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 10

CONCLUSIONS AND RECOMMENDATIONS

Abstract

Results of the quality assurance programmes discussed in this thesis indicate that health care quality in Hungary is underdeveloped, compared to countries of Western Europe (CWE) in terms of structure, process and outcome. The population’s health status is poor as well; in 1995, the difference between life expectancy at birth for Dutch and Hungarian men was 9.4 years in favour of Dutch men. The health care budget is limited and has been decreasing even in absolute term.

Solutions to health care problems are usually sought in more money. Just put more money into the system and quality will appear, and the effectiveness and efficiency of the health care system will improve. However, it is very often not possible because of two reasons:

a) Resources are limited, what is even more important is that whatever resources are available for financing organisations, the government and the public at large want to know how the resources are going to be used. Health care has to be accountable.

b) There is a significant difference between health care budgets in Hungary and in the welfare states. In order to get closer to the core problems of Hungarian health care quality let us assume that the Hungarian health care system receives exactly the same per capita annual budget as is available for health care in the Dutch, Canadian or Swedish systems. Do we predict, that in this situation Hungary will achieve health care of the same quality overnight? According to the author’s hypothesis the answer is no. The real question is what factors other than budget size make the quality of these health care systems different. This theoretical frame can be used to define the most important problems which might be responsible for the poor quality of care and identify key strategies and actions to improve the quality of the health care system.

Studies (quality of hospital care; patient satisfaction and patients’ reports in hospitals; preoperative assessment in surgery; risk-adjusted surgical site infection surveillance; the quality of nursing care; prevention and treatment of pressure ulcers; and quality of primary health care – physicians’ and patients’ reports on system performance) presented in this thesis show, that:

- quality assurance can be implemented and used in Hungary in the transition period of the health care system,
- effectiveness of health care quality can be improved by assurance initiatives in Hungary,
- quality assurance initiatives might contribute to cost containment in Hungary.

According to the results of the various quality assurance programmes of this thesis, failures of quality are more often due to poor organisation than to a lack of resources in Hungary. Thus, these findings show that there is plenty of room for further improvement. The most important findings are summarised and the key methodological steps are discussed in this chapter.

The author is grateful to Professor Frans Rutten, Institute of Medical Technology Assessment, Erasmus University, Rotterdam, for his helpful comments on paragraph 10.5.
10.1 Research questions and hypotheses

The general aim of this study was to increase knowledge about the possible role of quality assurance in improving health care effectiveness and efficiency and its relationship to the costs of health care services in the transition period of the Hungarian health care system. In particular, this study was designed to answer the following questions:

(i) Do quality assurance initiatives in Hungary improve the effectiveness of health care?
(ii) Do quality assurance initiatives in Hungary contribute to cost containment?

These two questions were addressed in relation to the following topics:

- quality of hospital and primary care: patient satisfaction and reports (Chapter 5 and 9),
- quality of preoperative assessment in surgery (Chapter 6),
- nosocomial infection surveillance: surgical site infections (Chapter 7),
- the quality of nursing care: prevention and therapy of pressure sores (Chapter 8).

According to the literature, quality assurance methods were implemented successfully under various circumstances in many countries through almost countless ways in order to achieve diverse quality improvement goals. Evidence shows that quality improvement can be achieved through appropriate implementation of quality assurance methods. Based on international literature the following two hypotheses were formulated.

**Hypothesis 1:** Quality assurance can be implemented and used in Hungary in the transition period of the health care system.

**Hypothesis 2:** Once implemented, quality assurance activities can improve health care quality and contribute to cost containment.

10.2 The validity and generalizability of the findings

In this thesis the incentive of the author was to look at a series of quality assurance initiatives in Hungary. The reported quality assurance studies represent various health care settings, e.g.: primary care (Chapter 9) and hospital care (Chapter 5, 6, 7 and 9); deal with diverse medical activities such as diagnostics (Chapter 6), medical care (Chapter 6 and 7), nursing care (Chapter 8), patient satisfaction and patient reports (Chapter 5 and 9); and refer to the two most important features of the outcome of health care such as patient satisfaction (Chapter 5 and 9) and clinical outcome (Chapter 7 and 8). It seems fair to conclude that major areas of quality assurance have been addressed. In order to show the impact of quality assurance on health care, the context in which these initiatives took place was also described.

Validity and generalizability have been discussed in each chapter. The relatively high number of study participants, patients, professionals and organisations, the high level of willingness of participation in the various quality assurance programmes and the high completion rate within each study suggest that we have now sufficient experience in this area to make some general conclusions about the current situation and possible future development of quality assurance in Hungary. Although not all aspects and areas were adequately
addressed, quality assurance studies of this thesis provide a useful baseline for further development. Paragraphs 10.2.1, 10.2.2 and 10.2.3 provide some key information about the study population, case mix and quality of care measures.

