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Setting Standards

by

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and abridged from

A method for developing standards for measuring service organisation in the National Health Service

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1.1 Accountability in health services

Unlike its fellow professions in the church and law, medicine has been transformed by technology. The scope for diagnosis and treatment has grown faster than our ability to evaluate or pay for it and with this growth has come a new generation of technical specialists. A largely pastoral art has been converted, at great cost, into an interventive science.

The rapidly developing potential for health care has focused attention on issues which were previously relatively trivial, such as who should be responsible for health services and, especially, who should pay for them. Social reformers in various countries have eventually accepted that access, at least, to health services should be a right rather than a privilege but it has become apparent that universal provision is no guarantee of universal health. Indeed increasing investment in health services may not only provide diminishing returns, but excessive intervention may be positively harmful.

This realisation has provided good reason to reconsider the traditional role of curative services and to explore the possibilities of preventive medicine. Thus health planners have increasingly sought to involve the consumer in taking responsibility not only for individual health but also for the planning and control of services for the population. Also, the public is becoming increasingly aware that, whether contributed through insurance premia or through direct taxation, it is ultimately the public's money that pays for any health system. These factors, together with a generally raised level of public information and education, have led to the emergence of the consumer as an influential critic.

Similarly, health service employees both as individuals and as organised unions have taken a keener interest in the way services are run. This is not only because they are offered more participation by modern managers but also because they recognise that the application of health service

resources ultimately determines the levels of manning and of remuneration.

The initial emphasis of this new wave of thinking on health services concerned the most immediate and measurable problem of the cost of provision. Little consideration had been given to the quality of services until it became clear that the demand for resources was infinite and that some limits had to be placed on how the available money was spent. The prospect of arbitrary economic cuts was a powerful stimulus to planners and providers (including the clinical professions) to attempt to set a value on the quality of services in order to determine priorities for limited resources.

Thus, since the early 1970s, developed nations have been experimenting with a variety of approaches to measuring the cost and quality not only of individual clinical episodes but also of services as a whole. There is a worldwide trend towards increasing central funding in health care[45], and considerable pressure has been therefore applied by governments to ensure that both public and private providers of services are accountable for expenditure and for standards.

Paradoxically, this pressure has been greatest in the largely non-governmental health systems of Canada and the United States, where responsibilities for the provision and review of services are explicitly defined in relation to the federal, state, provincial and municipal legislatures.

For example, each private or voluntary hospital is required to have by-laws which are in keeping with state or provincial law, which are legally binding and which detail the mechanisms for ensuring that all services and personnel (including medical) are accountable to the incorporated board.

1.2 Control in the NHS

By contrast, national influence in the British National Health Service is mediated almost entirely by fiscal control rather than by legislation. Successive government policies have assumed that the answer to inefficient use of resources lies in macro-economic reform such as reorganisation of the structure rather than in microeconomic monitoring of effectiveness and efficiency of services as they are delivered to patients[46]. Such an approach is effective in controlling the budget of the NHS in global terms but it is largely unable to control the quality or quantity of services at local level[7]. In particular, this strict financial control leads to the paradox that doctors in the NHS have more autonomy than doctors in a free-market system. An open-ended system of payments such as in the United States breeds controls, but a closed budgetary system permits doctors to be left relatively free from external questioning of decisions[39]. Also, doctors have considerable management control by virtue of their direct responsibility for patients. This is also partly true of other clinical professions but, in the National Health Service, it was the doctor who was specifically assured 'freedom to pursue his professional methods in his own individual way, and not to be subject to outside clinical interference'[49]. Clinical freedom and jealously guarded local autonomy effectively limit the ability of the DHSS to influence rational control. Indeed there is .pa mounting evidence that health policy is to a large extent made at the periphery by those ostensibly responsible for implementing it[40]. This means that attempts by the DHSS to impose central expectations are unlikely to succeed unless the proposals appeal to the local service providers[53]. However, more recently by the introduction of clinical budgeting and accountability locally, and of a limited prescribing list nationally, the DHSS is beginning to exert more direct control.

But, quite apart from the special position of the clinical professions, it is still not clear whether the health service is directed from the DHSS at the centre, or by the health authorities at the periphery. Even the tight government control of inputs showed signs of weakening; the manipulation

of resources in terms of norms of provision was clear in the DHSS policy documents of 1976[18] and 1977[21] but was dropped from 'Care in Action' in 1981[15], reflecting a new policy of less directive intervention. Norms, argued Klein, are the language of economic growth and were no longer politically appropriate[40]. But at the same time as the DHSS was seeking to disengage itself from the NHS to promote greater local freedom and flexibility, Parliament and parts of Whitehall, including the Treasury were expressing concern over financial control and accountability in the NHS.

