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EDITORIAL

ASSESSMENT OF A TECHNOLOGICAL PACKAGE USING A PREDICTIVE TOOL

Bryan Jennett
University of Glasgow

Assessment should apply to established as well as to emerging technologies, to procedures as well as to machines, and to packages of tools and for clinical problems. Packages of tools include intensive care units and transplant surgery. Clinical problems requiring a variety of high technology responses include coronary artery disease, renal failure, and cancer in various locations. In practice few technologies prove never to be useful while none are always useful. The aim of assessment is to discover for each technology the sliding scale of value in terms of benefits and burdens for various types of patients and so to define the limits of appropriate use (5). But assessment itself is a costly business that may be regarded as a waste of resources unless it is carried out economically and it subsequently has an influence on the provision and use of that particular technology.

No one method of assessment is appropriate in all circumstances. Different problems are posed by the evaluation of drugs, of diagnostic equipment, of surgery, and of technological packages. Yet there are some commentators for whom the only acceptable evidence is a randomized controlled trial (RCT). Like some of those whom they wish to put on trial for promoting technologies that have been inadequately evaluated they are themselves uncritical champions for their own product—the RCT. Randomization gives no guarantee that evaluation will be well designed, well executed, or well analyzed. Moreover, many of the merits ascribed to randomization are no more than the characteristics of competent data collection (which is prospective, with strict protocols and entry criteria, and with assiduous follow-up). What is more validly claimed for randomization is that it tends to balance between treatment groups prognostic factors that are both known and unknown. This makes it likely that comparisons are made between patients whose outcomes were expected to be similar if they had been treated in the same way.

For several conditions there are now available prognostic models derived from banks of rigorously collected data from large numbers of patients. Such models can be applied prospectively to patients from different centers in order to predict

Table 1. Predicting Death after Severe Head Injury

	Expected deaths	*Actual deaths*
Patients in San Francisco predictions based on Glasgow cases	241.7	242
Patients in Glasgow predictions based on San Francisco cases	379.6	380

Source: Ref. 9.

outcome. If, when this is done, the actual outcomes correspond closely to those predicted, it can be assumed that no important unknown prognostic factors have been omitted from the model (9). It is then possible to make comparisons between patients who are well balanced for these prognostic factors.

This method has proved useful in identifying the value of different packages of intensive care for severe head injury as well as of separate components within such packages (6;7). Prospective data collection began in Glasgow fifteen years ago and information is now available for 2,500 patients from five centers in three countries, all survivors being followed for at least six months. Scales of severity of brain damage in the early stages and of outcome after six months were devised and subjected to tests of interobserver variation. Protocols included data on changes in the patients' conditions during the first week as well as details about investigations and treatment.

Wide variations were found between centers in the methods of management used. These differences were utilized to compare the influence of certain aspects of management on outcome, using geographical rather than historical controls. Once the first few hundred patients had been collected it became clear that the outcome in all centers was similar even though each had used a different treatment regime. To identify the relative predictive power of a number of variables, their occurrence was related to the probability of death using logistic regression. Age and severity of brain damage were found to be closely related to outcome. A predictive model was evolved that was based on combinations of a small number of reliable and readily available features.

This model was then used to predict outcome in one center based on data from another center that had used diffferent treatment. There was a close correspondence between the number of actual deaths and the number that were predicted (see Table 1). This goodness of fit between the probability of death and the proportion dying makes it highly improbable that unknown variables are important in influencing outcome after severe head injury (9). When the outcome of patients treated with specific methods was predicted from similar patients not so treated there was again a close correspondence (see Table 2), indicating that these measures had not influenced outcome (2;7). A similar technique was subsequently used by Knaus to compare the influence on outcome of the different regimes of management used in general intensive care units in the United States and in France (8).

As computer storage of patient data becomes commonplace, the value of this method should become more widely recognized. Surgeons should particularly welcome this approach because it provides an opportunity to assess not only

Table 2. Outcome after Severe Head Injury: Stratified for Age, Coma, Intracranial Haematoma (1258 Patients in Three Countries)

	Number of deaths			
	Without this therapy		*With this therapy*	
Therapy	*Expected*	*Observed*	*Expected*	*Observed*
Steroids	232.4	232	193.6	194
Tracheostomy	320.2	319	106.8	108

Source: Refs. 2;7.

emerging procedures, but also the many operations that are part of current practice but have never been adequately evaluated. Contrary to the comments of some critics, surgeons have a good record for doing trials in spite of the much greater difficulties encountered when testing drugs (3). However, the recently published international trial of transcranial bypass for patients at risk from stroke highlighted the cost and timescale that random trials can entail. This trial cost $9m and took eight years to complete; it showed eighteen years after this operation had been introduced that it was of no value for any of several subsets of the 1,377 patients studied (10). It was then revealed that some surgeons had withheld large numbers of eligible patients from the trial, leading to doubts being expressed about the validity of its conclusions (1;11). If a bank of data about the prognosis of patients at risk from stroke had been available this new surgical procedure could have been evaluated more rapidly and less expensively, and without having to put surgeons in a situation where they felt unable to cooperate fully in evaluation. The fiasco in Britain of surgeons and randomizers confronting each other over the lithotripter might have been avoided if urologists had begun to assemble a data bank of patients with renal stones who were being treated by conventional means as soon as they heard the initial reports about lithotripsy (4).

Reliable prognostic indicators are essential for good decision making in medicine. The commonest excuse for the inappropriate use of life-extending high technology is prognostic uncertainty. But prognosis is also important for assessment and for discovering when the use of a technology is appropriate. For a therapeutic technology to be shown as effective, it must produce outcomes that are better than those predicted for similar patients not exposed to that particular technology. Prognostic models can also be useful in identifying subsets of patients for whom a controlled trial may be appropriate and this can considerably reduce the number of patients required for a statistically valid result.

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