10.2.1 Study population; patients and health care settings

A large number of patients and health care settings participated in the studies on which this thesis is based:
- in three study rounds 8,200 patients in 31 hospitals were enrolled in the patient satisfaction questionnaire survey called National Survey of the Quality of Hospital Care between 1993 and 1997, and the established quality assurance mechanisms for patient satisfaction measurement were investigated in 59 other hospitals (Chapter 5),
- altogether 46 hospitals participated in the study on preoperative assessment in surgery between 1992-1997 (Chapter 6),
- more than 6,000 patients in 20 hospitals participated in the Risk-Adjusted Surgical Site Infection Surveillance in Hungarian hospitals, between 1992 and 1996 (Chapter 7),
- more than 6,000 patients in more than 60 hospitals participated in the study of quality assurance of prevention and treatment of pressure ulcer between 1992 and 1998 (Chapter 8)
- almost 5,000 patients in 91 general practices were enrolled in the study of quality of primary health care: physicians' and patients' reports of system performance, 1994-1996.

10.2.2 Case-mix

- Age: adult patients participated (18 year-olds and over)
- Origin of patients: primary care and hospital patients representing both urban, semi-rural and rural areas and basic, medium and top level care settings,
- Surgical vs. medical patients: participating patients represented both surgical and medical patient populations,
- Diagnoses: patients with diverse surgical and medical diagnoses were involved,
- Severity of illness: three severity of illness scoring systems were used: ASA classification (Chapter 6), NNIS risk index (Chapter 7) and Norton Scale (Chapter 8).

10.2.3 Quality of care

Various quality measures were used in the presented studies associated with structure, process and outcome. Results from the studies of this thesis show that both structure and process quality improved. 'Intermediate' outcome was assessed in all studies. The following dimensions of quality assurance were addressed in the quality assurance studies of the thesis:
- structure: various quality assurance professional groups/committees were created to assist the institutionalisation of quality assurance, such as infection control and (Chapter 7) pressure ulcer committees (Chapter 8) in health care settings, and national societies on quality assurance, infection control and prevention and treatment of pres-
Conclusions and recommendations

More than a 100 infection and pressure ulcer nurses were trained as part of the programme to foster professionalisation. These professions were first introduced and were put on the official list of the ‘health care professions’ in Hungary by the programmes presented in this thesis.

- **process:** various quality assurance tools and methodology for assessment, such as questionnaires, data collection forms as well as guidelines were created, adapted and implemented as part of the programme (Chapter 5, 6, 7, 8 and 9).

- **outcome:** diverse outcome measures were used in the studies, such as patient satisfaction in hospital and primary health care (Chapter 5 and 9), nosocomial infection - surgical site infection (Chapter 7), incidence of pressure ulcers (Chapter 8).

### 10.3 Conclusions

This thesis provided direct evidence that quality assurance in the field of patient satisfaction, preoperative assessment in surgery, risk-adjusted surgical site infection surveillance and prevention and treatment of pressure ulcers can be implemented and used and the effectiveness of health care services can be improved in a group of Hungarian hospitals and primary health care settings (Chapter 6, 7, 8 and 9). Based on empirical data from the quality assurance studies the first research question of the thesis (Do quality assurance initiatives in Hungary improve the effectiveness of health care?) can be answered: ‘Quality assurance initiatives in Hungary can improve the effectiveness of health care’. The first hypothesis cannot be rejected, the accumulated evidence show that quality assurance can be implemented and used in Hungary in the transition period of the health care system. Conclusions and recommendations are based on available empirical data and closely related to the first research question and the first hypothesis.

Some studies provided evidence on improved effectiveness related to a group of 7 county hospitals (Chapter 6) and it was assumed that the findings are relevant to the rest of the county hospitals and other hospitals of the same size and function, with in total 50%-55% of the hospital capacity in Hungary in terms of hospital beds falling in this category. Other studies, such as Chapter 5, 7 and 8 provided evidence on a much broader group of hospitals, as a result of the participation of a large number of Hungarian hospitals.

In contrast, no empirical data of good quality have been yielded by the quality assurance studies presented in this thesis, concerning the second research question: ‘Do quality assurance initiatives in Hungary contribute to cost containment?’ And due to the lacking empirical data the second hypothesis such as ‘Once implemented, quality assurance activities can improve health care quality and contribute to cost containment.’ cannot be rejected or accepted. The thesis provided some evidence that quality assurance initiatives in Hungary might contribute to cost containment (Chapter 6, 7 and 8). Cost containment is a very difficult issue to be discussed in the Hungarian health care system, due to the lack of agreement on the meaning of quality and cost, and because no standardised costing mechanisms are implemented in the Hungarian hospitals in general, and as part of quality assurance programmes in particular. In the current stage of the transition of the Hungarian health care system these issues can be addressed on a more theoretical level which is provided in paragraph 10.5. This theoretical frame of quality improvement and cost contain-
ment is considered as one of the results of the quality assurance studies presented here; furthermore, it forms part of the major recommendations to show the direction of further research in the future in Hungary.

