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ABOUT THE AUTHOR

Charles Shaw

The author is a UK trained clinical doctor, who spent six years as medical director of the general hospital in Bermuda. This exposed him to many New World ideas, like hospital standards, medical bylaws, credentialing, clinical audit, and the Canadian Council on Hospital Accreditation.

He tried to introduce these ideas to UK and Europe over a time frame of 30 years. The author has written a lot about medical audit, conducted research in community hospitals, provided training in public health, obtained a PhD degree (“standards in the NHS”) and has written a book (“Good practice in small hospitals”) which became the first standards for a UK accreditation programme. He developed quality credentials as hospital general manager (NHS), national quality assurance project manager (King’s Fund, London), founder of the Hospital Accreditation Programme (now CHKS), civil servant (advising the Department of Health on how to deliver Margaret Thatcher’s promise of mandatory medical audit) and health service research (CASPE).

In 1985, he was of the ones who contributed to the foundation of the International Society for Quality Assurance (now ISQua). Charles Shaw has produced many publications, conducted collaborative research for WHO, World Bank, European Commission, and consulted various countries in quality of care. His terms of reference are usually about technical interventions, such as performance indicators, clinical audit or hospital standards, at provider level.

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Situational analysis to inform initial findings was conducted in close cooperation with the heads of departments at the Ministry of Health; and with directors, deputies and key staff of relevant institutions including the National Evaluation and Accreditation Council, National Health Insurance Company, National Center for Health Management and State Medical and Pharmaceutical University “Nicolae Testemitanu”. Findings from the field were informed in cooperation with the directors, deputies and medical personnel of Municipal Hospital Nr.1, Research Institute for Mother and Child Health Care, National Scientific and Practical Centre for Emergency Medicine, district hospitals in Cahul, Orhei and Ungheni, Medpark International Hospital, primary care centre in Orhei and the Territorial Medical Association in Botanica.

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about the strengths and weaknesses of the quality of care system in the Republic of Moldova; and for his feedback on the framework of health-care quality in the Republic of Moldova.

This document has been produced within the “EU-WHO Universal Health Coverage Partnership: Supporting policy dialogue on national health policies, strategies and plans and universal coverage”. The views expressed herein can in no way be taken to reflect the official opinion of the EU and WHO.

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LIST OF ABBREVIATIONS

AGREE	Appraisal of Guidelines for Research and Evaluation
CNAM	National Health Insurance Company
CNEAS	National Assessment and Accreditation Council for Health
CNMS	National Centre for Health Management
CNSP	National Centre for Public Health
IMS	Provider of health care services
ISO	International Organization for Standardization
ISQua	International Society for Quality in Health Care
OECD	Organisation for Economic Co-operation and Development
SMPPhU	State Medical and Pharmaceutical University “Nicolae Testemitanu”
SPH	School of Public Health

EXECUTIVE SUMMARY

Introduction

In 2014, the Ministry of Health of the Republic of Moldova requested the World Health Organization (WHO) to provide technical assistance to support the national health authorities and institutions in quality improvement. Using an established national assessment framework, the first step was to identify what policies, structures, methods and resources for quality and safety are currently available in the Moldovan health system. Following feedback of the initial findings, and discussion with the Ministry of Health, national agencies, clinicians and managers, five small groups were designated to review specific themes.

These themes concerned respect for the rights of patients, and the development of health-care institutions, professional management, clinical practice and clinical professions. Each group was provided with briefing and background papers including initial analysis of the situation in the Republic of Moldova, and international comparisons and references (Appendix 2). A sixth working group, comprising the leaders of the previous groups, focused on how the five themes could be integrated and institutionalized within the health system. Feedback from all the working groups was compiled into a first draft report circulated to stakeholders and presented to the National Health Forum in October 2014.

Findings

This analysis documents that many of the policies, structures and methods for improvement common to other countries have been initiated in the Republic of Moldova over the past ten years. Many of these have not been fully implemented, supported, integrated or systematically evaluated for impact. For the purpose of designing a national plan, this report explores the opportunities for future achievement and for learning from the past.

Culture

Quality is seen as a separate domain and is not regarded as an integral part of the provision of medical services. The prevalent culture is one of top-down control by central government, reinforced by the perceived superiority of tertiary centres over secondary and primary care. This encourages patients and staff to move to specialized, high-cost central institutions.

Individual and organizational culture is generally unmotivated and resistant to change; systematic evaluation is seen as a threat rather than an opportunity for improvement. Barriers include resistance to transparency, unwillingness to share performance data between competing institutions, and a perceived risk of being criticized and punished.

Policy

The *Healthcare System Development Strategy 2008–2017* proposed development and implementation of a system to improve the quality of health-care services, and ensure respect for patients' rights. The introduction of health insurance has addressed one dimension of quality by increasing access to care. Many normative acts prescribe technical solutions to improve clinical effectiveness (such as national clinical protocols, indicators and internal clinical audit) and place responsibility for implementation on local committees; little practical assistance or incentive is available at institutional level to fulfil those responsibilities. Barriers to implementation, and the impact of the strategy, have not been evaluated.

The values and principles of a plan for quality and safety should be included in the national strategy for health and in the proposed *Code for Health* – not just as a separate chapter, but embedded within every section.

Organization and management

Management, communication and data flows are essentially vertical; there is little opportunity for sharing or learning within and between the Ministry of Health, national centres and health-care institutions. Quality and safety are cross-cutting issues which demand an integrated national approach to defining, measuring and improving standards in health care. There is no central resource to identify, collate and exchange methods, benchmarks and tools for improvement or to analyse and learn from adverse events and system failures.

Multiple committees and functions prescribed by the Ministry of Health (such as quality councils and committees for medical audit, bioethics, pharmacy, infection control, accreditation, clinical protocols) exist in most institutions but there is no documented evaluation of how well they function or integrate with management systems.

Methods

External assessment

External assessments of health-care institutions are labour intensive, disruptive and expensive. There may be opportunities to standardize training of inspectors, audit techniques and sampling, and exchange of data and conclusions. Public information and exchange of feedback between institutions would promote safety and learning.

Medical and clinical audit

The current external medical audit system is based on reported non-compliance rather than systematic examination of clinical priorities – a mechanism for financial control rather than clinical learning. This largely excludes assessment of clinical outcomes and makes little use of databases or clinical indicators.

Quality councils are required to adapt national clinical protocols to the current capacities of service providers, consistent with evidence-based principles. Other than audits by the quality councils, there is no recommended system for internalizing guidance within clinical departments and teams, or for its use in peer review, learning and continuing education. Measurable audit criteria are not included in many national guidelines.

Effective clinical audit requires skills, time and data which are currently scarce in many health-care institutions. Priorities should be determined locally to address issues which have high impact (in terms of risk, costs or numbers of patients) or where there is wide variation in clinical performance (such as in clinical procedures, outcomes or patient experience). Systematic comparison of current practice against evidence-based standards should be undertaken by clinical teams and developed and recognized as an economic and effective vehicle for continuing professional development and medical education within the workplace.

Patient safety

The Republic of Moldova has adopted international definitions of reportable (to multiple agencies) adverse incidents and near misses concerning medical devices, pharmaceuticals, blood transfusion, nosocomial infection and natural disasters. However, there is no mechanism for receiving and analysing data on other adverse events such as patient falls, decubitus ulcers, clinical complications or medication errors. Despite various normative acts, the process for reporting infections and adverse events is wholly unrealistic and ineffective.

Resources

Data and information

During the development of this report, almost all respondents agreed that the Moldovan health system is rich in data but poor in information. This is not a new discovery: a 2007 report from WHO's Health Metrics Network recommended that monitoring and evaluation should be supported by performance indicators, standardized data sets and flows and an integrated medical information system.

Vast amounts of data are reported upwards to the Ministry of Health and national agencies but much of it is neither used nor shared. Clinicians and managers receive little timely, reliable information that would enable analysis and improvement of their own performance, or comparison of clinical, managerial and financial performance within and between health-care providers.

Training

There is a shortage of training on quality management for continuous professional development of both clinicians and managers. Quality and safety have been introduced in the basic undergraduate medical curriculum but not in specialty training and continuing medical education. More specialized training is needed for quality coordinators and assistants.



Funding

Much could be achieved in the Republic of Moldova without any additional funding, especially if the impact of existing resources and opportunities for efficiency saving were monitored more closely (e.g. extended hospital stay, rational use of drugs, use of minimally invasive procedures and day surgery).

However, core funding should be allocated for national coordination of improvement efforts; protocol development, distribution and monitoring; provision of information to patients and the public; in-service and university-based training; and external technical assistance.

Recommendations for action

Many recommendations have been provided as options to address the gaps, barriers and conflicts identified by this report. These could form the basis of a national framework for quality and safety, or even a national strategy, but the action plan must come from consultation, communication and ownership of the public and many stakeholders within the Republic of Moldova. This discussion could begin with agreement of the following common strategic visions.

1. Legislative framework supports values and principles of quality, safety and performance by enabling information exchange and cooperation between responsible bodies.
2. Key dimensions and principles of quality in health care are agreed nationally as a basis for sharing methods and results of assessments and evaluations.
3. Professional self-regulation, peer review and clinical governance complement top-down external assessment.
4. Financing of system and institutions rewards achievement based on evidence of performance.
5. Performance of individuals and institutions is assessed on demonstrated achievement, improvement and learning, rather than non-compliance, errors or failures.
6. Technical developments are consistent with available guidance from intergovernmental sources, especially Council of Europe, European Commission and WHO.
7. Clinical protocols and clinical practice are consistent with international standards.
8. Corporate and individual learning is based on feedback, and sharing results of systematic audit and evaluation.
9. Information systems are integrated and shared between managers, clinicians, financing and supervisory bodies.
10. User-friendly public Internet allows access to all official reports, evaluations and performance data.

Why quality of care?

Over the past years, WHO has supported and contributed to development of the health sector in the Republic of Moldova. The approach has ranged from specific work on maternal health and perinatal care, HIV and tuberculosis to structural aspects of service provision in primary care and hospitals, as well as medicines. However, despite many existing initiatives, there has been no comprehensive approach to quality of care. The recent universal health coverage debate concentrating on access to services, financial protection and quality of care has provided an opportunity to launch the process of strengthening quality of care systems throughout the entire Moldovan health sector in 2014, supported by the “EU-WHO Universal Health Coverage Partnership: Supporting policy dialogue on national health policies, strategies and plans and universal coverage”.

Health 2020, the new European health policy framework, is guiding the health-system strengthening efforts of WHO European Region Member States: aiming to improve the health and well-being of populations, reduce health inequalities, strengthen public health and ensure people-centred systems that are universal, equitable, sustainable and of high quality. The ways in which services are delivered across the full continuum of care are central to improving the performance of health systems. Hence, the WHO Regional Office for Europe is developing the Framework for Action towards Coordinated/Integrated Health Services Delivery (CIHSD) with the goal to support countries with policy options and recommendations that target key areas for strengthening the coordination/integration of health services. This framework is in line with the vision of Health 2020 and the values of universal health coverage as the delivery of care must be of high quality and people centred in order to secure improvements in health and equity.

The Healthcare System Development Strategy for the period 2012–2017 and the 2014–2018 Institutional Development Strategy of the National Health Insurance Company are examples of important strategic health-sector documents that include the objective of improving quality of care and patient satisfaction. The work on quality of care makes a direct contribution to the realization of these objectives by providing strong global evidence based on internationally accepted principles for improving quality of care, tailored to the health-care system of the Republic of Moldova and reflected in a set of recommendations for the national health authorities to follow.

It is also important that all efforts in quality systems are coordinated among institutions associated with quality of care and that adequate environments to support quality improvement are in place and constantly improved. Capacities and instruments at institutional level need to be consolidated and stakeholders should reach general agreement and understanding of the values and dimensions of quality, principles of measurement, improvement strategies and organizations’ responsibilities in this process.

1. Introduction

Enthusiasm for improvement began with the development of quality control in the manufacturing industry after the Second World War. The quality assurance movement in health care was led by individual champions, professional organizations and provider institutions in North America in the 1960s, spreading to Australasia and western Europe in the 1980s.

The definition and assessment of quality were originally left to technology professionals and economists. In the context of health systems, it is now increasingly the domain of patients, of a well-informed public and electorate, and of a competitive market which compares performance with other countries. The growth of technology and information, demands for transparency and public accountability, and the limits of financial and human resources oblige every country to describe and reform its health system according to internationally recognized standards of structures, process, performance and results.

The language and emphasis has changed over time, ranging through various dimensions of quality such as effectiveness, efficiency, equity, appropriateness and timeliness of services. Splinter groups have included clinical effectiveness, patient centredness, integrated care, clinical governance and patient safety – each taking a particular slice of what should be an integrated cake. Constant relabelling and fragmentation of basic quality systems at institutional, professional and governmental level have been major barriers to learning and improvement.

Most countries have developed health-care regulation to fulfil governmental responsibility to protect patients and the public through licensing (of institutions and of professionals) and legislation for institutional internal systems. Many countries have supported the role of professionals, academics and researchers in self-regulation and improvement against evidence-based standards for health services. Another approach to quality management is based on International Organization for Standardization (ISO) industrial systems which the European Union (EU) has formally adopted for goods and products, and will likely extend into services including health care.

