Promoting quality in health care

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Ten Years of Health Systems Transition in Central and Eastern Europe and Eurasia

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This draft paper is part of a series commissioned by USAID to provide a conceptual framework and overview of the main thematic topics of the USAID conference "Ten Years of Health Systems Transition in Central and Eastern Europe and Eurasia." Following the conference, each team of authors will revise the papers, compiling the final versions in a book by the European Observatory on Health Care Systems, which will be made available to conference participants in early 2003.

Executive Summary

Promoting quality in central and eastern Europe (CEE) and the countries of the former Soviet Union (FSU) is difficult because of the lack of resources and inappropriate structures inherited from the Soviet model of health care provision (Semashko). Even with limited resources, it is apparent that the quality of care provided is often much worse than it need be. The paper begins by looking at how quality was organized in the Soviet model. It identifies as a major problem in quality the widespread use of ineffective treatments. The paper explores the critical lack of a clinical tradition of evidence-based medicine in the region, and describes the old system of quality assurance based on promulgation of standards and norms, and the punishment of individuals who failed to heed them.

The second part of the paper develops a general conceptual framework for the quality of health care and its improvement. The level of quality problems in health care is in stark contrast to those in other industries, which have a long history of using quality management systems to improve quality (such as the car manufacturing industry), increase customer satisfaction (such as the hotel industry) and reduce errors (such as the aviation industry). Since the 1990s, with popularization of the work of organizational theorists such as Deming and Juran, the concepts of quality management have become increasingly influential in improving quality in health care. Emphasis has shifted from structures, standards and norms to outcomes and process that are linked to outcomes through scientific evidence. This is often referred to as the "Outcomes Movement." This approach has been operationalized in a widely used definition of quality in health care is that has been developed through a process of consensus by the US Institute of Medicine: "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."

The paper goes on to explore the implications of the definition, focusing on the critical concepts of outcomes, likelihood and professional knowledge. For the former Soviet Union, a critical issue is what constitutes professional knowledge. Another critical issue is how this knowledge is delivered to the patient (the organization of care). Soviet medicine was isolated from the emerging developments in clinical epidemiology and evidence-based health care, with the result that randomized controlled studies were very rare. Soviet medicine relied on a special form of professional guidelines called "methodological recommendations," which were developed and driven into the system using a top-down approach. Guidelines should be based on a systematic review of the literature, using critical appraisal skills (meta-analysis) to combine all randomized controlled trials.

The third part of the paper explores how to put evidence-based guidelines into routine clinical practice. This is the critical step an improving the quality of care and outcomes. As experience with evidence-based guidelines has accumulated, it has become clear that their production is not sufficient to change clinical practice. To make improvements in health care one must tackle its two key components: content and organization. The content of care must be compatible with the best scientific evidence available. Organization of care means the way in which health care is delivered through the processes and systems of care. The paper presents a conceptual model for reorganizing the processes of health care to enable the implementation of evidence-based practice.

The final section of the paper examines some aspects of what has happened in the CEE and FSU in quality improvement and in applying modern health care quality improvement methodology. Given limitations of space, the paper highlights two successful examples of development projects that have improved the quality of care in practice. The case studies reviewed in this paper show that it has been possible to introduce systems to enhance quality of care in countries in transition, with significant improvements in effectiveness, efficiency and patients' experience of care.

In conclusion, evidence-based medicine and the application of modern health care quality improvement methodology are the critical issues that need to be explored over the next ten years of health reform, if there are going to be real improvements in the quality of care. As long as there is widespread use of ineffective treatments, it is unclear whether increasing the level of funding to health care will lead to real improvements in health. Furthermore, even improvements in "efficiency" may not lead to improvements in outcome. Hospitals may improve their throughput, but if the treatments are not effective this will not lead to improvements in health. The goal is to improve the health of the population, which has been deteriorating since transition, and this requires a focus on improved outcomes. This, in turn, requires that interventions funded from scarce public resources are based on scientific evidence of their effectiveness.

Introduction

The fundamental goal of a health care system is to promote health. Clearly there are certain prerequisites if it is to achieve this. It requires adequate resources, which are not just financial but include trained staff and appropriate facilities, equipment and pharmaceuticals and it should be organized in a way that makes it possible to provide care that meets the needs of its population. It must be accepted that the lack of resources and inherited, often inappropriate structures place the health care systems in central and eastern Europe and the former Soviet Union at a disadvantage as they seek to promote high quality care. Yet even in these difficult circumstances it is apparent that the quality of care that is provided is often much worse than it need be. In some countries many treatments provided are ineffective, employing resources that could be better used in other ways. Simple maintenance issues, such as provision of adequate lighting or safe electrical wiring are ignored, while hospitals invest in technology that is under-used. Patients are treated with little respect, in ways that contrast with the changing nature of personal interaction in the growing commercial sector.