And finally another result of these quality assurance programmes might be that the participating organisations accepted the challenge for the first time. The more experienced an organisation becomes with a particular change, the more likely it is to repeat the change - because it knows how to make it. If a particular change becomes causally linked with success in the minds of organisational decision-makers - irrespective of whether such a link in fact exists - reinforcement effects will make repetition even more likely. Thus, once change is initiated, the change process itself may become routinized and subject to inertial forces. This creates repetition, that is, the tendency to maintain direction and emphasis of prior actions in current behaviour. Experience with change of a particular type is therefore predicted to increase the likelihood that the change will be repeated in the future.

10.4 Recommendations

Based on the findings of the quality assurance studies of the thesis the following recommendations can be made:

a) Quality improvement activities in the field of patient satisfaction, preoperative assessment in surgery, infection control, prevention and treatment of pressure ulcers and patient reports in primary care, should be promoted and broadly disseminated to all hospitals. Smaller hospitals (municipal hospitals) ‘below the critical mass’ (Paragraph 6.5.2) might also be able to participate in quality improvement initiatives through various forms of management assistance, such as twinning hospitals, more extensive networking, sharing experience and time of quality assurance professionals and quality management with county hospitals. The most appropriate technique should be identified, piloted, implemented and maintained in the near future, assisted by regulation or legislation, for instance, within the accreditation scheme which is currently being established.

b) Quality improvement should be identified as an important tool of health policy and planning. According to our experience, some form of quality assurance activity has to be in place in order to allow for a particular problem, and the extent of the burden it creates, to be identified. (The example of quality assurance studies on pressure ulcer - Chapter 8 - and infection control - Chapter 7 - showed that the magnitude of the real problem was in contrast to the officially reported data.)

c) A good professional body on quality assurance, supported by a strong quality improvement research institute, would be a good way of achieving quality improvement, for which there is evidence of effectiveness in other countries of Europe.

d) More comprehensive data collection is needed as a routine in all kinds of health care settings where quality is intended to be improved. Experiences from the presented quality assurance programmes showed that over 80% of time and resources were spent on collection of basic data and quality checks of these data. Further quality improvement activities seem to be very difficult, if not impossible, without more focussed and structured data of good quality and sufficient amount.
e) The results show that health care settings might absorb innovations/changes without them changing. One working quality assurance programme does not necessarily mean that the whole system has changed and the concept of quality has been implemented. In order to improve and maintain quality of care the quality concept has to be further implemented in the Hungarian hospitals, assisted by appropriate legislation, funding and audit.

f) Massive training on basic methodologies should be provided to the quality assurance staff. Introduction of quality assurance tools and teams in the absence of basic capabilities to collect, analyse, interpret and present data is likely to be unsuccessful in the long run. Experiences from the quality assurance studies presented in this thesis show that although, data collection and processing were often successful the analysis of the data was done at a very basic level, followed by no appropriate interpretation and presentation of findings. As a consequence of this, interventions were not executed. It is also a special hazard in Hungary that there is a tendency to hire quality consultants (both from abroad and from Hungary) to introduce quality assurance in hospitals that do not have the basic infrastructure and trained and experienced staff to support quality assurance projects.

g) A national quality improvement policy should be formulated for the longer run. Long-term strategic goals have to be clear and known. This policy should clearly separate areas where quality assurance should have an important role from areas within the health care system where other types of activities (e.g. legislative, management, financial, crisis management) and actions have priority. It is important to recognise that some systems are not worth saving and must be overhauled completely; tinkering just will not have the desired impact.

h) Steps have to be taken in order to achieve the support of the health care professionals and their professional organisations. Quality of care cannot be improved without the active involvement of the professionals. In Hungary ISO certification is widely believed to be equal to quality improvement. Professionals do not speak the language of the ISO and ISO is not taken as a good tool for achieving professional goals, it should not be a surprise because ISO is not designed to do so.

i) According to the experiences from these quality assurance studies improvement cycles have to be run rapidly so that organisational learning can be immediate. Quality improvement cycles have to be directly proportional to the degree of the implementation of the quality concept of the given organisation. Planning 'ideal' large scale experiment and creating 'big databases' over many weeks or months or even years consume enormous personnel resources, erode momentum and enthusiasm and reduce risk tolerance. Small rapid-cycle experiments maintain commitment and encourage risk taking and creativity.

j) An appropriate legal frame and economic/reimbursement incentives should be created (perverse incentives should be kept at the lowest minimum level) in order to strengthen the development and implementation of quality improvement. Quality improvement might save resources (e.g. in the field of infection control) in the long run, but quality improvement (training, creating programmes, indicators, guidelines) requires investment. Treating of pressure ulcer for instance is considered to cost more than preventing it, yet preventative measures can be themselves expensive. Separate
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budgets have to be devoted to quality improvement programmes at national and local/organisation level.

k) Awareness of the exact meaning of quality and costs issues should be improved among politicians, policy makers, regulators, managers and professionals in order to show that the investment in quality has good return in both economic and societal terms and to assist their decision on how much resources should be channelled to improve quality.

