspects of the system. The impact of this single event can alter the organization over long periods of time.

This hurdle is not limited to the context of service reconfiguration. Changes within the healthcare system are bound by the context within which they are being implemented. One could argue that evidence producing tools should not be preoccupied with these external factors which impact adoption or implementation of change. This is a factor influencing the decision independent of evidence and should be considered as such.

Alternative approaches to inform the decision

If decision analysis modeling does not offer the optimal approach, what other approaches are available to inform service reconfiguration decisions? Researchers could push to have a stronger evidence base developed before undertaking modeling exercises. The danger with this approach is the double-edged sword of decision analysis; the decision is being made now and if cost-effectiveness is going to be included in the decision making process, the information must be produced now. Thus, researchers must proceed with the best data they have available at the moment. However, the process may be iterative and the model may be revisited as new evidence is generated.

It is important to distinguish between the lack of **published** data and the lack of data. Through the DASH experience and its partnership with decision-makers, many unpublished non-academic data sources have come to light. In fact, there is a wealth of data within hospitals that have never been used for academic research. This may be no different to many other decision analysis based evaluations, however, if research with decision-makers is to become common place, researchers may have to work more within the context of such participants and their context is not limited to nor defined by academic publications.

Several of the hurdles for decision analysis limit the generalisability of the model. However, if we adopt a perspective of “local information to inform local decisions” then generalisability becomes irrelevant. Service reconfiguration must happen within the local context and perhaps the most useful outcome decision analysis can offer is a structured framework that can be adapted to be relevant in other contexts. Perhaps this is the most constructive deliverable that projects such as DASH can offer; a local solution relevant to local decision-makers and a tool that can be adapted to other local situations.

Indeed there are process gains from the structured framework that a decision analysis model offers. The process itself breaks the macro decision into a series of sequential smaller decisions and forces consideration of the relative costs and benefits of each option. This in and of itself may be a useful step in the decision making process.

Conclusion

As the demand for economic evaluations of non-traditional modifiable factors in health, such as service configuration, increases it is important to consider the methodological weakness of research tools. We have identified four main methodological challenges to the use of a decision analysis framework to assess service configurations.

The DASH research team has dealt with these challenges by developing a model with a highly North-east England lens. The baseline service configuration is defined by the current service configurations within the region (no stroke service); the alternative service configurations included are limited to the feasible reconfigurations within the region (establishing a local stroke service, a telemedicine model and a patient transfer model). Since each of these service configurations are already operational within the region, the data needed to inform the model is all available from local non-academic databases. The advantage of the DASH approach is two-fold. First, the research will produce context relevant results. The decision analysis model is produced within and thus directly relevant to the North-east England stroke service. Second, the need for local data to inform the model will strengthen existing, as well as establish new, relationships between the academic and NHS; a key element to producing research that will have a meaningful impact of the direction of local health care. In adopting the local lens approach, the research team has traded off generalisability, portability and the national relevance of our findings.

The broad application of decision analysis must be carefully weighed against the methods strengths and weaknesses. However, there are many strengths offered by the structured framework provided by a decision analytic approach. Nonetheless, for HESG some possible questions for debate might be:

1. Do we have an issue with decision analysis that is unique to service reconfiguration?
2. Have other evaluations coped with this issues, and, if so how?
3. To what extent do the “untraditional benefits” identified matter? Is it a concern that they do not fit within a QALY framework?
4. How can any “knock-on” effects of reconfiguration be dealt with?
5. Given that an advantage of decision analysis is the structure it gives to thinking through a problem in the absence of data, how big a problem is the lack of rigourous data to inform the model?
6. Have we made the correct assessment of how to deal with the external factors?

BOX 1

A multidisciplinary team composed of health economists, epidemiologists, qualitative researchers, clinicians, senior hospital managers and managers of ambulance services in North East England was funded in a recent round of NIHR programme grants for applied research. The topic of the research is ‘Development and evaluation of hyperacute services for patients with acute stroke’ (DASH). The main research objective is to identify the optimal organization of pre-hospital and acute stroke care and to improve outcomes for stroke patients by enhancing the evidence base for future health services interventions. The research plan is multipronged with 4 major phases of work; 1. to improve patient, public and professional awareness of stroke symptoms and treatments, 2. to determine the views of patients and carers of hyperacute stroke treatment, 3. to model and implement service reconfiguration options to achieve optimal hyperacute stroke treatment, and 4. to determine the feasibility of paramedic-delivered hyperacute stroke treatments. Decision analysis is the main research tool for phase 3. This phase addresses the issue of cost-effectiveness of in-hospital stroke service configurations. This involves development of feasible service delivery models, economic modeling of the costs and benefits of each model and lastly, working with policy-makers to allow them to understand what shifting from their current service to an alternative would involve and what relative benefits they could expect.

BOX 2

Five service configurations are included in the model; 1. no stroke service, 2. 9:00-5:00 Monday-Friday stroke service provided by the local hospital, 3. 24-hour stroke service provided by the local hospital, 4. 24-hour stroke service provided at the local hospital by an off-site stroke team (telemedicine), and 5. 24-hour patient redirection to a centralized stroke unit. These five service configurations were selected among the many possible permutations because they are either in use in North East England or seen as a feasible alternative to the current service configuration. Each alternative differs by the cost of running the service and the achievable or observed thrombolysis treatment rate based on published data. Although no stroke service is considered the baseline, each alternative is compared sequentially to all other service configurations. This allows for decision-makers to place their own service within the context of the model and identify the associated costs and potential benefit from a service reconfiguration.

Reference List

(1) National Institute for Health Research. Best research for best health: Implementation plan 6.5. http://www.nihr.ac.uk/programmes_research_programmes.aspx, accessed 29/07/08 .

(2) Drummond MF, O'Brien B, Stoddart GL, Torrance GW. Methods for the Economic Evaluation of Health Care Programmes. 2 ed. 1997. Oxford, UK, Oxford University Press.

(3) Sandercock P, Berge E, Denis M, Forbes J, Hand P, Kwan J, et al. A systematic review of the effectiveness, cost-effectiveness and barriers to implementation of thrombolytic and neuroprotective therapy for acute ischemic stroke in the NHS. Health Technol Assess 6[26]. 2002.

(4) Saver JL, Yafeh B. Confirmation of tPA Treatment Effect by Baseline Severity-Adjusted End Point Reanalysis of the NINDS-tPA Stroke Trials. Stroke 38, 414-416. 2007.

(5) Fagan SC, Morgenstern LB, et al for the NINDS trial investigators. Cost-effectiveness of tissue plasminogen activator for acute ischemic stroke. Neurology 50, 883-890. 1998.

(6) Sinclair SE, Frighetto L, Loewen PS, Sunderji R, Teal P, Fagan S, et al. Cost-Utility Analysis of Tissue Plasminogen Activator Therapy for Acute Ischaemic Stroke: A Canadian Healthcare Perspective. Pharmacoeconomics 19[9], 927-936. 2001.

(7) Roger Boyle, National Director of Heart Disease and Stroke DoH. Mending hearts and brains:Clinical case for change. www.dh.gov.uk/publications, accessed 29/07/08 .

(8) Price C, Clement FC, Gray J, Ford G, for the DASH investigators. A systematic review of service configurations for thrombolysis delivery in hyperacute stroke. Expert Review in Neurotherapeutics , In press. 2008.