None of these systems can provide a total solution, nor can they work effectively without active coordination throughout a health system – and preferably across borders. The quality of health care was firmly on the WHO agenda in the 1980s but many countries made little effort to define or implement a national strategy until prompted by circumstances such as:

- evidence of unacceptable and unexplained variation between institutions (and countries) in terms of mortality and clinical outcome;
- recognition, based on systematic studies repeated worldwide, that 10% of

inpatients are damaged by hospital admission (ranging from prolonged stay to disability and death);

- introduction of universal health coverage stoking demand for objective measures of performance to select preferred providers, monitor contracts and determine payment tariffs.

Although intergovernmental organizations such as the Council of Europe, WHO and the European Commission respect the right (and responsibility) of Member States to govern their own health systems, they have also offered substantial resources and technical advice to make quality systems compatible across borders.

Whatever the trigger that turns public policy towards the quality and safety of health care, every country would benefit from having an integrated national framework for improvement, based on existing achievements, identified opportunities and reference to the international experience.

2. How this report developed

Context of WHO mission

In early 2014, the Ministry of Health of the Republic of Moldova requested WHO to provide technical assistance in quality improvement systems, to support the national health authorities and institutions in strengthening this area and to identify the gaps and weaknesses to be addressed in a national plan for quality improvement. WHO expressed the initial task as:

- situational analysis of how quality is implemented in the Moldovan health system across various dimensions;
- agreement with stakeholders on the existing gaps and common grounds for developing a national strategy for health-care quality improvement;
- developing an informed analysis of the current strengths and weaknesses of quality management in the health system, and indicating options for improvement at national and at institutional level.

Situational analysis

An initial assessment was made from review of public documents and stakeholder meetings in April 2014, using a format developed to enable the WHO Regional Office for Europe to identify existing policies, organization, methods and resources available for the quality and safety of health care nationally (Shaw & Kalo 2002). Each section of the format is introduced by a statement of principle as shown below.

- **Policy:** The government's values, vision and strategies for quality improvement are comprehensive, consistent and based on evidence and consultation. They are explicitly stated and disseminated to purchasers, providers and the public.
- **Organization:** There are effective mechanisms to integrate and implement the national policy within national and local government, and between all stakeholders and sectors of health-care provision.
- **Methodology:** Effective methods for quality improvement are systematically promoted at national and local level, consistent with experience and scientific evidence. Adoption of demonstrated quality methods is recognized and rewarded in organizations and individuals.
- **Resources:** The national programme identifies responsibility for funding and providing the basic knowledge, skills and information required for quality improvement.

Strategic working groups

Following feedback from the initial findings, and discussion with stakeholders, five small groups were formed to focus on specific themes:

1. empowerment of consumers
2. institutional development
3. management development
4. clinical practice development
5. professional development.

Each group was provided with briefing meetings and background papers including initial analysis of the situation in the Republic of Moldova, and international comparisons and references (see Appendix 2) including:

- values, standards and methods adopted internationally (from Shaw, 2003)
- international reference sources available on the Internet
- international indicators of performance at clinical, institutional and national level.

Workshops were provided on specific technical issues, including:

- development and application of performance indicators
- international experience and standards for accreditation programmes
- criterion-based clinical audit.

A sixth working group, comprising the leaders of the five small groups, focused on how the five themes could be institutionalized within the health system.

First draft report

Feedback from all the working groups, in writing and from a series of discussion meetings, was compiled into a first draft report. This was circulated to stakeholders and presented at further meetings in Chisinau, Orhei and Ungheni, and then to the National Health Forum in October 2014. As a results, this report incorporates the outcome of those further discussions.

3. Values and policy in Republic of Moldova

Quality and safety culture

Quality is seen as a separate domain and is not regarded as part of the medical services provision process. The prevalent culture is of top-down control by central government, reinforced by a perception (with little hard evidence) that tertiary centres are superior to secondary and primary care. This encourages patients and staff to move to specialized, high-cost, central institutions.

Individual and organizational culture is generally unmotivated and resistant to change; systematic evaluation is seen as a threat rather than an opportunity for improvement. Barriers include resistance to transparency, unwillingness to share performance data between competing institutions, and a perceived risk of being criticized and punished.

In general, the workforce has limited knowledge of quality management or the skills required to take an active part. Some commented on conflicts of interest arising from one person holding several leadership positions (e.g. within institutions, specialized committees and professional associations).

Strategic intentions

The principles of WHO's health for all policy and the provisions of the United Nations Millennium Development Goals and Tallinn Charter can be found in national policy and strategy documents, such as the National Health Policy 2007–2021 and the Healthcare System Development Strategy for the period 2008–2017. The latter proposed (paragraph 67) that, "improvement of the quality of the healthcare services and increase of the patients' satisfaction shall be attained as follows:

- develop and implement a system that could ensure and improve the quality of healthcare services;
- strengthen the system of accreditation in the healthcare system;
- ensure the observance of the patients' rights."

The CNAM Institutional Development Strategy 2013–2017 identifies a strategic goal to, "improve access and quality of medical services", but there is no explicit national plan for implementation. Current inspections and audit aim to identify errors and non-compliance in organizations and clinicians, rather than achievements and opportunities for improvement. The infrastructure of quality systems in health-care institutions is based largely on ministerial orders, many of which prescribe excessive detail and do not allow flexibility, integration or development of systems either at local or at national level. Professional self-audit and self-governance are underdeveloped; professions are not organized effectively.

All providers contracting with the CNAM must be accredited but almost all (except 1–2%) of public facilities are already equally accredited. The CNAM cannot identify preferred providers in the public sector even though capabilities vary widely both between and within institutions. In the few instances where institutions are partially or conditionally accredited, this is taken into consideration when contracting services. Unless the CNAM is able to adjust tariffs according to more discriminating grading of institutions, it can neither differentiate between them nor provide incentives for institutional development. Discussion may consider whether the National Assessment and Accreditation Council for Health (CNEAS) should grade institutions and constituent services to differentiate high, medium and low compliance with standards; the CNAM could modify tariffs accordingly.

Legal framework

A plethora of legal instruments and Ministry of Health orders provide a basis for most of the quality systems which are found internationally (Boxes 1 and 2). The 1995 health-care law has been under review for several months.

Box 1. Laws that make reference to protection of patients' rights

Law No. 411-XIII of 28.03.1995 on health care.
Law No. 552-XV of 18.10.2001 on assessment and accreditation in the health-care system.
Law No. 263-XVI of 27.10.2005 on patient's rights and responsibility.
Law No. 133 of 08.07.2011 on personal data protection.
Law No.1402-XIII of 16.12.1997 on mental health.
Law No. 10-XVI of 03.02.2009 on state supervision of public health
Law No.190-XIII of 19.07.1994 on submission of petitions.
Law No. 982-XIV of 11.05.2000 on access to information.
Law No. 105-XV of 13.03.2003 on protection of the rights of consumers.

Several topics (e.g. malpractice, incident reporting) are now being considered for legal clarification. Gaps and conflicts in existing laws and regulations will inevitably emerge if central agencies are expected to change their ways of working and collaborate more effectively with each other. For example, CNEAS legislation includes no allowance for withdrawing accreditation certificates.

The CNEAS has submitted a draft modification of the law on assessment and accreditation of medical institutions including procedures for withdrawal of the accreditation certificate. The draft has been granted government approval and now awaits parliamentary ratification.

The legal basis for all national agencies may need review in order to promote integrated functioning.

Incident reporting

Legal advisers in the Ministry of Health are now working on an incident reporting framework, using examples from Romanian laws. International principles of health-care risk management (e.g. those of WHO, European Commission, Council of Europe) should be incorporated to enable the development of systems compatible with other European states.

Malpractice

Currently, doctors in the public sector have no malpractice insurance, and laws on liability are not specific to health care. Discussions now include options for establishment of indemnity schemes and the Ministry of Health is drafting proposals for law on malpractice. Meanwhile, either the institution concerned or the CNAM pay compensation for damages awarded by the courts.

Professional regulation

Legally, the award of a (medical) diploma is confirmation of competence and confers a right to practise; there is no formal licensing procedure. A law to establish a medical council was approved in late 2013, allocating numerous roles and responsibilities encompassing a wide scope of functions and different domains, including: development of clinical protocols, participation in accreditation procedure, selection of directors of medical institutions, protection of rights of professionals, formulation of training policies, certification, introduction of new providers, and development of various health policies. Due to the recent approval of this law and the amount of responsibilities given to the medical council, it is still too early to assess its impact on professional regulation.

Radiation protection

There appear to be some inconsistencies between international standards and legislation in the Republic of Moldova. For example, the current (former USSR) Moldovan law limits radiology workers to a six-hour day but the European norm is that all such workers wear personal dosimeters to protect against radiation.

Box 2. Regulations that make reference to quality management

Infrastructure

Order no. 139 of 03.03.2010 on ensuring quality of care in health-care institutions – approving the regulatory framework for quality councils of health-care facilities.

Order no. 61-p § 2 of 18.06.2012 on the Council of Experts of the Ministry of Health, which approves the regulation of Council activity.

Order no. 999 of 21.12.2011 on approval of the activity and structure of the National Centre for Health Management.

Order no. 46 of 31.01.2006 on organization in the republican level IMS, a subdivision for monitoring, evaluation and integration of health services.

Order no. 533 of 04.06.2012 on establishment of Ministry of Health specialized committees, which approves the regulation of committees' activity.

Workforce, professional regulation and training

Order no. 58-p § 1 of 03.05.2011 on approval of the Regulation on quantification of credits for continuing medical education.

Order no. 59-p § 2 of 04.05.2011 on approval of the Regulation on certification of medical and pharmaceutical personnel with secondary specialized education.

Order no. 75-p § 1 of 02.06.2011 on approval of the Regulation on certification of physicians and pharmacists.

Order no. 1143 of 14.11.2012 on approval of the Regulation on contest based appointment of IMS heads of subdivisions.

Clinical protocols and guidelines

Order no. 124 of 21.03.2008 on the methodology for development and approval of national clinical protocols.

Order no. 429 of 21.11.2008 on methodology development, approval and implementation of institutional clinical protocols.

Clinical audit

Order no.519 of 29.12.2008 on the internal medical audit system.

Performance indicators

Order no. 569 of 11.07.2011 on approval of the list of health-care quality indicators.

Order no. 489 of 15.07.2010 on the classification of essential pharmaceutical services and quality indicators.

4. Organization and management for quality in Republic of Moldova

Ministry of Health

A Ministry of Health order of March 2008 designated a Quality Management and Standards Department and an advisory council to coordinate the development and approval of national clinical protocols. Initially, this Department was a formal unit of the Ministry of Health, but now the Division for Performance and Quality of Health-care Services is responsible for implementing state policy on quality and safety of care.

Separate departments perform other quality-related functions, including:

- medical personnel management
- primary care
- hospital and emergency services
- medicines and medical devices
- public health
- analysis, monitoring and evaluation of policies.

Various specialized committees support the role of the Ministry of Health and facility managers by:

- improving clinical processes/outcomes through comparison of best practices agreed and current practices of the medical facility;
- determining whether knowledge, skills and existing resources are used properly;
- measuring performance and taking corrective or disciplinary action for poor performance;
- encouraging medical staff to deliver quality and safe services.

Accountability throughout the health system

National level

Numerous ministerial orders identify relevant structures and responsibilities in health-care facilities (Box 2). Total responsibility for quality management lies at institutional level but there is little technical advice on methodology or communications within and between institutions, or with the Ministry of Health. An organizational chart would be valuable to show how responsibilities for quality and safety are allocated or shared within and between the Ministry of Health, expert committees and national agencies within the health-care system.

There is no centre identified to coordinate or issue practical advice on health technology assessment, guidelines, protocols, clinical audit and indicators at national level. At present, the CNMS lacks sufficient resources to perform the tasks stipulated in its operating regulation (analysis of indicators, reports on services provided by facilities, assessment and monitoring of implementation of clinical protocols, medical standards, assessment of patient satisfaction).

Local government

Municipal health departments and district council health committees are required to coordinate implementation of state health policy at the level of subordinate institutions. Territorial public health centres coordinate public health activities at community and administrative territory levels (Law No. 10-XVI of 03.02.2009 on state supervision of public health).

Institutional level

Ministry of Health Order No. 519 (29.12.2008) requires that:

- “based on the available resources, the heads of health-care facilities shall implement and maintain a quality assurance system for provided medical services;
- employees of health-care facilities shall guarantee the achievement of quality tasks as established by the management;
- each health-care facility shall implement the key organizational and management procedures in the quality assurance process and the internal clinical audit.

Ministry of Health Order No. 139 (03.03.2010) gives further instruction to implement a quality management system as an integral part of the overall management of a medical institution. The director or chief physician of the medical institution becomes directly responsible for quality management, including a quality council. Responsibilities of the quality council include:

- strengthening of internal practices;
- (institutional) assessment and analysis of quality of care;
- implementation of internal medical audit, analysis of mortality, nosocomial infections, medical records, etc;
- peer review to assess quality of care and staff self-assessment as part of the internal audit.

The quality council should report to the facility’s staff and administration on the results and performance of activities at least once per quarter, and should display the relevant information on its website. At present, self assessment of medical staff is not widely implemented and is not considered part of continuing medical education.

Discussions among the working groups reported general concerns about accountability for improvement, including:

- lack of opportunities to hold heads of divisions/departments responsible for improving performance;
- personal job descriptions and contracts of employment lack clear definitions of managers' responsibility (at all levels) for the quality of services rendered;
- frequent reorganization of institutions dealing with quality management in health care nationwide (e.g. Ministry of Health, CNMS, specialty commissions).