10.5 Future development

The empirical data from quality assurance studies presented by the author are not sufficient to give a good answer the second research question: ‘Do quality assurance initiatives in Hungary contribute to cost containment?’ and to reject or accept the second hypothesis such as: ‘Once implemented, quality assurance activities can improve health care quality and contribute to cost containment.’ Some evidence provided (Chapter 8) shows that it is likely that quality assurance initiatives contribute to cost containment, but a deeper theoretical reflection is needed to really address this topic. One of the results of this thesis is the formulation of the following theoretical frame and its operationalisation, presented as a checklist (Paragraph 10.5.2.10), which should be implemented in order to assist the development of effective and cost-effective quality assurance programmes and costing of quality in Hungary.

10.5.1 Need for evaluation of the effectiveness and cost-effectiveness of quality assurance programmes

In an environment where hospitals and other health care institutions compete based on quality, offering new and better services in order to improve a competitive edge to win more or better contracts, quality assurance is a very important tool. Quality assurance programmes are among the important resources, including what the health care organisations purchase in order to assure that this competitive edge is going to be achieved and stabilised. Purchasing quality care and quality assurance programmes as a process should itself be subjected to improvement. Similar or same goals might be achieved through the implementation of very different quality assurance programmes. Structure, process and outcome oriented programmes can be used separately or in almost infinite combination. Numerous process or/outcome indicators can be used as well as various education, training, regulation and control methods can be implemented. There are many other ways of improving the effectiveness of quality assurance, e.g. to achieve achievable benefit not achieved in a cost-effective way. Administrative, financing and regulatory tools can be used, education, training, licensing, accreditation, peer review, audit and guidelines can be employed. Health care settings have to purchase effective and cost-effective quality assurance programmes to improve their capacity of providing cost effective quality services. What do these quality assurance tools have in common? How to select the one of them that should be implemented, to what extent and in what combination, over what time frame?

As was discussed earlier in this thesis the author uses Williamson’s (1978) definition of the main aim of quality assurance namely: “The main aim of quality assurance activities 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 goals of quality assurance is
to improve the effectiveness of health care. Quality assurance should bridge the gap between efficacy and effectiveness, and what is equally important: effectiveness of the quality assurance tools is not enough it should be done in a cost-effective way. This is a rather narrow, but very practical focus of quality assurance used in this thesis.

10.5.2 How to achieve quality improvement in an effective and cost-effective way?

In the following part of this chapter a list of necessary steps are listed and an explanation is given of what has to be taken into consideration before any kind of quality assurance activities are started.

10.5.2.1 Cost-effective quality improvement

Cost-effectiveness analysis is generally used to select those interventions in health care, which have increased benefits against relatively low costs when compared to alternative interventions. Often cost-effectiveness information stems from studies under controlled situations and reflects efficacy rather than effectiveness. The area of application of this tool can be extended to the whole process of care: not only the question of which intervention should take place given a specific health care problem but also the more broad question of the efficiency of the whole process of care should be addressed. This question can be formulated as: ‘given the current way of diagnosis and treatment of a certain health problem how can a budget be allocated in such a way that the increase in health status is maximised considering all relevant phases in the process of care’.

A number of questions arise when considering such extended application of cost-effectiveness analysis:
- What phases in the care process should be distinguished?
- What sources of information are available to determine current levels of investment and effectiveness for these phases?
- What is known about the relative efficiency of strategies for improvement of the quality of care in these phases?
- What decision rule can be applied to determine the optimal resource allocation from the available budget?

Regarding the phases of care to be distinguished we suggest to use the following phases and related issues (modified from Tugwell et al., 1985):
- Contact with health care: does a patient contact a health care provider and if so, does he do so in a timely fashion?
- Diagnosis: is each patient diagnosed appropriately and timely?
- Indication: is cost-effective care indicated?
- Provision of care: is cost-effective care provided?
- Patient compliance: does the patient follow advice correctly and timely?

The interesting property of a care process as described in such phases is that inefficiencies in one phase influence the effectiveness of investing in another phase. For instance, actually providing appropriate care is less effective when the more severe cases do not contact the
health care sector or when patients are often diagnosed inappropriately. The effectiveness of investment in strategies to improve the care process in one phase is therefore conditional upon the current level of investment and effectiveness in each of the other phases.

