Quality assurance and audit: lessons from North America

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Americans will always do the right thing, after experiencing all other alternatives. [Winston Churchill]

As British rheumatology moves inexorably towards increasing privatisation, knowledge of the history of quality assurance in America and Canada may be instructive. The American experience with quality assurance programmes prompted a Committee of the Institute of Medicine of the National Academy of Sciences to conclude that for Medicare recipients 'the current system to assess and ensure quality is in general not very effective and may have serious unintended consequences'. The Canadian system has similar roots but to date has avoided some of the excesses of the American system. This paper traces the growth and contrasts the system of quality assurance in America and Canada.

The concept of quality assurance in North America began in England. Dr Francis Clifton, a nineteenth century English doctor, promoted the basic principles of the process, as did Florence Nightingale in the 1860s. The most direct link occurred in 1910. Dr Ernest Codman, an eccentric Boston orthopaedic surgeon, explained his concept of end result to Dr Edward Martin and urged that every hospital should follow up every patient they treated long enough to determine whether or not the treatment was effective. If the treatment was not effective the hospital should then try to find out how to prevent similar failures in the future. Dr Martin thought this was one of the important reasons why an American College of Surgeons should be established: 'An American college would be a fine thing if it could be this instrument with which to introduce the end result idea into hospitals; in other words to standardize them on the basis of service to the individual patient, as demonstrated by available records.'

At the time most American hospitals were little more than boarding houses for poor and sick patients. Patients were not examined when they were admitted and because histories and diagnoses were seldom recorded, medical records were useless. Most hospitals also lacked the equipment for conducting proper evaluation of patients. No efforts were made to determine a doctor's competence and no one was held accountable for the quality of care rendered to patients.

From these modest beginnings the American College of Surgeons was born, and a system of standardising hospital equipment and hospital work was developed. By 1951 the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association joined with the American College of Surgeons to form the Joint Commission for Accreditation of Hospitals as an independent non-profit organisation. The commission first offered accreditation to hospitals in January 1953.

The Canadian Medical Association withdrew in 1959 to join the recently incorporated Canadian Council on Health Facilities Accreditation (CCHFA) along with the Canadian Hospital Association, the Canadian Long Term Care Association, the Canadian Nurses Association, and the Royal College of Physicians and Surgeons of Canada. Although the mission of the council was originally very close to that of its American cousin, it developed somewhat differently. The health care reform which took place in the early 1970s socialised medicine and eliminated for-profit hospitals and third party health care providers. The main concern of the council throughout the 1970s and early 1980s was to develop standards for accreditation and ensure compliance with these standards.

Until recently in Canada cost containment has not been the dominant issue as it has in the United States. The emphasis has been to develop standards to achieve individual patient's satisfaction rather than to contain costs. In Canada implementation of a quality assurance programme is necessary for accreditation by the CCHFA, and accreditation is voluntary. Teaching hospitals, however, must by contract be fully accredited.

Canadian quality assurance activities traditionally concentrate on structure and process. Only recently has outcome been used to measure the impact of health care services, and this interest in outcome is a direct consequence of increasing health care costs, which comprise 8-5% of the Canadian gross national product. The council has decided to develop a model to study the use of resources and the performance of staff, the so called 'CCHFA Outcomes Project', which may be a prelude to cost containment policies.

In the United States quality assurance activities increased in the 1960s because of government financing of health care and because good value was required. Early on, researchers were divided as to whether quality should be measured by evaluating the process by which care was delivered or by evaluating the outcome of the intervention. With time the outcome school of thought won, but it was also clear that the methods used to measure quality drove the results of the evaluation. By the 1980s, after nearly two decades of research, quality of care and quality assessment has
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Table 1  Quality of care

