



COUNCIL FOR MEDICAL SCHEMES

CLINICAL GOVERNANCE MODULE

*Prepared by:
Prof. JV van der Merwe*

*Acknowledgement:
Kgomotso Mashaba*

TABLE OF CONTENTS	PAGE
1. WHAT IS GOVERNANCE	1
2. WHAT IS CLINICAL GOVERNANCE	2
3. CONTINUOUS QUALITY IMPROVEMENT HEALTHCARE PROGRAMMES	3
3.1 Quality of providers	7
3.1.1 Accreditation	
3.1.2 Peer Review	
3.2 Quality of healthcare	10
3.2.1 Quality of service	
3.2.2 Quality of care	
4. EVIDENCE-BASED MEDICINE	13
5. RISK MANAGEMENT	13
6. CLINICAL AUDIT	13
7. CLINICAL GUIDELINES	20
8. DISEASE MANAGEMENT	27
9. OUTCOMES	30
10. BEST PRACTICE	33
11. CONCLUSION	39
BIBLIOGRAPY	43

1. What is Governance?

According to the *Concise Oxford Dictionary (10th Edition)* – Governance is the action or manner of conducting the policy and affairs of (a state, organisation, or people).

Corporate Governance is concerned with holding the balance between economic and social goals and between individual and communal goals... the aim is to align as nearly as possible the interests of the individuals, corporations and society – Sir Cadbury.

The seven characteristics of good governance

- **Discipline** : Commitment to adhere to behaviour that is accepted to be correct and proper
- **Transparency** : How well management makes available accurate and timely information that is meaningful
- **Independence** : The extent to which mechanisms minimise or avoid conflict of interest
- **Accountability** : The presence of mechanisms to allow for accountability
- **Responsibility** : Behaviour that allows for corrective action and penalises mismanagement
- **Fairness** : Systems must balance the rights and interests of all groups
- **Social responsibility** : The awareness and response to social issues with an emphasis on ethical standards

Source: CLSA Emerging Markets in the King Report 2

The literature shows that boards have three main tasks. These tasks are developing a strategy, mission and policies; managing the setting; and, being accountable to the people that the board of trustees represents. Therefore a leadership role. This is achieved by the board being involved in policy formulation and strategic thinking, both long-term activities that are needed to ensure the success and sustainability of the organisation. Another part of boards' policy formulation role is to determine the organisational values i.e. defining what behaviours are acceptable or not to the organisation. Not only must the board define such values, but also ensure that reward and punishment is associated with compliance or non-compliance with these values. Conformance is achieved by the board ensuring accountability in terms of legislative requirements and member's wishes.

Defining standards of conduct for the management of an organisation and the accountabilities and responsibilities of its board and directors does not in itself guarantee improvements in quality and management or reductions in corporate risk. It is difficult (and in large organisations inappropriate) for individual directors to have direct personal control over every aspect of their organisation's activities. What is needed is to decouple control by defining the operational standards, policies and procedures to be followed throughout the organisation. Further more, to establish ways of

measuring activities that can reassure directors and the board that the organisation is working as intended, that any risks are properly identified and that action is being taken to reduce them.

The language of corporate governance and control assurance is foreign to most clinicians, many of whom may wish to deny that they work within an organisation at all, but rather imagine that the organisation exists to enable them to fulfil their vocation and is to be criticised if it fails to provide the resources for them to do so. Nevertheless, these concepts are important to a proper understanding of how clinical governance has come about. It may be viewed as the extension to clinical activity of well-established trends in corporate governance, which in turn reflect moves to define more transparently the responsibilities and accountabilities of organisations and those charged with running them.

The business philosophy and strategies of the medical scheme industry have been dominated by funding and administrative priorities. Health care needs to become part of centre stage. A strategic health care focus whereby the health care (“clinical”) strategy of the group must be aligned to the business (“financial”) strategy, since they are intertwined. The business and clinical principles should be in harmony.

2. What Is Clinical Governance?

Clinical Governance is a framework through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

But more than that, it is generally accepted that clinical governance demands a major shift in the values, culture and leadership, to place greater focus on the quality of clinical care and to make it easier to bring about improvement and change in clinical practice.

For clinical governance to be successful, all health organisations must demonstrate features such as:

- An open and participative culture in which education, research and the sharing of good practice are valued and expected;
- A commitment to quality that is shared by staff and managers, and supported by clearly identified local resources, both human and financial;
- A comprehensive programme of quality improvement systems (including clinical audit, supporting and applying evidence-based practice, implementing clinical standards and guideline, workforce planning and development);
- Regular board level discussions of all major quality issues for the organisation and strong leadership from the top;
- Clear policies aimed at managing risk;
- A tradition of active working with patients, users, carers and the public;
- An ethos of multi-disciplinary team working at all levels in the organisation;
- Good use of information to plan and assess progress.

Few would argue that the way an organisation is led, the extent to which staff are involved in planning its development, the willingness to embrace constructive criticism and new ideas, as well as a determination to break down barriers between professional groups, are hallmarks of an organisation in which quality is likely to thrive. Clinical governance ensures both the organisation as a whole and its individuals are accountable for the clinical quality of the service.

3. Continuous Quality Improvement Healthcare Programmes

Continuous quality improvement in healthcare is a positive comprehensive programme, which includes expert opinion and involves peers in evaluating quality healthcare, outcomes and ethical behaviour of professionals. It is educational and the objective is to develop the individual to strive towards the highest quality of healthcare, service, ethical behaviour and communication with patients.

The philosophy is that of a continuous process which means that it is operating at all times in the organisation. It is crucial to the success of this philosophy that it must involve all the people within the organisation, and thereby strengthens the relationships between the various departments and people within the organisation. In keeping with the philosophy of continued quality improvement, **meeting customer expectations and needs, is one of the most accurate definitions of quality.**

Figure 1 depicts four values applicable to healthcare, plotted on a diagram and analogous to a compass. The crossing of the axes is the lowest point and the extremities of the axes are the optimal points on the scale of values. This “health compass” represents an ideal healthcare system that is attempting to meet the needs of individuals and populations.

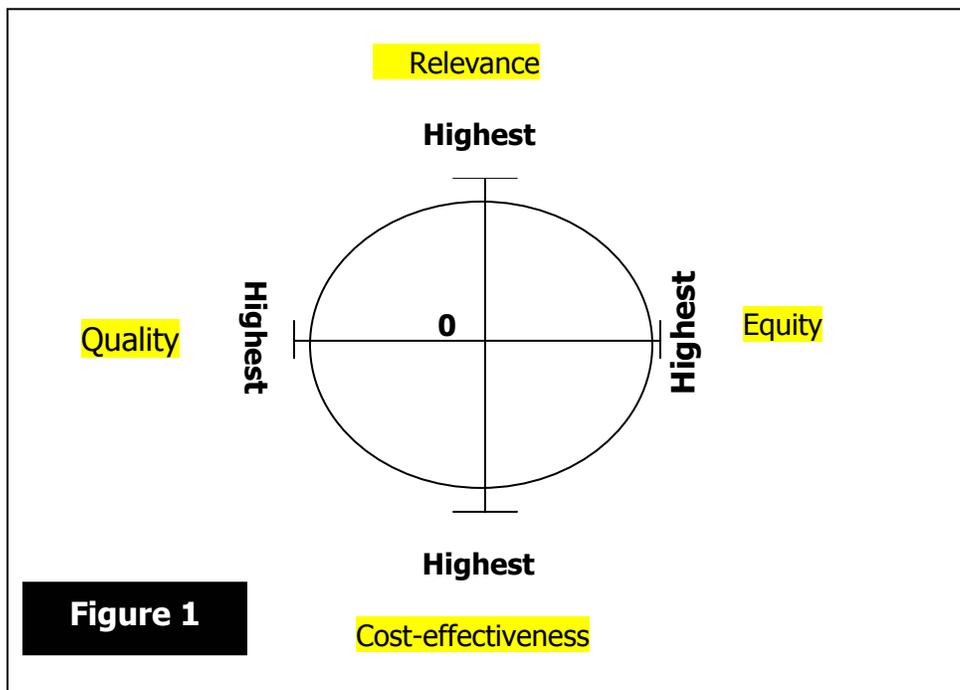
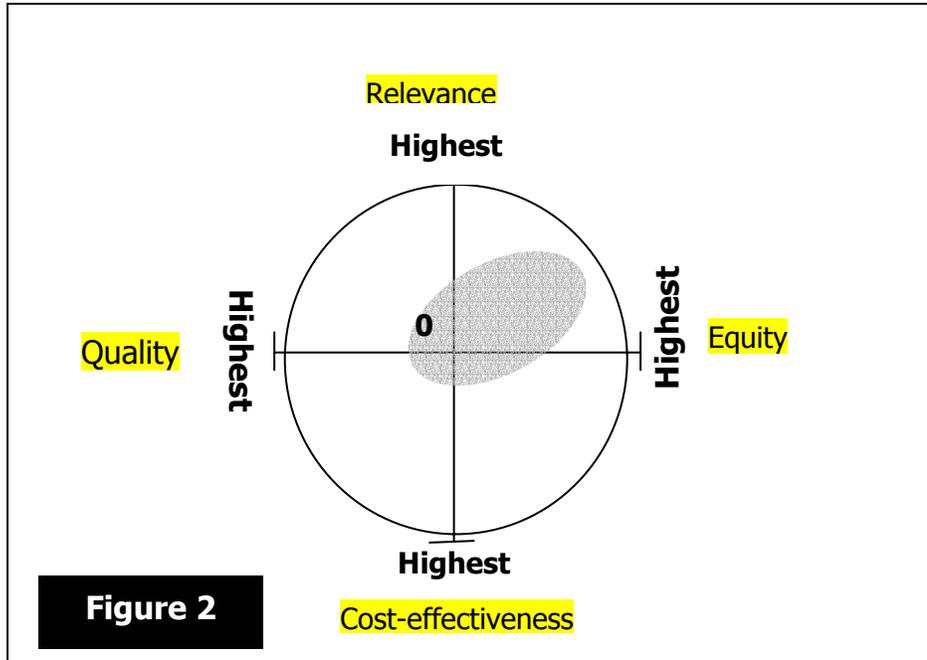
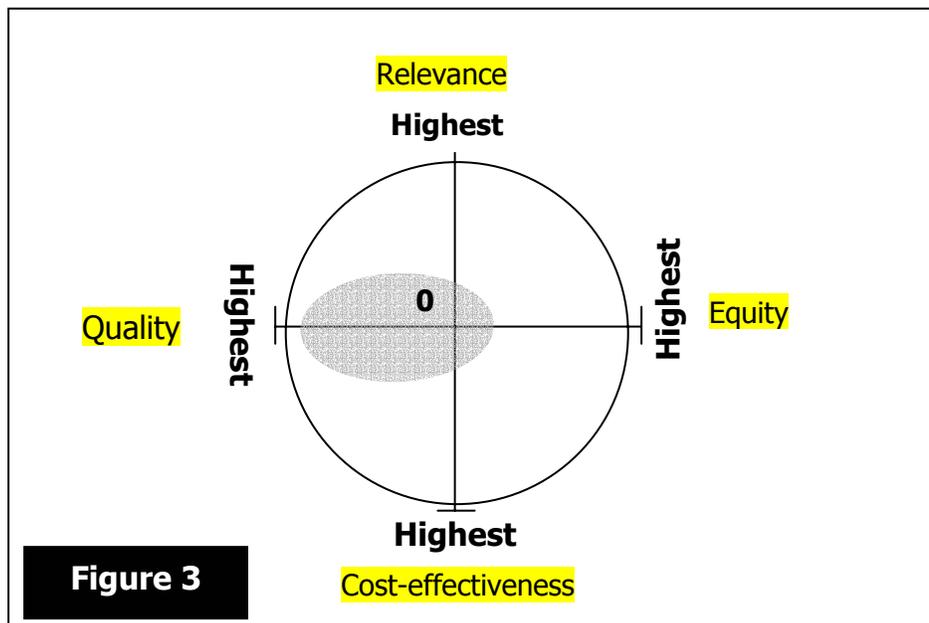