When considering the available evidence on current levels of investment and effectiveness it is clear that especially information about the effectiveness of present interventions is lacking. In the ‘Public Health Status and forecasts’ program in the Netherlands (Ruwaid and Kramers, 1997) the actual performance in each phase of the care process for 10 disease categories was investigated. It was found that such performance could only be described in qualitative terms and that virtually no quantitative data on actual effectiveness could be found. As we are moving from effectiveness of the health care interventions and other health care services to quality improvement the next challenge is to find information on the effectiveness of investment in quality improving strategies. In this respect it is helpful to see whether information on the achievable effectiveness in an optimal situation is available. Such information will be different for the distinct phases. For instance, for the fourth phase of health care provision information from prospective randomised controlled clinical trials may be useful to take as a benchmark for current effectiveness levels. But for other phases other sources of information should be used. Epidemiological data may inform about actual patient numbers as against expected numbers, as would be relevant to assess whether all patients are identified (e.g. relevant in tuberculosis and diabetes). Also studies on actual compliance may inform about potential benefits to be gained by programs to improve patient compliance. Identification of a gap between actual and attainable effectiveness is not enough. For optimisation it is necessary to know the relative cost-effectiveness of different strategies for quality improvement in each phase. The bulk of evidence here is on the relative cost-effectiveness of diagnostic and therapeutic strategies (what should be done?) rather than on the cost-effectiveness of improvements in the process of care (how should it be done?). Increasingly studies on the effectiveness of quality improvement programs include consideration of the relative efficiency of such program.

Finally a decision rule should be specified to inform the optimal allocation of an available health care budget. Taking an incremental perspective resources should be allocated such that the increase in health status is maximised considering the actual care process (e.g. for a specific disease) and all possible strategies to increase effectiveness in all 5 phases of the care process. When all required information is available including the relation between the relative efficiency of investment in one phase and current levels of investment and effectiveness in the other phases the optimal allocation can be determined through application of appropriate operations research techniques. Given the lack of information a more heuristic approach may be required. This would involve a global investigation of bottlenecks in each phase of the care process and a consideration of strategies to fix identified problems. For such limited number of strategies the relative efficiency given the order of implementation should be assessed in order to select the optimal combination of strategies to be applied.

10.5.2.2 Scientific evidence and interpretation

Before starting quality assurance activities scientific evidence should be collected about the topic under study related to efficacy and effectiveness (Paragraph 10.5.2.3) and manage-
mention innovation quality should be taken into consideration as well (Paragraph 10.5.2.4). Scientific evidence of healthcare services are exhaustively discussed by many authors, however, interpretation of evidence - clinical vs. social effectiveness - under a certain socio-economic and cultural conditions in a given country is equally important. Tanenbaum (1996) reviewed 42 references of Canadian and US policy-making to determine how different value systems can influence the use of evidence in policy-making. The author concluded that because of different culture and different decision making process the knowledge about effectiveness and ineffectiveness which is usually expressed in terms of probabilities, has different contribution in decisions in both countries. Canadian policy-makers overstate the social applicability and the US policy makers the individual applicability of outcomes research findings. Hope (1998) stressed that knowledge gained from evidence-based medicine is likely to be used principally by those groups that already hold the power. If this is so, the response should be that the knowledge is readily available to all groups, and particularly those with less power over the health care budget. There is another aspect of this issue presented by Oliver, Rajan, Turner et al. (1996). They argued that some health care professionals opposed evidence-based care on the ground that it would increase anxiety, reduce compliance and create problems. They reviewed patients’ reactions to information sheets on ultrasonography which were based on current best knowledge and gave full disclosure of benefits and adverse effects. They concluded that ultrasonography is an established procedure which has functions other than what might be defined as clinical effectiveness, for example many women believe it is socially desirable to view the foetus on the screen and receive assurances that the baby is healthy.

10.5.2.3 Scientific evidence of quality assurance

Are there some kinds of scientific evidence that the chosen quality assurance activity is effective to narrow the gap between efficacy and effectiveness in the field of the particular piece of health care technology? According to the literature, for instance, scientific evidence is available to show that practice guideline setting and implementation is a good tool in changing physicians' behaviour and probably improve outcome. (Grimshaw and Russel, 1993; Grimshaw and Russel, 1994; Grimshaw, Freemantle and Wallace, 1995)

10.5.2.4 Evidence of effective management innovation

"We think in quantum leaps but mostly implement in small steps " this is one if the most important issue argued by Homma (1998). The improvement of effectiveness and cost effectiveness of quality assurance requires that the focus of quality assurance has to incorporate the entire patient process (x,y,z ..., w). This argument is consistent with many previous studies from inside and beyond the world of healthcare. (Deming, 1992; Juran, 1988 and 1992; Berwick, 1998; Caldwell, 1998; Good ideas (e.g. guidelines) are not self-implementing. The function of QA can be shown as QA = f (x, y, z, ..., w). The study published by Keston and Enthoven (1998) shows an excellent example for this function. Between 1993 and 1995 the average length of stay for hip replacement decreased from 17 days to 6.3 days. The cost reduced by 9000 US dollars, and the quality of care improved in terms of nosocomial infection, venous thrombosis and dislocation of the hip. The authors
identified 14 clinical and management innovations that they considered to be relevant to cost reduction and quality improvement such as: 1) clinical guidelines; 2) pre-operative patient education; 3) antibiotic prophylaxis; 4) anticoagulant prophylaxis; ... 8) standardised nursing care; 9) early transfer to 'skilled nursing facilities'; 10) early discharge; ... 14) the use of modular prostheses allowing parts to be replaced. In this above function x can be equated to the 1st management and clinical innovation (clinical guideline) and the w can be equated with the 14th one (the use of modular prostheses allowing parts to be replaced). In this way process utility can be taken into account when making guidelines.