In particular, the House of Commons Social Services Committee criticised the DHSS in two reports (on perinatal mortality[69] and on public expenditure[68]) for its approach to policy-making and for its failure to ensure that authorities were complying with national priorities. Also, the Public Accounts Committee was concerned about cost variations in services between regions and the Auditor General criticised manpower control, hospital catering and the use of hospital buildings[55].

Thus, at about the same time as the Area tier of the NHS hierarchy was being dismantled in order to provide more local autonomy, the Secretary of State was obliged to reaffirm budgetary control by introducing annual reviews of regional expenditure as a means of strengthening accountability[14]. The next step was to require regions to set up an evaluative process which is more effective at implementing operational policies than the planning cycle had been in the past. Pilot schemes had already been established with a view to examining process and outcome of services in four regions[15] and, it was thought at the time, the success or failure of these schemes could have helped to determine the future role of the regions, and the relationship of the DHSS to district health authorities.

The DHSS "blue book" dealt at length with the preparation and presentation of strategic and operational plans[20]; it mentioned the importance of monitoring whether the plan remained relevant to the objectives and whether performance was in line with the plan. However it gave no guidance on how

the process or results were to be evaluated, and health authorities were left to resolve that problem locally. Subsequent planning circulars which superseded the "blue book" gave detailed instruction in the preparation of plans, option appraisal, manpower targets and performance indicators. But still few authorities have succeeded in closing the feedback loop other than in financial terms. The planning cycle has therefore had little effect yet on the quality of process or outcome.

1.3 Evaluation of Health Services

Definitions

The variety of motives and methods for evaluating health services has produced a "confusion of vocabulary which fits the confusion of ideas"[31]. Each specialism brings its own jargon to be misunderstood.

For the purpose of this thesis the words "standards" and "services" need especially to be clarified.

Standards

Chambers defines standards as, "a basis for measurement, an established or accepted model; a definite level of excellence"[29]. This emphasises three different characteristics - of measuring, of usualness and of degree of goodness; a standard is therefore a tool of measurement rather than the object of it. Crow also points out that the commonness implied by "standards" refers to its agreement "by common consent" rather than its universal achievement[11].

In the context of implementing standards in health services, statements fulfilling the above definition may be referred to as "guidelines." There is little real difference in nature between guidelines and standards, but there is a significant administrative and moral problem of declaring standards which cannot be enforced. Hence the series produced by the

Canadian federal government[23] is called "guidelines for standards" and emphasises the importance of adoption or adaptation by local agencies (that is, by those who really can enforce them).

The World Health Organisation[34] defines a standard as, "an explicit statement of conditions to be fulfilled" in qualification of a stated general objective or policy. This is taken further in the PSRO Program Manual[13] which calls standards, "professionally developed expressions of the range of acceptable variation from a norm or criterion." This introduces the idea of consent (from the professions) but implies that a "standard" is a tolerable deviation from a previously established value judgement. Donabedian commends the vocabulary of Slee[26], who cites a standard as "the desired achievable performance of value with regard to a given parameter"[66]. This also introduces the need for a standard to be what is achieveable rather than what is actually observed.

Vuori describes a standard as "the value on a criterion that indicates the boundary between acceptable and unacceptable quality"[74]. This has the merit of relating standards to quality but is less easily applied in practice than "an explicit statement defining an attainable level of quality" which is the working definition used in this thesis.

Health Services

This phrase is used to describe the system of organisation and management as compared with the individual elements of care which take place within it. In terms of quality assessment, the two concepts are complementary in that the effectiveness of a clinical regime or programme is an amalgam of efficacy and of the environment or system in which it is applied. But methods appropriate for developing standards for evaluation of the one may not be applicable to the other.

Practical problems

The concept of evaluation and review in the NHS is widely supported, for a variety of reasons, by politicians and planners at all levels and, to a limited extent, by clinicians also. For them the question is not whether it should be done, but how it should be done.

Evaluation, like any form of measurement, requires the subject under study to be observed and then compared with some yardstick or expectations. The comparison of observed with expected results is relatively simple when applied to numbers, as in service budgeting or in manpower planning, but such evaluation is limited to resource inputs.

Numerical measures of process and outcome which are available, such as operating or mortality rates, usually give only a proximate index of the service provided. Most aspects of the NHS which have so far defied evaluation are complex systems and have no such indices.

