Hungarian health care in transition; studies on the improvement of the effectiveness of health care in Hungary by implementing quality assurance

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Chapter 3

STUDY ON THE CONTENT AREA OF QUALITY ASSURANCE
AND KEY CONCEPTS OF THE THESIS

Abstract

The main aim of this chapter is to describe the key concepts used in the thesis. The key concepts of the thesis include quality, and its key dimensions, from the thesis point of view, such as efficacy, effectiveness and efficiency of health care services.

This chapter will focus on exploring the role of quality assurance as a tool to implement and improve effectiveness and efficiency. Multidisciplinary research needs explicitly stated concepts and terminology. However, the terminology of quality assurance, which has central importance in this study, is frequently used interchangeably and sometimes in a rather confusing way. There is no widely accepted agreement over fundamental concepts in the literature. Another factor that adds to the importance of this chapter is the fact that experts in the field of quality assurance (quality management, improvement, continuous quality improvement, total quality management) frequently use terms (same words) differently, or in contrast, use different terminology with the same meaning.

The author is grateful to Professor Frans Rutten, Institute of Medical Technology Assessment, Erasmus University, Rotterdam, for his helpful comments on paragraph 3.4, 3.5 and 3.6.
3.1 The concept of quality, quality in health care and quality assurance

This paragraph looks at the concept and dimensions of quality in the product and service industry as well as in health care services, and discusses the meaning and function of quality assurance.

3.1.1 The concept of quality in the production and service industry

The concept of quality came from the industry. In the industry TQM/CQI was pioneered by Shewhart, Deming, Feigenbaum, Juran and Crosby. Their most important contributions are summarized below shortly:

- **Shewhart** created and implemented the control chart and the Plan, Do, Check, Act (PDCA) Cycle. (Deming, 1986). He wrote that price alone is not an indicator of value. Price without understanding of quality is meaningless. Decisions based on price alone are almost certainly more expensive in the long run than necessary and lead to undesirable results. He highlighted the importance of variation as well.

- **Deming** made a great contribution to TQM, and is known for his 14-point programme of recommendations for management. He focused on process, rather than structure, on the ever continuous cycle of improvement, rigorous statistical analysis of objective data. One of his main activities was to describe, analyse and eliminate process variations.

- **Feigenbaum** together with Juran, he provided the theoretical frame for TQM. According to Feigenbaum the goal of quality, is to meet satisfactorily whatever customers believe to be their requirements for the service or product. Feigenbaum (1991) wrote: “Quality is the capability of a product to fulfil its intended purpose of use, produced with the least possible cost.” Product and service quality, according to Feigenbaum, can be discussed as: “The total composite product and service characteristics of marketing, engineering, manufacture, and maintenance through which the product and service in use will meet the expectations of the customer.” (Feigenbaum, 1991)

- **Juran**’s definition for quality is: “fitness for use” as defined by customers. He stated that: “Quality is doing the right things right in the first time.” (1988) He pointed out the importance of the mission of the organisation and the individual departments. He also highlighted that the quality goal has to be specific. The often quoted Juran’s Quality Trilogy are: 1) quality planning; 2) quality control; 3) quality improvement.

- **Crosby** set up four ‘absolutes of quality’: 1) conformance to requirements (do it right at the first time); 2) defect prevention is the only acceptable approach; 3) zero defect is the only performance standard; 4) the cost of quality is the only measure of quality which means that the cost of producing quality (zero defects) are less than the losses associated with nonquality defects. (1979)

Numerous definitions are used to describe quality in this field. Many approaches and conceptual developments discussed by Klazinga (1996) show the well amplified position of the concept of quality associated with industry. In the field of industry quality is a tool to increase selling, to keep or increase the market share. In contrast, the concept of quality in the service industry, is far less elaborated, because of several historical and methodological
reasons. (Hertog and Kunst, 1992) In the production and service industries several quality systems are in use to measure and assure the quality. The most well-known quality systems are: a) the International Standard Organization (ISO) 9000; b) European Quality Award; c) the British Standard 5750 (1987) in the UK; and the Malcom Baldrige National Quality Award System in the USA (Ovretveit, 1989 and 1992).

3.1.2 Defining quality

According to Dumas (1987), there are three cumulative, levels of quality: a) Conformance quality - conforming to specifications: having a product or service that meets predetermined standards; b) Requirements quality - meeting total customer requirements: having perceived attributes of a service or product that meet or exceed customer requirements; and c) Quality of kind - quality so extraordinary that it delights the customer: having perceived attributes of a product or service that significantly exceed customer expectations, thereby delighting the customer with its value. Jaeger at al. (1994) pointed out that quality assurance is like the term of conformance quality. But they explained later that: "The confusion that surrounds the use of the two terms CQI and QA stems in large part from the difference in quality as conceptualised in the work of early leaders in the health care quality movement and the somewhat simplistic popularisation of TQM by health care groups and organizations. If one, such as Donabedian, reads carefully the initial quality efforts in health care, there is surprisingly little difference between that conceptualisation of quality and what TQM leaders in industry have written." The similarity or difference depends to a large extent on how the terms 'conforming to specifications', 'predetermined standards', or 'customer' are defined. Quality is a very multidimensional term and key players of health care might have a very different vision about conformance and might have different requirements. Quality is a function of the conformance, requirements and quality of kind in the level of providers, patients, public at large, financing institutions, and regulators. The elements of quality are defined in various ways depending on the actual model. Quality elements according to Ovretveit (1989) are client quality, professional quality and management quality. The European Quality Award's (1999) quality elements are: leadership (10%), people management (9%), policy & strategy (8%), resources (9%), process (14%), people satisfaction (9%), customer satisfaction (20%), impact on society (6%), business results (15%). The numbers in brackets show the weights, or relative importance of the different elements of quality. Components of quality have to be clearly listed but this is not enough. The way we give values (weighting) to the quality elements and we judge the conformance (scoring) is equally important and even more difficult.

3.1.3 Quality in health care

The profound changes associated with quality in health care that happened during the past decades are probably best described by Boyce (1996) who pointed out: "debates in health care quality forums have shifted in recent decades from whether quality can be measured to how best to measure quality in health care." A comparison of quality from the industrial versus from a health care perspective shows that the two are similar and both have strengths and weaknesses. (Donabedian, 1996) The industrial model is limited in that it: 1)
ignores the patient-practitioner relationship; 2) downplays the knowledge, skill, and motivation of practitioners; 3) treats quality as free, ignoring quality/cost trade off; 4) gives more attention to supportive activities and less to clinical ones; 5) provides less emphasis on influencing professional performance via “education, retraining, supervision, encouragement and censure.” (Donabedian, 1996) On the other hand, Donabedian suggests that the professional health care model can learn from the industrial model: 1) new appreciation of the fundamental soundness of health care quality traditions; 2) the need for even greater attention to consumer requirements, values, and expectations; 3) the need for greater attention to the design of systems and processes as a means of quality assurance; 4) the need to extend the self monitoring self governing tradition of physicians to others in the organization; 5) the need for a greater role by management in assuring the quality for clinical care; 6) the need to develop appropriate applications of statistical control methods to health care monitoring; 7) the need for greater education and training in quality monitoring and assurance for all concerned. (Donabedian, 1996)

The meaning of quality is discussed by several authors both in the industrial and health care settings. (Cyert, 1975; Crosby, 1979; Donabedian, 1980; Steffen, 1988; Juran, 1988 and 1992; Reerink, 1990; Feigenbaum, 1991; Worning, Welch and Grover, 1991; Mainz and Klazinga, 1992; Klazinga, 1996) The definitions of quality provided by different authors differ to a great extent reflecting the multidimensional character of the quality in health care. The most important characteristics or dimensions of the quality of health care: 1) accessibility; 2) timeliness of care; 3) efficacy of care; 4) effectiveness of care; 5) appropriateness of care; 6) efficiency of care; 7) continuity of care; 8) privacy of care; 9) confidentiality of care; 10) participation of patient and patient family in care; 11) safety of care environment; and 12) supportiveness of care environment. The meaning of ‘good’ medical care changing over time. During the 1960s, in many countries (US, UK) governments were committed to the idea that more care is better. This still is the case in Hungary, where financial incentives push the whole curative health care sector into this direction.

As policy makers and governments became more and more involved in third party payment and increased their cost-consciousness, the meaning of quality changed dramatically as compared to the traditional physician's view. Previously the discussion on appropriateness was focused on benefit and disbenefit of the patients. In contrast, now purchasers are concerned with the opportunity costs on spending on health care when the same resources might yield more valued benefits if spent on other goods and services. Quality is weighed against its cost. Another important difference from the traditional physician perspective emerges in the OTA definition of efficacy and effectiveness, which refers to the probability of benefit to populations, rather than to individual patients. The Office of Technology Assessment (OTA, 1988) defines the quality of medical care as “the degree to which the process of care increases the probability of outcomes desired by patients, and reduces the probability of undesired outcomes given the state of medical knowledge. ... Which elements of patient outcomes (health and satisfaction) predominate depends on the individual patient or condition.”

The definition of quality by Donabedian (1980) pointed out that: “Its expected ability to achieve the highest possible net benefit according to the valuations of individuals and society”. These dimensions are difficult to define, but it is not ‘a mission impossible’ to do this.
(Reerink, 1990) “The quality of care”, as discussed by Donabedian (1989) “has three components: the goodness of technical care, judged by its effectiveness, the goodness of the interpersonal relationship, judged partly by it contribution to technical care, and the goodness of the amenities.”