National agencies

National Health Insurance Company (CNAM)

- provides control of quality and quantity of care delivered;
- assesses compliance with terms of contract provision of medical services re accessibility, quantity, timing, quality and cost of health care provided;
- protects interests of beneficiaries/insured persons;
- controls management of compulsory health insurance funds;
- ensures fairness and social justice in process of health insurance system implementation.

National Centre for Health Management (CNMS)

- ensures implementation of state policy on health management and evaluation of health-care services;
- develops integrated medical information system;
- participates in testing of clinical protocols and evaluation and monitoring of their implementation;
- in cooperation with Ministry of Health and nongovernmental organizations participates in conducting quality assessment of health services studies;
- develops, selects, presents and analyses health system activity indicators at primary, secondary and tertiary levels;
- conducts studies to determine impact on indicators of health-care services;
- collects, summarizes, processes and analyses statistical information in the area of public health;
- submits proposals for structural changes in the health system.

National Assessment and Accreditation Council (CNEAS)

- informs relevant institutions about requirements for assessment and conditions for accreditation;
- undertakes compliance assessment of health-care institutions;
- develops recommendations for institutions' compliance with accreditation standards;
- determines decisions on accreditation of entities in the health sector, and issues certificates of accreditation.

The CNEAS is governed by a presidium chaired by the deputy Minister of Health but including insurers, professions and patient associations. As the Ministry of Health

approves both the standards and the recruitment of assessors, accreditation is not an independent process.

Ministry of Health Order No. 569 (11.07.2011) approves a list of quality of care indicators, and assigns to the CNMS responsibility to:

- develop and submit for approval a mechanism for monitoring and evaluation of quality of care indicators;
- select from the approved list those indicators that are relevant for monitoring in the next year based on the results of monitoring in the current year.

Ministry of Health Order No. 139 (03.03.2010) assigns to the director of CNEAS responsibility to control implementation of the principles of quality assurance of medical services according to the following organizational standards:

- assessment and accreditation of medical institutions;
- provisions of the Regulation Framework for Quality Council of Health-care Facilities;
- regulation of internal medical audit and other regulations with respect to quality of care.

The same order recommends that the CNAM should organize evaluation of implementation of principles of quality medical services (in the context of checks carried out in medical institutions falling within the mandatory health insurance system):

- according to the provisions of the Regulation Framework for Quality Council of Health-care Facilities, regulation of internal medical audit and other laws with respect to quality of care.

Other relevant national bodies and their responsibilities are summarized below.

National Centre for Public Health (CNSP)

- supervises health of the population and new technologies, investigations and equipment;
- applies science and medical practice in the area of preventive medicine;
- carries out performance investigations;
- organizes monitoring of nosocomial infections;
- ensures monitoring and evaluation of quality and effectiveness of sanitary and epidemiological regimes (local public health services/centres issue sanitary authorization permits to health-care facilities).

Republican Centre for Disaster Medicine (CRMC)

- develops guidance and procedures for internal and external disasters – compliance is mandatory for CNEAS accreditation;
- makes five-yearly inspections and other unscheduled visits – costs of compliance are borne by the institution.

Medicines and Medical Devices Agency (AMDM)

- ensures access to safe, effective, affordable and good-quality drugs (monitoring of drug quality is performed through the Pharmaceutical

Inspectorate);

- monitors adverse drug reactions.

State University of Medicine and Pharmacy “Nicolae Testemitanu” (SMPPhU) and the medical colleges

- responsible for basic training, specialty training and continuing medical education for doctors and pharmacists.

School of Public Health Management (SPH)

- contributes to training of specialists in health economics and management.

College of Physicians

- by endorsement, participates in policy development.

Specialty associations

Specialty associations are expected to maintain accurate registers of specialists. In practice, few do –concentrating more on scientific meetings than on self-governance. There is little interspecialty cooperation although a coordinating body did once exist and remains on the statute book.

The legal status of professional specialty associations, their authority and responsibility for self-governance need to be clarified and their fulfilment evaluated.

Health-care institutions

The Healthcare System Development Strategy for the period 2008–2017 (paragraph 37) states that, “The low quality of the health services is caused, to a great extent, by the lack of programs that would determine the service providers to satisfy the needs of the beneficiaries to the maximum, by the fragmented approach of the quality management, by the mechanisms still insufficiently developed of performance-driven motivation of providers.” Paragraph 39 of the same document reports, “The institutional infrastructures do not correspond to the requirements of providing high quality services. The mechanisms for including in the price of services the needs related to infrastructure are also insufficiently developed thus limiting the possibilities for long lasting institutional development.”

Ministry of Health Order No. 139 (03.03.2010) required implementation of a quality management system to be an integral part of the overall management of a medical institution from 2010. Directors/chief physicians of medical institutions were to be directly responsible for quality management of their institutions, including a quality council. In reality, the multiple committees and functions of the quality council prescribed by the Ministry of Health (e.g. committees for medical audit, bioethics, pharmaceuticals, infection control, accreditation, clinical protocols etc.) exist but there is no documented evaluation of how well they function or integrate with management systems.

5. Methods for improvement in Republic of Moldova

External assessment

Drugs and devices

A new law and establishment of the AMDM in 2013 brought the Republic of Moldova in line with EU directives on manufacturing and marketing of medicines and medical devices. This includes the introduction of an information system to track the use of appliances (e.g. surgical implants) and to monitor failures and adverse reactions to drugs and devices.

Institutional certification and licensing

All health-care institutions must be registered as legal entities; this requires certification of environmental and fire safety by the Ministry of Internal Affairs.

Licensing is mandatory only for private health-care institutions (under the Ministry of Economy) and requires registered entities to have sanitary authorization following inspection by the CNSP. The public providers do not require licensing to be authorized to provide services, but the sanitary authorization is mandatory for them. However, a current accreditation certificate is not mandatory for licensing – only 65% of private medical institutions and 77% of pharmaceutical institutions are accredited, compared with 99% of public medical institutions. The licence is valid for five years.

Safety permits (e.g. fire, radiation) are often issued on payment of fees but without site inspection to verify compliance.

Institutional supervision

The CNMS supervises specialist services (e.g. oncology, cardiology) in district hospitals and runs external medical audits. The CNAM monitors service contracts and receives monthly and quarterly statistical reports from providers (but does not publish an annual report). The CNEAS inspects institutions every five years: those with reports scoring 90%+ are accredited; those with 75% - 90% are given conditional accreditation (for six months). The majority are fully accredited (1–2% denied accreditation; 6-7% granted conditional accreditation, once only) but these indicators are changing: in 2014 - 77.8% of public providers were fully accredited, 16.3% were partially accredited, 5.9% were conditionally accredited and 2.9% were denied accreditation; in 2013 - 82.5% of public providers were fully accredited, 6.6% were partially accredited, 10.9% were conditionally accredited and 0.8% were denied accreditation; in 2012 - 92.1% of public providers were fully accredited, 3.7% were partially accredited, 4.2% were conditionally accredited and 1.6% were denied accreditation.

CNMS

The CNMS maintains a wealth of information on its database. Quarterly analyses of current trends are provided to the Ministry of Health and national agencies, but little information reaches the clinicians and managers who could use it to analyse and assess their own performance. Standardized topic analyses on priority issues should be directed at clinicians, specifically those which affect the most patients, have high risk, involve most expense, or show wide variation in clinical process and outcome.

CNAM

CNAM experts review the records of every patient treated in the preceding period (some 3000 cases per expert). Of these, 10–15% are selected for expert visits to discuss and explain deviations from the protocols with the doctors involved. Such visits end with a concluding meeting at which a summary of the visit and recommendations to improve service quality are presented to the administration and staff of the institution.

External assessments are labour intensive, disruptive and expensive. There may be opportunities to standardize training of inspectors, audit techniques and sampling, and exchange of data and conclusions. Public information and feedback to institutions would promote safety and learning.

CNEAS

Introduction of the health assessment and accreditation procedure in 2002 was associated with both greater standardization of management processes and medical care, and increased awareness of opportunities for quality improvement. Depending on the capacity of the facility, the evaluation procedure ranges from the involvement of one expert for a two-day period, to 12–15 experts for a three-day period (for hospitals with multiple profiles with a capacity of around 800 beds).

The scope and methods of the CNEAS and its impact on the health system deserve independent evaluation in the context of a national plan for quality improvement and of related organizations which monitor, supervise, regulate or assess the performance of health-care institutions. This could include the extent to which the current accreditation programme meets the needs of the Ministry of Health, CNAM, service providers and patients. The Healthcare System Development Strategy for the period 2008–2017 (paragraph 38) notes that, “The process of accreditation has not become compulsory for all providers when contracting services. The possibilities of contracting as an instrument of improving the allocation of resources on the basis of the population needs and motivating the providers with a view to obtaining the best results are still insufficiently applied” (see Box 3 for response).

Following the Ministry of Health/CNEAS team study visit to the Haute Autorité de Santé in France, the CNEAS plans to initiate collaboration with the International

Society for Quality in Health Care (ISQua) in order to strengthen CNEAS's institutional capacity to harmonize health-care assessment and accreditation standards and international accreditation.

Box 3. Response to paragraph 38 of Healthcare System Development Strategy for the period 2008–2017

CNAM Order No. 159-A of 15.09.2008 on contracting medical institutions under the mandatory health insurance system, approves the list of documents required from medical institutions. The certificate of accreditation and its accompanying letter is one mandatory document that both public and private providers are required to submit for contracting purposes.

If the health-care facility is not accredited, or is conditionally accredited, the contract for providing medical assistance under compulsory health insurance concluded with the CNAM (Annex to the contract: "Special conditions") specifies the deadline for submission of the certificate of accreditation. Where the medical facility fails to present the certificate, the CNAM reserves the right to terminate the contract with that institution.

Also, under the terms of Government Decision No. 1636 of 18.12.2002 the CNAM may terminate the contract on provision of medical assistance concluded with the medical facility if the provider is subject to insolvency proceedings, dissolution, reorganization or its licence/certificate of accreditation or its sanitary authorization permit is withdrawn or expires.

Medical laboratories

CNEAS standards for laboratory accreditation are consistent with ISO 15189 and ISO 17025.

The Republican Centre for external quality control performs quarterly testing for haematology and serology, clinical and biochemical parameters (haemoglobin, leukocytes, platelets, urine proteins, haemostasis), hormones and serology. Some laboratories are part of international programmes such as Prevec, Spain and Chile (monthly – biochemical parameters); Bio-Rad Laboratories, United States of America (biochemistry and immunology); RIQAS, United Kingdom of Great Britain and Northern Ireland (quarterly – biochemistry, immunology, haematology and serology).

Currently, the CNAM does not give preferential tariffs to laboratories which have established quality assurance programmes.

Certification

One private diagnostic centre has ISO 9004 certification and is considering Joint Commission International (JCI) accreditation as ISO is useful for controlling documents and management systems but has little relevance to health care.

Rights of patients

Policy

The Healthcare System Development Strategy for the period 2008–2017 acknowledges that, “The receptiveness of the system towards the population ... depends on the degree of involvement of the citizens in the process of establishing the healthcare policy [and] still remains a serious problem” (paragraph 22) and that improvement should, “ensure the observance of the patients’ rights” (paragraph 67).

Ministry of Health Order No. 139 (03.03.2010) requires quality councils to provide public information, including an annual report on quality assurance of health and regular publication of information on the quality of medical services offered. This order also requires “analysis of opinions, suggestions and comments provided by staff and patients”.

Definition of patients’ rights

Legislation passed in 2005 defines patients’ rights and legal principles in the Republic of Moldova, but this has not been tested against Council of Europe recommendations. A Ministry of Health order of March 2008 requires the Quality Management and Standards Directorate to develop national clinical protocols, including a patient guide. Rights are embedded in CNEAS standards but compliance is low. The CNAM publishes a booklet on the rights of beneficiaries; these refer to entitlement to free services as well as some more general rights (e.g. to safety, privacy, information).

Rights of children in hospital

A WHO report published in 2014 describes findings and recommendations of the assessment of children’s rights (using a tool developed by WHO Regional Office for Europe) in 21 children’s hospitals in the Republic of Moldova (Fernandes Guerreiro, 2014). This notes that the Republic of Moldova has not adopted a national-level charter on children’s rights in hospitals and that health care is delivered in accordance with national guidelines and protocols, although “these should be aligned to international standards”. Recommendations include both consolidation of the existing system of child protection and adoption of pain management protocols in all hospitals.

CNAM strategic plan

The CNAM Institutional Development Strategy 2013–2017 includes a strategic goal to improve access to, and the quality of, medical services. To this end, the CNAM aims to run public campaigns about health-care quality issues (from September 2014) and to develop a system to present information related to medical institutions’ performance and quality indicators to the public.

In addition, the CNAM acts as a reference point for patient complaints which have not been resolved internally (there is no ombudsperson). Patients' rights could be a major strategy for improvement – for example, publication of a national charter; distribution of patient versions of clinical practice guidelines (currently printed inside the several hundred protocols, not issued as stand-alone leaflets). Many complaints result from poor communication and/or information.