1.4 The social context of standards

Common to a variety of social institutions is the concept of standards as a means of regulating society in a particular way. In addition to this, professions concerned with the law, the church and medicine also regulate themselves according to (generally implicit) standards. But the organisation of the environment within which they work is less clearly regulated.

British law is derived from two main sources: judicial decision based on precedent and custom (common law), and codified legislation drafted and ratified (at least in theory) by representatives of the electorate (statute law). These implicit and explicit standards are monitored by a number of agencies (most formally by the police) and disputes and infringements are evaluated by an independent judiciary. By contrast, the origins of

biblical codes of practice and laws are even less clear and are open to interpretation between the extremes of fundamentalists and liberals.

More recently, international scientific standards have provided absolute measures for physical units and industrial processes. This approach was promoted by increasing mechanisation and world trade but its authority and origins are due more to technology than to any publicly accountable body.

These legitimate but widely differing concepts lead to general questions on the nature of standards in health services. In particular they ask about their origins, their application and their essential characteristics.

1.5 Determinants of standards

The reasons why standards are formulated in health services are closely related to their intended function but have been summarised by Vuori as motivated by ethics, safety or economy[74].

The sapiential authority with which the clinical professions influence the health system and the individual patient emphasises the obligation to set and maintain standards on behalf of the consumers (and even administrators) of services since the latter do not themselves have the technical expertise to do so. The overt measurement of quality in health services should not be seen merely as a mechanism for controlling inappropriate professional practice in the entrepreneurial environment of North America. European countries, and Britain in particular, have the relative advantages of smallness and a greater degree of central control of service planning and professional education but a nationalised health system also has disadvantages. In particular, the lack of market competition between service providers removes some of the incentive to seek and to demonstrate the provision of good health care. Professional ethical concern has led to prescriptive standards, for example in medical post-graduate training, but there are few standards relating to subsequent professional practice or, more generally, to the adequacy of the health care system.

The adage ascribed to Florence Nightingale, "primum non nocere" summarises the second motivation of health service standards - that no harm should be done. Standards visibly directed at safety of patients and staff are readily comprehended and accepted. The penalty for failure to define or apply such standards may be unnecessary loss of life - indeed, many current standards and codes of practice have been devised specifically to prevent the recurrence of some such disaster. For these reasons not only have standards of safety become an accepted tradition, but so have statutory mechanisms for their reinforcement, tantamount to inspectorates. Such regulations include those relative to building, fire safety, health and safety of employees and, more specific to clinical care, protection from ionising radiation[17] and dangerous pathogens[16].

Until early in the twentieth century, available health technology was neither expensive, nor particularly effective. The need to discriminate either clinically or economically was therefore limited but, as art turned to science and as the potential for health spending was seen to become infinite, governments, planners and paying agencies sought to regulate the resources entering the system. In response, professional bodies also developed their own standards of provision; for example, the Royal College of Nursing (RCN)[58] and the College of Occupational Therapists[10] issued formal guidelines, and the Faculty of Anaesthetists[41] and the Royal College of Psychiatrists[54] commissioned and then used discomfiting reports to argue for minimum standards of staff and equipment.

1.6 Objectives of standards

The practical applications of standards in health service management have been ascribed to three goals: the practitioners' concern for improving quality; the managers' concern for regulation and control; and the planners' concern for policy development. Although each of these may involve an element of research, Crow emphasised the difference between standards of (nursing) care and standards for research[11]. The one is concerned with effectiveness, the other with efficacy.

The prime objective of quality assurance programmes is to improve the quality of service and this requires objective measures of actual performance in terms of standards established for expected performance. Thus, the hospital accreditation systems of North America and Australia identified their major responsibility in establishing standards in response to "an identifiable need to measure or enhance the quality of a particular aspect of care or service"[35,8,2]. The stronger the professional involvement in the development of standards, the greater is the (perhaps paradoxical) tendency to emphasise resources, rather than process or outcome. This may be at odds with cost-effectiveness but WHO argued that the model medical care programmes of Sweden and Finland aim to increase the quality of care within existing resources[78]. Similarly, in the UK, even non-governmental reports have been increasingly mindful of the scope for improving services at little or no extra cost. In 1975 the joint report of the British Geriatric Society and the Royal College of Nursing acknowledged that, "much can be achieved by a review of practice and by a change of approach"[4]. More recently, this has been echoed by similarly professional bodies in relation to mental handicap[52] and maternity services[44].