The level of quality problems in health care is in stark contrast to some other industries, which have a long history of using quality management systems to improve quality (such as the car manufacturing industry), increase customer satisfaction (such as the hotel industry), and reduce errors (such as the aviation industry). Since the 1990s, with popularisation of the work of organizational theorists such as Deming and Juran, the concepts of industrial quality management have become increasingly influential in health care. Its advocates claim it is as effective in service industries as manufacturing, and has great potential in health care.[1,2] Much of health care falls far below the quality levels achieved in industry but there are examples of success. For example, deaths related to anesthesia occurred at rates of 25 to 50 per million in many industrialised countries. Improved monitoring, the widespread adoption of practice guidelines, and other systematic approaches to reducing errors has reduced this to less that 5 per million.[3,4,5]

This paper focuses on the provision of high quality health care. It begins by arguing that the Soviet model of health care provision, despite its achievements in providing basic universal care, had many important weaknesses. Some of these weaknesses, such as an inappropriate deference to opinions of senior professionals even when not supported by evidence, were also present in western countries at one time. However understanding of evidence of effectiveness, and its role at the heart of efforts to enhance quality of care has advanced greatly since then. Thus, the second part of the paper provides a definition of quality and explores its components, in particular focusing on the knowledge base underpinning it, specifically how one can know if an intervention is effective.

The Soviet system

At the heart of the issue of quality of care in the countries of the former Soviet Union is the nature of medical knowledge during communist rule. It should be noted that the following section applies mainly to the former USSR where access to ideas developed elsewhere was extremely limited. The situation was much less problematic in many parts of central and eastern Europe and in the Baltic Republics that had been able to maintain contacts with western scientists.

The isolation of many parts of the former Soviet Union becomes apparent when one looks in detail at clinical practice. Superficial comparisons have tended to obscure the magnitude of the differences in routine treatment for many common disorders.

Many health facilities contain equipment that is either unknown or long abandoned in the west. Examples include an array of machines to provide electric, magnetic, laser, and ultraviolet light therapy. Many common treatments are similarly unfamiliar. They include the use of ATP and co-carboyxlase for the treatment of myocardial infarctions, the use of hepato-protectors for hepatitis, antibiotics for asthma, and auto-injection therapy for allergies. So why did these treatments become accepted medical practice in the Soviet health care system and not in the west?

One factor is the ideological domination of science during the communist period. Marxist-Leninist theory taught that many of threats to health were transient, attributable to the transition to communism, and thus expected to resolve spontaneously over time.6 There was a rejection of experimental methods, an absence of open and effective peer-review and an extremely hierarchical academic structure. As a consequence, knowledge accumulated only with age, leading to many ideas that had no scientific basis and which were often harmful. The use of transfusions to treat undernourished Romanian children is only an extreme example. This problem is exemplified by the legacy of a Ukrainian agriculturalist, Trofim Lysenko.7 Lysenko rejected Mendelian ideas, arguing that change in plants arose from adaptation to changing circumstances within a few generations. Although he was eventually discredited in the 1960s, his views remained widely held for several decades and the academic culture that allowed him to thrive was that in which many senior Soviet scientists were trained. They were well aware of the personal consequences of expressing a view that challenges the official orthodoxy.8

Although many of the particular beliefs that emerged from this system are now of only historical interest, their true legacy is of a culture in which dissent and open debate, especially with those in senior positions, are often strongly discouraged.

The issues involved can be illustrated further by considering a specific example: the use of hyperbaric oxygen chambers. Hyperbaric oxygen chambers are enclosed chambers containing oxygen at increased atmospheric pressure. They increase oxygen levels in the blood and thus the body tissues. In theory, this might be thought to have a positive effect where a disease is characterized by lack of oxygen, such as a myocardial infarction. Of course, while

the problem may be a localised lack of oxygen in body tissues, the cause may be, for example, a lack of blood supply, so that increasing concentration in the blood will have no effect. This is confirmed by the lack of effect found in randomised controlled trials undertaken in the west, which have identified only two clinical conditions for which hyperbaric therapy is effective: decompression problems in divers and gas gangrene. Yet in the USSR hyperbaric oxygen treatment was specified for over 100 clinical indications and the treatment remains in widespread use throughout the former Soviet Union.