<table>
<thead>
<tr>
<th>Benefits</th>
<th>%</th>
<th>Problems</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Produce optimal improvement in a patient's health</td>
<td>41</td>
<td>Lack of doctors' support</td>
<td>48</td>
</tr>
<tr>
<td>Emphasize health promotion and prevention</td>
<td>32</td>
<td>Lack of understanding</td>
<td>22</td>
</tr>
<tr>
<td>Involves an informed patient in process and decision</td>
<td>20</td>
<td>Lack of time or personnel or non-MD support</td>
<td>67</td>
</tr>
<tr>
<td>Based on scientific medicine</td>
<td>8</td>
<td>Lack of indicators or criteria</td>
<td>6</td>
</tr>
<tr>
<td>Provided with sensitivity and concern</td>
<td>6</td>
<td>Lack of money</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 2  Perceptions of hospital quality assurance programmes.* The percentage of hospitals listing each response is shown

<table>
<thead>
<tr>
<th>Benefits</th>
<th>%</th>
<th>Problems</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programme started</td>
<td>41</td>
<td>Lack of doctors' support</td>
<td>48</td>
</tr>
<tr>
<td>Improved documentation for review of programme</td>
<td>32</td>
<td>Lack of understanding</td>
<td>22</td>
</tr>
<tr>
<td>Improved patient care</td>
<td>20</td>
<td>Lack of time or personnel or non-MD support</td>
<td>67</td>
</tr>
<tr>
<td>Accreditation by Joint Commission for Accreditation of Hospitals</td>
<td>8</td>
<td>Lack of indicators or criteria</td>
<td>6</td>
</tr>
<tr>
<td>Improved risk—management for potential litigation</td>
<td>6</td>
<td>Lack of money</td>
<td>2</td>
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*Data are taken from reference 7. The overall response rate was 48%.

become a permanent fixture in American hospital health care and is increasingly a protective means to ensure minimum standards at a time when there is intense pressure to stem the rising costs of health care, which currently consume over 11% of the United States gross national product. In both Canada and the United States any discussion of quality assurance has become inextricably tied to resource management and pits a basically humanistic enterprise (medicine) against the values of business (profits and losses).

Meaning of quality of care
Quality of care is a boundless phenomenon and very much in the eyes of the beholder with its meaning reflecting different perspectives and perhaps different goals. Quality for employers who pay for health care benefits is value for money spent; for hospitals that the patient be discharged before the DRG-defined length of stay has been exceeded; for patients that they are feeling and functioning better. The American Medical Association defines quality of care as that 'which consistently contributes to improvement or maintenance of quality and/or duration of life' (table 1).5 Donabedian, one of the chief theorists in this field, emphasised that quality of care is a resultant of the benefits of care minus the risks and costs, and that quality of care is that care which is perceived by the patient and not necessarily that perceived by society. However, 'the attributes that define quality are not clear at all'.6

Quality assurance programmes in the United States and Canada
The quality assurance effort in the United States is in fact a number of different programmes and since 1979 has become a growth industry. At the heart of it lie the quality assurance programmes which are mandated by Joint Commission for Accreditation of Hospitals for all hospitals. For many hospitals these have been ad hoc hospital chart audits. The reviews may be looking for evidence of inappropriate care or targeted specifically to a procedure or complication. An example of the former would be to review all inpatient admissions to ensure that some minimal standard of charting is achieved by noting whether allergies were ascertained, that a physical examination was done, etc. Because of the complexities of medical care, developing specific guidelines beyond that of simple documentation has been difficult. To augment this type of review audits have been set up to examine specific practices, such as the number of one unit blood transfusions, their indication, and outcome; transfers within the hospital to an intensive care unit; readmissions within a month, etc.

These are labour intensive studies. At the Brigham and Women's Hospital, a Harvard teaching hospital with 700 medical, surgical, and obstetric beds, the quality assurance programme requires three full time quality assurance analysts, a secretary, doctors from major departments, and full time staff from departments such as radiation therapy, obstetrics and gynaecology, the nursing department, and a variety of others. The tissue committee is a major activity of the department of pathology and surgery and is separately staffed. Precise cost accounting of the effort is not possible but is estimated to be between $300 000 and $500 000 a year for the time of the personnel participating. Closely allied to this quality assurance programme is the 'utilisation review system', which reviews the appropriateness of admissions, a vital concern for hospitals because if admissions are deemed inappropriate insurance carriers will not pay for the admission. The utilisation review activity of our hospital requires five and a half full time professionals and a secretary.