Gremy[31] described modern health systems as behaving, in the words of the poet Rimbaud, like a drunken ship deprived of any control and navigation system. Managerial, rather than professional control tends to emphasise accountability in terms of quantity rather than quality. Nevertheless it is acknowledged that "mutually acceptable standards of performance (are) essential before the word 'monitoring' could be said to have any meaning"[37]. Specifically, in order to monitor, for example, nursing care we must first define the role and responsibility of nurses[75,59].

Unlike the health professionals whose principal concern is with scientific and technical quality in the care of individual patients, the planners need standards for making decisions on the efficiency and adequacy of the overall health system. Vuori[74] drew a distinction between the performance of the system and performance within the system.

1.7 Practical requirements

The literature reveals little consensus on the preferred characteristics of standards in health services. This is due to confusion between the way in which a yardstick is used, and the yardstick itself. Also, desiderata for a qualitative standard cannot be as rigorous as those for a numerical measure. However, a combination of viewpoints suggests certain requirements.

In order to be consistent, standards need to be written in terms of tangible elements. The American Joint Commission on the Accreditation of Hospitals (JCAH) has stated that compliance with them must be observable and measurable[35].

Standards need to be relevant to a valid overall goal or policy[26,80]. More specifically, Vuori emphasised the need to provide some predictive value based on established evidence, for example, that a good outcome results from adherence to the standard.

Clinicians in particular are concerned lest standards stifle innovation and perpetuate mediocrity. Standards must be constructed so as to be applicable in a variety of circumstances and locations, and they must be adaptable with time[74,35].

In order to achieve any degree of compliance (especially voluntarily), standards need not only to be reasonable but also to be seen to be reasonable. In saying this, Vuori quoted the need to conform with "generally accepted notions of high quality care"; but he did not refer to the problems of obtaining that sort of consensus, especially between different professional groups.

The experience of the JCAH has shown that idealistic standards provoke less effort towards compliance than more moderate ones which have been demonstrated in practice.

The problem orientated approach of the JCAH to their development ensures that standards arise in response to a demonstrated need. "Standards" which are universally accepted and implemented have no practical value, but detract from those which are not.

1.8 Approaches to standards

This section reviews some elements of health services which have been or may be the subject of standards, and some characteristics of the standards themselves.

Subject

Theoretically, any aspect of a health service may be evaluated and therefore be the subject of some standards. In practice, however, these have fallen into a spectrum ranging from broad policy formulation at national level to details of clinical practice at the level of individual patients. The World Health Organisation (WHO) summarised options for health programme evaluation as major programmes (such as child health), individual services (such as ambulance transport) and institutions (such as health centres or training schools[80]). These may be further developed with reference to planning, organisation and operation[23] - in keeping with the broad divisions of the functions of management.

A workshop organised by the European office of WHO made a more specific catalogue of existing "guidelines" - by which were implied, "recommendations made explicit by central or local authorities or by associations of health care professionals"[79]. The particular concern of that list was long-term care but it served as an example of many other aspects of health services for which standards already existed. At the more general end of the spectrum these included systems of health service planning, systems of medical education and licensing of professionals, accreditation of hospitals and other facilities and the commissioning of research. More specific and local subjects included arrangements for

consumer participation, cost-containment measures and health care practice. With exception of the latter, these elements were concerned primarily with the organisation of services rather than with what they achieved. The difference in emphasis is itself the subject of considerable debate.

Focus

With minor modifications appropriate to individual subjects, the model of health services comprising structure (the resources applied), process (the application of resources) and the outcome (the results achieved) has been widely used in their evaluation. The advantages and disadvantages of these approaches have been extensively reviewed in relation to the measurement of clinical care[74,27,47,64,67,48], but are not totally applicable to the development of standards for management of programmes and services. The former refers to performance of the provider and the latter to the performance of the system[76,63].

Structure

In the past standards relating to structure have tended to be generated by governmental agencies rather than by professional groups; they were used mostly as a tool for planning and fiscal control[78]. Klein has pointed out that the Guillebaud Committee, conducting in 1956 one of the first evaluations of the NHS, made no attempt at measuring output but concentrated entirely on resource consumption[40]. Subsequently, "norms of provision" became a hallmark of successive policy documents from the DHSS[21,18] and, although they were noticeably absent from Care in Action[15], the well-established RAWP formula[19] continued to allocate money with no particular regard for how it was actually spent. More recently, the Short Report on maternity services[70] recommended that "core standards" be set up for the provision (but not use) of obstetric staff and equipment.