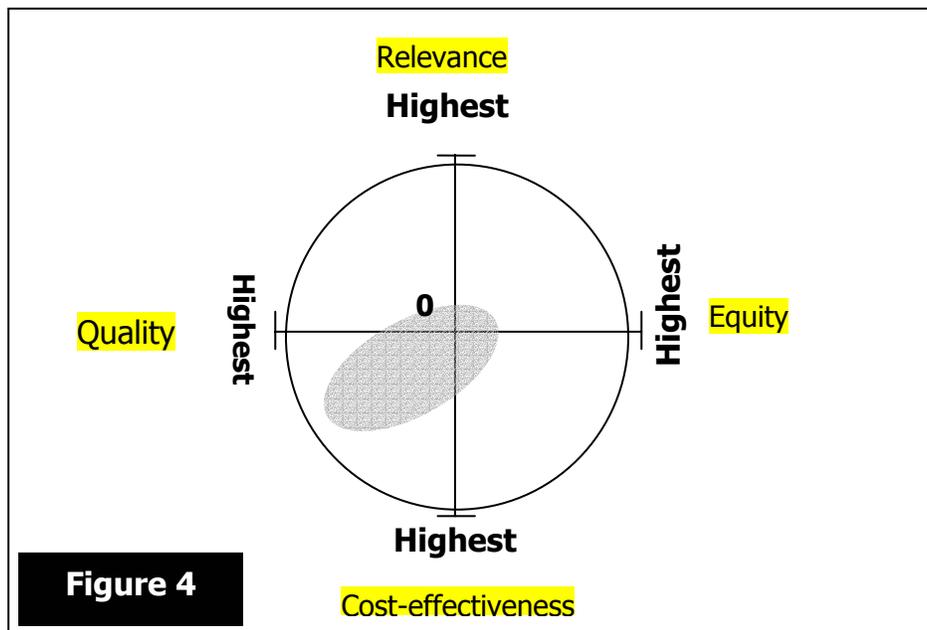
Figure 2 is a schematic representation of the healthcare scenario in the former communist countries and probably applies also to healthcare in third world countries.



The situation in the private sector of the USA, as well as to some extent in the same sector in South Africa is schematically represented in figure 3.



Managed healthcare focuses their healthcare programmes as depicted in Figure 4



Relevance in healthcare can be defined as the degree to which the most important problems are tackled first. Although priorities may be interpreted in different ways in different societies, primary attention should be given to those who suffer most to ailments that are most prevalent, and to conditions that can be addressed with locally available means. High quality care uses evidence-based data and appropriate technology to deliver comprehensive healthcare to individuals and populations, taking into account their social, cultural and consumer expectations.

The rise in healthcare costs is due to universally observed phenomena: specialisation in healthcare, which implies the use of costly procedures; increased access to health services due to socio-demographic changes; increased demand from individual consumers as expectations for better quality of life result from wider access to information. As these phenomena will persist and even be amplified in the future in any society, all health policy-makers and healthcare providers concerned with the health reform process must give urgent attention to the containment of cost without compromising effectiveness in healthcare. Cost-effective healthcare systems are those that have the greatest positive impact on the health of society while making the best use of its resources. Equity, which is central to a socially accountable healthcare system, means striving towards making high-quality healthcare available to all.

At the moment it is perceived that the private sector provides quality and is accessible but at a cost, whereas public facilities are considered to be cheaper, accessible and not necessarily of good quality. It is therefore alleged, that managed care can bring the best out of these, i.e. that accessible good quality of care at a reasonable cost can be provided.

Consequent upon that, it becomes important to select measures that will serve as markers of success. These require a clear understanding of the overall process and its output, as well as an understanding of how customers judge the quality of the healthcare service provided to them.

Principles:

- What is quality? Whose criteria do we use? Do we use the organisations? Managers? The health providers? Outside forces (politicians, funders, etc.?), or the customers?
- Quality assurance is oriented towards meeting the needs and expectations of the patient and the community;
- Quality assurance focuses on the way healthcare workers and managers do their work, their activities, and processes of healthcare delivery;
- Quality assurance uses data to analyse how healthcare providers are working and delivering health services;
- Quality assurance needs improved communication;
- Quality assurance encourages a multidisciplinary team approach to problem solving and quality improvement.

A quality assurance system defines the roles, responsibilities, processes and procedures within the organisation in order to ensure that every staff member is accountable and is involved in the quality assurance process.

Quality assurance can be defined as a programme that monitors and evaluates the quality and appropriateness of care and service provided and to pursue opportunities to continually improve the care and service.

3.1 Quality of Providers

Introduction

Healthcare in many countries is undergoing reform intended to limit costs while improving the management of quality of care. The reforms are superimposed upon prior policies that governments used to help citizens obtain acceptable quality of care at affordable costs. These policies derive from a series of different models for managing quality and cost of healthcare.

In the earliest era, the **professional model** predominated: patients chose a doctor usually by reputation, and paid the doctor themselves. Professionals make a commitment to help other people within a framework of professional values - that include competence, beneficence, benevolence, non-maleficence, concern for justice, promise keeping, truth telling, compassion, and respect for the person and dignity of others.

Gradually, because of rising costs, the **regulatory model** emerged: governments and insurers began paying for care. As new tests and treatments have emerged, and healthcare costs have risen alarmingly, governments and insurers became preoccupied with using regulation and budget controls primarily to curb costs of care.

In our present era, the **market model** has come into vogue as the means to deliver healthcare more efficiently: it borrows ideas and methods from the business world. While variants exist, in the fullest form of the market model, providers compete with one another for the rights to deliver certain healthcare benefits in return for capitated payments. Within the budgets set by capitation payments, providers are free to determine how best to organise the delivery of care. The payer is transformed into a “prudent purchaser”, demanding comparisons of cost and quality of care in order to choose the best value in healthcare from among competing providers. Providers in turn compete in reducing costs and improving quality in order to capture sufficient market share to survive. Incentives are created to modify behaviour of providers and/or to further the vision or business of a particular group. Furthermore, business principles, i.e. discounts for bulk buying or cash payments are introduced into a market not accustomed to it.

Within this market model we see a conflict between the idea of a profession as a calling associated with virtues, and that of a profession as a career with entrepreneurial emphasis. It can be said that in the modern world professionals are increasingly adopting the characteristics of modern industry - the term “medical industrial complex” has been coined. Economics and governance issues are increasingly intruding on decision-making in medicine. There is more concern about health service budgets and about laws and regulations pertaining to health and the healthcare professions. The focus is on material means and/or profit in the delivery of healthcare. Accountants and managers are becoming increasingly influential in making decisions that affect patients and healthcare professionals.

The Physician’s Unique Role

For the past hundred years, physicians have been the central force in defining the character of the healthcare system. Priorities in funding medical research and technology, characteristics of medical insurance and the reimbursement system have all developed, for better or worse, under the control of physicians. However, the highest degree of influence in the industry does not lie with physicians engaged in research, public policy or teaching. Instead, real influence lies with private practitioners, and is exerted through their day-to-day practice decisions. The physician in private practice plays a unique role in that he or she may wear a variety of hats at any given times.

The Physician's Unique Role

As agent for the patient, the physician determines for the patient what services are provided and by whom. Doctors develop a pattern of practice, referring their patients to providers with whom they have established relationships; physicians thereby control the flow of patients to other providers of medical services.

As purchaser of health services, the physician "buys" tests, procedures and supplies on the patient's behalf, yet has no financial responsibility for these purchasers.

As co-ordinator of the "healthcare team", the physician directs and co-ordinate activities of a number of "ancillary" or "allied health" providers, such as physiotherapists, pharmacists and nurses. Even though these workers are not employees of physicians, physicians exert substantial authority over them in issues related to patient care.

As provider of healthcare services, the doctor bills the patient for his or her own services, including professional services, hospital visits and lab tests performed in the office.

As investors in healthcare, some physicians maintain investments in providers of ancillary services. This situation creates an incentive for the physician/investor to refer patients to the provider in which he or she has a financial interest. As a result, there is the potential for treatment decisions to be based on economic self-interest, instead of the needs of the patient.

As franchise owners, physicians represent a special category. These doctors hold virtual "franchises" for the provision of certain services rendered in the hospital such as X-ray or laboratory. Inside the hospital, patients have no choice of laboratories or radiology groups; so hospital-based physicians have an effective monopoly on the services they offer.