Those using this treatment are quite convinced of its effectiveness in treating conditions as diverse as liver cirrhosis, myocardial infarction and prematurity. The reason for these very different beliefs only becomes clear when the evidence base is examined. It is true that there are many papers in the Soviet literature that support these uses. However the vast majority are from research in basic science, in particular from experts in biophysics and physiology. In a laboratory situation, hyberbaric oxygen chambers can increase oxygenation of tissues in certain circumstances. Yet the real question is whether the findings in these rather artificial settings translate into a measurable clinical effect. This can only be addressed by a properly designed study based on the principles of clinical epidemiology.

Unfortunately much Soviet medical research papers suffered from many methodological limitations. They were typically single centre studies using historical controls. Randomised controlled studies were very rare and Soviet medicine was isolated from the emerging developments in clinical epidemiology and evidence-based health care. As a consequence it continues to be difficult, in some places, to engage in meaningful discussion about evidence because of the very different paradigms that apply. This is seen by some as the greatest issue in addressing quality of care in the former Soviet Union. It will require a profound change in understanding of evidence. The challenges are apparent in the few areas where there has been sustained international contact concerning detailed clinical management. Evidence for the effectiveness of Directly Observed Therapy Short Course (DOTS) treatment for tuberculosis has met with resistance and, although implemented in pilot projects, it has not been possible to change practice more generally in the network of Russian tuberculosis dispensaries, where ineffective treatments such as vitamin C injections and artificial pnemothoraxes remain common. Similarly, there has been little success in implementing syndromic outpatient management of sexually transmitted infections.

A second factor was the lack of consumer orientation that pervaded the communist system. Again, this was most obvious in the USSR, as authorities in some of the satellite states, whose populations were more familiar with developments in the west, were forced to respond to popular demands from time to time. Individuals were limited in their ability to employ either of the usual strategies to force an improvement in how they were treated; exit (by going elsewhere) or voice (by expressing publicly their concerns). As a consequence, services in all sectors were unresponsive to their clients. This was accentuated in health care, which was a low political priority and where the inevitable information asymmetry, which places health professionals in a position of power, was exacerbated by the absence of alternative sources of information.

Formally, however, the Soviet Union did place an emphasis of quality control. This included the development of standards and norms related to the organization of health care and to clinical practice, a system of quality assurance reviews, and mechanisms of regulation. Similar systems were in place in most of the other socialist countries.

The Soviet system incorporated a very elaborate system for setting standards in health care. These standards covered a broad range of issues including what health care facilities are "needed" for a particular population in a particular setting. This was elaborated in terms of levelsa of care; what services should be provided at each level, their staffing, equipment, and supplies. Another important aspect was the so-called "volume of services" to be provided in each clinical diagnostic entity. This was a set of instructions that outlined what a physician should use in terms of diagnostic tests, procedures, treatment, and other services for different diseases. In cases of disputes, this was the reference against which physicians could be held accountable.

The standards were set by senior physicians appointed by the Ministry of Health. Most often, they would be developed by an expert from one of the large number of institutes in the major cities. It would then go through a review by one or more peers after which a designated staff member of the Ministry of Health would authorise it, making it the official standard (the Soviet term is "normative standard"). Standard setting was a top-down process and the perspectives of practicing physicians and other staff, and the realities they faced, were not taken into account. There was no systematic process for updating the standards.

The standards took different forms including books published for use by the different organs of the Ministry of Health. The standards related to "volume of services" were published in the form of directives "prikaz," or "methodological recommendations" which often accompanied the prikaz.

In addition, the Soviet health care system had a large, well-developed system of quality inspection. This role was fulfilled by the so- called "sanitarno-epidemiologicheskaya slujba." Interestingly, this was quite separate from the Ministry of Health and so acted as an independent arm of the government. It was a large organization of inspectors who systematically examined health facilities to check for compliance with the standards. Their roles went beyond health care delivery facilities and included, for example, restaurants and other food outlets. They focused on structures, record keeping, equipment, and cleanliness rather than clinical practices. Much of what they practiced was conceived as contributing to infection control, although in practice this was often ineffective, in part because of an inadequate knowledge of modern microbiological issues.