10.5.2.5 Scientific evidence supporting 'achievable benefit not achieved' (a massive gap between efficacy and effectiveness)

Given the limited resources and difficulty in changing professional behaviour quality assurance activities should be focused on those areas of clinical practice where good evidence exists and change would be worthwhile. Measuring the size of the gap between efficacy and the effectiveness is crucial. Policy makers, administrative and clinical decision-makers at all levels need this information that allows them to increase the use of rational decision making in order to manage changes successfully. Due to the diminishing marginal utility of additional spending massive difference should be present between efficacy and effectiveness in order to be able to present significant improvement within a relatively short time frame with potentially cost-effective way. Cost utility ratios, cost per QALY for instance, also change in the real world due to the diminishing marginal utility of additional spending which might have a major influence on decision making. In other words it means that more spending is required close to the last parts of the gap (ceiling effect), that is why conditions related to cut off points (CE ratio) should be identified. Due to the different conditions, patient sample (co-morbidity, severity of illness) and settings, efficacy defined by RCTs cannot be achieved most of the times. There are differences in the actual effectiveness due to the limited availability of resources (financial resources, knowledge, staff) and the differences of the wellness, appropriateness and effectiveness of the quality assurance tools. The achievable benefit of every given situation has to be defined carefully, by benchmarking in any given quality assurance programme. The level of achievable benefit has to be defined, predicted and explicitly stated within all quality assurance programmes (risk assessment included). The same achievable benefit targets can be used only in countries where: a) local conditions of care are the same or very similar. 'Local condition' is not a technical term, local conditions incorporate socio-economic, cultural, geographical factors from which the actual characteristics of the 'local conditions' are derived; b) the state of medical science is the same. According to this hypothesis achievable benefit, as a crucial corner stone of every quality assurance activity, has to be tailor made. Different aspects have to be taken into consideration, e.g. the size, location and teaching status of the hospitals.

10.5.2.6 Clear, and explicit goals

The importance of clear and explicit goals was highlighted by many authors. (Juran 1988, Williamson 1978, Donabedian 1980) It is important to take into consideration that the
duration of the quality assurance programme might have a profound impact on the results and costs and cost-effectiveness (discount rate) of the quality assurance programme. Programme specification is needed not only in terms of what to do but in terms of timing as well. The time frame of the evaluation should be standardised as well in order to make evaluation easier/possible.

10.5.2.7 What are proper outcomes in quality improvement?

Patients with a specified outcome should be the unit of analysis, not the events itself. Particularly, because events can differ in severity and consequences.

10.5.2.8 Cost per unit of additional benefit has to be calculated - incremental cost

As was stated earlier the main aim of quality assurance is bridging the gap between efficacy and effectiveness. If we want to do this in a cost-effective way, an important question has to be explicitly addressed and listed among the goals: to what extent should this gap be bridged? Figure 10.1 shows the production function of quality assurance tool X.

**Figure 10.1 Production function for quality assurance tool X**

The higher the capacity to benefit from a medical service associated with a given quality activity, other things being equal, (not necessarily, also depends on the efficiency of the QA activity) the greater the benefit from the quality assurance activity. Assuming this to be true, the effectiveness of this group of services should be improved first. As additional budget becomes available, other groups with less capacity to benefit can be taken care of. As this happens, the benefit per the unit of budget expended declines.

By rank ordering the interventions we can create a production function curve with a slope:

\[
\frac{Y2 - Y1}{X2 - X1} \text{ or } \frac{dY}{dX}
\]
(Y2 - Y1)/ (X2 - X1) is the slope of the chord (straight line between two points on a curve) from point number 1 to point number 2, both of which must lie on the curve. The slope of the curve at a point (dX/dY) is the limit of the slope of this chord as the abscissa of the second point approaches the first. That is, the slope of the function at the point is the derivative rather than the slope of the chord. Marginal cost (marginal cost per unit produced) where the unit might be a year of life saved, a patient day in the hospital, a case per cancer detected etc. The marginal cost of the n+1st unit is defined algebraically as (the total cost of producing n+1 units) minus (the total cost of producing n units).