The Cost Spiral

The cost of medical care continues to increase due to a complex series of interactions between the care delivery system and the system for reimbursement. These interactions take several forms - incentives for providers to perform greater numbers of procedures of greater complexity; cost shifting, in which losses incurred in an area of operations are compensated for by raising the rates in another; vulnerability to wage inflation; duplication of programmes and equipment through attempts to attract patients and physicians; a rise in the practice of defensive medicine in attempts to minimise exposure to lawsuits; and increases in the cost of malpractice insurance.

Together, these cost factors create a cost spiral as payers create new cost controls and providers find new ways to maximise reimbursement. The common factor in these interactions is that they stem from the continued predominance of the fee-for-service reimbursement system. This payment basis provides a "safety valve" in that providers can easily raise prices to revenue lost to cost-control measures.

3.1.1 Accreditation

This is a process of measuring the professional's highest professional standards and to ensure that these are complied with. This would incorporate:

- **Credentialing / Certification**

- ⇒ Qualifications of our providers.
- ⇒ Registration with SAMDC, etc.
- ⇒ Previous disciplinary actions.
- ⇒ Involvement with organisations, hospital privileges, etc.
- ⇒ Other professional qualifications. These are features other than his basic degree, which impact on his quality of care. For example, the professional may have extensive experience in doing ultrasounds, etc.

- **Re-certification**

Internationally, continuing professional development is becoming more and more important to ensure professional competencies and re-certification. Therefore, CPD plays an important role in maintaining quality. The Medical and Dental Professions board has implemented a system of compulsory CPD and re-certification extending over a five-year cycle.

- **Environment of Care**

A comprehensive review of the environment the professional works in. His clinical, operational and management system would be looked at.

- **Clinical Performance**

A continuous process of reviewing and informing the professional of his clinical performance compared with his peers. Feedback and suggestions of further education would then be given. Audit systems would provide the information for this.

- **Questionnaire on the Physician**

Questionnaires could be used to assess the health care provider from the point of view of:

- ⇒ Patients.
- ⇒ Colleagues.
- ⇒ Staff members.
- ⇒ Consultants that he refers to.
- ⇒ Self-assessment.

3.1.2 Peer Review

Peer review is a method of improving the quality of healthcare by evaluating medical practice as assessed by doctors from similar practice settings and equivalent levels of training. It is a form of professional self-regulation.

External peer review is a form of peer review in which a group of practising doctors from similar practice situations and experience evaluate the medical care given by, or the ethical behaviour of another doctor in response to a complaint with a view to maintaining quality medical care. It is voluntary and conducted by doctors other than those with whom the respondent works on a daily basis.

The important thing to stress on the question of peer review is that it is complimentary in nature so that complaints are satisfactorily resolved between the complainant and the practitioner without recourse to the law. Even though it is voluntary, practitioners should be encouraged to co-operate fully with the Peer Review Committee.

3.2 Quality of Healthcare Programmes

A programme that monitors and evaluates the **quality** and appropriateness of care and service provided and to pursue opportunities to continually **improve** the care and service. The three main elements of quality assurance include: setting standards; measuring compliance of standards; and, responding positively to deficiencies in complying with standards.

The quality of healthcare programmes entails the quality of **services** and **care**.

3.2.1 Quality Of Services

Service means consistently meeting and, at every opportunity, exceeding the needs of patients and other customers. Today patients have more choices. It is often how they are treated that determines which facility they choose. Furthermore, the service that the organisation gives is their link to the outside world (customers, patients). Good service also depends on the ability of people to work well together – not just with patients, but with co-workers too. To evaluate the quality of service that an organisation gives, the following should form a template from which to work:

- **Accessibility and Convenience**
As we mentioned at the beginning, it is very important that the facility one offers is readily accessible. We may take things like parking facilities, etc. for granted, but these are some of the most important things for patient satisfaction and continual loyalty.
- **Time**
Everyone's time is important to them and if a patient's time is respected and therefore long waiting periods is avoided, this also assures satisfaction.
- **Affordability**
The service should be affordable to most clients.
- **Courtesy**

The first impression that a patient gets of a service is at the desk as he or she arrives. Staff courtesy is of the utmost importance in this regard. This can be compartmentalised into:

- ⇒ **Acknowledgement** – patients need to be taken seriously and acknowledged as soon as they arrive. A prompt and courteous greeting is important, and at this time, one's full attention is given to the patient;
- ⇒ **Clarify** – before patients' needs can be satisfied, you must have clarity of what the needs are;
- ⇒ **Meet and exceed the needs** – only after you have clarified the needs can you then attempt to meet and exceed them;
- ⇒ **Confirm** – ask for feedback from the patient by making sure the patient is satisfied. This is a **critical** step! It demonstrates your commitment to the patient. Treat every patient's needs with empathy, and treat them with respect to maintain or enhance their self-esteem.

A formal patient satisfaction **survey**, which assesses the **clinic/physician's personnel, promptness of service, information to patients**, etc, should be undertaken.

3.2.2 Quality Of Care

Quality management incorporates such activities as:

- Disease management
- Outcomes studies (e.g. high risk obstetrics)
- Patient education (e.g. hypertension education, smoking cessation, weight management and other preventive health programmes)
- Patient grievances
- Quality improvement (including the compilation and analysis of physician quality data).

Organised efforts to reduce the gaps between evidence and practice and to improve medical care have evolved under several rubrics: quality assurance, total quality management and continuous quality improvement, technology assessment, outcomes management, practical guidelines, audit, practice parameters, clinical policies, standards, treatment protocols, appropriateness criteria and other closely related terms, managed care algorithms.

4. Evidence-Based Medicine

Evidence-based medicine remains a hot topic for clinicians, purchasers, planners and the public. So what is it?

Evidence-based medicine is the conscientious, explicit, judicious use of current based evidence in making decision about the care of individual patients.

The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgement that individual physicians acquire by clinical experience through clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and companionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centred-clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer.

Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current based evidence, practise patterns becoming rapidly out of date, to the detriment of patients.

Evidence-based medicine is not “cookbook” medicine. Because it requires a bottom-up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in a slavish, cookbook approach to individual patient care. External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all and, if so, how it should be integrated into a clinical decision. Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patients' clinical state, predicament, and preferences, and thus whether it should be applied.

Evidence-based medicine is not restricted to randomised trials and meta-analysis. It involves tracking down the best external evidence with which to answer our clinical questions. Because the randomised trial and especially the systematic review of several randomised trials, is so much more likely to inform us and so much less likely to mislead us, it has become the “gold standard” for judging whether a treatment does more good or harm. If no randomised trial has been carried out, we must follow the trail to the next best external evidence and work from there.

Objective evidence becomes particularly relevant in the area of technology and pharmaceuticals. The question can be asked whether technology drives the practice of healthcare or *vice-versa*. Often devices and techniques are introduced and pursued by providers with ill scientific judgement as to their real value and cost effectiveness. Commercial factors also come into the equation.

5. Risk Management

What Is Risk Management?

Risk management is a term that was first coined by insurance companies in the US during the 1960s to describe the control of expenditure on the generality of claims. The increase of medical and dental malpractice lawsuits led the insurance companies to apply the same techniques to the health sector. Public and private healthcare providers developed risk management programmes to prevent injury to patients, visitors and staff to control liability of costs.

Risk can be defined as hazard, danger, and exposure to mischance or peril. It implies the potential for unexpected or unwanted outcomes. So in clinical work, risk management can be defined as the process of systematically focusing on methods of reducing both the severity and frequency of recognising adverse clinical risk for each individual.

It is the systematic process of identifying, evaluating and addressing actual risk through a well-designed programme that prevents, controls and minimises risk exposure.

This includes the timely identification and management of existing risk to protect parties, patients, staff and the public, including visitors and outside contractors. Risk management is concerned with the minimum level of legally and professional acceptable care, and covers awareness of all risk to the continued survival and integrity of an organisation, such as recruiting and retaining staff, commercial competition, and financial loss.

Adverse events and medical error in health care have been recognised as an important public health problem. Clinical risk management will be a significant component of clinical governance, as it will target preventable adverse events and encourage a systems approach in examining contributory factors leading to these events. It aims to the frequency and effect of negative events. Clinical risk management is concerned with identifying, managing and preventing unexpected events in patient care that may result in patient harm. It aims to reduce the probability of adverse patient events by analysing and improving sub-optimal healthcare processes.

Clinical audit is one method of identifying untoward incidents and near misses. Formal incident reporting systems are another method.

Clinical risk in primary care

Potentially hazardous areas for primary care seems:

Failure to examine

For instance, failing to identify and manage pregnancy; beware of this pitfall in a couple who have had a sterilisation, but it has not proved effective. Other common errors are ectopic pregnancy, acute abdomen and torsion of the testes and glaucoma, and less acutely, delayed diagnosis of malignancy. The test will be that the practitioner took an appropriate history and performed appropriate examinations to put themselves in a position to reach a diagnosis or make a referral.

Minor operations:

Failure to document fully or send appropriate samples for histology.

Ill children

Where there is a risk of sudden deterioration (meningitis; acute asthma)

Failure to visit

Delay or failure to visit produce about a third of complaints to statutory councils. It is the doctor's responsibility to decide if a visit is indicated, even if the caller is seeking advice and does not specifically request a home visit.

Informed consent

In primary care, this has often been informal and implicit – taking off your shirt suggests you are happy for the doctor to examine your chest; proffering an arm shows willingness to give a blood sample. For more interventionist procedure (fitting IUDs, steroid injections into joints) explicit consent may be needed. There is some consensus that a side effect less likely than 1% is so “rare” that you need not alarm the patient by raising it. It seems reasonable that this cut off should be related to the nature of the adverse effect as well as its probability; a 1% chance of a inducing a miscarriage should be raised.

Drug and prescribing errors

Repeat prescriptions and the possibility of abuse; illegible or ambiguous scripts may lead to confusion of generic and trade names or where drugs sound similar: chlopropamide, chlorpromazine, chlormethiazole. Confusion over units, especially micrograms; drug interactions and allergies; drug with variable or changing doses (such as insulin and warfarin); and, expiry date, batch numbers and storage for dispensing practices.