A further major component of quality, which is of outstanding importance, is to eliminate inappropriate care e.g. inappropriate hospitalisation and hospital stay, supplier induced demand. (Rigter, Meijler and Breeman, 1992; Grover, 1991; Tophill, 1992; Welch and grower, 1989; Mozes, Schiff and Modan, 1991; Aplone et al. 1991; Rice, 1989; Dranove and Wehner, 1994; Pelps 1986; Cromwell and Mitshell, 1986) In the words of Brook: “When you or I visit a doctor, we want to be assured that we will receive the services that we need (that is the application of the service expected to produce more health than harm) and, likewise, that we will not receive services that we do not need. This is what is meant by appropriateness. (Brook, 1991) Inappropriately selected care may be ineffective or harmful, and therefore inefficient.” One definition of inappropriate care is that: “Inappropriate use of a facility comes about through providing unnecessary care, through providing necessary care using a resource not suited for the level of care actually provided or required, and through less than complete use of time during the course of care.” (Donabedian, 1973) The importance of appropriateness can be shown by, for instance, studies conducted in the UK, which typically found that around 15-25% of admissions can be classified as inappropriate. (Torrance, Lawson, Hogg et al., 1972; Pringle and Falk-Whynes, 1994)

3.1.4 Quality assurance in health care

There are many descriptions and definitions of quality assurance in the literature. According to the World Health Organization, the objective of quality assurance is to “improve the outcome of all health care in terms of health, functional ability, patients well-being and consumer satisfaction” (WHO, 1988) Quality assurance, according to BSI (1987) is “A management system designed to give maximum confidence that a given acceptable level of quality of service is being achieved with a minimum of total expenditure.” Donabedian (1989) maintained that: “Quality assurance protects and enhances quality through system design and performance monitoring.” “Quality assurance is at base an effort to find and overcome problems with quality - that is, to change the performance and behaviours of practitioners, institutions, and systems toward those that are more appropriate and acceptable (in terms of health outcomes, or expenditures, or both. (Palmer, Donabedian at al. 1991)

The conceptual framework for quality assurance was developed by Donabedian. His widely accepted model of structure, process and outcome is an important tool to guide research and development. (Donabedian, 1966; Donabedian, 1982; Donabedian, 1988) The concept consists of three main elements: a) structure; b) process; and c) outcome.

a) Structure

Structural measures apply to health care settings at all levels from individual practitioners to large organisations and agencies, irrespective of their size, characteristics, location, own-
ership, governance licensure and accreditation status. For health professionals variables include demographic and professional characteristics. According to Donabedian (1980) the structure: “includes the human, physical and financial resources that are need to provide care”

b) Process

The process of care encompasses what is done to and for the patients. Measuring the process of care against criteria that reflect professional standards (statement of expectation) is the most common way to assess quality. It can be done in the entire health care system. The process of care assessment is not without drawbacks. Although it is commonly assumed that optimal process of patient care yield optimal outcome, the relationship between process and outcome is not always demonstrated. When this link is missing, measuring process may not truly point out the problem that needs to be solved. Process measurement is often done against explicit professionally established criteria, but often there is no agreement and consensus on best practice among professionals. Finally process data sources are poor, varied among health care settings (intensive care versus home care) and the predictive value of process measures in various settings might be different in relation to outcome. In some settings process measure may be less appropriate than outcome measure. (Lohr, 1992) One of the most important aims of quality assurance is to eliminate process errors in the health care work setting. Occasional errors are inevitable and the potential of human error must be recognised before appropriate caution will be taken. (Deusinger, 1992) According to some authors, claims data can be used to achieve this goal. Despite the potential utility of claims data, clinicians are sceptical about them as a substrate for clinical research. Clinicians’ concerns are centred around two issues - the quality of the data and the fairness of comparison that are made. (Steinberg, Whittle et al. 1990)

c) Outcome

As Donabedian (1982) stated in his famous book: “I shall use “outcome” to mean a change in patient’s current and future health status that can be attributed to antecedent health care. By postulating a rather broad definition of health, I shall include improvement of social and psychological function in addition to the more usual emphasis on the physical and psychological aspects of performance. By still another extension I shall add patient attitudes (including satisfaction), health related knowledge acquired by the patient, and health related behavioural change.” Measuring outcomes, the effects of care on patients, health and well-being, has received considerable attention in the 90es. Outcomes encompass a wide range of variables associated with the presence or absence of illness, impairments or handicaps, physical functioning, emotional health, pain and other symptoms, days lost from work, daily life activities and satisfaction. Although the lack of process-outcome links can undermine outcome assessment, it is limited by the fact that outcomes are not routinely and uniformly recorded, it requires time, manpower and money. The growing interest in health outcomes has been labelled the ‘third revolution in health care’. (Relman, 1988)
It is important to take into consideration that health outcomes are about values and not just technicalities. The need to make choices make it imperative to consider whether what is achieved is also what is most valued. It is important to know what the patients and the community want from their health services. According to Shiel (1997) the challenge lies not in measuring the outcomes of health intervention but in deciding what the objectives of the health system ought to be. As Mooney agreed upon and pointed out: “There is a need to reflect more on what both patients and the community want from their health services and there is sometimes insufficient recognition of the role of the health outcomes movement in achieving this.” This topic is closely related to the efforts made in the past decades and are made currently as well to set up basic benefit packages. (Cotton, 1992)

There are many ethical and economic perspectives related to the outcome. The relationship between outcome and equity is important for health policy. It is not enough to consider horizontal equity, the equal treatment of equals, but we have to examine vertical equity the equation i.e. the unequal, but equitable, treatment of unequals. What system for weighting outcomes might be used? (Mooney and Jan, 1997) Evidence-based outcome oriented procedures are increasingly used in public health. (Chapman, 1997)

One of the most important aims is to compare outcomes among providers. In order to assess the effect of hospital care on patient outcomes, it is essential to take into account the differences for instance across hospitals. Hospitals are different in mix of diagnoses, the severity and complexity, social and financial conditions and health behaviour of the patients treated. Unless adjustments are made for these differences no valid comparison can be made. The two major problems with existing health outcome measures which limit their utility as accountability tools are risk adjustment and attribution. (Boyce, 1996) Risk adjustment models which adequately and appropriately account for all the confounding factors for given health care interventions are currently unavailable. (Iezzoni, Ash et al. 1995; Localio and Hamory, 1995) Problems with attribution means that when a series of interventions is involved, it may be difficult to ascribe health status changes to any individual intervention. Difficulties of the comparison between providers and the need for standardised outcome measurement and interpretation are stressed by the following example. An important question is highlighted as well, namely whose point of view should be used among providers, financing organisations, regulators or the public?

3.1.5 The main aim of quality assurance

According to the definition of the World Health Organization, for instance, the objective of quality assurance is to “improve the outcome of all health care in terms of health, functional ability, patients well-being and consumer satisfaction” (WHO 1988) Berwick’s (1994) definition of quality practice is more concrete, one of the most important purpose of quality activities, according to him, is ‘narrowing of practice variations’ - require an explicit description of the thresholds of impact, cost and risk. As Reerink (1987) stated: “The purpose of quality assurance is to assess and, if necessary, to improve health care delivery. Its focus is on increasing effectiveness and efficiency, not on fighting excessive cost, fraud or excess.”

“The main aim of quality assurance activities”, according to Williamson (1978), “is to assess and improve the actual benefit of a given health care service where there is further
benefit achievable but not achieved. In other words, one of the most important goals of quality assurance is to improve the effectiveness and efficiency of health care. "According to various authors, quality assurance might have a very different aim and function. In this thesis the author is focusing the 'bridging function' of the quality assurance which means to improve effectiveness and to make the gap narrower between efficacy and effectiveness.

3.1.6 Outcome, benefit, risk and needs

Williamson (1978) pointed out the importance that the value of outcome to the patient, family, community or to the nation have to be thoroughly evaluated and documented. A value of a given health care outcome, as he further explained, is relative not an absolute attribute, it may be perceived differently among individuals or between larger social groups. The value of health outcome represents the sum of positive, negative and neutral effects of a given treatment, prevention or intervention. In relation to efficacy very often only positive values have been encompassed, whereas in relation to care interventions as a universal characteristic the often neglecting harmful side effects or risk-to-benefit ratios, have to be accounted as well, particularly in long term. (Williamson 1978) "Benefit minus risk" is highlighted in the conceptual exploration of quality of health care by Donabedian (1982) as well. Williamson and co-workers (1991) further explained the importance of the outcome-benefits orientation: "There are several important conceptual factors in developing an outcomes orientation. First, and foremost, the product of health care needs to be defined as 'benefits achieved,' not 'units of service,' as some suggest. Second, benefits must be defined in terms of outcomes, not improved processes or structures. Finally, outcomes must be defined as encompassing the entire spectrum of health care results for both consumers and providers, including health, economic and societal results. Societal outcomes include such examples as education, satisfaction, or ethical legal results. The implication of benefits achieved as the product of health care helps us define quality in terms of the extent to which achievable benefits are achieved in any specific area. The purpose of quality management is thus to identify "achievable benefits not achieved" and apply requisite interventions to increase these benefits, that is to effect improvement. Quality assurance is a tool to improve benefit of the recipients of health care, that could be a subgroup or group of the population. In order to achieve this goal it is necessary to determine both the average benefit per person and the number of persons involved. (Williamson, 1978)

A useful application, introduced by Williamson, of the concept of achievable benefits of health care related to three basic quality assurance indicators, efficacy, effectiveness and efficiency. Efficacy shows the maximum benefit achievable by a given intervention under idealised conditions, effectiveness show the actual benefit achieved under actual condition. Efficiency is the relation to benefits achieved and the accompanied costs. "... the concept of achievable benefit not achieved", as Williamson (1978) formulated, "indicates that benefit of health care that is possible given the state of medical science and local conditions of care, but that is not being attained, whether due to insufficient provider performance or to misallocation or inefficient use of available resources." Within theoretical frame "benefit minus risk" can be easily calculated. However, both benefit and risk are multidimensional, changing over time and valued (weighted) differently by individuals or groups. Because of its central importance of risk related to uncertainty and outcome, risk should be discussed...
in some detail. Many tests, diagnostic procedures, prevention and screening are virtually risk-free and do not produce much discomfort. Patients would not risk having or avoiding these ones. It is mentioned virtually because inappropriately used procedures can result in false positives for instance, and to further examine or treat false positives is a real danger. Good examples for that is a routine chest X-ray in ASA 1. patients before operation.

The capacity to benefit competing groups of patients may vary e.g. the poor may benefit less, per unit of expenditure, than the rich because of e.g. their genetic endowment, their work, their leisure, and household behaviours, and their education, housing, income and wealth. If resources are allocated to those who benefit most, the poor may get less care and health inequalities may be increased. Equity issues such as these cannot be ignored in a publicly funded health care system. The competitive market, if it is successful in allocating resources, on the basis of capacity to benefit, will be constrained by public regulation in order to meet socially determined equity targets. (Maynard, 1993)

Benefit and needs are closely related, needs are quite often formulated as capacity for benefit. To measure needs is not an easy task. For many procedures estimates of aggregate need in population remain highly insecure, with inadequate information about: 1) their effectiveness in different subgroups of patients and the indications for treatment, 2) the numbers of the population for whom the procedure is appropriate, and 3) the acceptability of the procedure to patients. (Frankel 1991; Sanderson and Hunter 1997) The extra-welfarist approach attaches great importance to the identification of potential for benefit. In its most rudimentary form ‘need’ for health care would seem to imply that someone is better off with the ‘needed’ treatment than without it. Thus health services are needed only if the outcome is desired and there is no alternative (or more cost effective) way of realising it. Since inputs are nearly always substitutable, it will not normally make sense to say that a specific resource in a specific quality is needed. Since there is no effective treatment for such condition, it is nonsensical to say that persons suffering from such conditions need health services. Since health services are needed for what they enable to be accomplished, in a world of scarcity judgements must be made about the value of what might be accomplished. Some services are bound no to be supplied in the light of such judgement and so it does not make much sense to require that all needs should be met. One of the first lesson of ‘needology’ is the lesson of the ethical acceptability of unmet need.