Average cost of the n+1 units is defined as (the total cost of producing n+1 units) divided by n+1. So marginal cost of the n th unit of benefit Xn - X n-1/ Yn - Yn-1

If we look at it from the opposite point of view, (having the cost as independent variable) we can calculate the marginal average benefit. In this case it can be shown that in certain parts of health care marginal benefit is decreasing. But the whole thing basically depends on how we conceptualise, measure and account and discount(!) the total benefit and the total cost. Discounting is important because both investment (cost) and benefit happen in time. It is important how to value future benefit and how to discount investment over time. If we go a bit further we can see in our hypothetical production function curve that Y2 - Y1 can be negative when the total benefit can go down till zero or below the 0 level. This theoretical frame can be used to explicitly define the amount of the gap between efficacy and effectiveness which should be bridged with the help of the given quality assurance tool. Figure 10.2 show different quality assurance tools and different amount of improvement of effectiveness can be achieved in cost-effective way when the added benefit / added cost ratio is favourable.

Figure 10.2 Quality assurance tools with different effectiveness and cost-effectiveness

The figure shows that to improve effectiveness, to achieve greater part of the achievable benefit not achieved is not imperative, costs issues have to be taken into consideration. For example, if the gap between the actual benefit and the achievable benefit is large, this situation, at least theoretically, offers much room for the improvement of effectiveness, to achieve greater part of the benefit currently not achieved. But, for example, if 70 percent of
the benefit not achieved might be achieved in a very good costs per ‘added unit of benefit achievable achieved’ (marginal costs: the change in total cost that results when benefit is varied by one unit), and than the unit of additional benefit achieved is going to be high, probably further improvement of effectiveness is not desired. (Probably this amount could be used elsewhere with higher efficiency.) The decision depends on value judgement to a substantial extent. For example when we have a sentinel event (indicator), for instance maternal death, in this case zero defect is the only acceptable level, and effectiveness has to be 100%. Every benefit has to be achieved. Another example from the field of screening: 100% compliance of the target population in mammography screening would be ideal. But as is clearly demonstrated by examples from the UK and the Netherlands, to improve compliance over 80 or 90 percent would be very expensive if not impossible. The same can be demonstrated in relation to vaccination. To improve vaccination rate over 95%-97% would be extremely expensive and even not necessary. It is statistically evident that the chances that two unvaccinated individuals will meet and get infected or even cause epidemic are small.

10.5.2.9 Affordability

Another crucial point which has to be taken into consideration: will the given health care service be affordable if it is provided at a higher level of effectiveness. As was discussed earlier, additional spending has a diminishing marginal utility both related to the health care services (for example, costs/QALY ratio is getting higher) and associated with quality assurance activities. The most troublesome for policymakers, payers, and patients alike, in all probability, are costs of care. All parties emphasise to use an explicit grading system of the costs of services provided to support decisions. (Stevens, Colin-Jones and Gabbay, 1995) One possibility, when applicable is to provide cost utility information about the given piece of health care service which is in the focus of the quality assurance activity (Table 10.1) in addition, however, some kind of costs per added unit of benefit should be calculated also about the quality assurance tools applicable in the given situation.

### Table 10.1 Cost utility categories

<table>
<thead>
<tr>
<th>Resource requirements</th>
<th>Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 0.5 million Ft. per life year ((\text{m}^2))</td>
<td>A</td>
</tr>
<tr>
<td>More than 0.5 million Ft. but less than 5 million Ft per life-year</td>
<td>B</td>
</tr>
<tr>
<td>More than 5 million Ft. but less than 10 million Ft. per life year</td>
<td>C</td>
</tr>
<tr>
<td>More than 10 million Ft. per life year</td>
<td>D</td>
</tr>
</tbody>
</table>

\(\text{m}^2\) or quality equivalent

In UK the category A is less than 3,000 Pounds; B is between 3,000-10,000 Pounds; C is 10,000-20,000 Pounds, and the category D is more than 20,000 Pounds. Categories in Table 10.1 are based on costs of the Hungarian health care system. To further support the decision on which topic in the health care system might be chosen to improve its quality, which means in this context, to bridge the gap between efficacy and effectiveness, available scientific evidence should be combined with costs information. (Table 10.2)
Table 10.2 Scientific evidence and cost-utility

<table>
<thead>
<tr>
<th>Quality of scientific evidence / Cost Utility</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>++</td>
<td>++</td>
<td>#</td>
<td>##</td>
</tr>
<tr>
<td>II</td>
<td>++</td>
<td>+</td>
<td>#</td>
<td>##</td>
</tr>
<tr>
<td>III</td>
<td>+</td>
<td>#</td>
<td>#</td>
<td>##</td>
</tr>
<tr>
<td>IV</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Not-effective based on scientific evidence</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Harmful, based on scientific evidence</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

++ = strong scientific evidence, very good cost-effectiveness
+ = good or fair scientific evidence and good or fair cost-effectiveness
# = good or fair scientific evidence and low cost-effectiveness
## = strong, good or fair scientific evidence and very low cost-effectiveness
0 = no scientific evidence available
— = not effective based on scientific evidence associated with varying amount of costs
— = available scientific evidence shows that the given health care service is harmful if provided associated with varying amount of costs

Health care is a diverse field, resources and time for quality improvement are restricted, in contrast, the number of topics are endless. Quality improvement should be focussed at the most relevant aspects of care and at problem areas with the greatest impact on patients and care providers and the maximum chance of improvement. (Grol, 1996) By using the table 10.2 competing quality assurance programmes can be graded according to the their underlying scientific evidence and cost-effectiveness. In this way research and policy making are linked.