Staff issues

It is incumbent on the provider to take responsibility for locum staff. In extended roles, staff are asked to carry out tasks beyond their level of training or competence. Nursing staff are entitled to decline duties and responsibility if they feel they cannot discharge them in a safe and skilled manner and to voice concern over limitations in their knowledge and competence. Defence union indemnity is another important factor to cover the liability of personal claims.

Medical records

These need to be:

- Comprehensive;
- Written contemporaneously with the events not retrospectively;
- Factual – avoid subjective or defensive comments or vague terms like “OK”;
- Entered with a frequency appropriate to clinical setting;
- Signed, not initialled, and dated: error should be amended and signed;
- Legible and permanent – ink not pencil;
- Written with commonly understood and un-ambiguous abbreviations.

Communication

Failure to keep patients adequately informed if outcomes are likely to be poor; failure to explain setbacks; failure to inform fully of complications and side effects.

6. Clinical Audit

Introduction

Within the managed healthcare scenario strong emphasis is placed on audit to assure quality of care. It appears that the old saying “physician heal thyself” has now changed to “physician audit thyself”. This paradigm shift strongly implies that previous, negative perceptions regarding audit has changed.

The quest for a perfect model is an ongoing, multidisciplinary process and questions to be addressed are: “What is excellent healthcare and how is it measured?” Is it measured by costs, outcomes or consumer opinion? This directs the process of audit away from the question “what are we doing wrong?” to “what can we do better?”. Healthcare providers therefore no longer perceive audit as a threatening process, but as a powerful and positive tool in assuring quality care.

Before examining the various definitions of audit, it may be useful to note some activities that are often mistaken as audit:

- **Clinical Research**

Audit determines existing knowledge whereas research is concerned with new knowledge.

- **Surveys**

Audit is not a survey, but surveys are indispensable for audit as they provide the information needed for audit. Patient questionnaires, peer reviews and other surveys should not be designed to identify only areas that need improvement, but also to highlight the areas and activities in which we excel.

- **Data Collection**

Routine data collection will often not collect data to identify the underlying cause of problem areas and clinical research requires complex data collection. Specific data collection is required for audit purposes.

- **Disciplinary Action**

Audit may reveal aspects of inappropriate care, but the emphasis is on improving care - not on investigating individuals.

Definitions

Audit is the systematic critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient.

Audit is in fact the evaluation of the quality of medical care as reflected in medical records. The setting and maintenance of the highest possible standards appropriate for the situation. The nursing profession considers the audit process as a retrospective evaluation of care based on the documentation of that care reflected in the patient's record.

Audit is the ongoing process by which the desire of healthcare professionals, to provide superior quality care including the process of diagnosis and treatment, outcomes and quality of life of patients, and the utilisation of all resources are assessed, evaluated, discussed, improved and monitored.

Characteristics of Audit

For audit to play a positive role in the quest for superior quality care, the process should have the following characteristics:

- **Educational**
Focuses attention on a particular feature of care, encouraging providers to think critically about their practise.
- **Confidential**
A cornerstone of audit is that confidentiality of patients reviewed and professionals who manage them, is maintained.
- **Multidisciplinary**
The design of an audit study and action programmes should be discussed with all staff.
- **Relationship to Management**
Local management must ensure that an effective system of medical audit as well as a monitoring plan is in place.
- **Service Efficiency**
Usually falls under resource management rather than under control of health professionals. Efficiency relates to the quality of service rather than quality of care.

The **PIAF** principle can be applied, as it is a continuing spiral upwards to the goal of audit - to provide excellent healthcare:

- Practise - What is being done at present?
- Information - Specific data collection on current practice.
- Analysis - Interpretation of the data in relation to what should be done.
- Feedback - To providers with suggestions for improvement.

Audit Committee

An executive audit committee is usually formed to co-ordinate audit activities and results and to oversee and standardise methodology of the subcommittees, which should be representative of the various clinical disciplines.

Limiting Factors of Audit

Although very powerful, audit has certain pitfalls that must be understood:

- **Knowledge of individuals responsible for the audit**

If the individuals performing the audit have limited knowledge of a subject, the results will reflect the lack of knowledge, rather than the state of the situation.

- **Inference**

Audit hinges on inference, the supposition that the quality of care was or is inferior.

- **Standards**

Available standards should be evidence-based against which the process of care can be judged.

- **Authoritarian**

Audit should not become a tool that restricts the advancement of medical knowledge.

- **Biased Findings**

Acceptable statistical principles must be adhered to, to prevent unfounded criticism of clinical care.

- **Generalisation**

Results cannot be generalised to other areas as data is not controlled. It also cannot be concluded that audit produced change, only that change occurred.

- **Retrospective**

Audit is often a retrospective process of quality control and is designed to lower the chance of deficiencies occurring. It cannot however remedy poor care already received by an individual patient.

Conclusion

The principles of a good audit can be summarised as follows:

The aim must be to improve the delivery of care. Trained staff should be used and confidentiality is a prerequisite. The simplest methods should be used to avoid time-consuming, costly and inefficient audits. A collaborative and focused approach should be adopted.

There are far more important effects that result not from the information obtained from the audit, but from the process of audit itself. This is the famous “**Hawthorne Effect**” - whereby the very process of examining human behaviour or activity, improves that activity. Audit thus signals to health professionals that their work is being monitored and that they are accountable to their patients.

7. Clinical Guidelines

Introduction

Imagine a world where every patient received the best-known treatment. Now identify the barriers to realising such a Utopian ideal. Many people would nominate “resources” and happily leave it at that. But, as a comparison of healthcare systems across the world shows, spending more money is not the only answer. Ignorance, incompetence, poor management, and a sometimes deliberate disregard of established knowledge all get in the way of best practice. How can we improve the outcome of care, given roughly the same resources?

Although the extent of gaps between research evidence and clinical practice is difficult to ascertain, it is not hard to understand why they occur. The medical literature is vast, and clinicians have limited time to read it. For example to develop the guideline on cataracts in adults, 6 948 articles were reviewed. Even if practitioners do take the time and trouble to assemble, sort, and synthesise evidence, they are confronted by the perish ability of evidence, so that evidence forays must be repeated periodically. For example, studies of the efficacy of digoxin in patients with congestive heart failure in sinus rhythm show a benefit, but these studies were all done before the advent of angiotensin-converting enzyme (ACE) inhibitor therapy, and it is not known whether digoxin now has any incremental value for patients for whom ACE inhibition is appropriate. Furthermore, the evidence that is generated from most applied research in healthcare and service provides incomplete coverage of the clinical situations that confront practitioners, so that application of evidence in practice is far from straightforward.

Knowledge of how a clinical problem should be managed is often insufficient to change behaviour. For example, physicians may feel pressured by patients to refer them unnecessarily, may order unnecessary diagnostic tests because of concern about liability or may feel compelled to practise according to local standards even when these are not consistent with evidence-based practice guidelines.

For each patient a variety of options must be considered, such as what to include in the history taking and physical examination, which diagnostic test to order and which therapeutic and preventive interventions to recommend. Estimating the outcomes associated with each option and then weighing the consequences of each choice is complex and time consuming. It is clearly not feasible for each clinician to do this adequately for all the decisions that must be made daily. Instead, physicians rely on simple decision rules - guidelines - that suggest what to do for patients with typical conditions.

Some fear that “cookbook medicine” will reduce doctors’ self respect and could reduce patients’ confidence in them. Some critics of guidelines believe that clinical freedom, like other sorts of freedom, cannot be limited without being lost. These are not trivial problems: they strike at the heart of what it means to be a doctor. If doctors are not required to exercise judgement what are they there for? Clinical freedom implies the obligation to do what is best for the patient at all times, not the right to do whatever one pleases.

Several studies have found substantial variability in both procedure use and procedure outcomes. The results have been confirmed in virtually all studies in all countries that have examined the issue. The variability in healthcare delivery and outcome is pervasive.

The studies have important implications. The conclusion seems inescapable that equally sick patients with similar preferences are treated very differently in different settings. Assuming that the goal of a healthcare delivery system is to provide high quality cost-effective care, using tests or therapies only where appropriate, the studies imply that tests and therapies are either being overused or underused in some settings. Concerns about healthcare costs have focused renewed attention on this variability, hoping that standardising care delivery will yield substantial cost savings permitting the best use of healthcare resources. The implication is true for all countries regardless of the healthcare delivery system or size of the healthcare budget, since all countries face the need to maximise the use of available healthcare resources. Strategies that help to standardise the delivery of healthcare by minimising undesirable variation are essential from a global community perspective.

The effectiveness of most care is not so obvious, and rigorous evaluations are needed to determine whether the perceived benefits are real and worthwhile. To ensure that good research is translated into good clinical decisions clinicians must be informed consumers. A large amount of medical information is not supported by valid research, including some articles published in prestigious medical journals and recommendations made by leading authorities. Clinicians must be selective about what they read and heed to ensure that it is applicable and valid. The opinion of authorities and one's own clinical experience are not adequate to validate the results of research. To make informed decisions clinicians must be informed users of medical research and have the ability to appraise it critically.

The introduction of guidelines for the use of skull radiographs in patients with head injuries in the United Kingdom decreased utilisation, from 65/1000 attendances to 32/1000. This was achieved without any untoward incidents and suggested a potential saving of 3.3 million pounds.

Definition

Should you treat a 75-year-old woman with a systolic blood pressure of 180 mm Hg? Should you refer a 65-year-old man with symptomatic, benign hypertrophy of the prostate for surgery? What should you tell a woman of 55 who wants to know whether she should start hormone replacement therapy? How should you manage a case of acute myocardial infarction in a 45-year-old man? Should you order glucose tolerance test for a 35-year-old woman who is in her 26th week of pregnancy? Should you refer a 25-year-old man with acute low-back pain for spinal manipulation? What should you recommend to a sexually active girl of 15? How should you manage acute otitis media in a child of 5? Clinicians are confronted daily with decisions such as these.

Practice guidelines are official statements that outline how to prevent, diagnose and treat specific medical conditions and how to perform certain clinical procedures. By 1993, 1 500 practice guidelines had been developed in the USA alone.

At the simplest level, care-plans can be thought as “road maps” of patient care. In this context care-plans are expected courses of care for patients undergoing routine or standardised procedures. In general, the typical care-plan will include as categories laboratory tests, diagnostic tests (e.g. X-ray) or procedures, patient education activities, ancillary services, consultations, and discharge planning services that should occur in the expected course of care for an individual patient each day. By making explicit how the care should be provided across many caregivers and resource needs, the care can often be provided more efficiently.