Patient survey tools

Institutions are expected to publish the results of patient surveys on their websites, but there is no monitoring of whether this happens in practice, or what use the public makes of such information. Methodology is “guided by the Ministry of Health” but no practical tools are offered or shared between institutions. There is no mechanism for systematic assessment of patient satisfaction or to reflect results in the level of medical facility funding. The European Observatory on Health Systems and Policies HiT report commented, “Extensive data on health system responsiveness are not available for the Republic of Moldova; however, one recent survey found that 80.2% of respondents were satisfied with services provided in hospitals, although 53.4% were unsatisfied about the amount of OOP payments that they needed for hospital services and 49.8% were unsatisfied with the hotel services.” (PAS Center, 2011)

Complaint management

The CNEAS, CNAM and Ministry of Health all receive and manage complaints but there is no common pathway for analysis and learning. The CNEAS has recently set up a unit of six to seven staff to manage complaints. Every patient-care department has a complaints register, and written complaints can be addressed directly to the director of the institution. There is no independent ombudsperson or mechanism to bring together common problems at system level.

Information in national protocols

National protocols are intended to provide information for patients (patient annex in the clinical practice guideline), but this is not presented in simple language. The patient guide to acute myocardial infarction includes many unexplained technical terms; consensus of on-line readability scores concludes that this guide is equivalent to grade level 10 and reading is “difficult”.

Clinical practice guidelines and protocols

Development

Specialist committees have devised 219 national clinical protocols, 92 of which began with a project in 2008 (USAID funded, now ended). These protocols do include lay versions for patients (which must be photocopied for distribution), but no standardized templates for simple criterion-based audit. The Republic of Moldova joined the Guidelines International Network (G-I-N) and has access to their guidelines,

but has not adopted the Appraisal of Guidelines for Research and Evaluation (AGREE) principles for appraisal of clinical practice guidelines.

The continuing process of technology assessment and the development and revision of clinical practice guidelines (protocols), audit tools, patient information and indicators is neither fully funded, nor standardized and coordinated. For example, the current protocol for management of acute myocardial infarction is based on limited references to the international body of knowledge. The so-called indicators are not designed to audit compliance with the protocol (except time to hospital admission) as they do not measure clinical management, prescribing or outcome; and information for patients is not easily understood by the general public.

Implementation

Clinical protocols were introduced from 2008 and explained in a series of workshops in four centres around the country, but there is little ownership at the grass roots. There was wide consultation with central bodies, including the medical professional associations. There is no relevant in-service training in municipal and rayonal institutions.

In accordance with Ministry of Health Order No. 429 (21.11.2008), quality councils are required to adapt national clinical protocols to the current capacities of service providers, consistent with the evidence-based principle. Audit criteria are not included in many national guidelines. Other than through quality council audits, there is no recommended system for internalizing the guidance within clinical departments and teams, or to use it for peer review, learning and continuing education.

A report for the World Bank in 2014 found that 34% of clinical records in primary care showed full compliance with protocols and 15% were largely noncompliant. (PAS Center, 2011). Doctors tend to show more compliance with recommendations for diagnosis and referral to specialist treatment than recommendations for prevention, screening and monitoring.

Clinical audit

Ministry of Health Order No. 519 (29.12.2008) defines procedures for internal medical audit. Local quality councils are responsible for improving internal systems, institutional assessment and analysis of quality of care. This requires implementation of internal medical audit, including analysis of mortality, nosocomial infections and medical records.

Current external clinical audit systems are based on reported noncompliance rather than systematic examination of high risk/cost/volume issues – a mechanism for control rather than learning. This largely excludes assessment of clinical outcome and makes little use of databases or clinical indicators. The methods of sampling,

auditing and analysis do not appear to be well-defined or consistent between the CNMS, CNAM and CNEAS. There is little feedback or sharing of audit results, or comparison between departments and institutions.

Clinical audit committees use anecdotal case reviews and subjective expert analysis to mark medical staff, with little use of systematic comparison of practice against clinical guidelines or protocols. Monthly internal audit meetings may be held to enable hospital specialists to review clinical topics, but without the benefit of systematic data collection or the use of criterion-based audit which would be a practical approach in the absence of electronic information systems. Nurses and other clinical staff are usually not involved in clinical reviews.

Implementation of clinical audit requires skills, time and data which are currently scarce in many health-care institutions. Many specialties have clinicopathological conferences once or twice per month; these could be adapted to systematic rather than anecdotal audit.

Information systems

National strategy

According to the Healthcare System Development Strategy for the period 2008–2017 (paragraph 20), “the monitoring and evaluation system and its indicators are not yet harmonized with internationally accepted datasets and indicators”. There has been no systematic evaluation of the historical model and methods of data capture to identify redundant or absent features, but several recommendations arose from a 2007 report from WHO’s Health Metrics Network (HMN, 2007). The Healthcare System Development Strategy for the period 2008–2017 (paragraph 57) also reports:

“In order to strengthen the capacity of the health authorities to monitor and evaluate the healthcare system the following actions are provided:

- a. define the monitoring and evaluation indicators;
- b. define the standard datasets to be collected and the data flows in the system;
- c. gradually harmonize the architecture, technological platforms and standards of the Integrated Medical Information System.”

Due to be approved soon, the eHealth strategy focuses on computerization rather than defining the purposes of data collection and translation into information. Training needs are also mentioned but information technology (IT) is currently not in the SMPhU curriculum for continuing medical education.

The CNAM was set a target of September 2013 to “develop a system of presenting the information related to performance and quality indicators of medical institutions and their rating according to this” and to “develop a concept of information system

necessary for efficient handling of information (DRG, P4P, planning and reporting)” (CNAM, 2012).

At present, the Republic of Moldova lacks an integrated information system that would enable the assessment of patient care or the quality of clinical recording, or comparisons of clinical, managerial and financial performance within and between health-care providers.

The CNMS collects and analyses many data but provides feedback to managers or clinicians only when specifically requested. This organization could become more proactive – identifying significant variations, trends (time and place) and benchmarks to all concerned – but many facilities lack the analytical capacity to transform data into relevant information and evidence for the decision-making process.

Capture, coding and data quality

Clinical coding is subject to checks and sample records are audited against published protocols but, again, these procedures are not standardized. Training for coding clerks is in its infancy and there appear to be no internal checks (e.g. independent recoding of 10% by another clerk).

Geographical distribution of hospital deaths from acute myocardial infarction implies that the highest rates occur in urban communities. This may indicate systematic errors in residency coding such as recording the place of death rather than where the patient lived. Wide variations, such as those between annual hospital mortality rates from acute myocardial infarction, may deserve close attention – are they real, or an artefact of coding?

Verification of clinical coding could include examination of the CNMS database to identify anomalous variations and comparison of diagnostic ratios with international experience (e.g. AMI-STEMI vs non-STEMI; CVA haemorrhagic vs ischaemic).

There is no regular comparison of population prevalence of chronic diseases as a measure of under- or over-diagnosis in primary health care. This should be defined as a responsibility of public health, the Ministry of Health or the CNMS.

The Republic of Moldova needs to standardize data definitions and systems for capture, coding, aggregation and exchange. Some of this will emerge from the eHealth strategy but use of an independent agency – as custodian of health technology assessment, clinical practice guidelines, audit and indicators – should be considered.

Performance indicators

Clinical indicators

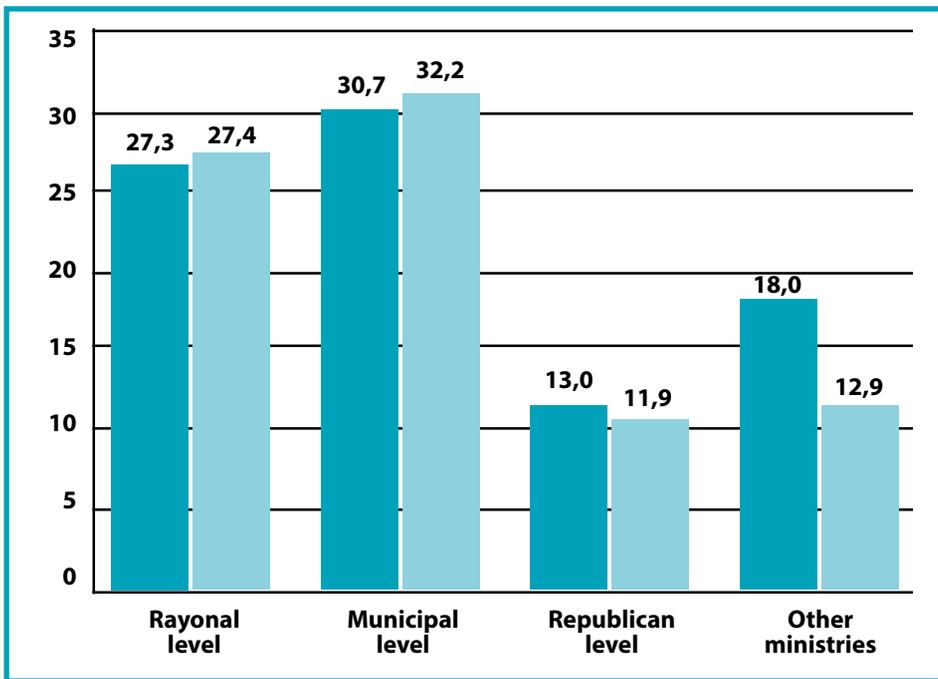
In primary health care, performance indicators are based on monthly self-assessment of compliance with 23 criteria. Criteria relate to management of common conditions

(e.g. cardiovascular disease, diabetes, cancer), child health and maternity, for which each centre keeps a current register. Numbers are reported to the CNAM and reviewed by their expert advisers.

The national rate for caesarian sections is 16%, varying between (and probably within) three levels of obstetric care. Published annually as absolute numbers in a tabular form, interpretation of data is virtually impossible and comparisons are not provided to the source institutions.

Limited use is made of data available from the CNMS to evaluate or improve health services. Key indicators are not routinely tracked over time, compared between institutions and fed back for verification and discussion among the clinicians involved. The figures appear to show that death rates for acute myocardial infarction are two to three times higher in the rayonal and municipal hospitals than in the republican institute.

Fig. 1 Hospital mortality rates from acute myocardial infarction, Republic of Moldova 2011/12



In comparison to Organisation for Economic Co-operation and Development (OECD) countries, these rates are high and indicate an opportunity for more systematic assessment of tracer conditions in the Republic of Moldova at population level (clinical epidemiology) and at patient level (clinical audit).

Adverse event reporting

The Republic of Moldova has adopted international definitions of adverse incidents and near misses relating to medical devices that are reportable to the AMDM. Adverse reactions to transfusion of blood components are reported to the National Blood Transfusion Centre; cases of nosocomial infection to the CNSP; and natural disasters to the CRMC. However, there is no clear mechanism for receiving, analysing and learning from experience of other adverse events. For example, no agency appears to accept responsibility for alerting hospitals to the hazards of concentrated electrolytes in ward stocks, or for taking steps to remove them.

Staff development

The Healthcare System Development Strategy for the period 2008–2017 (paragraph 45) reports, “From the viewpoint of the medical staff, the lack of clear definition of job duties (job descriptions), inappropriate supervision by the management, and low involvement in the decision-making process represent serious barriers for professional and managerial growth.” It has also been claimed that job descriptions are not consistent with doctors’ actual work requirements; personnel files exist on the Ministry of Health database but few institutions have any systematic appraisal or performance review.

Infection control

The practical guide approved by the Ministry of Health refers to infection control. One hospital disposes of chemical waste commercially but the volume of biomedical waste has overcome the incinerator used. Use of an autoclave/shredder has been mooted for safe disposal of waste, and sharps are now liquid sterilized before being recombined with general waste. This is not recommended in the guide.

Procedures for infection control (e.g. alcohol handwash, gowning, overshoes, use of red lines) appear to vary between facilities. These should be standardized nationally.

Patient safety

Observation indicates that patients are not always identified by bracelet, and large amounts of concentrated potassium chloride are evident in hospital ward stocks. Both are on the international list of so-called never events for patient safety.

6. Technical support for quality systems in Republic of Moldova

Training

Medical training

Undergraduate and higher medical training have been aligned to European practice. EU principles have been embedded in university courses for doctors, nurses, midwives and pharmacists since 2013. The medical curriculum includes evidence-based medicine, practice guidelines and clinical protocols and performance measurement. Continuing medical education is under a separate faculty.

Continuing medical education /continuing professional development

Doctors require 320 credit hours of continuing medical education for relicensing every five years: 250 of these must be in university or approved overseas programmes; the remaining 70 may be in other activities approved for continuing professional development in advance by the SMPHU.

Management training

A 2007 Order requiring those appointed to senior management positions to hold a Master of Public Health degree was rescinded two years later.

Quality management training

Ministry of Health Order No. 519 (29.12.2008) on internal medical audit requires the CNMS and the Quality Management and Standards Department of the Ministry of Health to organize training on organizing and implementing internal medical audit for employees of health-care facilities.

Ministry of Health Order No. 569 (11.07.2011) on quality of care indicators requires the SMPHU to ensure development and implementation of curricula for establishing and monitoring quality of care indicators within the School of Public Health Management.

A one-week postgraduate study course on quality management is available to managers at all levels but is not included in the annual training programme for doctors approved by the Ministry of Health. Courses included in the annual training plan for doctors (Department of Social Medicine and Health Management profile of the USMF) last for two months, including two hours of seminar or practical activity in the area of quality improvement.

Despite these programmes, several sources complained that Ministry of Health approved annual plans for continuing professional development of clinicians and managers lack training on quality management, thus continuing to limit the introduction of effective quality systems and the implementation of clinical protocols.

The CNEAS endorses the claim that efforts to introduce internal medical audit are compromised by lack of relevant knowledge and skills which should be provided to doctors in undergraduate education, specialty training and continuing medical education for senior staff.

The SMPHU does not agree that, “CPD offered by the University is not geared to needs identified by health-care organizations.”