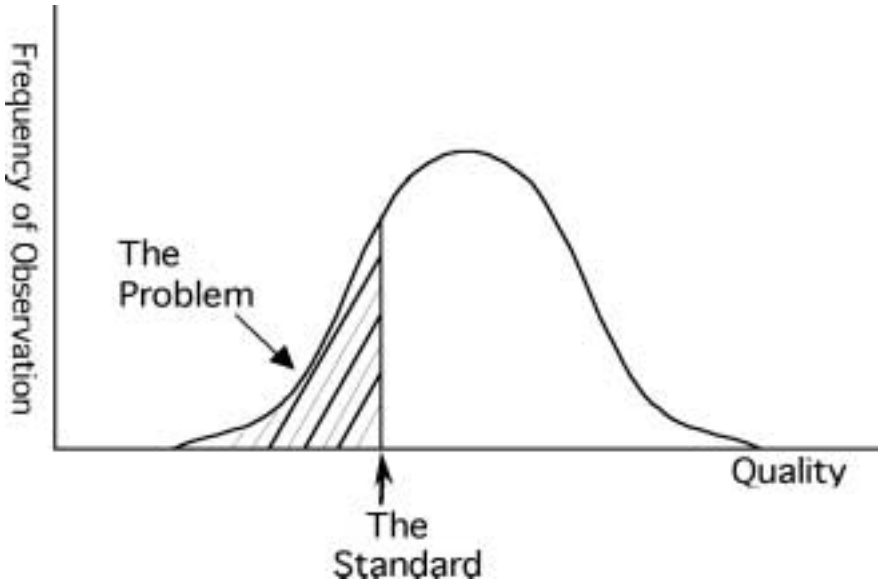
The inspection system was able to ensure some level of compliance with the standards. However it also had weaknesses. It was understood that inspectors would invariably find issues of non-compliance. Consequently the process and its outcome depended on the relationship the inspected facilities could strike with the inspectors. This created perverse in-

centives to try to please the inspectors, especially in the poorer, more remote facilities where the staff were "less connected" (with local leadership) and hence more vulnerable. It also created rent-seeking behaviour on the side of the inspectors.

Other regulatory mechanisms also existed in the Soviet Union. As an organ of government, the Ministry of Health was responsible for the licensing of physicians, certification of the facilities, and issuing directives to govern medical practice in the country. However, virtually all physicians worked for the government. The professional associations, which have played an important part in quality assurance in western countries, had a minimal role.

In its essence, this particular quality assurance framework (commonly known as traditional quality assurance) is based on developing standards, then measuring different providers against these standards, and giving some assessment of how they measure against this standard. Graphically, this can be expressed as follows (Figure 1):

Fig.1



For any given measurement of quality, one can express quality as a continuous variable along the x-axis of the graph. Somewhere along this continuous variable lies the standard, which has been developed for this particular quality issue. The standard becomes the cut off point below which quality is unacceptable. Depending on how stringent our standard is, more or less facilities will lie on either side of the cut off point.

There are two main weaknesses with this quality assurance framework. First, it is extremely difficult to develop standards that fulfil all the criteria required for a process of this nature. Ideally, the standards need to reflect the best available knowledge (which, as noted above, was a major problem), they need to be set high enough without being unrealistic, they need to be applicable to a variety of different settings, they need to be continually updated, and they need to be properly communicated.

Second, it does not provide a means for improvement. If properly used, it can serve as a quality assessment framework but it is not a quality improvement framework. This is especially the case when the quality measurement is the result of a complex system (as with most results which interest us in health care), not an individual action.

In summary, although there was a formal commitment to improving quality of health care during the Soviet era, it was largely unsuccessful. Obviously one factor was a lack of resources. The USSR simply could not obtain the modern equipment and pharmaceuticals being developed in the west, either because of a shortage of hard currency or, in the case of computerised equipment, western export controls. However it also faced problems of isolation from the developments known as evidence-based care, with a failure to see the weaknesses of its own system for accumulating medical knowledge. Another problem was the low priority given to consumer demands, unsurprisingly, as consumers had no choice but to accept what they were given.

In these circumstances even the most dedicated advocate of quality care would face problems, Unfortunately those who did try to tackle the situation adopted a model that, although perfectly in tune with the prevailing ideology based on norms and on command and control, exhibited the same weaknesses in health care as it did in agriculture and the wider economy. As a consequence, like the larger Soviet model, it was unable to meet the challenges it faced.

Towards an understanding of quality in health care

There has been a profound change in thinking about quality of health care in west in the 1990s. Drawing on earlier, seminal work by Donabedian, which drew a distinction between structure, process and outcome,9 it is often referred to as the "Outcomes Movement."

The new approach goes beyond earlier approaches such as the Soviet model described above and has two distinctive elements. The first is a departure from the former emphasis on setting standards for, and inspecting the structures within which care is provided, instead focussing on the outcomes of that care. The second involves a recognition that it is rarely individuals who are responsible for adverse events, but rather problems in the relevant system. 10,11,12

This approach has been operationalised in a widely used definition of quality in health care is that has been developed through a process of consensus by the United States' Institute of Medicine. This is "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."13 This definition offers a helpful framework to think about some of the key issues involved in quality, examining what some of these terms mean in practice.