Such measures have a bureaucratic appeal in that they are numerical, available and relate directly to the principal control mechanism of the

NHS, resource allocation. Moreover, they provide a certain comfort to service planners seeking to navigate between the Scyllan demands of clinicians for more resources and the Charybdic annual review of accountability. But they are not clearly relevant to the aims of the service (accepting that these are something to do with health); indeed Klein has argued that unless they are in some way related to outcome, their application becomes an exercise in economy, rather than efficiency[40]. In addition to this moral objection, Klein has also pointed out that norms of provision are the language of an expanding economy inasmuch as they encourage the concept that better services equate to more spending. Nor is the use of such norms appealing to clinicians; the Royal College of Nursing argued that they were not conducive to the concept of individual responsibility for standards, nor were they appropriate in the face of widely varying circumstances locally[58]. However, the College also pointed out that, although professional standards should concentrate on process and outcome, they must also take account of structure even though that structure is often beyond the control of those professionals.

Process

Except when they are set up with the express purpose of developing norms of provision, process is the language of the recommendations of professional working parties. Many of these reports are intended to reconcile the viewpoints and practices of different disciplines or specialties within them; examples include the Standing Medical Advisory Committee's report on antenatal care[44], the report on the organisation of the in-patient's day[37], and the Cogwheel reports on medical advisory structure[30]. The Royal Colleges and faculties have also alluded to standards of hospitals acceptable for the recognition of training posts, but these were largely implicit.

The relative paucity of explicit process standards in Britain (especially in acute services) contrasts with their relative prevalence elsewhere. In North America the independent accreditation bodies have developed them for

hospital and related services[35,8,2], the Canadian federal government has sponsored standards for a variety of acute and long term services, such as special care units[23] and in America, the professionally-led National Institute of Health has held a succession of consensus development conferences to define "good practice" in a number of activities. Outside North America professional, governmental and joint organisations such as the Australian Council on Hospital Standards[2], the Swedish Institute for Planning and Rationalisation of the Health Services[78], the Catalan Department of Spain[9] and the Dutch National Association for Quality Assurance in Hospitals[56], have also made explicit statements of good administrative and clinical practice.

Instinctively, clinicians prefer to judge their own work on process rather than structure since it seems nearer to their overall aims. But, as pointed out by the Royal Commission on the NHS, many of the procedures used by doctors, nurses and the remedial professions have never been tested for effectiveness[62]. In the absence of clearly demonstrated links between process and outcome, standards of process are therefore largely a matter of judgement by the professional providers "since they alone have the kind of experiential knowledge required in the management of uncertainty"[38]. But since this is true of professionals in all democratic countries it is necessary to look for some other reason for the British unwillingness to develop process criteria, such as lack of competitiveness in the NHS, preference for letting sleeping dogs lie or stout defence of clinical freedom.

Quite apart from the problems of obtaining professional consensus on standards of process, much criticism has been aimed at the wasteful use of resources which may be encouraged by "laundry lists" of procedures which a clinician may be expected to perform for a given condition[25]. However, this is less true for standards of process in health service management since organisational procedures are generally less expensive (and dangerous) than clinical ones.

Outcome

Standards of outcome (both of clinical care and of service management) have tended to be relative rather than absolute: good things (such as health and survival) should be maximised; bad things (such as death, infections, pressure sores and caries) should be minimised. But it is often difficult to determine to what extent any outcome can be attributed to specific treatment for a specific patient, let alone to a health service for a homogenous population. Furthermore criteria for success, such as five year survival in cancer treatment, may not be shared by the professional provider, the patient, the family and the health service generally.

A variety of efforts (amounting as Klein put it, to "a considerable academic industry"[38]) have attempted to develop a health index which could measure value added by health services to a given community[57,43,77]. More approaches have been developed for measuring individual clinical outcomes for specific conditions but these are generally too complex or costly to be readily applied to total populations.

The most recent academic industry has been the search for performance indicators as a numerical means of monitoring health service management[78,36,73]. These have concentrated on a few readily measurable proxies for health (such as mortality) and compliance with central policies, many of which are themselves merely norms of input or process.

Thus, theoretically ideal standards of outcome have found only limited application in health service management.

1.9 Factors which have affected the development of standards

The effectiveness of "standards" (in terms of compliance) depends largely upon who developed them, for what purpose and with what ultimate sanction. Although in practice they become interwoven (such as by one source using another one's sanction) standards may be seen to emerge from professional

associations, consumer pressure, legislation and DHSS and NHS directives.