Staff opportunity

Implementation of clinical audit requires skills, time and data which are currently scarce in many health-care institutions. Many specialties have clinicopathological conferences once or twice per month; these could be adapted to systematic rather than anecdotal audit.

Standard doctor contracts do not specify the time allocated to on-call, teaching (other than university), personal development or quality improvement (other than as a quality council member). The hospital operating budget includes a notional 2% for training.

Doctors might be more willing to engage in internal clinical audit and peer review if contracts specified allocation of time, meetings were arranged formally and systematic audit earned points for continuing medical education. This would reduce the need to be absent to attend university programmes, would benefit internal quality systems and be cheaper for the institutions.

Information

There is no central archive or clearing house for collection and exchange of information on the theory and practice of standards, measurements and improvement which is accessible to all health personnel. Qualitative and quantitative information is provided by several sources, including those described below.

- Statistical Yearbook of the Republic of Moldova (morbidity and mortality indicators, activity of the health-care providers) is developed by the CNMS and published on the Ministry of Health and CNMS websites.
- Activity reports from medical facility quality councils are submitted to the CNMS and published on the CNMS and IMS websites.
- Information on the activities of individual institutions are published on their own websites (e.g. mission, structure, services provided, events, seminars, conferences, courses, activity reports).
- Results of evaluation and accreditation of medical facilities are updated quarterly on the Ministry of Health and CNEAS websites.

7. Recommendations

Ten strategic visions

A state where ...

1. Legislative framework supports values and principles of quality, safety and performance by enabling information exchange and cooperation between responsible bodies.
2. Key dimensions and principles of quality in health care are agreed nationally (especially between the CNAM, CNEAS and CNMS) as a basis for sharing methods and results of assessments and evaluations (see Appendix 1).
3. Professional self-regulation, peer review and clinical governance complement top-down external assessment.
4. Financing of system and institutions rewards achievement based on evidence of performance.
5. Individual and institutional performance are assessed on demonstrated achievement, improvement and learning rather than non-compliance, errors or failures.
6. Technical developments are consistent with available guidance from intergovernmental sources, especially the Council of Europe, European Commission and WHO.
7. Clinical protocols and clinical practice are consistent with international standards.
8. Corporate and individual learning is based on feedback and sharing results of systematic audit and evaluation.
9. Information systems are integrated and shared between managers, clinicians, financing and supervisory institutions and departments.
10. User-friendly public Internet allows access to all official reports, evaluations and performance data.

Policy and vision

Towards an integrated national plan

This report and its recommendations could offer the Ministry of Health a basis on which to develop an integrated plan for improving quality and safety throughout the health system.

1. Development of the plan should actively involve professional groups, nongovernmental organizations and public representatives, balancing top-down control with bottom-up self-regulation and participation in management. It should also integrate the objectives and operations of national and local government agencies.
2. The Republic of Moldova has already incorporated European guidance into the development of legislation and quality systems relating to medical devices, pharmaceuticals and transfusion services. It is recommended that

all aspects of health services should align (wherever possible) with guidance from intergovernmental sources, especially the Council of Europe, European Commission and WHO (technical references are provided in the background papers provided to the six working groups – Appendix 2).

3. Plan should incorporate the provision of realistic incentives – supportive and appropriate environments for consultations, collaborative planning, evaluation of impact, review of strategy and also to reflect the orders related to quality and safety – in order to increase responsiveness (of individuals, institutions and the whole system) to the needs of patients and of the population.
4. Plan should determine priorities for international technical assistance, and define the principles and methods of interventions. It must therefore be acceptable to, and agreed with, foreign donors such as WHO, EU, World Bank, and Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ).
5. Plan should identify realistic milestones and a timetable for their achievement.

Closing the loop, enabling change

6. Principles of this report and of the proposed plan for quality and safety should be included in the national strategy for health sector development and in the current revision of the health-care law.
7. To enable more functional systems, legal advisers should seek advice based on research, evidence and experience from health sectors in other countries. Legislation should aim at facilitating operations and cooperation between public agencies rather than prescribing restrictive conditions.
8. CNEAS should grade institutions and constituent services to differentiate high, medium and low compliance with standards. CNAM should modify tariffs accordingly to encourage improvement in health-care provider institutions.
9. Ministry of Health and its agencies should give more attention to implementation and evaluation of existing strategies for improvement before extending or embarking on new initiatives. Evaluation should include consistency of implementation in time and location, and between hospital and primary care.
10. All authorities and agencies should aim to remove barriers and encourage doctors and other staff to share responsibility for quality and safety (e.g. provide protected time, performance feedback, data on variations in clinical process and outcome); link self-audit to continuing medical education and credit hours for recertification; and embed principles in professional codes of ethics.
11. To date, arrangements for managing quality and risk in health care have focused almost exclusively on doctors. Team working and communication is central to patient care so professions allied to medicine, especially nursing, should be provided with similar training and opportunities to share in clinical audit and risk management.

Organization and management

Ministry of Health and its agencies

12. The Performance & Quality of Health Services Division's responsibilities and authority relating to improvement (e.g. for policy monitoring, coordination between institutions, standards development, information sharing) should be identified in relation to other government agencies (especially CNMS) and other Ministry of Health departments in order to determine the appropriate level of staffing and support.
13. The appropriate role of the central coordinating unit should be defined through accurate mapping of gaps and duplications in functionality and responsibility, especially within the Ministry of Health, and on recognizing opportunities for integration, delegation and efficiency saving. For example, in the interests of consistent implementation and compliance assessment, standards should be compatible between related bodies in order to reduce variation in practices (e.g. on fire safety, infection control, medication storage and patient identification).
14. A national centre is required to collect and exchange information and practical tools such as standardized audit formats (and model results); templates for institutional quality manuals; examples of annual reports; and international and national literature.

Promoting professional self-governance

15. Doctors are required to accumulate credit points for continuing education on a five-year cycle, and salary supplements are awarded on deemed merit. Both systems are supervised by the SMPHU. An independent body, governed by representatives of the academic and clinical community as well as lay members, should establish a formal register of competent practitioners licensed according to regulatory and ethical principles. This is a condition of the free movement of skills across borders in the EU.
16. Apart from the expert advisory committees defined by the Ministry of Health there are few effective mechanisms for consultation and coordination of clinical governance within and between members of medical specialties. The networks and publications of medical specialists should be harnessed to encourage professional leadership, to provide practical and relevant advice, and to align peer pressure for participation in systematic audit.
17. Ministry of Health Order No. 139 (03.03.2010) specified the authority, responsibilities and payment of chairs of quality councils, and attached them to the post of deputy medical director. There is no opportunity to make a separate appointment or for medical staff to express their preference for the senior respected clinician who would be best qualified for such a challenging position.

Methods

External assessment

Enabling legislation

18. The regulations on which CNAM operates could be reviewed to simplify programmed on-site inspections and to share standardized audit methods with national and local mechanisms (e.g. CNEAS, clinical governance). Evidence of certification could be taken from official websites. Institutions should be required to document their own checks of doctors' malpractice insurance.
19. After 13 years, Law no. 552 on assessment and accreditation may be ripe for revision. This could include review of CNEAS's status as an independent agency – its institutional capacity could be strengthened by adjusting the normative framework to enable compliance with ISQua standards, and to allow innovation in methods such as frequency of assessment, graded awards and withdrawal of certificates.
20. CNEAS should be given the freedom to move away from a static five-year cycle towards more continuous and interactive development programmes for subscribing members. These could include web-based tools for self-assessment and guidance; regular statistical reporting and benchmarking; newsletters to highlight good (and occasional bad) practices; alerts on high-risk issues and never events; and links to resources (e.g. WHO Patient Safety Solutions).

Evaluating programme impacts

21. Standards for accreditation should incorporate criteria to test implementation of ministerial orders (e.g. concerning quality management, internal clinical audit, performance indicators) as well as concerns of other statutory and voluntary organizations (e.g. sanitary or environmental inspection, CNAM).
22. CNEAS's scope and methods and impact on the health system deserve evaluation in the context of the proposed national plan for quality improvement and of related organizations which monitor, supervise, regulate or assess the performance of health-care institutions.
23. CNEAS should be encouraged and supported to undertake a self-assessment (against ISQua standards) of its operations, accreditation standards and surveyor training in order to identify opportunities for alignment with international programmes.

Learning from assessments

24. External medical audits are performed by three national inspectorates (CNMS, CNAM, CNEAS). The timing, methods and results of these audits should be shared and rationalized to allow comparison and feedback between departments and institutions.
25. CNAM should work with CNEAS to develop criteria and procedures to recognize high-risk (error-prone) topics, and develop sampling techniques and simplified audit tools to reduce the burden (and cost) of inspection.

26. CNMS should tailor information to address identified clinical priorities; complication rates (e.g. post-operative infections) could be computed for comparison between institutions and to test completeness of recording, providing benchmarks for improvement and learning. The database should aim to provide standardized (rather than crude) mortality rates, time trends and seasonal variations.
27. If effective supervision of clinical practice can be demonstrated by internal clinical audit or external peer review by specialty associations, the accreditation programme should focus on organizational standards to support internal clinical governance. CNEAS assessments could thus use smaller teams of generic, rather than specialist, surveyors.
28. In primary care, CNAM performance indicators should be reduced and redesigned to release doctors from primary data abstraction. CNAM should analyse results to identify significant variations between doctors and clinics, and provide feedback with benchmarks for learning and improvement.
29. Despite the lack of routinely captured data in primary care, some performance measures may be derived from public health. These include comparative reported population prevalence of noncommunicable diseases (e.g. hypertension, diabetes) or hospital data such as inappropriate hospital contacts (e.g. admissions for uncontrolled diabetes, asthma, chronic obstructive pulmonary disease) captured by the CNMS.

Patients' rights

30. The rights of patients are described either in terms of eligibility for state health care or in legal or medical language which is difficult to understand. The Ministry of Health should not only take patients' advice to publish a charter of patients' rights but also coordinate the design, printing and distribution of information leaflets on common conditions between all relevant health facilities.
31. The Ministry of Health should identify a responsible authority to monitor and report publicly on compliance with Ministry of Health Order No. 139 (03.03.2010) that requires quality councils to issue annual reports (on quality assurance of health, analysis of opinions, suggestions and comments from staff and patients) and ensure regular publication of information on the quality of medical services offered.

Clinical protocols and practice guidelines

32. SMPhU staff members were largely responsible for the initial development and teaching of clinical protocols, and continue to maintain them even though funding has ceased. The Ministry of Health orders (No. 124 of 21.03.2008 and No. 429 of 21.11.28) prescribing procedures and structure for protocols may be due for updating which should include reference to international AGREE principles which are based on EU-funded research.
33. Continuing process of technology assessment and development and revision of clinical practice guidelines (protocols), audit tools, patient information and

- indicators should be fully funded, and standardized and coordinated by a single national agency, consistent with international principles.
34. Ministry of Health Order No. 124 (21.03.2008) on the methodology for development and approval of national clinical protocols refers to the use of international guidelines for clinical practice but not to the procedures for guideline development, or the inclusion of indicators and criteria for clinical audit of compliance. Based on international methods for guideline development – such as those of AGREE, the Scottish Intercollegiate Guidelines Network (SIGN) and the National Institute for Health and Care Excellence (NICE) – the advice could be republished as a guidance document and extended to include the use of common technologies and procedures (e.g. antibiotic prophylaxis, day-case surgery).
 35. The AGREE principles should be adopted for review of existing, and approval of new, national clinical protocols in order to improve their implementation.
 36. Ministry of Health Order No. 429 (21.11.2008) requires every institution to develop a local version of each national clinical protocol. If these are evidence-based there is little scientific or economic justification for undertaking the time-consuming process of complete redrafting. Local adaptation should be allowed to respond to identified variations in the local demography or epidemiology, or to take account of limited access to specialist skills, equipment and facilities. General indications and procedures for transferring patients should be defined in the standard operating procedures of each institution that should include local arrangements for triage and fast-track management where time is of the essence (e.g. for stroke, myocardial infarction, obstructed labour).

Clinical audit

37. Ministry of Health Order (No. 519 of 29.12.2008) on internal medical audit aimed “to ensure effective measures for preventing non-compliances and errors in the provision of health care”. It contains a wealth of information on topics including patient surveys and complaints, staff surveys and the grading of research evidence behind clinical guidelines. There is little practical guidance on how to audit against national protocols using existing data systems or systematic audit using samples of case records. The content should be simplified into a practical guide, with updated references and practical methods appropriate to the protocols, indicators and resources available in the Republic of Moldova. A separate volume should advise on non-medical quality management and patient safety.
38. Until electronic data systems are more widely available, simple medical audits should be based on manual capture of specific items from the patient records. These items should be provided in a standard template annexed to each issue of clinical practice guidelines. Well-defined criteria can be abstracted by trained non-medical staff to provide objective and quantified information for discussion among the clinicians involved. Criterion-based audit reduces the burden on quality councils, inspectors

and medical staff and enables peer learning and self-regulation.

39. Forms for the monitoring of facility-level implementation of protocols (required as Attachment 2 in Order no. 124 of 21.03.2008) should be designed for ease of data collection, calculation and quantitative analysis.