"Desired Outcomes"

At first glance, the desired outcome of health care should be obvious - survival. The goal of an intervention is to decrease mortality and extend life. At the aggregate level, this is captured mathematically as life expectancy. At the level of the physician, this is captured as survival after an intervention (e.g. 5 year survival after treatment for cancer).

Unfortunately mortality is an incomplete as a measure of desired outcomes. First, differences in outcome of many interventions take time to become apparent. Clearly differences in five-year survival following treatment for cancer can only be detected six or more years after the treatment was administered.

Second, as deaths following many interventions are uncommon, differences may simply reflect random variation due to small numbers. In contrast, measures of process may make it easier to detect differences in a timely manner. Thus, an analysis of monitoring scenarios to detect differences in management of myocardial infarction showed that use of process measures could identify important differences that would only show up in mortality after 73 years of data collection.14

Third, mortality neglects quality of life. Many health care interventions do not decrease mortality but they increase the quality of life: such as hip replacements, cataract extraction, or treatment of mental illness. Furthermore, there is often a trade-off between survival and quality of life, most apparent in palliative care for those with advanced cancer. A patient may reject an intervention that will improve survival, but only by a few weeks, but which will make him or her so sick that they have to be hospitalised. This illustrates the importance of taking into account patients' preferences as part of desired outcomes.

There are now many measures that can be used to measure quality of life. These can be divided into profiles, that measure quality of life on several dimensions, such as pain or mobility, and do not attempt to combine them, and indexes, that bring these measures together into a single value. They can also be divided into generic measures, which relate to overall quality of life, and disease specific measures, which focus on a single condition, such as arthritis or ischaemic heart disease.

These instruments have often remained as research tools. Some, such as the Short Form 36 (SF-36), a generic profile based on 36 questions, have however been adopted into routine practice in some places as a means of monitoring outcomes, for example following non-urgent surgery, However their main importance for policy makers and professionals in countries in transition is the need to be aware that they exist and to be able to interpret research that uses them.

A second issue is the relationship between the outcome achieved and the cost of doing so. Discussion of desired outcomes should take into account cost-effectiveness, a topic on which there is now a large amount of evidence.15,16,17 It is, however, important to note that cost-effectiveness studies are highly context specific,18 as both the combination of in-

puts and their costs will vary from one setting to another. A finding that treatment A is more cost-effective that treatment B in the United States does not mean that the same will be true in Ukraine.

"Likelihood"

The definition of quality emphasises the importance of increasing the 'likelihood' of desired outcomes. This indicates the importance, when comparing performance, to take account of the role of statistical probability. Specifically, if two hospitals are found to have different outcomes, can it be assumed that there is a true difference? There are other possible explanations. First, it may be due to chance, because the numbers involved are small. Second, it may be that the two hospitals are treating quite different types of patients, with different levels of initial severity. The first question is amenable to standard statistical techniques that make it possible to determine the probability that anobserved difference is real. The second question can be addressed by the use of additional data on severity to adjust for the characteristics of patients, although this is less straightforward and results should be treated with caution.

"Current professional knowledge"

The definition sets as its standard 'current professional knowledge'. This is one of the most contentious issues in quality and it has been at the heart of the evidence-based health care movement that emerged in the 1970s. The most famous proponent of a rigorous approach to evidence of effectiveness was Archie Cochrane whose seminal book Effectiveness and Efficiency was first published in 1972 and who gave his name to the international Cochrane Collaboration, which has taken a leading role in the development of evidence-based health care.19

Traditionally, in the west as in the Soviet bloc, knowledge of effectiveness was largely based on opinions of senior professionals, who based their judgements on their own experience. Although, in a very few cases, the effectiveness of an intervention may be obvious, as was the case with penicillin when it was introduced in the 1940s, this process is subject to numerous biases and it is now well recognised that it has both delayed the introduction of effective treatments, such as treatment with streptokinase for myocardial infarction, and allowed ineffective treatments to remain in use.

In nearly all cases it will be necessary to assess the effectiveness of a clinical intervention formally by comparing it with either no treatment or another established treatment (a control). However it is essential to ensure that those subject to the intervention being tested are identical to those in the control group. This is usually achieved by allocating subjects to the two groups at random. In a few cases randomisation may be very difficult or impossible, in which case comparison of groups may still be possible, but only with great care.20

However a single randomised controlled trial may be insufficient to establish the effectiveness of an intervention as there may be questions about whether the findings can be generalised to different settings or whether the study was sufficiently large to be confident that the result was not due to chance. These concerns have led to the development of systematic review, which seeks to identify and assess the quality of all studies that have examined the intervention in question. There is now a large methodological literature on both identification of studies and critical appraisal of their findings, which has revealed the potential for bias and thus misleading findings if not undertaken with adequate rigour. An associated technique is meta-analysis, a statistical method to combine the results of different studies.