Professional groups

Standards developed by professional groups have been motivated either by ethical concern for health services generally, or by concern for the defence or development of the specialty itself. The latter variety is sponsored by a single specialty, concentrates on norms of provision and is offered to members as a lever for obtaining resources locally. Examples include standards for occupational therapy[10] and for neurology[60]. Unless these standards have been adopted elsewhere, their impact is no greater than the sum of the influence of the individual members of a specialty.

Standards developed in conjunction with another professional group (such as the British Geriatric Society and Royal College of Nursing, on geriatric care[4]) have concentrated more on process, and on making existing resources work better. They were therefore more likely to be endorsed by health service policy-makers and planners and to be approved by other professional groups not initially involved.

Consumers

Consumer pressure is concerned more with the accessibility and humanity of the health service than with its scientific and technical quality. Despite the statutory presence of community health councils in each district, popular television programmes and special interest groups have proved the more effective watchdogs on a national scale. Consumer surveys have limited impact on the NHS, but independent organisations enjoy, for example, the freedom to espouse "national" standards and to monitor them more aggresively than would be politically decent for anyone else. The National Association for the Welfare of Children in Hospital thus pointed out to the medical public[71] how little progress had been made since the 1959 Platt report[51] in improving parental access and facilities in children's wards - despite specific endorsement by the DHSS (in a policy

memorandum to health authorities[22]) in 1971.

Legislation

Legislation of standards in health services is intended primarily to promote safety. Thus it is outcome-oriented, but its standards outline codes of practice and norms of provision. An inherent problem of legislating standards in a rapidly developing arena, such as health services, has been that technology and good practice may develop faster than the law can adapt to it. Details of implementation have thus been left to the interpretation of official inspectors, or to voluntary codes of practice developed by those working in the field.

Although the NHS was technically exempt from such general legislation, the Health and Safety of Work Act has, by the use of persuasion and legal sanction, focused effective attention, for example, on the safety of operating rooms[33]. Since it was drafted for the benefit of employees, rather than patients, the Act deserved particular credit for increasing awareness of infection hazards in hospitals.

DHSS/NHS

Ultimately, control of the NHS has been effected by resource allocation, but numerous circulars dealt also with process and management issues. This purpose may therefore be seen partly as cost-containment but also as a means of directing the development of priorities in the periphery. It is possible that the introduction of annual reviews and a more aggressive approach to operational and strategic planning will provide a more effective means of implementation of central policy in the future. (It might also offer a good vehicle for standards and recommendations developed independently of the DHSS). But DHSS and NHS policy has often failed to reach the grass-roots in the past, despite the sanctions theoretically available.

2.0 Minimal and optimal standards

In an ideal world with infinite resources, maximal standards of provision would be possible. In reality, diminishing returns on health service investment, combined with increasing costs, suggest there must exist an optimum achievable level[6,72]. Realistic options therefore lie between having no standards and having optimal standards.

The purpose of the most basic standards would be to prevent gross errors[73]; at this level, it may suffice merely to catalogue what should not occur, rather than to recommend what should[1]. This provides maximum safety with minimum restriction.

A more positive approach is to set standards for minimum achievement, without placing an upper limit (a "one-tailed" standard). The Short report on perinatal and neonatal mortality noted that five major reports in the previous ten years had made recommendations on the need to apply minimum standards to obstetric and neonatal care[70]. The Short report went on to urge the establishment of such standards for staffing, equipment and buildings (but made only brief mention of standards of practice). The Secretary of State at the time was not convinced of the need for minimum standards which might "interfere with the local assessment of priorities" and might even be regarded "as a maximum beyond which health authorities would not need to go". But two years later the DHSS was on the verge of producing a set of "core standards"[12]. At the same time the Maternity Services Advisory Committee was working on Maternity Care in Action, the first of a series of explicit guidelines on how clinicians and administrators might better organise ante-natal care[44].

To use optimimum standards is to seek perfection in that no section of a health service is likely to achieve all targets all the time, but it should achieve most targets most of the time. Optimum standards do not imply a state of perfection. However, with reference to clinical review, Sanazaro has pointed out that such standards have tended to encourage

disproportionate attention to elements not appropriate to an individual situation[65]. Moreover, Brook and others have shown that many situations, which proved adequate in terms of outcome, had appeared inadequate when compared with optimum criteria[5].

In brief, it would appear that for political and practical reasons, minimal standards of structure and process would appear to be a realistic goal.

