Procedures for evaluating innovatory proposals

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The constant advance of medical technology fuels ever increasing expectations of the health service by the public. During much of the history of the NHS there has been steady real growth in health funding, and consequently it has been possible to assimilate innovation as it occurred. In recent years, however, strict financial limits have been imposed. This financial discipline must lead to choices being made between options for development of services on the basis of their likely benefit to the population and their value for money. Hitherto it has been difficult for those concerned in decision making to control innovation, particularly the so called "creeping developments" initiated usually by clinicians on the basis of change and advance in practice. These lead to unobserved incremental changes in a service that then takes on an unanticipated form and may generate unplanned costs. Implementation of the recommendations of the NHS review[1] with its emphasis on obtaining good services, value for money, and greater cost accountability by clinicians should lead to changes in health management and clinical practice that may inject a greater degree of rationality into health planning. Such will be the case only if appropriate planning systems are available to both managers and clinicians.

We believe that choices should be made explicitly and, as far as possible, rationally for only in this way may the balance of funded innovation remain in the best interests of the community. We recognise that the process of selection between options can entail comparisons of unlike things—for example, extending expensive treatments for lung cancer or providing better care facilities for the mentally handicapped. The choice between proposals in different specialties must necessarily entail personal ideologies and competing value systems, hence it would be naive to offer some supposedly rational calculus of choice. An acknowledgement that some important aspects of decision making do not possess an easily encapsulated rationality and therefore cannot be reduced to an algorithm, however, does not mean that other key elements may not be tackled on agreed lines with criteria likely to be acceptable to most ideological stances. At the least the political process, in which competing ideologies and pressure groups operate, can be made more consonant with the interests of society by explicating the factors in the decision making process. The element of decision making where there is likely to be consensus is the criterion of worth for options—that is, whether a treatment is of proved efficacy; whether it is cost effective; and whether it is likely to be acceptable to patients.

Proposals

Two major flaws exist in the machinery for consideration of possible innovations. Firstly, there is rarely a structure that allows parallel as distinct from sequential consideration of suggestions that must compete for a limited sum of money. Currently proposals are usually funded as they arise so that once resources dry up a new idea, however good, may be seriously delayed or abandoned. Secondly, no accepted format exists for submitting an innovative proposal that allows its proper evaluation.

These difficulties can be dealt with by adapting the model used for the assessment of applications to organisations that fund research. Here a tranche of proposals is usually considered at the same time after a given closing date. Once those that are obviously unsatisfactory have been discarded the remainder will be graded both on technical merit by using an agreed scale and on external considerations such as their perceived importance. This process often entails critical appraisal by an outside reviewer or referee and may require redrafting and resubmission of the application perhaps with the help of the grant giving body. A similar process can and should be used for the assessment and analysis of innovatory proposals. Once the proposal has received the favourable advice and recommendation of a disinterested reviewer it goes for consideration for funding, and the competing proposals; the overall strategy of the region, district, or unit; and the available budget are taken into consideration. The reviewer's task will be time consuming and call on several skills and perhaps resources. The same is true for generating proposals in a satisfactory form, and initial money must be available to enable bids for innovation to be initiated.

The second flaw—the absence of a satisfactory frame or checklist—can be tackled in the same way. Most applications for funding must be submitted in a standard form and explicitly answer questions on methods and costs. A similar process should be applied to requests for innovation. Some form of checklist or template is required. We suggest one based on the need to have a clear description of the proposal; goals and expected outcomes that encompass not only biological indices (for example, enhanced life expectancy) but also quality of life, acceptability to patients, and social impact; and an indication of possible hazards. Further sections should cover capital and running costs; existing evidence for benefit derived from the work of the proposer or from elsewhere; time scale; and the methods by which the project is to be studied so that it can be either expanded or, given certain information, cut back or abandoned (see appendix for outline of checklist).

The criteria and headings we present are not new, but they are rarely applied systematically in decision making. We suggest that the checklist approach gains particular power when it is policy that all cases for innovation follow a format that requires acknowledgement of the checklist and a serious attempt to answer all the questions. In a given context certain items may be inapplicable but even so the proponents of innovation should advance argument for exemption. Thus the checklist can not only help in structuring decision making but also serve as a guide to the proponents about the kind of evidence they must assemble to have

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a fair chance of success. Cases for innovation should be eligible for discussion at policy making levels (such as board meetings of health authority management) only after the checklist has been satisfactorily completed. In consequence, propositions whose sole foundation is anecdotal evidence, appeals to "authority" or "clinical freedom," the charismatic personality of the initiator, and the games of academic bluff or managerial self advancement would more easily be exposed and challenged.