3.1.7 The importance of risk assessment

Related to treatment, operation or other intervention the following question should always be asked: what risk of side effects, nosocomial infection, or even death would be acceptable. First of all we have to make clear statements and distinction between uncertainty and risk, then we have to spend some time to see how to measure risk and use this information. Probability and uncertainty in medicine are extensively discussed by many authors. (Sox and Blant, 1988) Probability, uncertainty and risk are often used interchangeably but these are different concepts with profoundly different consequences or outcomes in practice. It is also important to make a clear distinction between risk and uncertainty. As Friedman (1985) explained, Knight (1921) proposed a distinction between ‘risky’ and ‘uncertain’ situations. Risky situations, in his terminology, are those in which each possible
outcome has a known probability of occurring. Uncertain situations, again according to Knight, are those in which the probability of each outcome is not known. Risk can be calculated, the ‘benefit minus risk’ calculation can be made. In contrast, if the uncertainty is not known, the ‘benefit minus uncertainty’ calculation cannot be made. It is doubtful whether quality assurance activities under uncertain conditions produce any benefits. In order to improve effectiveness there is a need to stratify patient population, to measure the risk related to a given patient population and to adjust achievable benefit and effectiveness by this rate of risk. Without risk stratification achievable benefit might not be defined. As some authors (Moorhead, 1989; Phillips and Kawachi, 1990) pointed out, hospital information systems have made great improvement in their ability to collect resource utilisation and cost data, but it is not possible to provide comparative data that allow for the monitoring of the quality of care provided in different organisations. Maynard (1998) stressed the importance of comparative data on quality in improving existing performance.

Risk adjustment is widely used now. Risk adjusted outcomes: mortality, readmission and complication rates can be used to monitor quality of care. According to Desharnais et al. (1991) risk adjusted indices can be used to achieve the following goals: a) identifying patients records for peer review; b) comparing variations in outcomes; c) monitoring changes in outcomes following a change in the delivery system; d) measuring the size and the gap between the efficacy of technology and the effectiveness of this technology (this is especially useful related to the diffusion of new technology form the US where the patient access to new technology is determined by the patient’s ability to pay, and access not based on effectiveness of this technology.)

The effect of the medical service offered to the patients depends on how sick was the patient when she or he entered the health care facility. A broader effect on a given patient population relies on the patient-mix, case severity and social-mix. Every patient population has its own risk-profile. In health care effectiveness of a given medical (prevention, diagnostics, therapy, intervention) or nursing service depends on the risk of the given service and the way it is provided (infrastructure, technology, skill of the staff etc.) to the patients. This is the risk profile of the given health care setting. An effective intervention has different outcomes and may or may not improve the health status of the population based on different risks. The absolute level of risk cannot be measured most of the time, or if it can be measured it is not important. What can be measured is a relative risk, the risk compared to the accepted level of risk. This accepted level of risk (some call it safety) can be defined in accreditation standards in order to decrease uncertainty. As a consequence of the above statements: effective drug delivery or treatment is an abstract term which is generally non-existing in the real world. A given drug or service is effective in a given patient population stratified by risk.

It is very important to take into consideration, that the existing risk is closely related to the variation of outcome and can create a situation: it is when good apples look bad. A significant amount of outcome variation is associated with the different risk profile of the patient population and the different risk profile of the given health care setting. Significant amounts of risk cannot be squeezed out from health care. Very few studies compare the risk of for example iatrogenic illness to the benefit that could have been expected from the medical intervention. This is a major shortcoming. By separating the risks from benefits associated
with a course of action, and focusing only on the risks, readers are given the impression that net harm has been done - even when it is not necessarily so. For most clinical decisions, one can only attempt to achieve net benefit on the clinical decision, one cannot attempt to achieve net benefit, on the average, while expecting some probability of harm. (Fletcher and Fletcher, 1989) In their book: 'Health care for Elderly', Petersen and White (1989) discussed thoroughly the possible dimensions of risk from hospital admission to discharge.

### 3.2 Efficacy

Efficacy implies that the interventions have a certain power to produce the desired effect (Merriam-Webster, 1994) Efficacy is the ability to do something or do it well and produce the results that were intended. (Collins, 1990) As Williamson (1978) stated, quality assurance research must not include formal study of the efficacy of care interventions. Having some benefit of the given diagnostics, therapy or intervention is a prerequisite of subsequent quality assurance activity. Having efficacy is a typical yes or no type of question. Medical services are efficacious or not. However, there are different levels of evidence on efficacy. Classically the major source of evidence is the randomised controlled clinical trial (RCT). (Begg, Cho et al. 1996; Cappelleri, Ioannidis et al. 1996) According to a number of researchers this is the only source for evidence. RCT's are often meant to be trials under controlled research-based clinical or laboratory 'ideal' conditions. But 'ideal' conditions can be created in various parts of the health care services, for instance, in the field of primary health care (Cupple and McKnight, 1994; Palmer, 1996). There are relatively few RCTs available, until October 1997, the Cochrane Collaboration collected 150,744 RCTs. (Silagy, 1997)

There are many areas in health and medical care where, because of time, sample size, limited resources or ethical considerations RCT-based scientific evidence are not available (e.g. Pap smear), but quality should be improved. In these cases lower levels of evidence can be used (non-randomised trial with contemporaneous controls, non-randomised trial with historical controls, cohort study, case-control study, cross-sectional study, surveillance, series of consecutive cases, single case report) for subsequent quality assurance activity. There are many quality problems with efficacious services. In many cases efficacious technologies are underused, or inappropriately provided; not in the right time, not in the right place or not to the patients who might have some benefit out of it. Sometimes patients are even overtreated (Franks and Glancy, 1993). In summary: data on efficacy have to be present, and a formal study on efficacy is not a target area of quality assurance. Although, efficacy is not incorporated in quality assurance, it is important to define its relationship towards effectiveness and efficiency. The terms efficacy and effectiveness are often used interchangeably, but these two terms have very different meanings. Efficacy is the potential to produce an effect, effectiveness the production of an effect. Efficacy is mostly concerned with the benefits achievable from therapy or an intervention under ideal conditions, such as the ones found in a randomised clinical trial (Brook and Lohr, 1985, Cochrane, 1971, Sackett, 1980; Williamson, 1978). Figure 3.1 shows the key elements of efficacy. (Williamson, 1978)
As is demonstrated in Figure 3.1 an efficacy index can be formulated to determine the achievable benefit of care. This index shows the portion of the maximum conceivable benefit which is actually achievable. The maximum conceivable benefit demonstrates the desirable but in most of the time unattainable elimination of all patient risks, illness and disability in a given study population.

The efficacy index is computed as a rate of

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\text{Efficacy index} = \frac{\text{Achievable benefit}}{\text{Maximum conceivable benefit}} \times 100
\]

Sometimes efficacy is defined differently. A typical example for that is the definition of St. Leger, Schnieden et al. (1992): A clinical service cannot attain its goals unless its component parts and the way these relate to another, and the manner in which the service is targeted to the community, are themselves effective (in general usage of the word).
general 26% in the age-group 50-74 years and over (efficacy of the screening). (Nystrom, Rurquist et al. 1993; Fletcher, Black et al. 1993; Kerlikowske, Grady et al. 1995). Another meta-analysis of 6 RCTs published by Elwood, Cox and Richardson (1993) found that breast cancer mortality can be decreased by 34% as maximum in the age-group of 50-74 years. According to this, 300 lives can be saved yearly and this is the yearly achievable benefit in Hungary. However, because of various reasons, for instance lower compliance rate, the actual effect of the screening programme (effectiveness) is lower than what the effect could be under idealised conditions. (Kruse and Philips, 1987; Rimer, Keintz et al. 1989; Zapka, Stoddard et al. 1990; Lerman, Rimer, Trock et al. 1990; National Cancer Institute Breast Cancer Screening Consortium 1993;) Demonstrated best results, also benchmarking, can be used in order to define achievable benefit in different countries. Maas et al. (1989) predicted 12% breast cancer mortality reduction due to screening in the age group of 50-70 years. This percent can be used as ‘achievable’ benefit, as benchmark. Achievable benefit from mammography screening of the Hungarian female population over 50 years of age, defined by benchmarking, based on the results of Maas and collaborators, is 160 lives saved per year. If we further investigate the annual target population and the annual costs in Hungary, and if we see the Dutch experience of the 7 years building up periods, the compliance rate and the detection rate in relation to a very sophisticated Dutch health care system and extrapolate findings to a Hungarian situation, the actual achievable benefit for the same target population could be much lower than 12% breast cancer mortality reduction due to screening. This prediction should be taken into consideration when establishing a screening programme. (Gulácsi, 1999b)

3.2.2 Ethical dimensions

Efficacy has important ethical dimensions as well. In economic terms health care is a zero sum game. Resources spent on one services cannot be spent elsewhere. Money spent in the field where efficacy is given is a way to give value for the money spent on health care. There are two examples to show that lacking evidence of efficacy might be harmful for the patients or at least could cause major financial loss. Preoperative routines, routine chest X-ray, ECG and laboratory tests, have not been showed to be beneficial for patients but widely used in Hungarian hospitals (Chapter 6). Related to pressure sores prevention and treatment many procedures can be found, massage of bony prominence for instance, witch are not based on evidence to be beneficial (lacking efficacy) and might even be harmful to the patients. Although autologous bone marrow transplants (ABMT) in breast cancer cases proved to be not efficacious, it is being done and heavily advocated in Hungary. (ECRI, - formerly called Emergency Care Research Institute - analysed 40 studies of ABMT and similar procedures and 61 studies of patients receiving conventional therapy. The available data suggest that a high dose chemotherapy plus autologous bone marrow transplants not only fail to extend the lives of women with advanced metastatic breast cancer, but also is likely to be life shortening. (Stephenson, 1995)

Lacking evidence of efficacy of prostate cancer screening with prostate specific antigen (PSA) illustrates the usefulness of the concept of efficacy. Screening for the early detection of prostate cancer with serum prostate-specific antigen (PSA) is controversial because research has not yet determined whether PSA testing improves patient outcomes. (Smith,
Catalon and Herschmann, 1996) The therapy of prostate cancer is also problematic. Radical prostatectomy leads to high 10-year disease specific survival. However, a great deal of caution is needed in interpreting results, because it is still not evident that survival rate after radical prostatectomy is higher compared to the rate ... 'watchful waiting'. Krahn and colleagues (1994) published evidence based on the result of a study that PSA and DRE screening followed by radical operation increase life expectancy with an average of 0.6-1.7 days in the 50-70 year-old population. (Fleming, Wasson et al. 1993; Chodak, 1993) In contrast to the lacking evidence in 1995-97 a large group of men were involved in a state health insurance financed PSA screening programme in Hungary, and the population PSA screening is heavily advocated.

3.2.3 Efficacy: value in practice

Brook, Klamberg and McGlynn (1996) pointed out that:” ... we know that efficacy (the outcome of a procedure performed under ideal circumstances) may not predict effectiveness (the outcome of the procedure performed under usual circumstances), so that results from controlled clinical trials may mislead clinicians weighing the health risks and benefits of an intervention.” He illustrated this with two examples from the field of carotid endarterectomy and the care of heart attack patients. In both fields the experience has shown that these activities in the community-based settings have much lower effectiveness than its efficacy and the complication rates are not as low and outcomes are not as good as in controlled clinical trials.