Information strategy

40. There is need for a national strategy to develop and implement standard data definitions, common minimum data sets, procedures (for collection, validation, analysis, aggregation), data protection and feedback. Without national definitions, it is not possible to rely on performance measures to compare between institutions, departments and diagnostic groups; without consistency with international indicators, it is not possible to compare between countries.
41. There is general agreement that national data standards are needed; that the indicator set (prescribed by Ministry of Health Order No. 569 of 11.07.2011) and related collection procedures are due for review; and that collected information should be used for learning and improvement at individual, institutional and system level.
42. Some standardization and integration will emerge from the eHealth strategy but it may be considered whether an independent agency should act as custodian of health technology assessment, clinical practice guidelines, clinical audit, performance indicators (including incident reports) and information exchange.

Data quality

43. Trained technicians have been shown to perform data abstraction and coding more consistently and reliably than most clinicians. They are also less expensive and could free up clinical time – for example, by collecting data for primary health care indicators and screening case records for systematic clinical audit.
44. Verification of clinical coding should include examination of the CNMS database to identify anomalous variations and compare diagnostic ratios with international experience. Institutional systems should include independent recoding of a defined sample of records (e.g. every tenth record) by a second clerk. Data quality could also be monitored using the CNMS database to test completeness of recording, thereby providing benchmarks for improvement and learning.
45. There is no regular comparison of population prevalence of chronic diseases as a measure of under- or over-diagnosis in primary health care; this should be defined as a responsibility of public health, the Ministry of Health or CNMS.

Performance indicators

46. Ministry of Health, CNMS, CNEAS and CNAM (and possibly others) should collaborate to clarify what data they collect on clinical and managerial

activity which could be combined and standardized to produce informative indicators of performance at micro, meso and macro levels.

47. Details required for calculating standard performance measures are contained in the national database held by CNAM for the purpose of reimbursement of providers. The CNMS does not have access to the database for the purpose of calculating and comparing performance in terms of clinical process and outcome, or of efficiency of resource usage.
48. Ministry of Health Order No. 569 (11.07.2011) requires the CNMS to, "Develop and submit for approval a mechanism for monitoring and evaluation of quality of care indicators". The Order attaches a list of indicators that would be expensive to collect and difficult to interpret.
49. For the purpose of comparison across borders, the Republic of Moldova should aim to collect and aggregate data to be compatible with international indicators such as in the sets developed by WHO (PATH), the OECD and European Commission. For domestic purposes, indicators should be selected to measure specific national objectives (e.g. access to service, resource utilization) that should be developed using established procedures, such as those described by the Health Information and Quality Authority (HIQA), the regulatory body for health care in Ireland.
50. Current data capture systems and diagnosis-related groupings were designed primarily for the purpose of costing, financing and contract management, rather than for general management, clinical audit or comparisons between institutions. Evaluation and revision of these systems should take account of the needs of all legitimate users of activity data.

Incident reporting and learning

51. Some adverse events (e.g. reactions to drugs or transfusions) and nosocomial infections are reported to different centres. There is no national definition of what events should be reported or how data would be validated, aggregated, analysed and interpreted as a basis for learning and risk management at national or institutional level. Under-reporting appears to be widespread.
52. Reportable adverse patient events should be defined nationally and monitored as a development of the existing annual risk assessment by the Ministry of Health. This would ideally be through a formal system reporting to a national agency. Monitoring could also use the CNMS database; complication rates (e.g. post-operative infections) could be computed for comparison between institutions. Effective learning from past mistakes requires incentives for reporting, analysis and active monitoring of complaints and adverse events.

Resources

Training

53. The top management of most institutions consists almost exclusively

of medical practitioners who have no formal training in general, financial or risk management. This should become a requirement for new appointments, and continuation should be subject to performance appraisal and career development. These requirements should be included in standards for accreditation of institutions.

54. Undergraduate and higher medical training have been aligned to European practice, and the curricula include evidence-based medicine, practice guidelines/clinical protocols and performance measurement. Yet the large majority of clinical practitioners have very little opportunity to gain relevant knowledge and skills in specialty training and continuing education. Specific programmes for quality coordinators and technicians are required centrally, and the relevant knowledge and skills for clinical governance and evaluation should be actively promoted through continuing medical education, peer review and self-audit within the workplace.

Protecting clinical time

55. All authorities and agencies should aim to remove barriers and encourage doctors and other staff to share responsibility for quality and safety (e.g. provide protected time, feedback on performance, data on variations in clinical process and outcome); link self-audit to continuing medical education and credit hours for recertification; and embed principles in professional codes of ethics.
56. Many doctors currently spend many hours developing protocols, auditing records, collecting data and presenting results. However, there is no analysis of how much time this takes from clinical work; how much benefit results for patients or staff; or whether the time is used efficiently on appropriate activities. Guidance on medical audit should include estimates of medical time required; the strengths and weaknesses of various approaches; and measures of impact (e.g. quantified improvement in clinical outcome).
57. To minimize undue demands on senior doctors, non-medical staff could be recruited and trained in audit design, data capture, comparative indicators and other specific techniques for organizing systems and internal medical audit.

Finance

58. Realistic costs for developing quality management systems should be estimated and budgeted. Much of the time required could be recouped by transferring staff from less efficient methods and activities, by sharing information and workload, and devolving to meso and micro levels. However, training of coordinators and technical support requires the development of new courses and teaching, especially within the continuing professional development programme.

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Appendix 1.

A framework for health-care quality in Republic of Moldova

1. Existing policy on quality and health reform

The health system in the Republic of Moldova already has many orders and structures which contribute to improvement. This framework aims to clarify the language of quality in health care as a basis for coordinating efforts, standardizing methods and exchanging learning. The main headings are:

- values, dimensions and implications of quality
- principles of quality measurement
- principal strategies for quality improvement
- organization and management of quality in Republic of Moldova.

2. Values, dimensions and implications of quality

The aim of the Ministry of Health is to enable the provision and coordination of health services which are:

- equitable – health care is accessible, affordable and timely, and is provided to all who need it regardless of gender, ethnicity or socioeconomic status;
- patient-centred – health care will be responsive to, and respectful of, the patient's values and choices to promote patient satisfaction at every health-care encounter;
- safe – health care ensures that patients and staff do not suffer undue harm from the treatment itself or from the manner of its provision;
- effective – any form of treatment or patient care will be based on guidelines that follow current scientific evidence;
- integrated – services are organized to provide continuity over time (for instance within one hospital) and between providers (for example, referral to and from secondary care);
- efficient – waste is avoided and resources are used appropriately to ensure optimum benefits for patients and the population.

Implications of a comprehensive quality improvement plan

An effective quality improvement programme will change the way everyone works, at every level of the health system. For example, it would promote:

- transparency – reasonable consultation with stakeholders will be included in developing policies, standards and guidelines that impact on the provision of health care; results of institutional assessments will be available to the relevant public;
- professionalism – the provision of care will be guided by the code of ethics of the respective professions, clinical governance and increased self-regulation;
- evidence-based health care – current scientific knowledge will guide health policy, the management of health-care institutions and the care rendered to patients;

- top-down, bottom-up approach – supervision and inspection will be reduced by staff participation in self-assessment, self-regulation and quality improvement;
- accountability – all health-care providers, direct and indirect, will be held accountable for their actions or inactions;
- training – the principles and practice of quality improvement will be included in undergraduate training, postgraduate training and continuing professional development.

3. Principles of quality measurement

Quality should be assessed from the viewpoints of major stakeholders (such as users, care providers, taxpayers, politicians, and health managers) and against explicit criteria which reflect the underlying values of society.

What can be measured

The most commonly quoted elements of a “good” health system relate to Donabedian’s adaptation of the concept of input–process–output in industrial manufacturing.

- Structure
 - Human, financial, technical resources (investment).
 - Allocation in terms of time, place and responsiveness to the needs of populations (access).
 - Fairness in sharing costs and benefits (equity).
- Process
 - How the resources are applied.
 - Efficiency in use of time and resources.
 - Economy by avoiding waste.
 - Safety and reducing risk.
 - Appropriate care based on scientific evidence.
 - Continuity and acceptability of patient-focused care.
 - Public information (choice, transparency, accountability).
- Outcome
 - What results are achieved (performance).
 - Population health (health improvement).
 - Clinical outcome (effectiveness).
 - Meeting expectations of public and workforce (experience, satisfaction).
 - Value for money (cost–benefit).

Performance indicators

Common international dimensions define a good health service as:

- clinically effective: evidence-based practice, patient outcome, population benefit
- patient centred: respect for rights (economic and social), responsiveness to need
- safe: staff competence, clinical systems, facilities and environment.

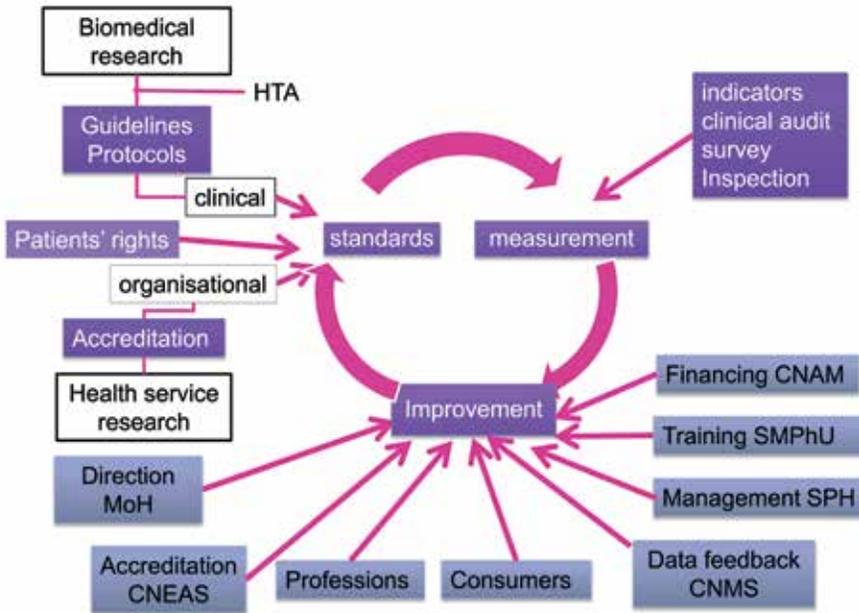
Performance indicators should be based on reliable data which describe these elements.

Concepts of improvement

In the past 20 years, the concept of improvement of health systems has moved away from top-down control, compliance and punishment towards bottom-up development, self-regulation and incentives; quality measurement has shifted from resource inputs to performance outputs.

Emphasis has moved from quality control and assessment to the definition of agreed and valid standards, systematic and reliable measurement of performance, implementing action for change, repeated measurement and continuous improvement in a cycle or upward-moving spiral (see figure below). The commonest failure of quality initiatives is to concentrate on standards and measurements rather than on changing the way people and organizations work.

Fig.2. Cycle of quality improvement



4. Principal strategies for quality improvement

A review by WHO of approaches to quality improvement has catalogued many structures and mechanisms which have been adapted to health systems around the world.¹ These can be classified in many ways, most simply according to the overall purpose, focus and various stakeholders concerned.

¹ WHO (2003). Quality and accreditation in health care services: a global review. Geneva: World Health Organization (http://www.who.int/hrh/documents/en/quality_accrreditation.pdf, accessed 29 January 2015).

4.1 Empowerment of consumers

This aims to promote the rights of patients, their families and the public by explicit definition of the rights and obligations of the population with respect to health services. The experience and expectations of consumers may be assessed by:

- local registering of complaints and compliments – systematic encouragement of patient feedback, analysis and reporting of results;
- appeals to national complaints authority – investigation, arbitration, analysis and national publication by health services ombudsperson;
- monitoring of patients' charter indicators – collection and publication of measures such as waiting times for appointments, admissions;
- surveys of experience and satisfaction – standardized local and national survey tools.

4.2 Institutional development

This covers the regulation, management and development of health-care provider institutions, and includes support for organizational systems, change management, self-regulation and performance management. Assessments against organizational standards may include:

- management systems – e.g. performance management, adverse event reporting, utilization review, data quality monitoring;
- self-assessment – e.g. with performance indicators, management checklists, internal departmental quality programmes;
- external calibration, certification and accreditation – of training, health institutions, services, equipment;
- external quality assurance – such as departments of radiology and clinical pathology;
- external publication and comparison of performance indicators;
- external professional peer review and supervision;
- statutory inspection.

4.3 Management development

Decentralization requires greater reliance on the knowledge, attitudes and skills of local management of resources, risks and communications, including:

- move from responsive administration to proactive management
- provision of management training
- appointment and promotion based on training, experience
- delegated accountability and authority for internal systems and resource management
- personal appraisal and career development
- training for clinicians in management.

4.4 Clinical practice development

Concepts of clinical effectiveness and evidence-based medicine have become the heart of quality in clinical practice. Clinical protocols and guidelines will be based on international best practices in order to ensure that services meet

evidence-based standards. The Republic of Moldova will establish a procedure to filter evidence-based guidelines imported from abroad according to defined criteria –including epidemiology, economics and service configuration. Guidelines will be consistent with the international AGREE principles.²

There is global, well-documented evidence that the mere distribution of clinical guidelines, however good, has almost no impact on clinical practice unless there are effective systems to adopt, implement and monitor them at local level.

A framework for a continuous clinical process improvement includes:

- systematic documented audit of clinical practice and results against standards based on evidence, with appropriate organizational change and demonstrated improvement;
- documented procedures for reporting, investigation and effective response to clinical incidents (including adverse events or near-miss incidents) for all medical specialties and clinical support departments;
- documented procedures to monitor and control potential risk to patients, public and staff from clinical and environmental hazards such as infection, radiation, medication, transfusion and noxious chemicals.