There remains the problem of that form of creeping innovation that is based on change in treatment that has been pioneered by using "soft" money. Such developments can too readily reach a point where they cannot—and from the clinical point of view sometimes should not—be stopped even though the initial support has run out. Obviously it is a managerial task to be aware of such possibilities and to modulate and incorporate inevitable innovatory change into the system we have described.

Discussion

Our model for the assessment of innovations and the relationships of clinicians, management, and advisory professionals may seem somewhat idealised. We believe that a move toward some minimum standard for the quality of the wholly rational element of the evaluation of innovation would, however, encourage more productive cooperation. The role of the reviewer would certainly be new in the health service but it could serve to sharpen everyone's thought processes. This might be a role predominantly though not exclusively for public health physicians as they are the only group currently to be found in all health districts who have some formal training in epidemiology, statistics, and management. They would, however, need help from those with the relevant technical knowledge in other specialties. They might act as reviewers for neighbouring health authorities rather than their own and be advisers to the proponents of innovation within their own authorities.

Our proposals offer the prospect of improving an important aspect of planning in the health service to the benefit of patients, health care professionals, managers, and policy makers. They would take the pressure off policy makers to respond hastily and perhaps inappropriately to orchestrated demands from powerful internal and external interest groups; all proposals no matter what their source would be subject to the same rigorous scrutiny and the grounds for implementation or rejection could be made explicit. Furthermore they could be fed back to those who want to innovate much as referee's comments on grant applications and papers submitted to journals are (sometimes) fed back to applicants and authors. Like all innovations our suggestions should be subject to debate, a pilot study, and evaluation. Ideally they should be tested in various units, districts, and regions throughout the country.

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Appendix

TEMPLATE FOR CHECKLIST

(1) Describe clearly and concisely the proposal, indicating how its development differs from and is likely to enhance current practice (what does it do, to whom, how, why, etc).

(2) What, in detail, is the proposal intended to achieve?

(*a*) beneficiaries, group number, etc

(*b*) demand—initial (numbers, cost); final (numbers, cost, containment of demand?)

(*c*) benefits (projected outcome)—quantification; monitoring, assessment (change in life expectancy, quality of life, morbidity, etc)

(*d*) problems/hazards.

(3) What, in detail, are the projected costs of the proposal?

(*a*) initial capital costs

(*b*) staffing implication

(*c*) anticipated marginal costs invoked on expansion

(*d*) if demand exceeds this present proposal what is the upper limit at which increased capital and staffing costs would occur?

(*e*) will other developments be lost or deferred or altered if this proposal is adopted?

(*f*) will any savings accrue?

(4) What is the evidence that the proposal will provide benefit?

(*a*) preliminary formal trial—was it randomised? Were the following aspects adequate? (design, size, conduct, analysis, interpretation); Was cost effectiveness or cost benefit assessed? Were the criteria of cost, benefit, and effectiveness appropriate to the presently envisaged realisation of the service? Do the findings of the trial justify the assertions under (2) above and can they be extrapolated to the kind of populations for whom this service is intended? If there have been several separate trials, are the findings reproducible and consistent? If not, how do the results affect the answers given under (2) above?

(*b*) experience of implementation elsewhere—Has the proposed innovation been practised elsewhere? Is there previously published or otherwise accessible work? What has been learned from this experience? What changes, if any, would be recommended for the present proposal? Was the demand for this practice contained? What costs were involved? Were the benefits consistent with those suggested under (2) above?

(*c*) If the answers to (*a*) and (*b*) are negative or equivocal—Should a formal study or trial be considered? Where should the study be done? How would such a study be funded? Should a decision on implementation be deferred until other people's findings are known?

(5) Are other developments, such as alternative methods of treatment or care, likely to overtake the current proposal? Should these be considered before any implementation?

(6) If the proposal is adopted how is it to be evaluated for

(*a*) Outcome

(*b*) Cost effectiveness

(*c*) Performance (relating to targets for continuation of expenditure).

If the service is being introduced on a pilot basis have criteria been agreed for the circumstances in which ultimately the service might be withdrawn?

1 Secretaries of State for Health, Wales, Northern Ireland, and Scotland. *Working for Patients*. London: HMSO, 1989. (Cmnd 555.)

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Correction

Sample size and power for comparing two or more treatment effects

In this paper by Mr Simon J Day and Dr David F Graham there is an authors' error in example 2, which describes using the nomogram for determining sample size requirements for two by two factorial experiments. The description for the main effects is correct but the error lies in the description for the interaction. Because the size of the interaction effect is determined by a contrast between four means and not two its variance is twice that of the difference between the overall treatment means. So after specifying the size of the clinically important interaction, proceed with using the nomogram as described for comparing two groups but note that the sample size indicated should now be *doubled* and this is the sample size required in each of the four subgroups.