2.1 Explicit and implicit standards

A critical characteristic which may differentiate standards is the extent to which they are directive and specific. As discussed earlier, unwillingness to codify implicit standards of practice is a national trait of health professions in Britain. The 200-page American accreditation manual detailing criteria for a "good" hospital began 60 years ago as guidelines for the recognition of training posts in surgery[35]. The nine pages of explicit standards for medical records contrast with the elegant simplicity of the statement of the Royal College of Surgeons of England that case records should be "accessible and of a high standard"[61].

Such guidance from the Royal College is not restrictive, it allows room for professional judgement based on values instilled during training. But it relies heavily on the assumption that the same values are shared by all observers, and it offers little help to the administrator who seeks to meet the implicit standard. For reasons of effectiveness and of efficiency the health service is increasingly subject to explicit evaluation for management and for planning. Such evaluation requires explicit standards.

Where these do exist in Britain, most refer either to resource inputs (norms of provision) or to good practice in the non-acute sector. Their advantage is that they require little expert interpretation and can thus disseminate positive ideas among the uninitiated. But if they prescribe not only a goal but also the route by which it is reached, they are likely to stifle innovation or restrict freedom. To avoid such ossification of

practice, standards may be expressed as desirable goals and merely offer some proven suggestions for reaching them. Every medical library contains volumes of explicit advice on diagnosis and treatment; some advice on non-clinical matters such as health service organisation should not be unacceptable in principle.

A further objection to explicit standards is that, if they are so much as acknowledged by funding agencies (in Britain, the DHSS), this implies an obligation to provide the necessary resources. This appeared to underlie the initial resistance of the DHSS to the Short report's recommendations on norms for equipment, staff and buildings[70]. But standards concerning process and good management have relatively little revenue consequence and would seem to provide considerable scope for improving services despite economic stringency or for providing existing services at lower cost[4,52,44].

A third problem is the difficulty of generating explicit standards which are sufficiently sensitive to local needs without being so indefinite as to serve no useful purpose. This was the reason given for the Health Advisory Service's refusal to provide general guidelines[3]. However, the publication of The Rising Tide has subsequently proven the concept to be feasible and valuable[32].

The arguments against explicit standards - restrictiveness, expense and formulation - are not insuperable. For the purpose of health service management (rather than individual clinical care) the advantages appear to outweigh the disadvantages.

2.2 Empirical and normative standards

Standards derive broadly from two sources: they may be normative (based on what "ought" to happen) or empirical (based on what actually does happen). Donald and Southern suggested that, "confusion springs from the considerable moral and professional imperatives associated with the golden

rule of providing the best of care for every individual"[28]. This has led to difficulty for members of the caring professions in discussing care on an empirical and objective basis - yet this is essential when considering the health system itself rather than the individual. In practice most standards owe something to both sources, but the concept provides a framework for discussion.

In their purest form, empirical standards are expressed numerically by comparing indicators for several similar activities and demonstrating their distribution. Outliers may deviate from the majority at either end of the range, suggesting a "two-tailed" standard. This technique has long been used in external quality control of laboratories and has also been applied by Yates using standard data derived in the NHS to show how individual hospitals and districts compare with their counterparts[81].

Qualitative data can also be collected by survey or systematic visiting to establish what is current practice and what effect it has. From this emerges a pattern equivalent to the numerical distributions referred to above. This method has for many years generated empirical guidance for the prevention of maternal mortality[50] and more recently for care of the elderly with psychiatric disorder[32] anaesthetic mortality[41] and the use of electro-convulsive therapy.

This technique is generally acceptable and credible to those working in the field, and it is relatively cheap to apply. Outliers tend to seek to discredit the accuracy of the statistic or the assessment of the observer (whose own values inevitably introduce an element of subjectivity). Moreover, the very choice of indicators implies a judgement of "goodness" which may be challenged. Among the target indicators in the strategic planning guidelines for the South Western Region (1983) was the percentage survival of births under 1000 grams, implying that this should be maximised in each district; but such a standard may not be morally, technically or economically sound.

The alternative to empiricism is to draw on "sources that legitimately set the standard of knowledge and practice"[27]. By picking the brains of experts, either directly or via authoritative publications, this method appeals to those who seek the highest standards and it is one of the principal sources of expert advice to the health service via working parties and standing committees.

Such committees usually consist of eminent people whose personal standards (and working situation) are above the average and who, when asked, will tend to propose standards higher still. Such standards may be too high to appeal to the average man surrounded by mediocrity.