3.3 Effectiveness

The importance of effectiveness was pointed out by various authors. As the Health Council of the Netherlands pointed out: “Effectiveness and efficiency in medical treatment are central to health care policy and gain in importance as the tension between the demand for care and the resources available increases” (Health Council of the Netherlands Work Programme 1998, 1997) Lomas (1990) highlighted: “Increasing interest in quality assurance and effectiveness in health care has been generated by three major things: about 20% of care is consistently demonstrated to be inappropriate, variations in practice cannot be explained by patient or facility factors, and decreased utilisation as a result of changing economic and regulatory incentives seems to lead to both inappropriate care and appropriate care reductions.” “An emphasis on effectiveness”, as Lomas (1990) stated, “constantly encourages us to focus on the objectives of health care delivery. How can we decide whether we are being effective without knowing what our objectives are?” Throughout the world, issues surrounding the clinical effectiveness of treatment are high on health care service agendas. These include the fact that so little of our health care has been shown to be effective by research methods. A very large proportion of our health care is simply not evaluated at all. This may be apply to as much as 80% of our procedures and treatments within medicine, and a much larger proportion within most of other health care disciplines. (Firth-Cozens, 1996) There is an important distinction between efficacy and effectiveness (Wooll, Battista et al. 1990) These authors explained: “Effectiveness may differ from efficacy due to factors related to provider the patient, and the health care sys-
tem: practising clinicians may perform the procedure differently or less consistently than investigators with special expertise and a standardised protocol, and they may follow up on results less thoroughly; patients may be less willing to or able than clinical trial volunteers to comply with screening and/or follow up; and the health care system as a whole may encounter financial or logical limitations in providing the service for appropriate persons and ensuring adequate treatment and follow up.”

The relationship between effectiveness and quality activities is also discussed. Phillips and Bero (1996) stressed: “Determining what is effective and measuring and incorporating patient preferences are key components of the move towards measuring quality and using quality information to guide patients and providers.” According to Donabedian (1989): “The first component of the quality is technical care. In essence, the quality of technical care is proportionate the to its effectiveness, which means its expected ability to achieve the greatest improvement in health that science, technology, and skills can now offer.” The other two components, the goodness of interpersonal relationship, and the goodness of amenities, are not in the focus of this thesis. Future focus on quality assurance as was predicted by Roper (1988) is: “the future will see increasing focus on the aspects of effectiveness - health outcomes - because it is now well recognised as the “gold standard” against which performance should be judged.” As Brook (2000) pointed out that: ‘Although the likelihood that a person will benefit from medical care is better now that it was a third of a century ago, largely as a result of investment in basic science and clinical research, there is no evidence that we are better today at applying what we know than we were 30 years ago. Indeed, we may be worse because of the complexity of medicine has increased so greatly.” These different views of effectiveness have a very important meaning to the current Hungarian situation, where increasing health care spending and a large health care capacity seems to have no impact at all on the health status of the population.

3.3.1 The era of beliefs: the more health care, the better

Osler noted that ‘a desire to take medicine is perhaps the great feature which distinguishes man form other animals’. This led shortly to the very widely held belief that every disease, or symptoms has its bottle of medicine or magic pill, an operation or other service which solve the problem or at list help. Patients expected the doctor to do something to help him: the more the better. (Cochrane 1971) People in this ‘golden era’ of medicine believed very much in science, not only in the medical field but in general. We had witnessed the invention of the clean cheap energy power, the fusion in the physics, benefits from the gene technology seemed so close to reality, unlimited source of row materials as results of space research, economy was growing, unemployment rate was low, social harmony and well being were present all over in the developed world. It seemed that economic barriers were down for ever. This beliefs crashed in the early 70’s. At the first glance because of the oil crises, but shortly after it became visible that problems are more profound. That time the ‘doing nothing’, or ‘watchful waiting’ were not among the set of elements of the health or medical care. In other word ‘zero action’ was not defined, even the ‘concept of zero’ (doing nothing) in health care was not invented or at least was not conceptualised.
3.3.2 The era of scepticism

As health care resources become more and more limited, and because the benefits in health status provided by health care services were less than expected by the public, or at least they were not proportional to the investment, research in both sociology and the medical community became critical. Some times later the public started to worry too and wanted to know more about how the money is spent on health care. The industry in the western world spent more money on health insurance than their competitors and started to loose market share. For instance automobile companies in the United States realised that they spent more money on health insurance of the employees than on raw materials. As soon as they became aware of this problem, the well trained young managers started to optimise health purchasing and devoted relatively less attention to other fields. Governments started to worry, too. Their contributions became higher and higher, pressure from industry and from the public tended to be more and more visible. At the same the health care became a real industry with hospitals in its centre. Specialisation and sub-specialisation, the booming and uncontrolled diffusion and consumption of the new and expensive health technology created a situation where traditional hospital management failed. To put it simply, there were very few competent individuals to control and manage this and there were no appropriate methods and data on and insight into what was really happening in the health care sector. Some decades earlier Cochrane (1971) pointed out in his famous book (effectiveness and efficiency, associated to NHS) that: “Most industrial organisation of comparable size would have had large research section checking on the effectiveness of the service it was providing. In point of fact there was no research of this kind for the first fifteen years of the life of NHS. Part of the trouble was that in 1948 medical research meant the Medical Research Council. The MRC inevitably was biased towards the pure and opposed to applied research.”

3.3.3 What are the contributions?

A key question can be addressed in relation to the effectiveness of services: Did the service contribute positively to the patient’s health status? This question has been asked very often, and it consists of two fundamental sub-questions, namely: What are the contribution of medical care to the health of the population, and can the effectiveness of health care be improved?

Health care is among the important factors attributable to the continuously improving health status of the population in the developed countries. In Hungary, however, despite the increasingly used health technology the population’s health status improved until the early 70s, then its improvement turned back and started to decrease. Because the answer is not always clear, viewpoints dependent, there is ample room for further discussion and research. Different authors represent a significant range of different opinions from the sometimes called nihilistic viewpoint up to the apologetic opinion. Some of the authors question the effectiveness of medical care. The key representatives of these writers are sometimes called the ‘nihilistic chorus’: (Aday, Begley, Lairson et al. 1993) According to this ‘nihilistic chorus’: Mckeown, Illich and Carlson: whatever improvement in health sta-
tus is achieved, the driving forces to obtain this are everything but medical care. In his well known and often quoted book: Medical Nemesis, Illich (1975) pointed out, perhaps in the most radical manner, that not only has medicine limited effectiveness but since 1950s it even has had potential to cause as much harm as good. Carlson (1975) reached a similar conclusion in his book: ‘The End of Medicine’, questioning that even a limited effectiveness of medical care seems to be non-existing. McKeown (1979) pointed out that environmental factors were important in improving the health status of the population. Fuchs (1974) pointed out the importance of non-medical interventions, such as lifestyles. Fuchs (1974) touched upon very important questions. He did not question the effectiveness and contribution of medical care but pointed out the decreasing marginal contribution (benefit). Milo (1983) presented evidence on the limited effectiveness of medical care both in acute and chronic care, and pointed out the importance of social change in avoiding the rather negative influences of modern life. Evans and Stoddard (1990) argued that spending great sums on health care reduces savings and investment and consequently have a negative effect on health status.

The writer of this thesis thinks that the above mentioned scepticism is in general correct. Health care has a potential to cause more harm than good. If we use health technology inappropriately, for instance not having primary health care doctors, unnecessary operations, PSA screening, hospital infection, inappropriate antibiotic regime etc. The authors in general did not separate medical care from health care, but these are two very different entities. They did not take into consideration that the result of medical care is not only increased life expectancy, but improved quality of life, and many things what are not related to the effectiveness of medical care but meet the expectations and requirement of the public, such as breast augmentation, cosmetic surgery or artificial insemination, etc. More and more areas and services are being incorporated into health care beyond medical care. Fields outside classical medical care are becoming more and more important including, for example, management, quality assurance, technology assessment, patient education and information, behavioural studies etc. This is echoed in the regulation as well. For instance the Joint Commission has 7 non-medical members on its board, the Canadian Council on Health Services Accreditation has one representative from the public and the Council is going to invite more representatives from the non-medical but health care field, such as social workers. The message that the above cited authors pointed out most importantly can be put as follows: the gap between efficacy and effectiveness is becoming wider and wider. The gap is between what health care could achieve and what it actually does achieve. In my point of view Illich, Carlson McKeown, Fuchs and others became important analysts and vehicles of the health care effectiveness improvement in the field of health care system research, with their positive scepticism (rather than nihilism).

3.3.4 Can the effectiveness of health care be improved?

Donabedian, Williamson, Brook and Wennberg accepted the limits of effectiveness of medical care and addressed a very practical question: can medical effectiveness be improved and if yes how? They argued that medical effectiveness can be enhanced and their work resulted in what is called today outcome research. Donabedian (1966) stressed the necessity
of quality measurement of medical care through the analysis of the impact of the structure, process on quality and outcome. Williamson (1978) in his book on health accounting stated that accounting a quality assurance system is analogous to the process of the financial accounting. This pioneer findings were further discussed by Williamson Moore, and Sanzano (LARGE QA)(1991); Brook and Lohr (epidemiology of medical care) (1985); Ellwood (outcomes management) (1988); and resulted in the era of accountability (Relman, 1988). At the same time investigation of the geographic variations and small area analysis showed tremendous variation in the services used and in mortality rates (Wennberg and Gittelsohn, 1973); Wennberg (clinical evaluation science) (1990); Health Care Financing Administration (1986 and 1987) resulted in a thorough investigation of outcome and establishment of clinical indicators through various national (Agenda for Changes, JCAHO), (O'Leary, 1987) and international efforts. According to Bernstein and collaborators (1997) setting clinical guidelines based on effectiveness criteria is one possible way to improve effectiveness.

3.3.5 Conceptual framework and definition

According to Wilson and Goldschmidt (1995) effectiveness has a very significant importance in quality management. "In the broad sense, health care quality management’s goal is to design and document effective interventions, to ensure and document their proper application in clinical practice, to measure and document health outcomes, and to use the resultant information on process and outcome variation to improve conformance to cost effective health care process and interventions’ effectiveness in producing health outcomes." (Wilson and Goldschmidt, 1995) According to Wilson, safety and effectiveness are interrelated. "If effectiveness is measured in terms of health status improvement - as it should be - any harm that the intervention may cause is counted automatically and thus safety, and cannot be considered separately, as the same measure captures both gains (in health status) and losses (injury or harm to patients’ health), to yield net health status improvement (or deterioration)." The major conceptual framework of effectiveness research derives from the work of Donabedian (1966). Donabedian first suggested categorisation of medical care in terms of structure, process and outcomes for the purpose of determining what aspects might have influence on quality. Effectiveness research reflects two competing but probably complementary definitions of effectiveness. One is the population perspective (macro level) or called epidemiology of health (Milo, 1983). Effectiveness research is focused on the question: what are the contributions of health care to the health of the population. The second is a clinical (micro level) perspective. In this level effectiveness research has a focus on the relationship between the structure and process of health care organisations on the health of patients. Donabedian and Wennberg called this level a ‘clinical evaluation science’, according to Brook and Lohr (1985) its name is epidemiology of medical care. The cause of the seemingly competing situation is that the unit of analysis for effectiveness is the whole population, while the unit of clinical practice is the patients, group of patient or even a single patient. What is effective for a group is not necessarily good for each member of the group. That is why clinicians often rely on personal experience over research data. They view effectiveness research as useful but not necessarily definitive. According to Cochrane (1971) effective service (prevention and treatment) have to have some positive effect, which may or may not based on evidence from RCT. He also pointed out the importance of taking
into consideration the potential of having some effect (being effective) in the short run but having potentially less good than harm in the long run (psychometric drugs).