Practice guidelines are becoming more and more important for several reasons. These include an emphasis on audit and improving the quality of healthcare; medical advances and increasingly complex clinical decision-making; unexplained variations in clinical practice; heightened public awareness of, and participation in, decision-making; and a more explicit debate about the use of limited resources. From a payer's point of view guidelines also have a role in supporting quality assurance and audit, including providing the framework against which care can be evaluated.

Perhaps the clearest definition is that of the Institute of Medicine, guidelines being “systematically developed statements to assist practitioner and patient to make decisions about appropriate healthcare for specific clinical circumstances”.

Ideally, clinical practice guidelines are the product of available evidence, clinical experience, and collective wisdom, and provide guidance for clinical actions that is true both to the strengths and limitations of evidence, and to the circumstances of clinical practice.

At their best, clinical practice guidelines are formulated in an explicit way that permits users and observers to follow and verify the process as being an accurate reflection of evidence and responsive to the circumstances of clinical practice.

Methods to Develop Clinical Guidelines

Practice guidelines are usually developed by a team of experts using one of four methods:

- In **informal consensus** development, the oldest approach, the experts engage in open discussion and decide on the recommendations subjectively, without formal decision rules.
- In **formal consensus** development, an approach that became popular in the 1970's, formal techniques (e.g. modified Delphi method) are used to score the opinions of the experts. Both informal and formal consensus development methods have the disadvantage of describing what **the experts think** is appropriate rather than **linking recommendations directly to evidence**.
- To respond to the inherent biases of consensus development methods, a third method, **evidence-based guideline development** became popular in the 1980s. In this approach, the expert panel follows a systematic methodology for gathering relevant studies, reviewing the data and linking the strength of recommendations to the evidence.
- The fourth method is the **explicit approach**, in which the potential benefits, harms and costs of treatment options are specified individually, and patient preference for each outcome are determined.

A useful practice guideline must walk a fine line between excessive specificity (e.g., a step-by-step recipe to be followed in every care) and excessive generality (e.g. diagnose and treat the depression optimally). The former is dangerous, not supportable by science, and ignores critical individual patient and treatment differences. The latter provides no guidance.

Characteristics of Useful Guidelines and Standards:

- **They must be comprehensive, that is, they should include all likely indications for the use of the procedure.**

Information from published reports, review of medical records, and consultation with experts is necessary to ensure that even unusual uses for a procedure are identified. Unusual uses are likely to be controversial, and, therefore, may be some of the indications for which a judgement of appropriateness is most needed.

- **They must be specific, clearly describing the exact conditions for which the procedure is recommended (or not recommended).**

More than any other characteristic, it is the high degree of specificity that differentiates the “new” guidelines from the old. It is specificity that makes it possible for the physician or reviewer to separate indications within a “family” into those that are appropriate and those that are inappropriate, and to compare alternative therapies.

- **Guidelines should describe in meaningful detail the distinguishing features that separate one indication from another. Specificity is in the details.**

The art of developing good guidelines is to identify the information about clinical characteristics and laboratory tests that is necessary for decision-making and to specify the threshold values and interrelations that discriminate between patients who will benefit from the procedure and those who will not.

- **They should clearly indicate the circumstances under which a procedure is appropriate, inappropriate, or when there is no consensus of informed opinion, indeterminate or equivocal**

These designations are straightforward, easily understood, and unambiguous. The purpose of guidelines is to inform, not to obfuscate. Clear statements of the judgements are the best ways to accomplish the objective.

- **Ideally, guidelines will be inclusive of all major relevant additional factors that must be taken into consideration in the decision to recommend a procedure.**

These include, but are not limited to, assessment of the risk of the procedure, severity of the disease, and comorbidity.

- **They must be manageable: The structure and presentation of indications must not be so complex that they are unusable.**

Criteria of appropriateness need to be translated into a form and language that permits ready use in everyday practice.

Will Practice Guidelines Increase Medico-Legal Liability?

In essence, since scientific knowledge can never fully address or keep pace with every treatment decision that practitioners must make for each patient, practitioners, as always, remain bedside scientists, using the scientific method on a case-by-case basis.

The good news is that the guidelines are not standards of care, meaning mandatory requirements for practitioners. Rather, they are rudimentary road maps outlining options in the diagnosis and treatment of particular conditions.

Nevertheless, guidelines would provide formal, written and therefore easily accessible normative statements. The possibility that clinical practice guidelines could be used to determine what is wrongful conduct in the legal sense is obvious.

The key, then, is to determine the extent to which clinical practice guidelines can be viewed as the expression of the legal norm - that is, the extent to which those guidelines adopted for separate purposes, nevertheless state the relevant legal standard of care. If the guidelines became legal norms, then parties, lawyers, judges and payers (e.g., self-insurance organisations) would evaluate the behaviour of healthcare providers from the point of view of the guidelines and make legal decisions accordingly. Did the physician's behaviour conform to the written standards? Clinical practice guidelines could discourage frivolous claims, lead payers into refusing to compensate or convince a judge to relieve a physician of any blame. Conversely, they could provide evidence that a claim is likely to succeed convince payers to settle and not litigate or simplify the judge's task by indicating clearly what amounts to negligent care.

Implementing Practice Guidelines

The overall goal of the practice guidelines movement is to maintain or improve the quality of care; thus, the movement involves not only defining the features of high-quality care through the process of guidelines development, but also devising mechanisms to ensure that practice reflects the guidelines. These mechanisms are referred to as implementation.

What are effective determinants of physicians' behaviour? A **Passive Diffusion model**, which assumes that simply publishing original research findings in medical journals will lead to the incorporation of this evidence into practice, is not useful. Nor the **Active Diffusion model**. In this model, research evidence is appraised and distilled into guidelines that are then provided as educational information to practitioners by a credible dissemination body. Successful implementation requires strategies based on understanding and control of educational, administrative, economic and social incentives and barriers.

Educational strategies work best when they are personalised, involve respected physician leaders and incorporate a high degree of interaction between the target audience and those presenting the information. **Feedback techniques** have had some success. It has been suggested that although feedback can change behaviour, removal of the feedback signal results in a return to non-compliant behaviour.

The use of **remuneration-based strategies** to promote compliance with guidelines is complex. There is very little systematic research on whether specific financial incentives can influence provider's behaviour in improving the quality of care.

A strategy that **focuses on patients** rather than on providers or administrators of care is also a possibility. Patients are active partners in the healthcare system. Although economic barriers to the delivery of care, such as co-payments, have been shown to reduce the amount of care received, evidence suggests that they reduce both necessary and unnecessary care. However, there is some evidence that the education of patients can improve their care-seeking behaviour as well as their compliance with appropriate therapy.

Any comprehensive programme to improve the implementation of practice guidelines is likely to involve a variety of strategies. It is consistent with the idea that these programmes are designed to draw on the natural desire of physicians to provide high-quality care.

Conclusion

It is clear that medical practice is not a simple application of medical science. It requires technical and scientific competence and an interpretative interaction between physician and patient.

Perhaps nowhere is the age-old tension between the science and the art of medicine more apparent than in today's growing movement to embrace clinical practice guidelines. Proponents enthusiastically argue that consensus statements on appropriate medical practices can be a boon to both physician and patient, providing them with the best scientific information available. The less enthusiastic suggest that such guidelines have the potential to unduly restrict physician and patient decision-making, to turn physicians into instruments of government cost cutting, and to further expose doctors and their organisations to legal liability.

Summary

- Practice guidelines have come to stay
- If initiated by doctors the focus will be on standards of care whereas if initiated by payors, cost will be the overriding consideration
- To be accepted and used, doctors should be part of the development process
- Guidelines should have the primary purpose of improving or maintaining high quality of care
- They should be cost-effective

It does mean however, that we must be willing to look beyond the production and publicising of guidelines if we want to ensure high-quality care.

8. Disease Management

Introduction

Disease management is one of several population-based approaches to medical care currently used in managed care circles. The basic premise behind disease management is that there is a more optimal way to manage patients that result in lowered costs, and it is possible to develop and implement a system of care that improves health outcomes.

Population-based medicine may use many of the same tools as traditional public health approaches, but they focus on the relatively short-term health needs of defined populations

because of the underlying economic incentives facing payers. It offers strategies for managing a population's risk, demands, diseases and outcomes.

The model of population-based medicine rests on the premise that if the healthcare needs of a population are known, programmes to decrease the costs of medical care received by that population can be designed.

Properly designed programmes would therefore be more efficient than similar efforts that might depend on individual physician-patient interaction. For example, population-based immunisation programmes have been shown to save costs.

Disease management involves a change from the classic model of an individual physician providing healthcare, as is present in the clinical setting, to a population-based systematic approach that identifies persons at risk, intervenes, measures the outcomes, and provides continuous quality improvement.

The three essential elements of disease management are:

1. A knowledge base that quantifies the economic structure of the disease problem and describes care guidelines;
2. A delivery system that co-ordinates all cares, primary, secondary, and social;
3. A quality improvement system to audit performance against evolving standards.

Disease management has become a popular approach in the healthcare system because of its association as a cost reducing strategy and its potential for broad application. Pharmaceutical companies, healthcare companies, as well as patient education companies are very keen to run it. Pharmaceutical companies have been accused of using the promise of disease management as a way to sell particular drugs. For example, companies with large investments in asthma drugs are leading the charge to develop asthma disease management programmes. The involvement of these companies increases the possibility that disease management becomes more of a marketing tool than a contribution to the healthcare delivery process, and also the possibility that control over healthcare may move from physicians to drug companies.

More important than who runs a disease management programme, is whether there is a good reason to believe that the proposed programme would work. Comprehensive disease management requires a deep understanding of the natural history of disease, to determine where in the life cycle of disease an intervention should be implemented. Because most chronic diseases have a long natural history, the same intervention could be implemented for patients who have pre-existing diseases (secondary prevention), or for those who do not (primary prevention). The economic consequences and time frame will differ because of the frequency of incidents, events or ability of the intervention to work.

For planning purposes the intervention itself can be encapsulated in the form of clinical protocols, or pathways (based on guidelines) that must be disseminate and applied. We have much to learn about the best ways to implement these programmes and change provider and patient behaviour.