For comparison, in the Montreal General Hospital, Canada, a McGill teaching hospital with 700 medical and surgical beds, the quality assurance programme requires one full time coordinator, one full time secretary, and a part time nurse. The coordinator's role is to develop and re-evaluate the standards of quality, supervise the non-medical quality assurance management committee, and provide consultation with the doctors who are responsible for the medical arm of the programme. The services of a medical record librarian are also often required. A rough estimate of the personnel salaries in this programme is between $100 000 and $150 000 a year.

For the United States as a whole the expenditure for hospital quality assurance activities is unknown in 34% of hospitals, less than 1% of budget in 42% of hospitals, 1–2% of budget in 18%, and greater than 2% of budget in 6% of hospitals.7 Quality assurance professionals and regulatory bodies recommend 2% of the operating budget as the minimum budget allowance for these programmes. A quality assurance director is a full time position in half the hospitals, but that position is typically held by a doctor who spends two hours or less per week. A minority spend more than 20 hours a week. This staffing is only for hospital care, and to the extent that there are ambulatory services within a hospital a separate quality assurance programme exists for ambulatory medicine. In
America there is no organised quality assurance programme for the vast majority of doctors in private practice, though there are some efforts towards quality assurance in large health maintenance organisations.

Whether these programmes are able to identify inappropriate care and whether they are cost effective are still central issues. Table 2 provides a subjective appraisal of these programmes.\(^7\) McSherry reviewed the experience of a utilisation review done between 1972 and 1975 in a New York teaching hospital and concluded that the programme was costly and achieved little in improving quality.\(^8\)

Use of administrative data for quality assurance
Another area of growing activity has been the use of administrative or billing information to manage resources and to identify potential problems with quality. For instance, the comparative performance report programme of Medicare alerts doctors who have billed Medicare for an unusually large number of services or procedures in comparison with their peers. The programme was mandated by the Omnibus Budget Reconciliation Act of 1989, which required insurance carriers to monitor and profile doctors’ billing patterns within each area of locality. In Massachusetts, the billing patterns of doctors are compared with billing norms for all doctors in the same specialty and locality, the latter defined by the average number of billed per hundred beneficiaries treated plus two standard deviations. Each year doctors who exceed the billing norms are sent a report and explanatory letter. Although the goal of the programme at present is to inform the doctor as ‘a starting point from which to analyse billing and practice patterns’, some rheumatologists have been denied reimbursement for intra-articular injections or determinations of erythrocyte sedimentation rates because rheumatology is not recognised as a specialty in many states, and their practice patterns are compared with those of general internists.

For comparison, in the province of Quebec, Canada, where the only reimbursement for doctors’ fees is carried out through the government’s ‘Régie de l’Assurance Maladie du Québec’ (RAMQ), a ‘Service of Medical Profiles’ staffed with five full time doctors is in charge of reviewing the billing profiles of deviant doctors. Outliers are identified by the central statistical department, and lists are generated every three months based on seven pre-established criteria. The profiles are adjusted for geographical area and type of practice. Seventy to ninety per cent of aberrant profiles can be easily explained by case-mix or exceptions. The remaining 10–30% doctors will be sent a letter stating that they have been identified as deviant in their billing practice when compared with colleagues of a similar geographical area. The letter appeals to the doctor’s conscience but does not request any answer.

If the profile of the doctor does not change the individual is visited by a doctor of the Service of Medical Profiles to discuss the matter. If ‘excess billing’ is explained satisfactorily the case is closed. If no satisfactory explanations can be given, however, the case is referred to a revision committee, an independent organisation of five doctors and one lawyer. On the basis of their deliberations a deviant doctor may be required to reimburse the RAMQ with money collected through unjustified billing. This process identifies a few fraudulent doctors but does not have any real cost containment impact.

Qualitative evaluation of individual doctors is done by a different organisation: ‘The Quebec Medical Corporation’ (Corporation des Médecins du Québec). The corporation is the licensing body for doctors in Quebec and is in charge of assuring the quality of medical services delivered. It achieves this through the ‘professional inspection service’ (service de l’inspection professionelle). All doctors who practice outside hospitals—and thus are not evaluated yearly through the quality assurance programme of a hospital—are visited by one of the eight full time doctors working with the corporation. During the visit audits of charts will be performed. If the doctor’s services are found to be deficient the corporation will recommend an update course, revoke the doctor’s medical licence for six months, and require that the doctor obtain further training before reissuing the licence.