Effectiveness concerns the results achieved in the actual practice of medical care with typical patients and providers, as contrasted to efficacy which is assessed by benefits achieved under ideal conditions. (Cochrane, 1971; Williamson, 1978; Sackett, 1980; Brook and Lohr, 1985) Effectiveness can be composed as a function of benefit achieved and the achievable benefit. (Figure 3.2)

**Figure 3.2 Effectiveness**

<table>
<thead>
<tr>
<th>Achievable benefit</th>
<th>Benefit not achieved</th>
<th>Benefit achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Errors of commission</td>
<td>Errors of omission</td>
<td></td>
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The net accomplishment of health care provided under local circumstances computed as a rate of:

\[
\text{Effectiveness index} = \frac{\text{Benefit achieved}}{\text{Achievable benefit}} \times 100
\]

The key element of any study of effectiveness is the comparison between actual practice and some standard. The standard may be absolute (e.g. the explicitly stated aims of the service) or comparative (e.g. the achievement of a differently organised service of the same intent).

"... the ultimate goal is to assess the outcome or impact of health care services on the population." (St. Leger, Schnieden et al. 1992) Lots of publications are focused on effectiveness of the most common medical and preventive activities. (St. Leger et al. 1993) The answer for the question ‘efficacy or effectiveness’ is critical for all part of the health care services and not only in the field of high technology but associated with common activities such as vaccination. (Clemens, Brenner, Rao et al. 1996) The effectiveness of the medical procedure depends on the indications set for that procedure. The question is: in which patients and compared to which other treatment options? In other words, ‘appropriateness’ and indication setting’ are inseparable. As Long (1992) stated: ‘... the concept of effectiveness in health care services performance can be defined as the measure of the degree to which the objective(s) of a policy programme, treatment, pattern of care, or resource group has been achieved. The critical feature of such a definition is the explicit link of the objectives of the service or procedure to actual performance: that is the achievement of the objectives. Effectiveness is thus bound up with the production of a desired effect, in contrast to efficiency the focus of which lies on the achievement of the maximal result with minimum effort or inputs. ... The very concept of effectiveness becomes meaningless unless clear objectives are identified and set in the establishment of a service or programme."

Effectiveness according to Holland (1983) is "... a measure of the degree to which a particular treatment of pattern of care in the population achieves its objective in medical, psychological, and social terms."

According to the US 'Essential Public Health Services Work Group (1994), to evaluate effectiveness, accessibility, and quality of personal- and population-based services are among the essential public health services. (Elbert, Barry, Bialek et al. 1997) There is a different definition for effectiveness discussed by Woolf and Battista et al. (1990): "The principle criterion in analysing the effectiveness of any medical practices is whether performing the proposed manoeuvre is likely to result more in more good than harm. There is an important distinction between this definition and of effectiveness and a more popular use of the term: the ability of a manoeuvre to reduce to reduce the incidence of severity of its target condition. The second definition omits consideration of the adverse effects of the clinical manoeuvre that may increase the incidence of non-target conditions."

Quality has many different meaning and dimension. Although, there might be a wider interpretation, in this thesis a rather narrow focus of quality is used. The author is mainly concentrating on the issue of measurement and improvement of effectiveness of health care services.

3.3.6 What should be the impact of quality assurance?

The impact of quality assurance could be structure, process or outcome related or the combination of the three elements. There are many different views concerning what should be the impact of quality assurance. Two markedly different opinions were discussed by Williamson, Moore and Sanazaro (1991) and Walshe and Buttery (1995).  

Williamson, Moore and Sanazaro (1991) stated that: ... the product of health care needs to be defined as "benefit achieved" not "units of service" and "... benefits must be defined in terms of outcomes, not improved processes or structures". Finally they argued that: "... outcomes must be defined as encompassing the entire spectrum of health care results for both consumers and providers including health, economic, and societal results." As they further discussed: "The purpose of quality management is thus to identify 'achievable benefit not achieved' and apply requisite interventions to increase these benefits, that is, to effect improvement." If the benefit must be defined in terms of outcomes, there is a need for more good quality outcome data, which are quite often lacking. As Gill (1993) stated that in the third years of contracting with the NHS: "The main aim seems to have been "damage limitation" rather than the introduction of imaginative approaches to quality improvement." The author pointed out that limited attention was paid to quality measurement such as generating indicators or other tools to measure quality of health care, and the absence of national consensus on appropriateness explain why it continues to be hard to use contracting to improve key dimensions of quality. In contrast, Walshe and Buttery (1995) argued that the impact of quality assurance could be defined narrowly as its effect on quality of health care delivered to patients or much broader defined as its effect on the healthcare organisation, the processes of healthcare provision and quality of health care delivered to the patients. According to their survey in the NHS the results of the audit
activity showed that 8 percent of the changes were related to the quality provided to the patients, 46% of the changes were associated with clinical practice, 33% were associated with service delivery, 5% were associated with organisational structure, 11% were associated with organisational culture and 10% were associated with the quality management as the result of the audit in the NHS. Between 1989 and 1994 the Department of Health spent over 220 million pounds on establishing medical and clinical audit in the NHS in England. (Department of Health, 1994) However, to evaluate quality of care requires resources. Lezzoni (1997) addressed a very important point in her article entitled 'How much are we willing to pay for information about quality of care?' As she argued computer files with discharge abstracts to examine no risk adjusted mortality rates can be purchased for $1000, in contrast when clinical data were reported and evaluated for quality of care in California, in 1990 the estimated annual cost was $61 million. In Pennsylvania hospitals are required to collect large amount of clinical data which are used to adjust mortality rate for risk since 1986, costs are estimated $17.43 per case.

3.4 Effectiveness of quality assurance activities

The importance of the effectiveness of quality assurance activities is pointed out by many authors, but there is scarce scientific evidence in the literature. As Phelps (1976) wrote two years after the introduction of the mandatory quality assurance in the USA: “The evidence used to justify these various regulations of quality has been, to be generous, sparse. The primary justification for many of these programmes is that the present state of affairs is scandalous so that change must lead to improvement. While not necessarily quarrelling with the premise, the conclusion is unwarranted. It therefore seems appropriate to begin to evaluate the evaluators, to develop a framework with which one could assess the gains to society from undertaking a quality assurance program of one type or another.” While there is a large number of approaches to quality assurance in use, there is no consistent and defined method. As Donabedian (1995) says: “... we do not know what such efforts accomplish in either altering behaviour or improving health.” Shortell et al. (1995) assessed the evidence of CQI in terms of quality and costs. They found non-conclusive evidence, based on their research: “it is difficult to say whether the CQI glass is half empty or half full”. Donabedian (1996) further discussed this topic in his article about 'The Effectiveness of Quality Assurance'. He argued that: “The large number of quality assurance interventions, separately and in combination, add another set of complexities to the task at hand. So does the imperfect state of our knowledge about effects of these interventions. True enough, there is an extensive literature to draw upon. But much of it is anecdotal; it merely describes what was done, and what seemed to have been accomplished, only in specific locations, during short periods of time. There are very few controlled studies. For example, of the more than 6,000 reports on continuing education gathered by Davis and associates, only 99 were deemed worthy of further analysis. Of these only two thirds reported a change in behaviour, and even fewer spoke of changes in outcome”. In 1998 at the 15th ISQua conference in Budapest a panel of experts came to a similar conclusion as in 1993. (Gulacsi, 1999a) Still little is known about and few evidence are shown that quality assurance programmes are effective and improve quality of care in a cost-effective way. Although some progress can be seen not much has changed since the 10th ISQua conference.

Often the ultimate goal of implementing quality assurance activities is to achieve, or get closer to, the best practice. However, substantial further improvement is needed to set up the ‘best practice’ for comparison purposes, to see ‘where we are now?’ and what is achievable. As Lewis and Foreman (1997) pointed out: "... it is impossible for even the most conscientious practitioners to assess whether they are over- or under-using LCDDTs (Low Cost Diagnostic Technologies) without information on the expected number of tests in a reference population. There has been very little research on what a “best practices” volumes profile would look like in a “standard population” (or in sub-populations with defined characteristics). (Chapter 9 discusses further and presents practical example) Establishing these target volumes would be no easy task, not least because they are logically tied to resolution of the “threshold” issues discussed above. Nevertheless, peer performance comparisons are powerful motivators, and without meaningful population-based targets economic and health status effects will be considerable."

Sometimes there are perverse incentives, often created by the financing system. In Hungary, for instance, under the current hospital financing mechanism (DRG) doing more and faster is equated with doing better. A very similar situation was discussed by Sheldon and Borowitz (1993) in relation to the NHS in the UK.

### 3.4.1 Peer review

Peer review is one of the oldest methods in quality assurance. According to Ertel and Aldridge (1977) peer review is: “the investigational, managerial, and educational process for systematically monitoring medical and health care which the judgements regarding provider performance and recommendations regarding corrective actions are based on a review of qualified professional peers who practice in the same community and who communicate the results of their efforts to the public”. Livingstone and Balachandran (1977) evaluated the effectiveness of the peer-review process, compared the costs and benefits resulting from peer review. They found that the benefits of peer review appear to substantially outweigh its costs in Florida. According to Kistemaker (1987) the peer review system in the Dutch hospitals has shown its viability. Smith, Atherly, Kane et al. (1997) investigated 20 references of the peer review process, the authors concluded that the peer-review process must be interpreted with caution and if peer review is to be used, priority should be given to increased use of outcome measures. Other authors came to the very similar conclusions. (Smith, 1998) The authors argued that peer review of the process of care has limited reliability. Berstein, Hofer, Meijler et al., (1997) reviewed 44 references of the peer review process. The authors pointed out that decision analysis performed much better that peer review by an expert panel in measuring the effectiveness and appropriateness of the process of care.