Examples of Components of Disease Management Programmes:

Component	Identification	Implementation	Measurement (Outcomes)
Health Risk Assessment	✓		
Chart Audit Protocols	✓	✓	✓
Database Analysis	✓	✓	✓
Psychometrics (such as quality of life)	✓		✓
Clinical Guidelines		✓	
Clinical Pathways		✓	
Clinical Trials		✓	✓
Professional Education		✓	
Patient Education		✓	
Automated Telephone Systems		✓	
Compliance Programmes	✓	✓	✓

Although disease management programmes have not yet been evaluated, some components of the programmes have been studied. For example, recent research has shown that automated telephone reminder systems can increase clinic attendance by nearly 35%, and that the use of home blood pressure monitoring can reduce physician office visits by 44%.

Disease management incorporates outcomes research technology into outcomes measurement and management programmes. There is only a technical distinction between outcomes management and disease management. Disease management does not require outcomes assessment as outcomes management. Outcomes management assumes that reviewing treatment and measuring outcomes, optimal therapy can be determined. This is a dynamic management model, that seeks to produce outcomes in a clinical setting and is therefore the application of outcomes research to practice. A uniform collection and coding systems of outcomes data in the population are necessary. To obtain this, the providers have to be linked through a computerised information system.

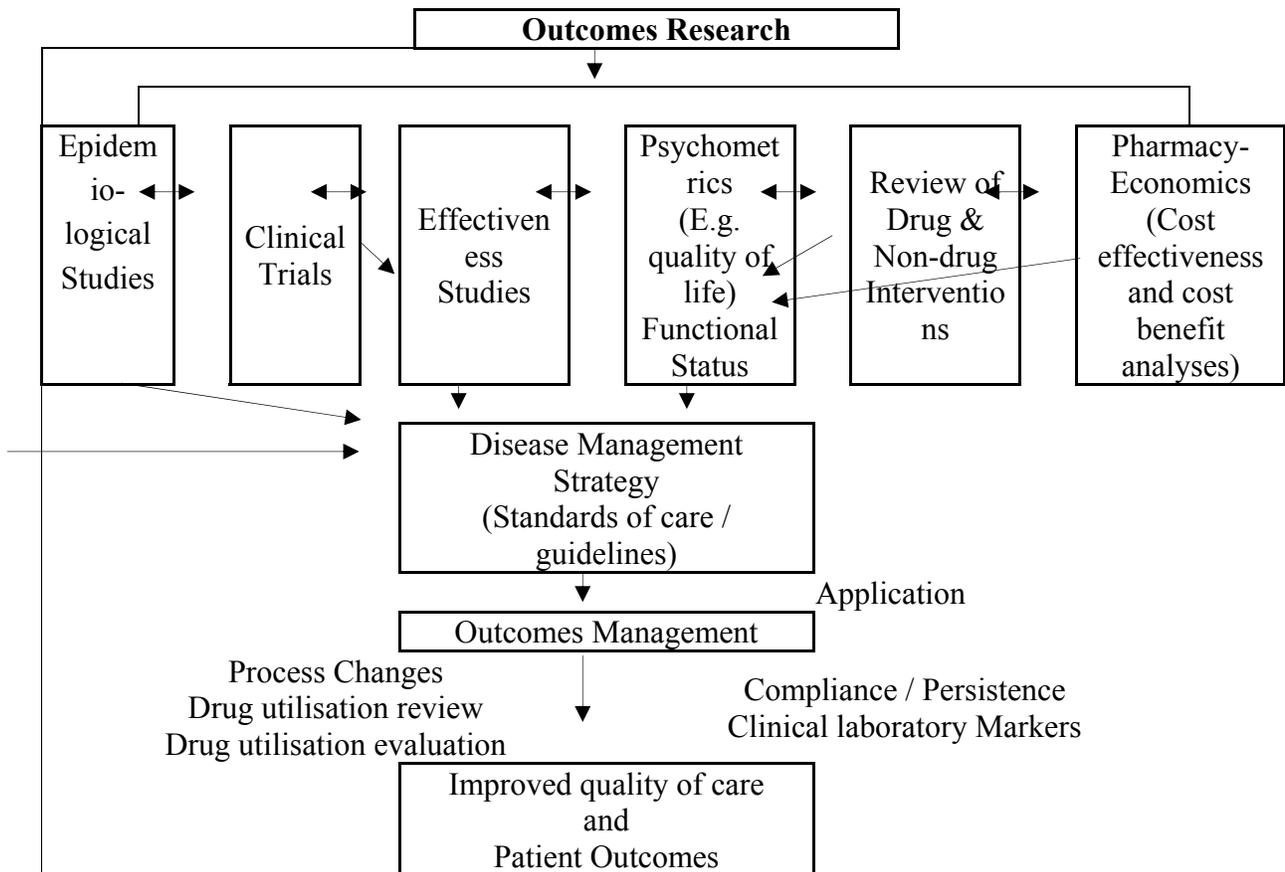
The new model for the management of disease is population-based risk and disease assessment, systems of disease prevention and health promotion, community-based intervention and providers network, evidence-based medicine and defined protocols of care with measurement of outcomes.

The application of outcomes assessment to the practice of medicine through disease management has already begun.

Population-based medicine, including disease management, is a new approach to medical care. It will not replace physician-patient-based medicine, but will coexist alongside it in the new network of delivery systems. It offers several promises, such as:

- To improve efficiency;

- To find system solutions to healthcare problems, they can show ways in which care can be improved by changing the delivery system rather than the persons who provide the service (long-term benefits);
- Can improve medical decision-making by allowing physicians to understand the other role players in healthcare delivery better, and exposing physicians to the full ramifications of their decisions (long-term benefits). **The multidisciplinary scientific basis of outcomes research and the manner in which it flows into disease management programmes:**



Continuous quality improvement of outcomes is the ultimate goal.

9. Outcomes

Introduction

An important aspect of disease management is the ability to measure and report health outcomes.

We have entered into an era of unprecedented growth in activity directed at the assessment of outcomes, the analysis of effectiveness and quality assurance in healthcare.

Definition

Outcome measurement represents an objective way to measure the end result of the healthcare intervention and health payers are demanding efficiency and value for their healthcare cost.

Measurement of clinical and other outcomes has become increasingly important to the stakeholders in a rapidly changing healthcare environment. The urge to improve outcomes and control costs has stimulated greater interest in cost-effectiveness studies which determine how well effective therapies work in the usual practice setting and how much they cost.

The application of outcomes principles to the practices of healthcare providers has resulted in efforts to implement disease management programs. These new efforts are based on systematic population-based approaches in identifying persons at risk, intervening with specific programs of care and measuring clinical and other outcomes.

There are at least three important factors that have led to the current emphasis on the assessment of effectiveness and outcomes:

- Cost containment, in this context outcomes is seen as an index of the effectiveness of different interventions that eliminate unnecessary expenditure and as a very important part of a system that will improve quality of care and will prevent deterioration;
- Sense of competition, buyers need to buy right to compare outcomes and quality;
- The third factor is lead by results of researchers who have shown important differences in the use of various medical procedures, and then questions about costs and optimal care appear.

The outcome measures have evolved from simple dichotomous ones such as survival or occurrence of a clinical event, to patient-orientated measures such as satisfaction with quality of life and functional status. The term outcomes have been linked to different measures ranging from physiologic values to quality of life assessment.

The reporting of outcomes differs, depending on the priorities of those examining the data. A clinician's interest will be clinical or humanistic outcomes, a health plan administrator may be interested in economic outcomes, patients are interested in humanistic outcomes. Current disease management programs include mixtures of all measures.

Types of Outcome Measures and selected examples:		
Outcomes	Types	Examples
Clinical	Clinical events	Myocardial infarctions, cerebra vascular accidents Blood pressure, measurement of cholesterol levels.

	Physiologic and metabolic measures Mortality and Morbidity rates	Death - specific cause (such as cardiovascular) or all causes (total) side effects - complications. Did group patients live longer; Did they show significant improvements in physiological measures of health status?
Economic	Direct medical Indirect medical	Hospitalisations, outpatient visits, emergency department visits Work loss, restricted activity days
Humanistic	Symptoms Quality of life Functional status Patient satisfaction Disability	American Urological Association symptom score SF-36 questionnaire, Nottingham Health Profile Katz Activities of Daily Living Scale, Karnofsky Index Group Health Association of America survey

Outcomes Research

Outcomes research is a rapidly evolving field that incorporates epidemiology, health services research, health economics and psychometrics. It can tell us more about the effectiveness of different interventions and may help increase the efficiency of existing systems for monitoring the quality of care. Maybe this information is all we need to formulate guidelines that will serve as a rational basis for decision-making and make medical care of a broad range of conditions more efficient.

Outcomes Management

“Is a technology of patient experience designed to help patients, payers and providers make rational medical care - related choices based on better insight into the effect of these choices on the patient’s life”.

- Outcomes management would be based on dependence of clinical standards and guidelines that doctors can use to select interventions.
- Outcomes management is a program in which clinical standards and guidelines are based systematically on patient outcomes.
- It would routinely and systematically measure the functioning and well being of patients with specific clinical outcomes.

It assumes that by systematically measuring outcomes and reviewing the treatment that preceded the outcomes, optimal therapy can be determined.

This process should lead to management recommendations, followed by re-evaluation of outcomes and a continuous opportunity for improved delivery of care.

This is a dynamic management model; it is not the same as outcomes research, which seeks to define the range of outcomes produced by alternative interventions. Outcomes management seeks to produce desirable outcomes in a clinical setting and is therefore the application of outcomes research to practice.

Outcome criteria that can be used for medical record screening processes:

- Death.
- Return to operating theatre within 7 days.
- Transfer from general ward to intensive care.
- Unplanned re-admission within 21 days of discharge.
- Cardiac arrest.
- Transfer to another acute care facility.
- Length of stay greater than 21 days.
- Booked for theatre and cancelled.

Goals of the Outcomes Measurement

These include increased understanding of the effectiveness of different interventions, the development of standards to guide physicians and third party payers in optimising the use of resources. The effort to determine the outcomes and effectiveness of different medical interventions and to use that information as an aid to clinical decision-making is a useful extension of basic clinical research.