Cochrane had once challenged health care professionals, saying "It is surely a great criticism of our profession that we have not organized a critical summary, by speciality or subspeciality, adapted periodically, of all relevant randomised clinical trails."21 His ideas were taken up by individuals such as Chalmers and led to the publication of a major systematic review of the effectiveness of interventions in obstetrics, a specialty that had been notorious for using interventions that were often based on little more than folklore, such as the use of enemas and perineal shaving before labour.22 This process evolved into the International Cochrane Collaboration, a network of researchers and practitioners who collaborate to collect and synthesise evidence, and whose methods have been adopted widely by organizations responsible for advising health policy makers in industrialised countries, such as the British. National Institute for Clinical Excellence. In 1998, the first Cochrane Centre in the former Soviet Union was established in the Russian Federation.

From evidence to guidelines

Having obtained the evidence of effectiveness, the next step is to apply it to routine clinical practice. This is not as straightforward as it might seem, especially where evidence is lacking or contradictory. As with the methods used to assess effectiveness, those used to develop and disseminate clinical guidelines are now increasingly well understood.

David Eddy, one of the leading experts on quality, has outlined six steps which should be carried out in developing practice guidelines: 23,24

1. A clear formulation of the problem to be evaluated;
2. A complete search of the medial literature;
3. A formal analysis of the information contained in the medical literature;
4. Estimation of the magnitudes of important outcomes and the uncertainty associated with each outcome;
5. Assessing patients' preferences for the various outcomes;
6. Design of the guidelines.

Eddy's definition makes clear that not all clinical guidelines are evidence-based. The traditional approach collapses these into a single step which Eddy calls "global subjective judgement."

There are now many sources of evidence-based guidelines, such as the British NHS Centre for Reviews and Dissemination. All of these have in common a reliance on systematic reviews of the literature rather than expert opinion of senior clinicians.

As experience with evidence-based guidelines has accumulated it has become clear that their production is not sufficient to change clinical practice. Similarly, individual interventions, such as education sessions, are often of limited effectiveness. Instead, change is most likely to be brought about as a result of a multi-faceted strategy combining a range of methods within an environment that is supportive of quality. This is discussed further later in this paper.

Who is responsible for enhancing quality?

A high quality health care system is the result of efforts by many different groups and individuals.

Governments play an important role, increasingly recognised as the idea of stewardship. This includes their roles in setting strategic direction for the health care system and ensuring that the resources needed for providing care are adequate. As noted above, this includes not only financial resources but also trained staff, appropriate facilities, and effective pharmaceuticals.

Those responsible for purchasing health care, such as insurance funds, also have an important role, in establishing funding regimes that promote, rather than obstruct the provision of high quality care.

In many western countries professional associations have also played an important role, establishing clinical guidelines and systems of continuing professional development. However the most important players are those involved in direct patient care. One way of doing this is described in the following section.

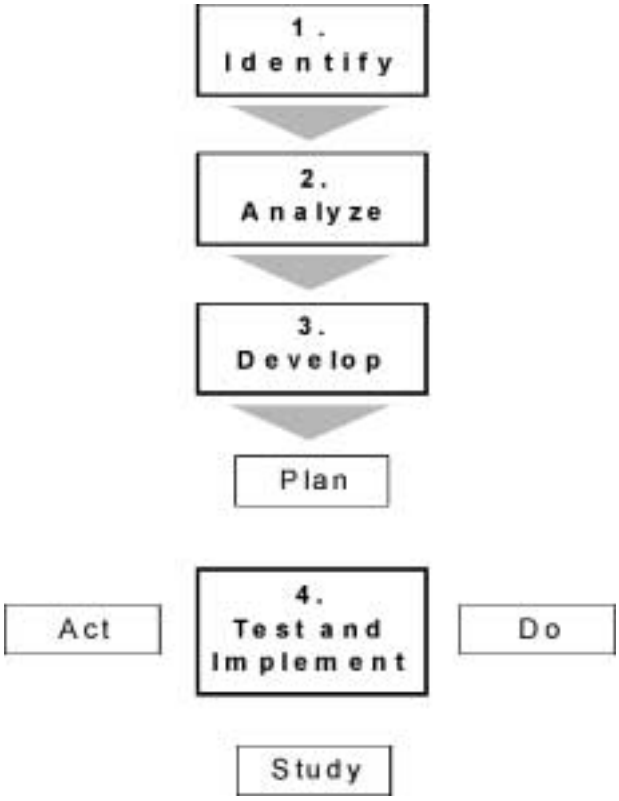
Modern health care quality improvement methodology 25

One approach to quality improvement methodology25 is based on the concept, that every system is perfectly designed to achieve exactly the results it achieves. Therefore, it regards improvement as essentially the result of changes in the systems by which work is accomplished. However the opposite is not necessarily true. Some changes may yield improvement, other changes may not do so, and some changes make even reduce quality.