### 3.4.2 Audit

Medical audit was defined in the White Paper (Working for patients, 1989) as a systematic critical analysis of the quality of medical care including the procedures used for the diagnosis and treatment, the use of resources, and the resulting outcome for patients. Macpherson and Mann (1992) argued that there was no data, no criteria, no time for medical audit and
there is no purpose in medical audit unless it changes professional behaviour. Gabbay and Layton (1992) pointed out that “extended audit of note keeping failed to sustain an initial improvement in practice; this may be due to coincidental decline in feedback to doctors about their performance.” In our resource-constrained environment a lot of attention is devoted to showing demonstrable effectiveness, the value of resources spent on quality assurance and other quality activities. As Donabedian stressed in 1993 in an interview: “...So part of the audit activity is not simply a reporting of activity but a documentation of real change and a reporting of that change. If we can do that, then we will be allowed to run our own affairs. If we cannot, sooner or later, someone is going to say this is a lot of activity without evidence of effectiveness; something else has to be done. To me, the lesson that we have learnt from the past 10 or 15 years of developments in the United States is the inability of professionals to put their own house in order, resulting in justification for public authorities to become more intrusive, more directive in their pursuit of quality assurance” (Baker 1993)

Although there is evidence of the efficacy of medical audit, there is little evidence of its effectiveness. (Walshe and Coles, 1993; Baker, Noelle, Farooqi, 1995) As Buxton (1994) stated: “Unfortunately there were very few controlled studies undertaken that could show convincingly that audit had a real impact on practice. Audit, now usually described as 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 for the patient. There is a significant degree of uncertainty about the effectiveness of audit activities but the costs are certain. Quality assurance is not free of charge. As Walshe and Buttery (1995) pointed out: “They require staff, clinician’s time, facilities, equipment, information and other resources. All these resources might be used in other ways such as to treat patients, to undertake clinical research, or to engage in education or professional development. The amount of opportunity costs of quality improvement may be arguable; however, their existence is indisputable. In the long run, the investment of health care resources in audit and other quality improvement activities has to be justified by their results”. (The justification of results is further discussed later in this chapter.) Elfström, Stubberöd and Troeng (1996) based on a literature review of seven references found that patients not included in medical audit have a worse outcome than those included. The authors concluded that clinical databases must be seen as suspect sources of patient data for audit and research unless the problem of missing cases has been explicitly addresses. According to Earnshaw (1998) patients who fail to be registered into medical audit are those who develop complications and are transferred to other specialities. Generally the result of all major surgical operations are probably worse than reported. Semple, Khaled and Maresh (2000) pointed out the importance of staff training associated with improvement of clinical audit. Johnston, Crombie, Davies et al. (2000) reviewed 93 publications on the benefits and disadvantages of clinical and medical audit. According to the authors, the main barriers to clinical audit can be classified under five main headings, such as: lack of resources, lack of expertise or advice in project design and analysis, problem between groups and group members, lack of overall plan for audit and organisational impediments. These findings stress the importance of complex management innovations in order to improve quality of health care. According to Spies, Mokking and Grol (1999) there are limitations of patient records as a source for audit valid quality assessment, their study showed that the patient records only provided 40% of the necessary data.
3.4.3 Accreditation status

Walshe and Coles (1993) pointed out that in 1993, at the ISQua conference in Maastricht a panel of eminent experts on quality assurance were asked what evidence existed to show that the massive annual investment in quality assurance resulted in higher quality of care. According to the panel there was little or no evidence. It was pointed out that there is no conclusive evidence that relationship between the accreditation status of hospitals and quality of care exist. (McGowan, 1995) A very similar panel of experts came to the same conclusion in 1998 at the ISQua conference in Budapest (Gulacsi, 1999a) Transparency of the decision making in the field of accreditation and certification should be further encouraged, as stated by the United States General Accounting Office. (GAO, 1999) Brook (2000) argued that: “The USA spends more money than probably any country in the world on hospital accreditation, yet study after study has demonstrated huge variations in quality of hospital care. There is no evidence to suggest that, in the absence of accreditation, the variation in hospital quality in the USA would be any greater”

3.4.4 Practice guidelines

According to Lohr, Eleazer and Mauskopf (1998): “Guidelines are meant to provide formal conclusions and recommendations about appropriate (inappropriate) and necessary (unnecessary) care for specified types of patients in specified types of practice settings.” In the medical field there is evidence from systematic reviews to show that practice can be changed, effectiveness and patient outcome can be improved. Grimshaw and Russel (1993 and 1994) and Grimshaw, Freemantle and Wallace (1995) and Grimshaw, Eccles and Russel (1995) showed through systematic reviews that practice guidelines can improve effectiveness through changing medical practice and achieve health gains if they are scientifically valid, guideline development, dissemination and implementation strategies are appropriate, and if the consultation is individualised. But as they stated: “Unfortunately, development of guidelines has largely ignored the issue of costs.” Scientific validity is an important issue because clinicians are often (probably mainly) faced with patients, who are generally excluded from RCTs, including patients with multiple health problems, older patients, children and women. (Lohr, Eleazer and Mauskopf, 1998) Klazinga (1994) stated that guidelines can enforce efficiency when developed within the framework of a consistent goal-method-effect scheme and applied as an integral part of personal quality assurance activities. Introduction of guidelines often does not change practice. The impact of the guidelines on patient outcomes are often absent or not studied at all. (Grimshaw and Russel, 1993; Hunt, Haynes, Hanan et al., 1998; Thompson and Oxman, 1999; Grol, 2000)

In the field of nursing and primary health care this kind of evidence is weak or lacking. Thomas, McColl, Cullum et al. (1998) undertook a systematic review to evaluate effectiveness and cost-effectiveness of clinical practice guidelines in nursing. They used the Cochrane Effective Practice and Organisation of Care Group (EPOC) register. Eighteen RCTs met the inclusion criteria which provide some evidence that care driven by guidelines can be effective in changing the process and outcome of care. Most of the studies suffered from various weaknesses. Only three of the eighteen studies provided evidence from randomised controlled trials in which the unit of randomisation and analysis were the health care profes-
tionals. In studies where patients were the unit of randomisation there was a possibility of the contamination of the control groups. Recently many researchers focussed heavily on efforts in various countries to evaluate how to transfer the results of clinical research into clinical practice and how to create and disseminate clinically evidence-based guidelines. Thorsen and Makela (1999) highlighted the importance of the economic evaluation of guideline implementation strategies and the investigation the impact of guidelines on the changing professional practice. The Cochrane Collaboration has created a new Group - The Cochrane Effective Practice and Organisation of Care Group to assist efforts in bridging the gap between evidence about effective and efficient health care delivery. Lohr, Eleazer and Mauskopf (1998) argued that differences, between effectiveness and efficacy is an important one. (Lohr, 1988; Brook and Lohr, 1985; Detsky, 1995). 'Evidence based medicine and clinical practice guidelines have become increasingly salient in the international health care community in the 1990s. (Lohr, Eleazer and Mauskopf, 1998) According to Worall, Chaulk and Freake (1998) little support exists to show that guidelines in primary care settings improve patient outcomes. As the authors stated: "Implementation of clinical practice guidelines in primary care settings does not consistently result in improvements in clinical outcomes." (EVB) Practice guideline vs. feedback to providers, or probably guideline for feedback to providers is most useful. Wilson (1998) came to a similar conclusion, he argued that little support exists to show that guidelines in primary care settings improve patients outcomes. Woolf, Grol, Hutchinson et al. (1999) pointed out that guidelines have potential benefits, limitations and harms, due to the fact that scientific evidence about what to recommend is often lacking, misleading or misinterpreted. Guideline setting should be based on scientific evidence. (Shekelle, Woolf, Eccles et al., 1999; Hurwitz, 1999; Thorsen and Makela, 1999)

3.4.5 Other quality improvement tools

Lots of quality improvement tools are used in various health care settings in several countries, which have varying levels of evidence that they work. The effectiveness of the printed educational materials alone, as Freemantle, Harvey and Grimshaw (1997) argued, appears limited. They pointed out that: "The value of additional implementation strategies is unclear for changing physician behaviours and improving patient outcomes." The role of opinion leaders are usually ranked very high in quality improvement. However, the effectiveness of local opinion leaders varies. Thompson, Oxman, Haynes et al. (1998) in their systematic review found 6 RCT trials of opinion leaders. Five from the six showed positive aspects of process of care, three studies tested effects on patients outcomes and one of them was positive. There are other quality improvement activities showing evidence of being effective as well. Randomised controlled trials show that educational outreach visits combined with additional interventions reduce inappropriate prescribing by physicians (Thompson, Oxman, Davis, et al., 1998), and computerised reminders increase the rate of use of most preventive services (Shea, DuMouchel, and Bahammode, 1997). Lomas (1991) compared the effect of audit and opinion leader education. He concluded that regulatory and economic incentives might be more effective. Palmer and collaborators (1996) answer to the question 'What makes quality assurance effective?' based on RCT results (in US) is: "Feedback to providers of data on their performance is a more powerful stimulus for quality improvement than is knowledge of guidelines or discussion of review criteria". O'Connell,
Henry and Tomlins (1999) showed evidence from randomised controlled trial that the feedback had no impact on prescribing levels of general practitioners in Australia.

### 3.5 Costs and savings/profit of quality assurance programmes

Health care managers and financing institutes often stated that improvement of quality of care is too expensive. Others argue that it is not too much quality, but rather too low quality that creates costs. Other experts pointed out that quality care and cost containment can exist simultaneously. Although, many studies have examined the relationship between quality assurance and productivity, none have conclusively demonstrated QA’s impact on productivity. Most likely, it is due to the inability to quantify the real costs of quality. (Donabedian, 1980; Batchelor and Esmond, 1989; Donabedian, 1988; Ullmann, 1985) Bliersbach (1989) found to his surprise that health care professionals still view cost and quality as “inversely related”, but quality assurance and cost accounting should be integrated. The most important barriers are lacking cost and outcome data and the lack of universal agreement on what should be the outcome of health care. Costs and potential savings should be determined and communicated in quality assurance feedback. (Bliersbach, 1989; Berwick, Godfrey, Roessner, 1991) Brook (1989) argued: “Viewing outcome and cost separately may create misleading analysis and misdirect management”

#### 3.5.1 The cost of quality

Studies conducted in industry showed that the cost of quality is estimated to equal from 20% to 40% of the total organisational total costs. (Crosby, 1984; Juran 1988) This cost is due to the waste of poor quality and unnecessary work, rework waste and redesign waste. Cost of quality, including the price of conformance and the price of non-conformance, was estimated by Berwick, Blanton and Roessner (1990) up to 50% of costs in health care. The American Society for Quality Control (ASQC) defines quality costs as: “a measure of costs specifically associated with the achievement or non-achievement of product or service quality.” (Hagan, 1986) More specifically, quality costs are the total of the costs incurred through:

a) investing in the prevention of non-conformance to requirements: identification of clients’ needs, education and training of employees, developing of quality monitoring and reporting systems, institution of quality administration, and planning and design;

b) appraisal of a service for conformance: quality audits, accreditation, licensure and certification review, calibration and maintenance of equipment, documentation, inspection and evaluation of services;

c) failure cost which can be subdivided into the costs of:

- internal failures: waste of any kind (unnecessary tests or supplies), investigation of defective tests, unnecessary repetition of tests or other services, wasted time, reinspection and correction;

- external failures: responding to patient complaints, insuring against liability or exposure to malpractice risk, loss of goodwill. (Suver, Neumann and Boles, 1992) Harrington (1987) estimated that from the total quality costs, 30% are generated
by external failure, 45% by internal failure, 20% are the costs of appraisal and 5% the costs of prevention. The main problem is that in many organisations the costs of quality are not reported in financial statements, simply because they are not available and many costs items (e.g. hidden costs of lost customers) can be evaluated only indirectly (e.g. reduced revenues). (Suver, Neumann and Boles, 1992)

Oakland (1995) discussed the costs of quality and cost-effective quality management in detail in industrial setting. He subdivided the total quality related costs into three parts such as prevention, appraisal and failure costs. He stated that: "The analysis of quality related costs is a significant management tool that provides:
- a method of assessing the effectiveness of the management of quality,
- a means of determining problem areas, opportunities, savings and action priorities.