A much more controversial aspect of the outcomes movement is the effort to develop guidelines that can be used by physicians in providing care, and by third party payers attempting to ensure the appropriate use of services. Conceptually, the steps in the process of moving from outcomes to guidelines are straightforward.

Although there are still many constraints, substantial progress has been made in the last few years basing the medical policies on current medical science. Indeed, managed care offers an excellent vehicle for speeding the dissemination and acceptance of outcomes data from researchers to clinicians.

10. Best Practice

Cultivating clinical quality / best practice

Healthcare quality improvement does not occur automatically. It must be carefully cultivated and nurtured if it is to take root and grow.

It is recognised that quality improvement is a long-term process. However, accountability drives quality – therefore it is important to formalise quality improvement efforts.

A formal “best practice” programme aims to establish a culture of quality and mobilise the resources required for health professionals to demonstrate and maintain a good standard of medical practice.

Defining quality / best practice

It will be difficult to develop an exact “index” for best practice and that no one set of quality measures is perfect. Furthermore, it should be understood that a quality performance profile will never give a complete picture of the way provider groups treat their patients.

Nevertheless, there are certain universal principles of good clinical practice that every practitioner should adhere to, such as:

Universal principle of good clinical practice:

- At all times, act in the best interest of the patient;
- Place the clinical needs of the patients paramount;
- Be professionally competent;
- Perform consistently well;
- Practice ethically and do patients no harm;
- Base clinical decisions on best evidence;
- Be an effective member of the professional team;
- Take action if poor practice places patients at unnecessary risk

Health professionals should be prepared to test themselves against others providing similar care, to see where they stand and to learn from this. This testing can be quite informal – for example, through visits, discussions and comparing results with colleagues. It may also be more formal – for example, through external review leading to accreditation or incentives.

It is recommended that a best practice index should be developed based on indicators, which can be measured, in the current environment. As the collection and analysis of health and disease information improves we can expect additional measurements to become available.

Best practice index

The following broad criteria have been identified for inclusion in a best practice index for practitioners within the provider networks:

- Professionalism
- Economical
- Clinical quality
- Quality of service

Professionalism

Credentialing

The first level of the quality assurance process is to ensure that the practitioner has the necessary qualifications and professional competence.

This aspect is measured by the following criteria:

- HPCSA registration
- CPD status
- Professional indemnity insurance
- Demonstrate qualifications, skill and experience for scope of practice, e.g.
 - Anaesthetics
 - Gastro scopes
 - Ultra sound

Facility accreditation

The facility in which the doctor/dentist practices would be accredited to ensure it adheres to certain specific standards .The facility assessment will cover aspects such as:

- Patient flow plan
- Sterile/non-sterile demarcation
- Medical waste disposal plan
- Fire extinguisher
- General cleanliness/neatness
- Availability of resuscitation equipment
 - Laryngoscope
 - Ambubag
 - Endo-tracheal tubes
 - IV line and IV fluids
 - Defibrillator

Economical (Cost-effectiveness)

Criteria to determine the cost-effectiveness of the practitioner could include the following:

- Cost per beneficiary (patient) per month
- Overall cost to treat a disease, e.g. Asthma and diabetes

- Cost of consumables
- Referral rate
- Number of procedures per consultation
- Cost of radiology/pathology generated per patient
- Cost per script

The economic index needs to be adjusted for age, gender, etc to ensure accuracy.

Clinical Quality

Steps to good care

In this category the focus will be on certain processes / steps, which are likely to improve clinical quality. Examples are:

- Adherence to scientific formulary
- Adherence to guidelines
- Consultation process and notes (according to SOAP system)
- Preventive care (screening and immunisation)

E.g. Rate of females > 20 who had a pap smear
 Rate of females > 40 who had a mammogram
 Rate of children < 6 who were immunised

- Patient education
 - E.g. Education on smoking
- Appropriate management of pre-defined diseases

E.g. Asthma

- ⇒ Prescribed inhaled corticosteroids for patients with chronic continuous asthma
- ⇒ Instruction on how to use a peak-flow meter

E.g. Diabetes

- ⇒ Cholesterol and blood pressure monitoring
- ⇒ Eye and feet examinations

Outcomes of care / results

The clinical outcome of treatment for specific diseases will be measured, e.g. Asthma and diabetes

- Asthma
 - ⇒ Hospitalisation rate of asthma patients

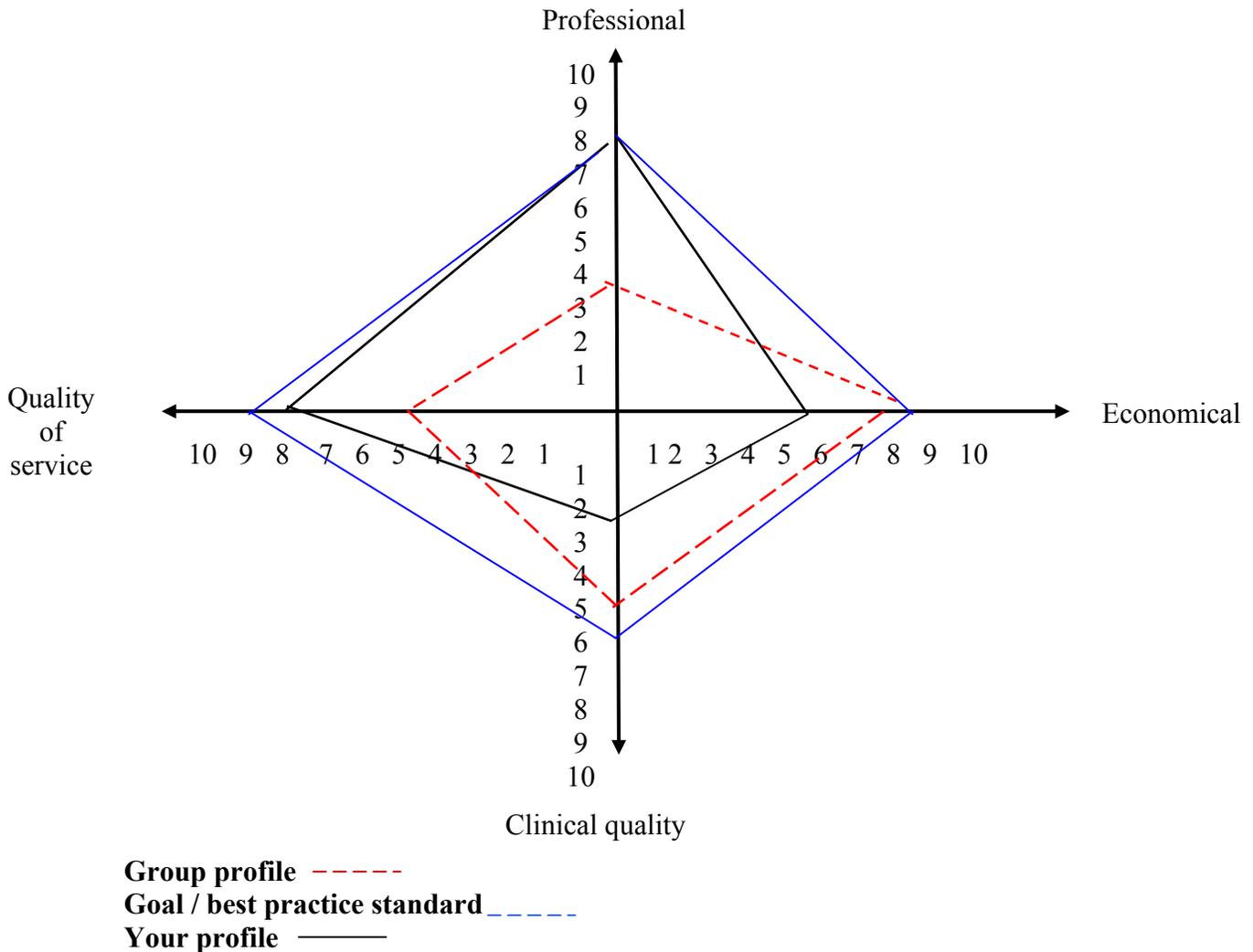
- Diabetes
 - ⇒ Hb1ac levels
 - ⇒ Blood pressure and cholesterol levels

Quality of Service

The perception of the patient about the care he/she receives, is a very important indicator of quality. The following aspects could be included in this category:

- Access to service (waiting times to get appointment and that spent in Consultation room);
- Complaints and grievances;
- Patient retention;
- Doctor’s communication and caring skills;
- Erall perception of quality care received.

Example of a best practice index profile



Strategies to encourage and incentivise best practice

Improvement requires change. Improving quality in healthcare involves changing the way things are done, changing processes and changing the behaviour of people and teams of people.

Perhaps the most important and difficult aspect of developing and implementing best practice initiatives within a provider network environment is achieving the buy-in of professionals. Most practitioners are sceptical about quality improvement programmes. Many perceive these programmes to be a threat to their professional autonomy, or an unreasonable demand on their limited time with patients.

Given this reality it is vital to recognise and reward the provider's commitment and efforts to delivering high quality care.

The following strategies could be used to encourage best practice:

Incentives

Incentives could be created in both monetary (financial) and non-monetary terms.

Non-monetary

- Exemption from certain managed care activities (hassles) e.g. Pre-authorisation, motivations
- Recognition - positive feedback
- Channeling of patients to "accredited" providers who adhere to best practice principles and processes

Monetary

- Pay the provider a bonus for practising quality care as defined per the "best practice index"
- Provider to share in the gains of "risk profits"

Education and communication

Typically health professionals receive little or no formal training in quality improvement theory and methods. It is recommended that opportunities be created for provider groups to advance their knowledge of improvement concepts and methods.

Offerings could include:

- ⇒ Communication on the value and objectives of best practice programmes
- ⇒ Training in concepts such as continuous quality improvement (CQI), disease management and systems theory
- ⇒ Offer CPD programmes to enhance clinical knowledge and competencies
- ⇒ Communicate regularly on results of best practice initiatives
- ⇒ Interact with participating medical groups to identify barriers and develop strategies and techniques for overcoming them

11. Conclusion

What principles should guide us as we pursue clinical governance?