Evidence-based medicine should be the explicit foundation of clinical education and professional practice. Clinical audit and peer review within the workplace is an effective and economical contribution to continuing education. It should be recognized as a professional obligation but requires management support, including:

- protected clinical time;
- scheduled departmental meetings for systematic clinical review;
- clinical data: routine indicators, ad hoc enquiries;
- audit assistance: clerical help to retrieve and return clinical records; to abstract data elements defined by the clinicians for criterion-based audit;
- information: access to validated methods, tools, comparative results appropriate to individual specialties;
- skills: few doctors have been introduced to systematic evaluation of medical care in undergraduate or postgraduate training.

4.5 Professional development

Current views on quality improvement favour focusing on systems and how they work, rather than on individuals and their competence. But this move away from blaming individuals when things go wrong should not cause neglect of the selection and development of staff, particularly clinicians. At national level, professional development includes systems of:

² Brouwers M, Kho ME, Browman GP, Cluzeau F, Feder G, Fervers B, Hanna S, Makarski J on behalf of the AGREE Next Steps Consortium (2010). AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Can Med Assoc J.* 182:E839–842 (http://www.agreetrust.org/wp-content/uploads/2013/10/AGREE-II-Users-Manual-and-23-item-Instrument_2009_UPDATE_2013.pdf, accessed 29 January 2015).

- professional ethics
- licensing and registration
- continuing professional development.

Approaches used at local level to assess clinical competence include:

- individual performance review or appraisal
- systematic periodic review of clinical appointments: local credentialing
- supervision of trainees and assistants
- external monitoring and accreditation of training programmes and clinical departments.

5. Organization and management of quality in Republic of Moldova

There will be effective mechanisms to integrate improvement efforts within Ministry of Health and government agencies, and between all stakeholders and sectors of health-care provision. A quality improvement capacity will be strengthened at central and facility level, and integrated within each institution's management systems and procedures.

Coordination of quality improvement and responsibilities for integration have been defined, including clear terms of reference, infrastructure and technical advisory structures to support the following elements.

- Quality improvement
 - o technology assessment, clinical practice guidelines, protocols, pathways, procedures for dissemination, explanation, monitoring, evaluation;
 - o organizational standards, institutional risk management procedures and systems (CNEAS);
 - o performance management, measurement systems (CNMS);
 - o quality management training;
 - o exchange of information and practical tools such as audit formats, quality manuals, annual reports, international and national literature.
- Licensing of clinical professional staff
 - o requirements for entry to professional registers;
 - o periodic relicensing, maintenance of registers;
 - o investigation of competence to practice.
- Health financing and insurance (CNAM)
 - o definition and measurement of performance for the purpose of service-level agreements, using national information system;
 - o positive rewards to institutions and clinical teams on the basis of clinical results, reduction of adverse events and compliance with approved protocols.
- Patient advocacy
 - o maintenance and monitoring of implementation of national charter;
 - o handling of complaints unresolved at institutional level;
 - o provision of standardized tools and methods for assessment of patient experience.

Appendix 2.

Background papers

1. Empowerment of consumers

International principles

Promotion of the rights of patients, their families and the public by explicit definition of the rights and obligations of the population with respect to health services. Patients who are made aware of their entitlements to health care and social rights will ultimately learn to increase their level of expectation from health-care providers and be the driving force for continuous improvement. Information on access, availability and performance of services should be in the public domain.

An increasingly dominant aspect of quality improvement is the involvement of patients and their families in what was once seen as the domain of clinical professionals. This is the result of several beliefs, including those listed below.

- Lifestyle significantly affects the health of individuals.
- Compliance with screening and treatment requires the commitment and understanding of the patient and, often, also his/her family.
- The public is generally better informed and less trusting of the professions.
- A satisfied paying patient is a commercial asset.
- Users increasingly assert moral and legal rights to consent and to make informed choices.
- Patients have responsibilities as well as rights.

European position

The most fundamental patient right of all is the right to safe care, and there is significant guidance at EU level on patient orientation in patient safety. In particular the Council of Europe has set out basic patient rights principles, such as equitable access to health care; protection of consent and private life; and right to information. Patients must be protected from the harm caused by poor functioning of health services, medical malpractice and errors.

These European-level principles have also been developed by national standards bodies in a number of European Member States, including on responding to patient complaints. Patients, and those acting on their behalf, should have their comments and complaints listened to and acted on effectively, knowing that they will not be discriminated against for making a complaint. The institution should have a clearly defined system to continually monitor, evaluate and improve the quality of care, and the information collected and assessed regarding patients' should be used by the institution management to develop the services they provide.

Communication is at the heart of safe patient care, and a number of European research studies and reports provide guidance on how to put this into practice.

This includes effective exchange of information between staff and patients; between staff members, units and other care institutions; and with the wider public, throughout the care pathway. First, patients have the right to be fully informed about any proposed procedures, together with the potential risks and benefits, as well as any alternatives (including the consequences of non-treatment) in order to participate actively in decisions regarding their health. This must take account of the ability of the individual to understand what is being proposed, and the ability to consent to treatment. Second, information about admission should be communicated clearly via the institution website and other media. In addition, the institution should use information channels of regional subcultures and cultural communities (e.g. websites, journals, meetings) for disseminating information about adequate hospital admission, and ensure that patients who do not speak the local language have a means of expressing themselves and being understood. Third, efficient handover communication between units, and between and amongst care teams, is essential for continuity of care, appropriate treatment and safety of patients. This regards the whole episode of care, including patient transfer, discharge, follow-up and completion. The right to freely seek health care in the EU places further requirements on the continuity of care. It is important to involve patients and families in the process of care, as they play a critical role in ensuring safe continuity of care.

Safety is enhanced further by involving patients in their own care and encouraging active decision-making. Patients should be provided with information about their medical condition and treatment-care plan and encouraged to identify themselves before receiving any medication and prior to any diagnostic or therapeutic interventions in order to avoid potential errors. Also, during their visits to institutions, patients should be provided with education about risk factors and high-risk behaviour that may lead to injuries or health problems in the future.

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Indicators

Health Consumer Powerhouse (2015). Euro Health Consumer Index (<http://www.healthpowerhouse.com/>, accessed 29 January 2015).

2. Institutional development

International principles

Much of the early development of quality in health care focused on improving the performance of individual personnel, teams and functions. Attention has now shifted towards their integration within and between organizations, largely because:

- the tradition of doctor-led patient care is moving towards multidisciplinary team working;
- competent teams cannot excel without an effective organization;
- many opportunities for improvement are between (rather than within) teams, functions and departments;
- patient-centred services and health maintenance need active coordination to ensure continuity within and between preventive care, primary care and hospitals.

International approaches

Policies and practices should be made explicit through relevant, understandable, measurable and achievable guidance on the organization of preventive, diagnostic and therapeutic services. Assessments against these organizational standards may include:

- self-assessment, such as with performance indicators, management checklists, EFQM Excellence Model and internal departmental quality programmes;
- external calibration, certification and accreditation (of training, health

- institutions, services, equipment);
- external quality assurance to standardize diagnostic accuracy (e.g. in radiology and clinical pathology departments);
- external publication and comparison of performance indicators;
- external peer review.
- statutory inspection, supervision and institutional licensing.

European position

Quality and safety management

Recommendations from the Council of Europe and the Council of the European Union form two key documents for patient safety, primarily at hospital level. The Council of Europe Recommendation states that; “patient safety ... should be valued as the primary priority of health care, even at the expense of productivity or ‘efficiency.’” The development of an organization’s mission and governance to support a high level of patient safety can be split into a number of domains, with guidance at European level drawn from a variety of sources.

Governance

Leadership of the health facility should ensure that quality is a priority issue within the organization and promote safety culture at all levels. Commitment of the governing body may be demonstrated by:

- approving an annual patient safety strategy/action plan which details accountability within the organization;
- approving a health and safety policy for staff;
- receiving regular formal reports on quality and safety;
- defining measures of clinical performance which are routinely reported to the board.

The management’s commitment may be shown by appointment of a designated leader of quality improvement and safety who is accountable to the management board, and by evidence of an active multidisciplinary group assigned to coordinate quality improvement and safety across the institution.

Facilities management

Several aspects of facilities management are closely associated with the safety of patients and staff. Institutions in Europe – and their patients and staff – have suffered major structural damage from earthquakes; loss of electric power for several days; baby thefts; and other events which, though rare, deserve attention to prevention or mitigation. There are few estimates of adverse events related to the physical environment in Europe but, of the 1747 sentinel events reported to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) during the accreditation procedure (January 1995–June 2002), 32 were hospital fires, 28 related to medical equipment and there were 23 instances of infants being abducted or given to the wrong family.

Emergency resilience

Central to disaster planning for hospitals is the risk that the capacity to deliver services could be degraded at a time when demand for them is at a peak. Therefore, the aim of a health sector disaster risk management programme must include reducing the vulnerability of hospitals to the impact of disasters. In 2010, the Pan American Health Organization (PAHO) published the Health sector self-assessment tool for disaster risk reduction to help health-sector managers to assess their own risks.

A survey of nine European states (and Australia) in 2010 noted wide variation in the regulation of hospital construction and that “In general, where mandatory elements are expressly identified, they are concerned with fire safety, security, lighting, environmental protection, and other areas that would naturally apply to any building accessible to the public. Some countries have regulatory authorities that licence health-care buildings on the basis of their adherence to standards concerning safety and quality of care.”

Utility supplies

Health-care facilities are highly dependent on reliable sources of electrical power, water and medical gases. The facility’s emergency management plan should include means to support essential building functions such as electricity, water, ventilation, fuel, medical gas and vacuum systems. In the United States of America, the Joint Commission analysed the root causes of sentinel events reported within the accreditation programme and in 2006 published general guidance for prevention and mitigation of the impact of power loss.

Fire safety

Facilities should be operated, equipped and maintained in a manner which ensures the safety of staff, patients and visitors. The institution’s management should ensure that the fire and other safety requirements are complied with in all circumstance and stimulates patients, members of staff and visitors to report immediately any unsafe situations. Guidance on EU legislation and its interpretation in construction is available from <http://ec.europa.eu>.

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- "C-section rate
- Patient based stroke 30 day in-hospital
- Patient based AMI 30 day in-hospital
- Post-operative thromboembolism
- Day surgery rate
- AMI patients prescribed aspirin at discharge
- Prophylactic antibiotic use."

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3. Management development

International principles

General management

Management development at system level aims at:

- strengthening central capacity for planning, policy development,

- implementation, supervision and performance management;
- defining lines of accountability throughout the health-care system;
- integration of vertical programme and institutional management by decentralization of management authority;
- empowering local managers to take responsibility for the application and organization of available resources.

When asked what would most improve quality in health care, many clinicians and managers quickly reply, “more staff, more equipment, more money”. The WHO review found little empirical evidence to support this but concluded that most improvement results from better management and use of existing resources.

Resource management

There is little evidence that greater health-care spending within a country buys more population health, but good services do not waste money.

- Policy and methods of resource allocation determine the service structure (staffing, buildings, supplies) on which activity and results are based.
- Equity and efficiency of resource allocation largely shapes the health-care provision for local communities.
- Even the richest cannot afford infinite insurance or public spending on health care; everyone is rationed at some point.
- Resources wasted on one patient are denied to another.
- Good clinical practice is efficient clinical practice.

Risk management

Health services are intended to improve health, but they also present many hazards which can damage health. Risk management plays a major role in quality improvement.

- Failures of operational procedures can damage patients and staff and lead to successful litigation.
- Failures of systems have caused major public scandals, public inquiries, severely adverse publicity and loss of public confidence.
- Errors and accidents increase costs to patients, providers and insurers.
- The only benefits of mistakes come from systematic learning, corrective action and dissemination of lessons to others.

Communications management

Information and its communication are essential to quality improvement:

- information should be accurate, timely and complete;
- it can enable management control and coordination of resources and services;
- it is central to the continuity and evaluation of clinical care;
- it is needed by patients to understand, share and evaluate their own care;
- poor availability, use and quality of health service data are common major obstructions to effective management and quality improvement;

- incomplete or delayed data cause under valuation and under funding of service providers.

International approaches

Decentralization of management requires greater reliance on the knowledge, attitudes and skills of local managers, which implies:

- move from responsive administration to proactive management;
- provision of management training;
- appointment and promotion based on training and experience;
- delegated accountability and authority for internal systems and resource management;
- personal appraisal and career development;
- peer networking.

Various expert WHO working groups have recommended that the role of managers in quality improvement should include:

- designated leadership, accountability, supervision, monitoring and communication of quality at sub district, district, regional and national levels;
- public accountability through reporting of quality improvement systems, and through objective external assessment by independent bodies;
- dissemination of quality information to civic groups with an interest in health, such as women's groups, health educators, legislators and mass media;
- coordination of multidisciplinary quality assurance projects using common protocols on topics such as perioperative, maternal and perinatal deaths and iatrogenic drug reactions;
- regular, systematic feedback of data on important process and outcome measures to individuals, organizational units and organizations.

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4. Clinical practice

International principles

Concepts of clinical effectiveness and evidence-based medicine have become the heart of quality in clinical practice. The background issues and pressures include:

- much evidence has accumulated of unacceptable variations in clinical practices and results among doctors who are treating similar patients in similar circumstances;
- adding together the results of existing biomedical research (meta-analysis) has greatly increased the power to define effective clinical practice;
- even when clinical evidence is consistent, clear and accessible it is often ignored in daily practice;
- scientific knowledge is growing much faster than individuals can interpret and assimilate it into practice;
- escalating costs force funding agencies to restrict access to expensive innovations that are not cost effective;
- there is increasing public awareness of, and demand for, new high technology and best practice.