In the United States the National Data Bank of the Health Insurance Finance Administration provides details of mortality at specific hospitals, which have been reported in the lay press and have incensed doctors. The publication of such death rates without adjusting for case mix or the severity of the diseases cared for is misleading but has also led to detailed studies to explain the differences.\(^9\) No such system exists in Canada.

The Health Care Quality Improvement Act of 1986, which was amended by public law 100–177, mandated a National Practitioner Data Bank, which was set up with a five year, 15.9 million dollar contract. The data bank includes malpractice payments, actions taken by state medical and dental boards against a doctor or a dentist, professional review actions, including the restriction or denial of clinical privileges by a professional group or by professional societies. This system started in 1989, and little experience has been accumulated about the costs or effectiveness of the system. Canada has such data available but no similar system. Malpractice is far less of an issue for the health care system. Canadian doctors are only one fifth as likely to be sued as their American counterparts, but the number of claims per doctor is growing at a similar rate in both countries and in the United Kingdom.\(^10\)

The use of billing information in America on a variety of orthopaedic procedures when fed back to the surgeons in the area seemed to modify the surgical rates at least temporarily.\(^11\) Documenting small area variations in prostatectomy surgical rates and collecting area specific complication rates, and providing information on outcomes and complications in prostatectomy also affected subsequent surgical rates.\(^12\)
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Practice guidelines
Another area of activity is producing guidelines for various procedures, laboratory tests, and health services. The major payer of health care in the United States, the Health Insurance Finance Administration, has put pressure on the professional societies to articulate a variety of explicit guidelines to be used in audits to compare practice against stated guidelines.

There is much to question and little evidence that guidelines such as these will improve the result for the patient or reduce the costs of health care. For instance, in Manitoba the introduction of guidelines on caesarean sections, in fact, coincided with increased caesarean operation rates. The Committee on Rheumatologic Care, the practitioner interest group of the American College of Rheumatology, has produced guidelines on Lyme disease, use of non-steroidal anti-inflammatory drugs, quantitative bone measurement, rheumatology referral criteria for general doctors, among others.

Outcome management and outcome research
The current enthusiasm for outcome management and outcome research in America is a rekindling of an old idea and although giving sustenance to a new generation of clinical investigators and health services investigators, is too complicated and unwieldy a model, we believe, for general dissemination and unlikely to result in immediate benefits for patient care. A recent example, in which variation in infection rates after total knee replacement were studied, shows how difficult the study of why outcomes vary can be. Even with time and resources, to determine why one doctor is better than another is a tedious and time consuming process. Many in the United States who manage quality assurance programmes have returned to examining process. This paradigm called continuous improvement is the dissection of the process of care.

Unlike quality assurance, which is adversarial, outcome oriented alone, after the fact, and takes the basic approach of looking for bad apples for disciplinary action, continuous improvement is a collaborative, supportive system of looking for exceptions, at the details of process, and aimed at improving the steps by which the best results can be achieved.

In summary, 30 years of quality assurance programmes in America and Canada teach us much about its possibilities and its limitations. Although from similar historical roots, the style of quality assurance programmes in America and Canada differs considerably. America's system is pluralistic, administratively complex (and expensive!). In contrast, Canada's system is smaller in size, less expensive, and run by doctors. Both are increasingly preoccupied with the 'bottom line' and with linking quality to cost containment efforts. Although no one argues that health care can be improved and that a portion of the expenditure devoted to health care should be used to evaluate how we are doing, the costs of the system and the responsiveness of the system must be examined carefully—particularly as most Western societies grapple with reconciling rising patient and society demands for health care and the increased costs of providing those services. The pendulum should swing from outcome, which is often beyond our ability to manipulate, to examination of the process or the care rendered. Most illnesses of modern society, certainly chronic rheumatic diseases, require care not cure, and improved care or process is the legitimate and most realistic goal of what we all wish from medical care.

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