1. Promoting good practice

- Clinical governance is increased corporate conformity with advice based on a systematic review of empirical evidence including an appraisal of cost-effectiveness and, as such, it is a form of good practice
- Those implementing clinical governance need to adopt a partnership approach with clinicians to achieve an acceptable balance between freedom and constraints as quickly and painless as possible
- Clinical guidelines reinforced by clinical governance will be particularly beneficial in care provided by multidisciplinary teams
- Clinical governance should aim to establish conformity with discretion

2. Eradicate bad practice

- Clinical governance, in itself, will not remedy bad practice
- Most cases of bad practice will be identified by repeated aberrant behaviour, either in one aspect of practice or over several areas of practice
- Frequently, malpractice is the result of gaps in current knowledge
- The purpose of addressing poor practice is to remedy where possible and to prevent always further malpractice. In simple mishaps and misunderstandings skilled mediation may be required
- Parallel systems will directly remedy bad practice

Implementing Clinical Governance: Turning vision into reality

Clinical governance provides the opportunity to understand and learn to develop the fundamental components required to facilitate the delivery of quality care: no blame, questioning, learning culture, excellent leadership, and an ethos where staff are valued and supported as they form partnerships with patients. These elements have perhaps previously been regarded as too intangible to take seriously or attempt to improve. Clinical governance demands the re-examination of traditional roles and boundaries between health professions, between doctor and patient, and between managers and clinicians and provides the means to show the public that the schemes will not tolerate less than best practice.

This guidance is intended to be developmental. In other words, its aim is to promote the measures, which will help health organisations develop good clinical governance. The guidance is not prescriptive as to the exact methods to be used.

Clinical Governance involves above all, shifting the level of quality provided by the majority of health organisations – those in the middle range of performance – closed to the performance of the exemplar services.

BIBLIOGRAPHY

A first class service: NHS Executive. United Kingdom; 1998.

Anderson G. Implementing practice guidelines. *Can Med Assoc J* 1993;148(5):753-755.

Aroskar MA. Ethics in Nursing and Healthcare Reform: Back to the Future. *Hastings Cent Rep* 1994 May-June;24(3):11-12.

Barry M, Fowler F, Chang Y, Liss CH, Wilson H, Stek M. The American urological association symptom index: Does mode of administration affect its psychometric properties?. *J Urol* 1995; 154:1056-1059.

Benetar SR. Healthcare Professionalism: Opening Address 1st Interim National Medical and Dental of South Africa Council Meeting; 1995.

Buch E & Wolvaardt J.E. Governance of medical schemes in South Africa. South Africa; 2001: University of Pretoria.

Bunch C. Review: Clinical Governance. *Br J Haematol* 2001; 112: 533-540.

Burns H. Disease Management and the Drug Industry: Carve out or carve up?. *Lancet* 1996 April; 347:1021-1023.

Campbell AV. Clinical governance – watchword or buzzword?. *J Med Ethics* 2001; 27 suppl 1:54-56.

Carr-Hill R, Morris J. Current practice in obtaining the “Q” in QALYs: a cautionary note. *Br Med J* 1991;303:699-701.

Clinical guidelines programme. The Medical Association of South Africa (MASA), August 1995; 4th edition.

Cornejo-Vegas S. Disease management and outcomes. Policy document, Board of Health Executives, Woodmead; 1997.

Does good science make good medicine? Incorporating evidence into practice is complicated by the fact that clinical practice is as much art as science [Editorial]. *Can Med Assoc J* July 1997;157(1):33-36.

Endicott J, Nee J, Harrison W, Blumenthal R. Quality of life enjoyment and satisfaction questionnaire: A new measure. *Psychopharmacol Bull* 1993; 29:321-326.

Englehardt TH, Rea MA. Morality for the Medical-Industrial Complex. *N Engl J Med* 1988; 319:1086-1089.

Evidence-Based Care Resource Group. Evidence-based care: 1. Setting priorities: How important is this problem? *Can Med Assoc J* 1994;150(8):1249-1254.

Evidence-Based Care Resource Group. Evidence-based care: 2. Setting guidelines: How should we manage this problem? *Can Med Assoc J* 1994; 150(9):1417-1423.

Evidence-Based Care Resource Group. Evidence-based care: 3 Measuring performance: How are we managing this problem? *Can Med Assoc J* 1994; 150(10):1575-1579.

Evidence-Based Care Resource Group. Evidence-based care: 4. Improving performance: How can we improve the way we manage this problem? *Can Med Assoc J* 1994; 150(11):1793-1796.

Farmer A. Medical practice guidelines: lessons from the United States. *Br Med J* July 1993; 307:313-317.

Fleischman AR. Physicians and Ethics in the Healthcare Reform Debate. *Hastings Cent Rep.* 1994 May-June; 24(3):10-11.

Fletcher IR. Clinical governance [Editorial]. *Eur J Anaesthesiol* 1999;17:471-473.

Gilmore A. Clinical practice guidelines: Weapons for patients, or shields for MDs?. *Can Med Assoc J* 1993;148(3):429-431.

Gray TA. Clinical governance. *Ann Clin Biochem* 2000; 37:9-15.

Haande R, Aaronson N, Limburg M, Langton Hewer R, van Crevel H. Measuring quality of life in stroke. *Stroke* 1993;24:320-327.

Hatziandreu E. Evidence-based medicine - revolution in process [dissertation]. Johannesburg: Astra health economics workshop; 1997.

Haynes RB. Some Problems in applying evidence in clinical practice. *Ann NY Acad Sci* 1993;703: 210-24.

HBO & Company. *Pharma Vitae 96*. In: Industry overview. Atlanta, Georgia; 1996.

Headrick L, Crain E, Evans D, Jackson M, Layman B, Bogin R, et al. National asthma education and prevention program working group report on the quality of asthma care. *Am J Respir Crit Care Med* 1996;154:596-5118.

Hedblom E. Disease management [dissertation]. Johannesburg: Astra health economics workshop; 1997.

Henry C, editor. "Professional Ethics for Healthcare Professionals". *Professional Ethics and Organisational change in Education and Health*.

HMO 101: An Orientation to Health Maintenance Organizations.

Holm S, Nielsen GH, Normp, Vegner A, Guldmann F, Andreassen PH. Changes in Moral Rationing and the Teaching of Medical Ethics. *Med Educ* 1995; 29:420-424.

Integration of information for patient care. *IMIA: Yearbook of medical informatics*. Stuttgart; 1996.

Jutras D. Clinical practice guidelines as legal norms. *Can Med Assoc J* 1993;148(6):905-908.

Kraman SS, Hamm GJD. Risk management: Extreme honesty may be the best policy [Medicine and public issues]. *Ann Intern Med* 1999;131(12):963-967.

Learning J. Review of clinical risk management. *Br Med J* 1996;313(7060):827.

Liang MH. From America: Cookbook medicine or food for thought: practice guidelines development in the USA. *Ann of the Rheum Dis* 1992;51:1257-1258.

Management Guidelines. *Arch Intern Med* 1996;156:477-484.

Medicare and Medicaid Guide: Medicare and Medicaid Patient and Programme Protection Act of 1987, USA.

Meenan R, Gertman P, Mason J, Dunaif R. The arthritis impact measurement scales. Further investigations of a health status measure. *Arthritis Rheum* 1982;25:1048-1053.

Onion CWR. Principle to govern clinical governance. *J Eval Clin Pract* 1996; 4: 405-412.

Orchard C. Comparing healthcare outcomes. *Br Med J* 1994;308:1493-1496.

Ott BB. The Human Genome Project: An overview of ethical issues and public policy concerns. *Nurs Outlook* 43(5):228-231.

Oxman AD. Coordination of guidelines development. *Can Med Assoc J* 1993;148(8):1285-1288.

Palmer RH. Managing Quality through Measurement and Improvement; 16th International Conference of the International Federation of Health Funds.

Pryor DB, Fortin DF. Managing the delivery of health care: care-plans/managed care/practice guidelines. *Int J Biomed Comput*. 1995;39:105-109.

Robertson-Steel I, Edwards S, Gough M. Clinical governance in pre-hospital care. *J R Soc Med* 2001; 94(Suppl 39):38-42.

Rush AJ. Clinical Practice Guidelines - good news, bad news, or no news? *Arch Gen Psychiatry* 1993;50:483-490.

Shomaker TS. Practice Policies in Anaesthesia: A foretaste of practice in the 21st Century. *Anaesth Anal* 1995; 80: 88-403.

Sisk JE, Gorman SA, Lenhard Reisinger A, Glied S, DuMouchel W, Hynes M. Evaluation of medicaid managed care. Satisfaction, access and use. *J Am Med Assoc* 1996; 276:50-55.

Snowden P. Practical aspects of clinical risk assessment and management. Br J Psychiatry 1997; 170 Suppl 32:32-34.

Stewart A, Greenfield S, Hays R, Wells K, Rogers W, Berry S, et al. Functional status and well being of patients with chronic conditions. Results from the medical outcomes study. J Am Med Assoc 1989; 262:907-943.

Swanepoel A. Best practice: Encouraging and supporting clinical quality improvement. Policy document, Board of Health Executives. Woodmead; 1999.

The Medical, Dental and Supplementary health Service Professions Act, 1974: Rules Specifying the Acts or Omissions in Respect of which the South African Medical and Dental Council may take Disciplinary Steps.

Thomson R, Lavender M, Madhok R. How to ensure that guidelines are effective. Br Med J 1995; 311: 237-242.

Ulrich E. Audit. Policy document, Board of Health Executives. Woodmead; 1997.

Van der Merwe JV. Continuous quality improvement healthcare programme. Policy document, Board of Health Executives. Woodmead; 1997.

Van der Merwe JV. Development of treatment protocols; 5th Annual NAPH Congress; 1995.

Wanted: guidelines that doctors will follow [Editorial]. Br Med J July 1993;307:218.

Wilson RM, Runciman WB, Gibbert RW, Harrison BT, Newby L, Hamilton JD. The quality in Australian health care study. Med J Aust 1995;163:458-471.

Wolf SM. Healthcare reform and the future of Physician Ethics. Hastings Cent Rep; 1994 March-April; 28-41.

Wolff AM, Bourke J. Reducing medical errors: a practical guide. Med J Aust 2000;173:248.

Woolf SH. Practice Guidelines: What the family physician should know. Am Fam Physician 1995;51(6):1455-1463.