Methods

Assessment of local clinical practice against expectations, whether stated or unstated, increasingly involves multi-disciplinary teams, rather than individuals or single specialties. It is becoming more systematic, using aggregated data rather than individual anecdotes, and should not be confused with research. Approaches include:

- clinical audit
- clinical indicators

- adverse patient events
- delay analysis
- confidential enquiry.

European position

Clinical practice

The EC Directive regulating cross-border health care requires that care, “shall be provided in accordance with... standards and guidelines on quality and safety laid down by the Member State of treatment”.

The original draft (2008) added that States should ensure that: mechanisms are in place for ensuring that healthcare providers are able to meet such standards; the application of such standards by healthcare providers in practice is regularly monitored and corrective action is taken when appropriate; (such standards) take into account “international medical science and generally recognised good medical practices”.

The Institute of Medicine concluded (2001) that, in the United States of America, “there are large gaps between the care people should receive and the care they do receive.”¹

These gaps included overuse, misuse and underuse of appropriate technology – and have a direct impact on quality, safety and costs.

Medication safety

Medication safety is central to patient safety since adverse drug events are the most frequent single type of adverse events. Evidence of the problem in European hospitals is summarized in the introduction to Council of Europe recommendations. Several national multi-centre studies on adverse events in different countries revealed that between 6.3% and 12.9% of hospitalized patients have suffered at least one adverse event during their admissions and that between 10.8% and 38.7% of these adverse events were caused by medicines. Of these adverse drug events, between 30.3% and 47.0% appear to be consequences of medication errors and therefore may be considered preventable. The reported incidence of preventable adverse drug events in European hospitals ranges from 0.4% to 7.3% of all hospitalizations. Some European studies indicate that the rate of intravenous medicine errors in hospitals is considerably higher than those involving oral medicines: in one study at least one error occurred in half of all intravenous medicine doses prepared on hospital wards.

Reflecting its significance worldwide, medication safety was the focus of four of the first nine patient safety solutions launched by WHO in 2007: look-alike,

¹ Institute of Medicine (2001). Crossing the quality chasm: a new health system for the 21st century. Washington, DC: National Academy Press (www.nap.edu, accessed 29 January 2015):236

sound-alike medication names; control of concentrated electrolyte solutions; assuring medication accuracy at transitions in care; and single use of injection devices. Emphasizing the importance of standardizing procedures to reduce errors, WHO offers standard operating protocols for download, such as Assuring medication accuracy at transitions in care and Managing concentrated injectable medicines.

The European Network for Patient Safety (EUNetPaS) was launched in 2008 to establish an umbrella network of all 27 EU Member States and EU stakeholders to encourage and enhance collaboration in the field of patient safety. A database of good practices has been developed (including medication safety) and some specific solutions implemented and evaluated (e.g. bedside dispensing, use of safety vests during medication rounds, reconciliation of medications on admission and discharge).

The most comprehensive European advice and guidance on medications safety is offered by the Council of Europe. Much of this refers to national-level initiatives on drug manufacturing, packaging, terminology, information and reporting systems, but many detailed recommendations relate to safe practices at institution level. Many of these reflect practices which are common in North America but relatively new to many European institutions, such as computer-based prescribing, unit dose dispensing, institution formularies and clinical pharmacy. According to the first European survey of hospital-based pharmacy services conducted in 1995 by the European Association of Hospital Pharmacists, unit dose medicine dispensing is not widespread throughout Europe, being used in only 6.5% of the hospitals.

Clinical practice guidelines

In order to address the issue of variability of practice guideline (PG) quality, an international team of PG developers and researchers (the AGREE Collaboration) created the Appraisal of Guidelines for Research and Evaluation (AGREE) Instrument. Since its original release in 2003, the AGREE Instrument has advanced the science of PG appraisal and quickly became the standard for PG evaluation and development. <http://www.agreetrust.org/about-the-agree-enterprise/agree-research-teams/agree-collaboration/>

Performance indicators

PATH (performance assessment framework for hospitals) is a performance assessment system designed by the World Health Organization to support hospitals in defining quality improvement strategies, questioning their own results and translating them into actions for improvement. <http://pathqualityproject.eu/index.html>

The OECD Health Care Quality Indicators (HCQI) project has been conducted in collaboration with OECD countries, a number of international partners (e.g. Commonwealth Fund, Nordic Council of Ministers Quality Project) and the International Society for Quality in Health Care (ISQua). The HCQI programme collects readily available care process and outcome indicators, and conducts

collaborative research and development on priority indicator areas (particularly primary care, mental health, patient safety and patient experience). The project also promotes the improvement of international information systems and indicator comparability. <http://www.oecd.org/health/>

Hospital care

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- C-section rate
- Patient based stroke 30 day in-hospital
- Patient based AMI 30 day in-hospital
- Post-operative thromboembolism
- Day surgery rate
- AMI patients prescribed aspirin at discharge
- Prophylactic antibiotic use.

Patient safety (OECD)

- Foreign body left during procedure
- Vascular catheter related infections
- Post-operative pulmonary embolism or deep vein thrombosis
- Post-operative sepsis
- Accidental puncture or laceration
- Obstetric trauma vaginal delivery with instrument
- Obstetric trauma vaginal delivery without instrument.

Health Promotion, Prevention and Primary Care Indicators (OECD)

- Asthma admission rate
- COPD admission rate
- CHF admission rate
- Angina without procedure admission rate
- Diabetes short-term complications admission rate
- Diabetes long-term complications admission rate
- Uncontrolled diabetes admission rate
- Diabetes lower extremity amputation rate
- Hypertension admission rate.

Mental Health Care Indicators (OECD)

- Unplanned schizophrenia any hospital re-admission rate
- Unplanned schizophrenia same hospital re-admission rate
- Unplanned bipolar disorder any readmission rate

Unplanned bipolar disorder same hospital re-admission rate.

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5. Professional development

Principles

Current views on quality improvement favour focusing on systems and how they work, rather than on individuals and their competence. But this move away from blaming individuals when things go wrong should not cause neglect of the selection and development of staff, particularly clinicians:

- technical competence of staff is essential to effective health care;
- interpersonal skills can increase patient compliance and satisfaction;
- communication failures are the commonest cause of major complaints;
- unethical behaviour has killed patients and seriously damaged organizations;
- competent staff is a major asset that rewards maintenance and development;
- senior management is morally, if not legally, responsible for ensuring that staff is competent, even if not employees.

Professional ethics

Ethical codes should be consistent with national policy, particularly with respect to patients' rights, evidence-based practice, peer review and continuing education.

Licensing and registration

There should be formal mechanisms to ensure that only competent professionals are allowed to provide health care to the population.

Continuing professional development

There should be continuing education and training for the professional development of health staff, at all levels, to keep them updated with current trends in clinical knowledge and in health care management. This should include regular, relevant and timely provision of peer review and learning within health-care institutions.

International approaches

In addition to national or state training, registration and licensing, approaches which have been used at local level to assess clinical competence include:

- validation of past history, current registration status and references during recruitment
- individual performance review or appraisal
- systematic periodic review of clinical appointment: local credentialing
- supervision of trainees and assistants

- external monitoring and accreditation of training programmes and clinical departments.

European position

Although EU legislation has a significant impact on the health workforce, for example through directives on working hours, and recognition of professional

qualifications, there is less direct EU-level guidance on workforce management at organizational level. Professional and patient mobility across the EU is starting to change this, however, and in light of EU directives providing for the recognition of professional qualifications and facilitating the provision of cross-border care, the “increased mobility of the workforce may therefore require workforce managers ... to review the adequacy of their recruitment and professional development measures”. It is incumbent on employers to seek to recruit and retain high quality individuals and, as WHO guidance emphasizes, to provide a working environment that facilitates high-quality care, and encourages staff to fulfil their potential and the organization’s aims.

Health and safety at work is governed principally by Directive 89/391/EEC, through which all employers have statutory and ethical responsibilities to ensure the safety and wellbeing of their staff. Specific guidance for health care is found in the Council Recommendation on patient safety. This states that employers (and others) should, “Promote, at the appropriate level, education and training of healthcare workers on patient safety”. This begins with appropriate induction training on issues of personal and patient safety, and continues by “embedding patient safety in ... on-the-job training and the continuing professional development of health professionals”² A Green Paper states that employers must facilitate clinical staff’s involvement in formal continuing professional development programmes, in the knowledge that “updating professional skills improves the quality of health outcomes and ensures patient safety.”³

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² Council of the European Union (2009). Council recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections. O.J.E.U. C 151/01 (http://ec.europa.eu/health/patient_safety/docs/council_2009_en.pdf, accessed 29 January 2015):4.

³ Commission of the European Communities (2008). Green Paper on the European workforce for health. Brussels (http://ec.europa.eu/health/ph_systems/docs/workforce_gp_en.pdf, accessed 29 January 2015):9.

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6. Institutionalization of quality and safety at national level

Published national strategies

Legislation

Although most national strategies for quality health care are based on a mixture of statutory and voluntary activities, their ability to reach every part of every organization depends largely on the willingness of individuals to participate. One approach is to require by national law that specified quality structures or activities are maintained.

Compliance with legislation covering certain aspects of quality is subject to statutory inspection in most countries. Such matters concern public health and safety and generally override national, professional and personal freedoms on, for example, questions of radiation, infection, hygiene, transfusion, medical devices, drug manufacture, complaints and licensing of facilities. They also include registration and, in some countries, re-registration of clinical personnel.

Because many countries organize and regulate health services and personnel at sub-national level, federal legislation is often implemented at the level of state, province, region or county. In almost all countries, the government has laid down the principles and left it to local purchasers, providers and insurers to implement them.

In the case of Austria, where 99% of the population is covered by compulsory health insurance, legislation was introduced in 1993 in response to public demand, increasing competition, limited funding, and the reform of hospital financing. Similar legislation in the Netherlands in 1996 extended to primary care and emphasized internal quality systems and self-regulation, with external accountability to the Inspectorate of Health and patient organizations. As in Austria, the Dutch law was prompted by a shift to market-oriented and service thinking and a concern that negotiations between providers, purchasers and consumers should include quality as well as volume and price. In Germany, health system reforms in 2000 were aimed at improving the supply of services and controlling the cost of health insurance.

Government policy

Few governments have a stand-alone policy for quality in health care. In many cases this is because the policy is implicit, or it is packaged with strategic reform or other operational initiatives. Even when government policy is transparent, its lifespan and interpretation are subject to the high turnover of ministers and quality-minded civil servants, which may be common in departments of health.

Comparisons between countries, such as between the United Kingdom and the United States, suggest that despite differences in structure, ethos and resources

there is much to learn across borders. Specifically, “systemic national capacity to remedy and improve quality in health care requires coordination and integration of activity at four levels”. These levels are:

- national policy formulation
- national- and system-level infrastructure for monitoring and oversight
- system-level governance and operational management
- clinical provision of services.

Organization and management

There should be effective mechanisms to integrate and implement the national/state policy within government, and between all stakeholders and sectors of health-care provision. A quality improvement capacity should be established at each district and facility level, which is integrated fully within each institution's management, planning, organization, systems and procedures.

- Coordination of quality improvement should be clearly defined within the ministry/department of health and family welfare.
- Accountability and mechanisms for implementing quality improvement should be defined throughout the health-care system.
- Support structures, such as agencies, boards, committees and networks (including non-governmental organizations, teaching and research institutions and professional groups) should be established, publicized and accessible.
- Obligations and contributions of professional bodies, and of medical, nursing and other clinical staff to quality improvement should be agreed and be made explicit throughout the health-care system.
- Role of professional licensing councils should be defined with respect to regulation; the setting and monitoring of clinical performance standards; and the development and dissemination of quality improvement methods.
- State ministry responsible for health services should issue general guidance and support to local managers to organize, support and monitor internal quality systems and to manage appropriate change.
- Within provider institutions, clinical staff should be organized to support peer review, clinical policy, continuing professional development and accountability.

Resource centres

Many countries have developed resource centres to support national quality programmes. The configuration of these resource centres, and their distance from government, varies between countries. Whether managed by government or outsourced, these centres should be governed by international principles. The functions should broadly include:

- technology assessment, clinical practice guidelines, advice to health insurers, evidence-based advice on innovations in health care;
- technology regulation (e.g. of medicines, appliances, prostheses, implants,

- equipment, transfusion, human tissue, laboratory medicine);
- provider regulation: inspection of private and voluntary health care (e.g. under the Clinical Establishment Act);
- organizational standards: assessment and recognition (accreditation) of provider institutions against published standards;
- patient and staff safety: to collect reports and to learn from adverse events; to develop and implement risk management systems;
- financial surveillance: value for money and financial audit of public services;
- public health and clinical data: to manage national care registers, clinical indicators, patient satisfaction databases.

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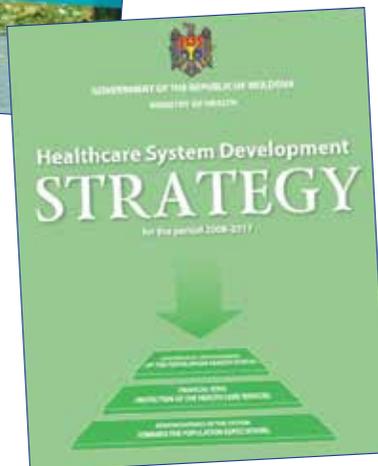
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