According to Oakland (1995): "The costs of quality are no different from any other costs, like the costs of maintenance, design, sales, production/operation, and other activities, they can be budgeted, measured and analysed." The relationship between quality management and financial management in European hospitals were examined and 24 statements were made as part of the Concerted Action Programme on Quality Assurance in Hospitals (BIOMED I.). (Rooze, Klazinga, Casparie, 1995)

3.5.1.1 Estimated costs and spending on quality

Greer and Dobson (1979) argued that the estimated costs of the nation-wide implementation of the utilisation review would have been $81.3-$107.6 million for 1976. The UK Department of Health gave a 400,000 Pounds grant to the clinical accountability, service planning and evaluation (CASPE) pilot project at Bloomsbury - which has been in the vanguard of developing a methodology for mechanised, routine monitoring of patient satisfaction. (Carr-Hill, Dixon and Thompson, 1989) Within three years in the late eighties and early nineties, the Department of Health of the United Kingdom spent about 140 million Pounds on developing medical audit programme in England. (DOH, 1991) Macpherson and Mann (1992) discussed that in the UK 24 million pounds was allocated to regional health authorities for audit purposes (data collection and criteria setting) in 1990/1991 and this was increased in 1991/1992. According to Walshe (1995) about 40 million pounds were spent each year between 1989-1994 on the direct cost of clinical audit. The average health care professional spent one hour a week on clinical audit, this costs are accounted 390 million pounds a year. As reported by the United States Agency for Health Care Policy and Research the costs per guideline ranged from $340,000 US to 675,000 US and the Dutch College of General Practitioners found the costs per guidelines to be $100,000 US. (Grol, 1996) As Maguerz (1997) explained, "A financial incentive has been developed by the French Ministry of Health to promote quality improvement programs in public hospitals: every public hospital is able to present a quality improvement project to a jury. If selected, the project is funded within the limit of 400,000 Francs (around $80,000 US). This incentive has been initiated in order to offset management constraints." Ballard and Cangialose (1997) discussed that " ... the largest external quality oversight effort in the US, the Health Care Financing Administration's (HCFA) Health Care Quality Improvement
Program (HCQIP) that currently allocates in excess of $220 million per year from US taxpayers for 37 million Medicare beneficiaries who are the subject of the quality improvement efforts of the peer review organization (PRO) program. There is considerable uncertainty regarding the return on this investment from any economic frame of reference, including that of Medicare.”

3.5.1.2 The interpretation of the costs of quality

Pure data on costs of quality are impossible to interpret. Partly due to the incompleteness of the costing, indirect and intangible costs are lacking in most of the cases. Intangible costs are less easily quantified but no less important. Indirect costs significantly influence cost-effectiveness ratios. Because of the significance of indirect costs, a greater degree of standardisation needs to be achieved. (Jacobs and Fassbender, 1997) And partly due to the limited information about savings in cost and benefit (in fiscal or non-fiscal term) as a result of the investment in quality.

3.5.2 Volume, costs and quality

Several examples that are listed and evaluated from the literature by Labelle (1986), show that the average cost of medical services depends on the volume performed if and where economies of scale exist. Average costs are lower when higher volume of services is provided. Estimating volume-average cost functions for an individual institution requires that institute-specific cost data be obtained. While there is an agreement that when economies of scale exists, close volume and cost relationship can be demonstrated, the volume-quality relationship is more uncertain. Uncertainties exist mainly because of the multidimensional nature of quality which is very difficult to define and because volume-quality data are not recorded routinely. Banta and collaborators (1991 and 1992) published reviews of the available literature on volume-outcome relationship. They concluded that in certain health care services strong volume-quality relationship can be presented such as CABG surgery, open-heart surgery, organ transplantation. Other authors came to a same conclusions. (Feeny, Guyatt, and Tugwell, 1986; Hannan, 1989) For further evaluation the volume-quality scenario should be subdivided into two parts, minimum number of cases and total number of cases. A minimum number of cases performed yearly in a certain hospital or department or team or provided by individual surgeon or physician is required in order to evaluate quality and costs. If we want reliable information about quality and costs requirements of statistics and epidemiology have to be satisfied and local variations have to be excluded. This intention is highlighted in recently proposed FDA (1998) rules which will require every radiological facility performing screening mammography to conduct a mammography medical outcomes audit program as part of their quality assurance program. A mammography medical outcomes audit has been defined by the FDA rules to be “... a systematic collection and analysis of mammography results and the comparison of those results with data from biopsy results.” The proposed rules will require as a minimum, that each facility correlate the biopsy or cytology results of its positive mammogram with the interpreting physician’s recommendations and report. It means, among others, that a minimum sample size is required.
3.5.3 Savings/profit and good quality of care

Some cost information related to quality, mainly direct costs of a given project can be found quite easily in the literature. Information related to the benefit and outcome of the QA activities is also possible to extract from the literature. Costs and outcome information, however, not standardised varies from programme to programme a great deal. Due to this fact interpretation and comparison of this information is practically impossible. (Table 3.1)

Table 3.1 Cost and benefit/outcome of quality assurance programmes

<table>
<thead>
<tr>
<th>Publication</th>
<th>QI tool and objective</th>
<th>Costs (direct costs)</th>
<th>Location</th>
<th>Savings (US, 1972-1974)</th>
<th>Outcome</th>
<th>Costs per unit of benefit improved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Livingstone and Balachandran, 1977</td>
<td>peer review, to decrease over-utilisation</td>
<td>$424,000</td>
<td>Medicare Part B reimburlements, Florida, 4229752 enrollees</td>
<td>$3,445,785</td>
<td>not measured</td>
<td>not measured</td>
</tr>
<tr>
<td>Greer and Dobson, 1979</td>
<td>implementing utilisation review</td>
<td>$81.3- $107.6 million</td>
<td>nationwide, US</td>
<td>not measured</td>
<td>not measured</td>
<td>not measured</td>
</tr>
<tr>
<td>Thompson, Palmer and Rothrock, 1983</td>
<td>audit, cost measurement of various aspects of audit</td>
<td>$1.92 million US</td>
<td>15000 cases in hospital</td>
<td>savings-cost analysis rise 7% of all budgetary direct cost</td>
<td>not measured</td>
<td>not measured</td>
</tr>
<tr>
<td>Carr-Hill, Dixon and Thompson, 1989</td>
<td>patient satisfaction measurement, questionnaire development</td>
<td>400,000 Pounds</td>
<td>nationwide, UK</td>
<td>not measured</td>
<td>patient satisfaction</td>
<td>not measured</td>
</tr>
<tr>
<td>Shockney, 1992</td>
<td>general QI to control inappropriate hospital admission</td>
<td>not specified</td>
<td>hospital</td>
<td>0.2 million US per year</td>
<td>not measured</td>
<td>not measured</td>
</tr>
<tr>
<td>Creps, Coffey, Warner et al., 1992</td>
<td>TQM</td>
<td>$4 million US, incremental costs, for four years</td>
<td>hospital</td>
<td>$13.8 million US, for four years</td>
<td>good quality(1)</td>
<td>not measured</td>
</tr>
<tr>
<td>Hsia and Ahern, 1992</td>
<td>general QI to improve hospital profit</td>
<td>not discussed</td>
<td>hospital</td>
<td>7.9% profit rise</td>
<td>good quality (0)</td>
<td>not measured</td>
</tr>
<tr>
<td>Macpherson and Mann, 1992</td>
<td>audit, data collection, criteria setting</td>
<td>24 million pounds</td>
<td>nation-wide</td>
<td>not measured</td>
<td>not measured</td>
<td>not measured</td>
</tr>
<tr>
<td>Waishe, 1995</td>
<td>clinical audit</td>
<td>40 million pounds</td>
<td>nationwide 1989-1994</td>
<td>not measured</td>
<td>not measured</td>
<td>not measured</td>
</tr>
<tr>
<td>Publication</td>
<td>QI tool and objective</td>
<td>Costs (direct costs)</td>
<td>Location</td>
<td>Savings</td>
<td>Outcome</td>
<td>Costs per unit of benefit improved</td>
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</tr>
<tr>
<td>Kerrigan, 1995</td>
<td>risk management</td>
<td>not discussed</td>
<td>hospital</td>
<td>a $3 million savings over 5 years</td>
<td>not measured</td>
<td>not measured</td>
</tr>
<tr>
<td>Maguerz, 1997</td>
<td>general QI</td>
<td>$80,000 US</td>
<td>hospital</td>
<td>not measured</td>
<td>not measured</td>
<td>not measured</td>
</tr>
<tr>
<td>Ballard and Cangialose, 1997</td>
<td>external peer review, HCFA's HCQIP program</td>
<td>$257 million/year</td>
<td>nationwide, US</td>
<td>uncertain</td>
<td>decrease differences between the observed and achievable in both care and outcome</td>
<td>not measured</td>
</tr>
<tr>
<td>Keston and Enthoven, 1998</td>
<td>general QI to improve total hip replacement</td>
<td>not provided</td>
<td>hospitals, US</td>
<td>cost per case reduced by $9000 US</td>
<td>outcome specified (^)</td>
<td>not measured</td>
</tr>
<tr>
<td>Black, 1998</td>
<td>medical audit to improve conformance with thrombolysis guideline</td>
<td>3,700-5,200 pounds in different hospitals</td>
<td>hospitals</td>
<td>not applicable</td>
<td>improved conformance with guidelines</td>
<td>from 101 - to 392 pounds per extra case given</td>
</tr>
<tr>
<td>Grol, 2000</td>
<td>general guideline setting</td>
<td>50,000 $US/guideline</td>
<td>primary health care</td>
<td>not measured</td>
<td>50-85% practitioner compliance with guidelines</td>
<td>not measured</td>
</tr>
</tbody>
</table>

(^) As a result of the programme, the number of cases increased by 33%, misscheduled cases decreased from 13% to 3% and cancellation went down 25%.

(a): no omission of medically indicated services; no provision of unnecessary services; and no complication to indicated services.

(^) cost of hip replacement, infection rate, venous thrombosis, dislocation of the hip.

HCFA: Health Care Financing Administration
HCQIP: Health Care Quality Improvement Program

To achieve savings and benefit/profit is a crucial requirement for quality assurance. As Donabedian says: “Still, I think that savings in cost are the dominant moving force as far as major purchasers are concerned, whether they are private or government owned. So quality appears mainly in the guise of value for money. I don't think it appears as a separate objective, in the service of which large scale purchasers are willing to pay extra money.” (Baker 1993) Livingstone and Balachandran (1977) conducted a study in Florida and compared the effectiveness, costs and benefit of different types of peer review systems used to decrease the over-utilisation of health care services covered by Medicare Part B reimbursements. They found that the benefit of peer review exceeded the costs rather substantially. Between 1972-1974 the net benefit was $3,445,785 US in Florida counties. The costs of peer review (professional time, travel expenses, executive, professional non-meeting time,
consultants, secretarial, clerical expenses) was calculated and compared to the benefit such as costs savings due to the decreased level of over-utilisation of health care services.