Using this framework, quality improvement can be considered to consist of four steps as follows:

Identify: The first step is to state explicitly what improvement is to be made. This is usually done by reviewing existing data in the light of knowledge of priorities for improvement amongst relevant. An example from primary care might be to improve the care of patients with hypertension. The system of care is conceptualised and its various components are determined. In this case, components might include updating clinical guidelines in accordance with the best evidence, organization of the process of health care delivery, developing a screening programme appropriate for the population at risk, and resource re-allocation to make the system work.

Fig.2



Analyze: Those providing care analyse existing systems of health care delivery, both clinical and organizational. The organization of health care processes is commonly represented in the form of flowcharts. Key aspects (such as diagnostic criteria, referral criteria, criteria for different interventions and drug use) of clinical care are also noted.

Develop: The evidence on the effectiveness of different interventions and organizational structures is compiled. The evidence is contrasted with existing clinical practices and decisions are made on the changes needed in existing clinical practices in order to become compatible with the best available evidence. The organization of health care delivery is reviewed and enhanced in order to enable the implementation of the updated practices. The

new system of health care delivery is normally formalized as a clinical guideline. The indicators reviewed and updated. This is to ensure that the effect of the changes in the systems of health care delivery could be measured through these indicators.

Test/Implement: The team considers how best to test the new systems of care on a small scale (Plan), the tests are then conducted (Do), the results are monitored and interpreted (Study), and then depending on the results, decisions are made regarding the next steps. These are to either implement the changes where the results are satisfactory, or not to implement them or modify them where the results are not satisfactory.

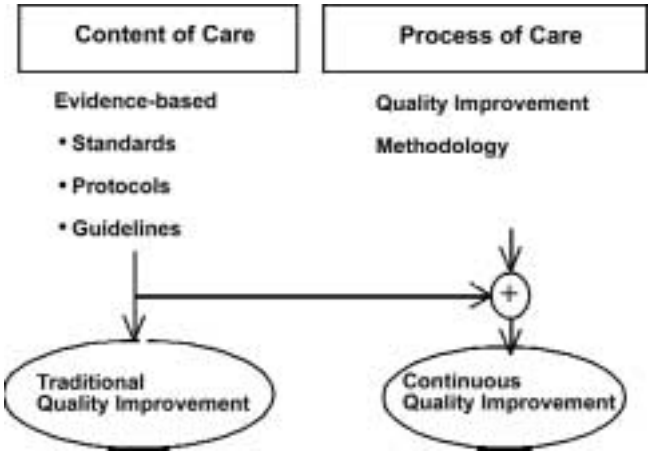
This approach to enhancing quality is based on a series of beliefs about individuals and organizations that are often markedly different from those that characterised the Soviet health care system and is based on the following four key principles:

Understanding work in the form of processes and systems: Delivery of health care can be expressed in terms of various processes that convert inputs from suppliers into outputs for customers by taking them through a series of steps where different actions are done to them. A system is the sum of all processes directed at achieving a single output or outcome.

The importance of teams: Since different professionals are involved in the various steps of a process and these professionals have their own insights into the processes they work in, to improve processes we need necessarily to involve them in bringing about improvement. This also plays a major part in their ownership of the new systems and consequently their commitment to implementation.

Customer focus: Quality can be seen as a function of the extent to which we meet the needs and expectations of our customers. This stresses the importance of eliciting and understanding the needs and expectations of patients and striving to meet or exceed them.

Figure 3 *Batalden's Framework for Clinical Quality Improvement 25,26*



Use of scientific methodology: As outlined earlier, quality in health care is based on evidence of effectiveness of both the interventions and the organizational framework within which they are delivered. These are intimately linked, as illustrated in Batalden's framework, which has proved helpful in several projects in transition countries.

In brief, the framework implies that to make improvement in health care one must tackle the two key components that constitute the care. These are the content of the care, and the organization of care. Thus, the content of care must be compatible with the best scientific evidence available. Organization of care means the way in which health care is delivered through the processes and systems of care. This requires re-organizing the processes of health care delivery to enable the implementation of the evidence-based practice.