Also, the political and professional complexion of the individuals and groups whose opinion will be sought will substantially determine the flavour of the emerging standards. One profession may seek to promote itself over another or there may be divisive disagreement on facts and values[27]. The Royal College of Nursing's Working Committee on Standards of Nursing Care[58] found difficulty in translating professional judgement into a framework for use by all nurses. Faced with a film of care being given on a ward, the committee readily agreed that the care was inadequate but was unable to define the criteria for such a judgement. Similar committees considering the organisation of health services in general have the same problems, but no recourse to films.

In the United States, the National Institute of Health[42] has organised a number of consensus development conferences to discuss scientific and technical issues with a view to advising clinicians and planners. So far the programme has not addressed organisational issues of the health services themselves, but to a large extent the Joint Commission on the Accreditation of Hospitals has. Their practice for the development and revision of standards is to combine the normative views of specialty organisations and individual experts with the empirical findings of the surveyors who visit the relevant institutions[35]. Government agencies responsible for regulation are then consulted on draft standards before

these are presented to the Board for ratification.

By contrast, in 1974 the Australian Council on Hospital Standards had very limited empirical experience and had to draft its original standards on the consensus of leading professional organisations[2]. Significantly, the accreditation guide made no reference to the fact that a large number of the standards were modelled closely on those of their Canadian counterparts; professional prejudice rarely smiles on imports from another country.

Similarly mindful of sensitivities, the Canadian federal Department of Health and Welfare produced a number of publications described as "guidelines for standards", emphasising that these are tentative and non-directive. Their problem has been to give constructive guidance without trespassing on the legitimate territory either of the professions or the provincial governments to whom responsibility for health care was originally mandated by the British North America Act. The federal-provincial advisory committee on health insurance requested a working party (mostly of civil servants) to obtain a consensus of "information, experience and opinion available in Canada and elsewhere"[23]. Six years later, in subsequent documents[24] this approach was reported to have been "generally acceptable to government, hospital authorities and the health professions".

In summary, the development of practical and acceptable standards involves a blend of normative wisdom with empirical observation supported by regular revision. In Britain, despite the theoretical advantages of a hierarchical health service, information about the variations, merits and demerits of management practice is surprisingly scarce. The purpose of the survey described in the next sections was to provide such information as a basis for developing empirical standards.

Practical application in health services

General comments

Although the general issues involved in setting standards are the same at national or at local level, the emphasis may vary on specifics such as the amount of research or consultation required. Also the appropriate approach to the proposed standards will depend heavily upon the focus; for practical purposes, standards fall into three types:

- service: standards for the organisation and management of a service or department, such as operational policies

- practice: standards for the performance of specific tasks by individuals, such as clinical guidelines

- practitioner: standards for individual competence in terms of knowledge, attitudes or skills, such as in professional training curricula.

Traditionally there has been a tendency to reject or avoid making such standards explicit on the grounds that they were either unnecessary or impossible to define. Increasing scrutiny by the public, professions, politicians and managers is now demonstrating the need to clarify and to reconcile the expectations of these groups if only in order to settle arguments about what we are trying to achieve. Such standards do not have to stifle innovation or to deny the logic of occasional exceptions - and clinical freedom, for example, can flourish within a wide range of acceptable practice; the challenge is to define that range.

A practical model

One characteristic of usable and acceptable standards is that they are responsive to practicalities, to local circumstances, and to new knowledge - in short, the first draft will be rewritten many times. Noone should be

deterred by the fear of not getting it right first time.

Explicit standards involve many ingredients which interact. The order in which they are added is less important than the fact that they are and that someone sets the ball rolling. A recipe might include:

- define the subject: perhaps a matter of concern in terms of quality, efficiency or merely gross variation compared with "common" practice elsewhere

- research the common wisdom: distill local opinion, expert literature and relevant legislation as to what "ought" to be common practice

- assess local practice: methodically compare these expectations with what actually happens

- reconcile the difference: the greater the discrepancy between observed and expected, the greater the need for explicit agreement either to reduce unrealistic expectations or to improve common practice. The resultant expectations provide guidelines for future standards.

- test the guidelines: canvass opinions and practice more widely (maybe in neighbouring districts, regionally or nationally)

- adopt the guidelines as standards: use whatever formal mechanisms are available and appropriate to endorse and disseminate the standards (such as the pharmacy committee or the health authority); incorporate them in handbooks or policy manuals

This cycle may take several months. Much of this time will be spent in demonstrating and mentally bridging the gap between what people expect and what actually happens; this negotiation between empirical and normative views is essential if standards are to be realistic and achievable.

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