Good quality care could increase hospital profits under prospective payment by 7.9 percent, according to Hsia and Ahern (1992). Good quality of care was defined as: no omission of medically indicated services; no provision of unnecessary services; and no complication to indicated services. Reviewing physicians identified 5.5% patients as falling to meet professionally recognised standards (poor quality) and 87.9% of the patients experienced at least one instance of omitting medically necessary services. Delivery of medically necessary services had a beneficial effect on hospital profits. In contrast Cleverley and Harvey (1992) pointed out that the link between high quality and high profit is difficult to document for health care services, as they stated: “Increases in quality are not reflected in higher profits because of the limitations on charges.” They found some evidence that poor quality hospitals are less profitable, but the causal relationship was not uncovered. (Whether the hospital is less profitable because of poor quality or the quality is poor because the hospital is less profitable is a question to be answered.) Hospital mortality rate was used in their study as quality indicator. Meyer and Feingold (1993) argued that standard treatment protocols improve quality and reduce costs by 10-26%. According to Lee and Clarke (1992) better quality can enhance hospital profitability through improved competitiveness. Statements were based on theoretical speculations. Cost of quality, including the price of conformance and the price of non-conformance, was calculated by Hughes (1992) in a 300 bed community hospital. The initial cost of quality was $8.5 million and was reduced by $2.1 million in less than 2 years. Savings were due to the zero defects on Medicare billing, and decreased over-use of services such as more appropriate use of narcotics, multi-dose medications, data processing, and laboratory services. Shockney (1992) showed evidence that hospital wide quality assurance and utilisation management programs do yield financial benefit. At John Hopkins Hospital a programme was created to identify opportunities to control inappropriate inpatient admissions, shorten patient’s length of stay, monitor the use of ancillary services and improve physician documentation in patient medical records. The programme resulted in around two hundred thousands dollar benefit yearly. Kerrigan (1995) showed that The Royal Victorian Eye and Ear hospital had a $3 million savings over 5 years through improved quality activities, mainly with the help of risk management. The importance and helpfulness of costing quality was concluded by Maycock and Shaw (1994) as a result of their study conducted in the outpatients department of Harrogate Health Care NHS Trust and Huddersfield Royal Infirmary, United Kingdom.

In many health care areas cost can be reduced with quality improvement. Keston and Enthoven (1998) reviewed 43 references in the field of total hip replacement. The authors identified 14 clinical and management innovations that they concluded to be relevant to cost reduction and quality improvement. Kaiser Permanente estimated that cost were reduced by 9000 dollars per case. Outcome was defined such as: cost of hip replacement, infection rate, venous thrombosis, dislocation of the hip. The authors concluded that there had been a significant improvement in quality during a period which cost had decreased significantly. Homa (1998) pointed out as well that cost can be reduced with quality improvement.
3.5.3.1 Quality of care and savings/profit under prospective payment system

Davis and Rhodes (1988) argued that the prospective payment system (PPS) had enhanced the quality of inpatient care “by discouraging unnecessary and potentially harmful procedures and by encouraging the concentration of complex procedures in facilities in which the high frequency of these procedures promotes efficiency”. Other authors came to a similar conclusion. (Draper, Kahn, Reinisch at al., 1990)

3.5.3.2 TQM, cost savings/profit and quality

Milakovich (1991) stressed the importance of the quality of care in health care settings in competitive markets which - according to the author - encourage managers to reorient health care systems from a cost-driven approach to the implementation of TQM. Creps, Coffey, Warner et al. (1992) integrated TQM and quality assurance at University of Michigan Medical Center. They found that the financial benefits of TQM were substantially greater than the costs. The costs of the four-year programme amounted to $4 million US, including incremental costs and staff time spent in training programmes, the benefit over the same 4 years period was $17.8 million, for a net gain of $13.8 million. TQM activities were implemented in the operating rooms of the hospital. As a result of the programme, the number of cases increased by 33%, mischeduled cases decreased from 13% to 3% and cancellation went down 25%. According to Roberts and Zangwill (1993) TQM reduces cost and/or increase customer satisfaction. According to their definition for TQM: “Continually serve customers better and more economically, using scientific method and teamwork, and focusing on removal of all forms of waste”. The authors made a distinction among: a) simple waste (waste of poor quality and waste of unnecessary work); b) rework waste; c) redesign waste; and d) waste of unnecessary work.

3.5.4 Accounting economic costs

When improving quality one can expect return on such investment, the time and other resources one spend improving quality has to produce a return. Improving quality might be a financial investment. In order to confirm or refute this statement economic costs have to be accounted carefully. There are many problems in accounting economic costs. Cost, prices as signalling device to market traders are not free. (Prices in markets related to health care are not reflecting real scarcity because of market distortions.) Methodological weaknesses may distort market signals and cause inefficient resource use. There are three additional points: a) costs information can be misleading if there is no consensus on what cost, in which way and by whose point of view should be accounted; b) costs information is also not free; c) at what level should information on cost be collected? This question is related to the packaging of care scenarios as well. Can we use costs information of an individual button when buying a jacket? The difficulty comes from the fact that the prospective payment system frequently underpays for some services and overpays for others in the various DRG categories. This is partly the reason why costs do not equal charges. Hospitals charge less than their costs for some items and services to some patients while charging more than their costs to others.
This cost-shifting makes economic analysis difficult. In many publications in Hungary, and presumably in other countries also, charges and payments (DRG) are quite often used for cost-effectiveness analysis because prices are not known. Based on this phenomenon Haley (1991) emphasised four methods for estimating costs: a) the first method for estimating cost simply sums all the charges and calls it “cost”; b) the second method involves multiplying the charges by the hospital’s overall cost-to-charge ratio and calling that the cost; c) the third method uses the second method at the department or ward level, and then sums all these weighted departmental subtotals; the fourth method is the so called micro-costing. It involves obtaining the complete list of all care items and services offered by the hospital and determining what it costs the hospital in goods and personnel to deliver each individual item of service. The fourth method is appropriate but very time consuming and costly to manage; this method was used in the study presented in Chapter 8.

3.6 Costs-effectiveness of quality assurance programmes

Thompson, Palmer and Rothrock (1983) pointed out that very little is known about the costs and cost-effectiveness of quality assurance programmes and discussed that the costs of the Ambulatory Care Medical Audit Demonstration Project was $ 1.92 million US and had a moderate effect on provider behaviour. Phelps and Mooney (1992) evaluated the cost-effectiveness of external quality oversight in the United States. According to their findings the top 25 medical activities generated a total loss of $7 billion dollars in 1987 which was the 15% of total health care expenditure for that year. Some quality assurance programmes such as Health Care Quality Improvement Program, HClQP appeared to be effective to make this loss lower. (Ballard and Cangialose, 1997)

The conventional understanding that increases in quality are associated with increases in costs and cost pressures are likely to affect quality adversely was reviewed, but the results were not consistent. It was concluded that the relationship between cost and quality was complex and the relationship is non-linear. (Harkey and Vraciu, 1992) According to the study in which a large number of Medicare hospitals were enrolled, some relationship was found of the cost–quality function. In the lowest and upper ‘class’ a positive cost–quality relationship was found, an increase in quality was associated with an increase in cost. In the mid-region where the largest number of hospitals are located, however, higher quality was associated with lower cost. The authors concluded that in these hospitals higher volume of services is associated with “fewer mistakes, fewer tests, and the choice of the more effective and less costly strategies of care”. (Harkey and Vraciu, 1992) These hospitals are able to increase profitability through improvement of quality. Positive relation was found between cost and quality by Harkey and Vraciu (1992) as a result of their study on 82 small and medium-sized hospitals. Quality was defined as perceptions of quality by patients, physicians, community residents and employees measured by questionnaires. Starfield, Powe, Weiner et al. (1994) argued that a clear relationship between quality and costs is lacking in primary care settings.

An obvious limitation was pointed out by Hadley, Zuckerman and lezzoni (1996) in the summary of the result of their study in which they analysed the effects of financial pressure and market competition using data from the Medicare program. They argued that there was no data of quality of care and its outcome. Few areas are being rigorously evalu-
ated according to the requirement of the cost-effectiveness of quality assurance. One area that has received a great deal of attention and does seem to be effective is reducing hospital infections. (This is the main reason why this topic was chosen as one of the most important topics of the study on which this thesis is based.) In the United States, an evaluation estimated that quality assurance programmes reduced nosocomial infections by 32 percent. (Haley 1986) The effectiveness and cost-effectiveness of infection control programmes are under continuous scrutiny. (Condon, Haley, Lee et al. 1988; Seto 1995; Mehtar 1995) In their article entitled ‘The cost of quality assurance in medicine’, Thompson, Palmer, Rothrock (1983) argued that costs are thought to be less important than the fact of effectiveness they stated: ‘An effective program in not finally justified until it is shown to be at least as cost-effective as other programs with similar types of benefits.’ The authors conducted a cost-effectiveness study of medical audit as part of the Ambulatory Care Medical Audit Demonstration (ACMAD) Project. The cost-effectiveness of the audit was calculated such as: how much money was spent per audited case across sites and topics. The case per costs were ranged from $17 for glucose at site and $339 for digoxin at site. The authors found that the cost of cost analysis was estimated 7% of all direct budgetary costs, the total direct cost of the project was $1.22 million over five years. Overall costs and cost-effectiveness expressed as cost per unit of improvement in patient outcomes was the focus of the study by Robinson, Thompson and Black (1998) to measure cost and cost effectiveness of audit of thrombolysis in some district general hospitals. Cost effectiveness was taken to be cost per audited case, cost-effectiveness expressed as cost per unit of improvement. Patients with suspected acute myocardial infarctions receiving thrombolysis have a better chance to survive. They found that the overall cost of the QI programme in hospitals varied between 3,700-5,200 pounds in the participating hospitals, while the cost-effectiveness ranged from 101 pounds to 392 pounds per extra case given thrombolysis. There are many competing demands for health care resources, of which quality assurance is only one. Expenditures on quality assurance have an opportunity cost which cannot be ignored.

There is a negative reason to evaluate quality assurance such as ‘do not waste resources’: resources from quality assurance programmes with low effectiveness should be reallocated to quality assurance programmes with a higher level of effectiveness and cost-effectiveness. Because quality of care is not optional any more, but is an expectation, or even mandatory, in many health care areas, it is even more important to choose the most effective and cost-effective quality activities to be implemented. There is a more positive reason as well, if evaluation demonstrates the effectiveness and cost-effectiveness of quality assurance programmes, of any types, it can be a powerful incentive for health care professionals to participate and for funding institutions to finance this activity.
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