Quality improvement as an organizational philosophy

Quality improvement is not, however, simply a technical exercise. Dr. Melnikov, who led a process of change in Tula Oblast described "a new work culture." This is one that emphasises improvement in health outcomes, in the patients' experience of care, and in efficiency of health care delivery. This improvement is seen as the core work of the organization, not as an add on. It is a culture that focuses on the system in which care is delivered. Consequently, individuals are not blamed for poor quality. It is also a culture that acknowledges the role of different professional roles in health care delivery and incorporates this understanding in its approach to improvement. Thus, teams of professionals become decision-makers. It is a culture in which leadership is facilitative and empowering. Thus the old style command and control system becomes obsolete. Importantly, as an organizational philosophy, it requires adaptation to the cultural environment it is to be implemented in. This is a cornerstone for its successful implementation.

Experience since transition

Since the transition individuals in many countries have formed professional associations to promote quality of health care. For example, groups from many countries in central and eastern Europe and the former Soviet Union participate in the European Society for Quality in Health Care (ESQHC) and the International Society for Quality in Health Care (ISQua). The remainder of this section reports the experience of two such groups.

In 1995 The National Center for Quality Assessment (NCQA) in Krakow, Poland assisted by USAID funded technical assistance, began to implement modern quality assurance methods in Polish hospitals. The initial phase led to several notable achievements.28

— A reduction in the waiting time for ambulatory ophthalmic surgery from an average of 71 to 10 days in a Krakow hospital.

— A reduction in the delay before surgery from an average of 5.8 to 1.1 days in a hospital in Lodz.

— An 18% reduction of repeat laboratory tests (due to loss of samples or results) in a Lodz hospital.

— Reducing the number of patients who waited for three hours or more for mammography from 18% to 7% at the diagnostic centre in Legnica.

— A reduction in outpatient waiting time for ultrasound examination from 14 to 7 days at a hospital in Krakow.

In 1998, the Health Committee of the US-Russia Joint Commission on Economic and Technological Cooperation funded by USAID initiated a programme to implement quality improvement methods in several oblasts in Russia.29

In a number of cases significant improvements in care were achieved, frequently leading to better outcomes at lower cost. For example, a programme to improve management of hypertension in primary care30 increased the number of patients managed in that setting by more than seven-fold. Hypertension related hospitalisations decreased by 85%, and hypertensive crises by about 60%. Although the cost incurred in primary care increased by 39%, this was outweighed by a reduction of 41% in the cost of hospital care, resulting in a net reduction of 23% in the cost of managing patients with hypertension.

An enhanced system of care for women with pregnancy-induced hypertension31,32 (PIH) was associated with a reduction in the rate of diagnosing PIH from 43% to 5.6% (based on evidence on what constitutes PIH), and a fall in hospitalisations of 61%. An economic analysis found an 87% reduction in the cost of care.

A new programme to improve care for neonates suffering from respiratory distress syndrome33 reduced cases of hypothermia to negligible levels and was associated with a 64% reduction in deaths due to respiratory distress syndrome.

The obstetric and neonatal programmes are now being implemented in all 42 hospitals in Tver Oblast. The hypertension programme is being implemented in general practices and polyclinics in Tula Oblast. This has been associated with a reduction in early neonatal mortality in Tver, from 10.8/1000 in 1998 to 5.3/1000 in 2001, although obviously other factors will be involved.

Conclusions: Enhancing quality of care in transition countries

The case studies reviewed in this paper show that it has been possible to introduce systems to enhance quality of care in countries in transition, with beneficial effects on effectiveness, efficiency and patients' experience of care. However, the scale of the task is enormous and quality of care haslargely been neglected by the international donor community. Over the last ten years of health reform, the main goal has been to increase financing and improve efficiency. Many countries have opted for health insurance, which has not significantly increased health expenditures, but more importantly, it has failed to improve the quality of health care and improve health outcomes.

In the next decade of health care reform, improving the quality of health care must be at the top of the agenda. This requires a large-scale effort to embed a culture of evidence-based health care in Eastern Europe and the former Soviet Union. This means profound changes in how research is organized, converted into evidence-based clinical guidelines, and how those guidelines are disseminated. This must be complemented by changes in the organization and financing of health care that often impede efforts to improve quality. As we have seen in the West, it is not enough just to produce clinical guidelines. The guidelines need to be implemented and this requires incentives to change behaviour. It also requires significant changes in the fragmented and uncoordinated Soviet model of health care delivery.

In conclusion, there is a need to move beyondissues such as health care financing to focus reform efforts on improving outcomes. This requires a re-thinking of health reform and a greater emphasis on the content of medical care.

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