10.5.2.10 Check list

Prior to the quality assurance programme for planning purposes the subsequent check list can be followed in order to set up an effective and cost-effective quality assurance programme. (Table 10.3) Information and some kind of evidence should be provided on the following four key aspects: quality assurance of health care service; quality assurance programme, and costs.

CLOSING SENTENCES

Over the past six years while the research underlying this thesis was being conducted, the author and many of his peers, who shared the same vision, were trying to apply a rational way of thinking, so indispensable in scientific research, to health care in a country where decisions have traditionally been made in a highly irrational way. Whether or not this ‘knowledge sharing’ exercise will result in improvements in quality that will be comparable to the satisfaction for those involved, remains to be seen.
### Table 10.3 Check-list

<table>
<thead>
<tr>
<th>Steps</th>
<th>Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quality of health care service</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>What is the main goal to be achieved? Is it structure, process or outcome related, or a combination of these elements? What is the 'added benefit' and what is the unit of added benefit, and how to measure? What measurement to be used?</td>
</tr>
<tr>
<td>2</td>
<td>Is the goal of the given quality assurance programme achievable based on scientific evidence under idealistic condition (efficacy)? How strong is the scientific evidence?</td>
</tr>
<tr>
<td>3</td>
<td>What is the current level of effectiveness? How 'big is the gap' between efficacy and effectiveness? What is the minimum sample size to answer these questions and is (at least) this minimum sample size present? Are there differences in effectiveness among functional or structural parts of the object of quality assurance (For instance, in case of hospital, are there differences among departments? In case of country, region or county, are there differences among hospitals?)</td>
</tr>
<tr>
<td>4</td>
<td>What is the chosen benchmark to set up a target achievement? The benchmark could be the neighbouring health care organisation or the best in the same district or country, or the leading organisation in the given field. What percent of the 'gap' between efficacy and effectiveness can be bridged?</td>
</tr>
<tr>
<td>5</td>
<td>What is the time frame of this development, and what is the benefit achieved during this time period with certain percentage for discounting?</td>
</tr>
<tr>
<td>6</td>
<td>What is the importance of this development and its relevance in meeting the needs?</td>
</tr>
<tr>
<td>7</td>
<td>Is there a high level of professional consensus related to the needs and methodology?</td>
</tr>
<tr>
<td><strong>Quality Assurance</strong></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>What type of quality assurance programmes could be performed in order to improve effectiveness? Make a list.</td>
</tr>
<tr>
<td>9</td>
<td>Is there scientific evidence available to demonstrate that the quality assurance programmes really improve quality, and how strong is the scientific evidence? What is the outcome of the given quality assurance programme: real outcome or surrogate outcome. (It might depend on the goal of the quality assurance programme. For instance, changing practitioners behaviour by setting and implementing guidelines can be an outcome of the programme if the declared main goal is to change professional behaviour, but can be a surrogate outcome if the programme aimed at improving the appropriateness of the high blood pressure prevention and treatment.)</td>
</tr>
<tr>
<td>10</td>
<td>Under what condition (legal, financing mechanisms, management system, social and cultural background) are these listed quality assurance tools functioning well and at what cost. Could these tools (or at least one of them) be implemented under our own actual situation? What kind of requirements can be identified (steps of complex management innovation) and should be provided to set up optimal conditions in which the chosen quality tool might work well with the highest probability</td>
</tr>
<tr>
<td>11</td>
<td>What is the expected shape of the production function curve for the given quality assurance programmes which might be implemented. (Try to avoid ceiling effect.)</td>
</tr>
<tr>
<td><strong>Costs</strong></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>All important costs elements of the quality assurance programme should be identified and collected. Calculate average medical malpractice claims in terms of dollar in the particular setting and area.</td>
</tr>
<tr>
<td>13</td>
<td>Indirect cost should be identified and estimated in a well defined and documented way.</td>
</tr>
<tr>
<td>14</td>
<td>Certain percentage of discount rate should be used.</td>
</tr>
<tr>
<td>15</td>
<td>Incremental cost-effectiveness ratios should be calculated.</td>
</tr>
<tr>
<td>16</td>
<td>Sensitivity analysis should be performed.</td>
</tr>
</tbody>
</table>
References

Grimshaw JM, Russel, IT (1994) Achieving health gain through clinical guidelines II: ensuring guidelines change medical practice, Quality in Health Care 3,45-52
Grol R (1996) Research and development in quality of care: establishing the research agenda, Quality in Health Care 5,235-242
Oliver S, Rajan L, Turner H et al. (1996) Some health care professionals opposed evidence-based patient choice on the ground that it would increase anxiety, reduce compliance and create problems for the organisation, BMJ 313,1251-1255