

Final report

Macedonian Health Sector Reform Project

Improving Quality of Health Care

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Recommendations on the regulation and organisation of quality and safety in health care

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Introduction

The terms of reference for this final report derive largely from the strategy on medical accreditation, published in 2001¹. The introduction to that document outlines the case for systematic review of licenses which are issued to doctors to practise medicine:

“At present, in Macedonia, there is not a measurable system of regulation in the medical profession ... Graduation from the Medical School and completion of one year's practical training (which is effectively a certificate of "attendance" rather than "satisfactory completion" of the practical training) and the “state exam” are the basic conditions for issuing a lifelong licence for doctors to work unsupervised as general practitioners...

Successful completion of postgraduate specialist training is a condition for issuing a licence to work as a specialist. There is no re-validation of licences. Although some CME activities are organised by the Macedonian Medical Association, they are not incorporated in the accreditation system because there is no revalidation of licences.”

Following adoption of the strategy for medical accreditation, the principles were extended to recommend changes to the Health Care Law 1994 to introduce:

- systematic adoption of evidence-based standards of practice as a basis for the development of clinical guidelines, and as a basis for specifying contracts between the Health Insurance Fund and health service providers (section 1)
- continuing professional development for doctors and dentists (section 2)
- robust licensing and periodic relicensing of doctors, dentists and pharmacists (section 3)

This current report was commissioned to identify the next steps needed to implement these proposals, and to specify the procurement of relevant technical advice. The initial assessment of the context and environment of quality and safety in health care in Macedonia identified two additional areas of development which, based on the experience of many countries, are essential to complement and sustain the development of practitioners as part of an integrated quality system. These are:

- effective internal systems for managing risk, quality and performance within health care organisations (section 4)
- a comprehensive national framework of values, policies and mechanisms to integrate new and existing activities into a coherent national programme for improvement (section 5)

Most of the problems observed, and the solutions offered, revolve around clarity of purpose and transparency – sharing intelligence and authority with stakeholders, and telling people what is going on

Most of the issues fall into one of four stages of the “quality” cycle:

- Agreed values of the stakeholders in health care eg patients’ charter
- Definition of targets, objectives and expectations eg clinical guidelines
- Reliable measurement and assessment processes eg performance indicators
- Effective mechanisms for changing individuals and organisations eg CME

Each stage of this cycle can be applied to four areas of current concern:

- Individual practitioner (doctor, dentist, pharmacist)
- Clinical process (preventive, diagnostic, therapeutic, palliative)
- Service delivery (organisation, management)
- Payments (appropriateness, efficiency, incentives)

Few of the recommended solutions require major capital investment, but making better use of existing resources, concentrating on changing the culture and behaviour of people and organisations, and providing the necessary local manpower and skills to do this. Training, infrastructure and better management are the central themes.

1 Evidence-based medicine

1.1 What are the objectives?

"All health professionals want to give their patients the best possible care. However these same professionals across the world face two particular difficulties:

- *First, the pace of scientific and clinical discovery has become so great that it is impossible for individual health professionals to remain at the forefront of knowledge across the wide range of subjects with which they have to deal.*
- *Secondly, the demand for health care - partly due to past successes, partly because of the emergence of effective new technologies and partly because we don't stop the use of less effective technologies - have exceeded the available financial and human resources."*²

Consistent with this international concern, Macedonia needs to develop:

- Guidelines for the management of clinical conditions
- Advice on when to refer to specialist care
- Guidance on the use of medicines, medical equipment and clinical procedures
- Information about and education in clinical audit

1.2 How may these objectives be achieved?

Access to international research, literature and experience

Defined principles and criteria for adoption or adaptation of international practice in Macedonia

Systematic appraisal of new and existing technologies

Definition of the clinical circumstances, institutional facilities, professional skills and safeguards which are necessary to make these technologies appropriate in Macedonia

Development of agreed clinical pathways, practice guidelines and protocols:

- to reduce variation in clinical practice and improve clinical outcomes
- to provide rational criteria for allocating health insurance funds
- to help patients understand and participate in their care

Development of effective systems within institutions for adopting these clinical standards, for auditing local performance and for demonstrating improvement and rewarding compliance

1.3 What is the current position in Macedonia?

Guidelines

There are regulations to control the licensing of drugs and medical devices, but there is no mechanism to coordinate guidance on how these, or any other technologies are most appropriately used. Nor is there an agreed definition of the criteria for appropriate admission, discharge or transfer between primary, secondary and tertiary care. The MoH is responsible for issuing standards for resource inputs (eg equipment, staff) but there are no standards for service delivery or performance. The MoH also issues a « positive » list of basic drugs (by generic name) which may be prescribed and dispensed free of charge.

Clinical audit

External “professional supervision” is spasmodic and subjective. Formal, standards-based internal supervision scarcely exists.

The Strategy for medical accreditation says:

“Medical Audit is a critical self-analysis on the part of the doctors. It should improve the medical profession and is controlled by the Doctors’ Chamber...Audit is based on the standards that are established by the medical professionals from the Specialist Societies in MMA. In future, the professional colleges should create their own standards Medical Audit can be of two different types - peer review from the same speciality and self-assessment. An Audit Body has to be established to prepare the documents for the Audit”

Comment [C1]: This is a very narrow view of audit

These proposals may be moderated by adding that:

- In most countries, audit is strongly encouraged by the professional licensing body, but not controlled by it
- Professional colleges should also follow the same international principles for guideline development
- Depending on the subject under scrutiny, peer review may properly involve several medical specialties (eg anaesthetists, radiologists), other professions (eg pharmacists, therapists) and clinical teams who daily work together (eg nurses).
- Clinical audit is best organized within the work setting in primary or hospital care

Information resources

Clinical and management staff need access to standards and practical guidance on tested quality improvement methods and examples of results. Some of this can be provided by local libraries, such as in journals, but the wealth of information on websites (if it is in the right language) commends investment in Internet access. 10-15% of senior doctors are estimated to have Internet access from the workplace, but many more from home.

Evaluation skills

Few doctors or managers have the technical knowledge and skills to assess and improve performance and to manage change within organisations. Training should include a general understanding of professional accountability and the scientific basis of medicine, and specific tools such as statistics, critical analysis, epidemiological methods, data capture and clinical coding. Managers and directors of institutions are usually clinicians who have no formal training in management of planning, personnel, budgets and organisations.

1.4 Which organisations are involved?

Health Insurance Fund (HIF)

The national HIF is slowly revising the formula for funding hospital budgets and for capitation in primary care, but current hospital payments continue to be based on

previous years' spending and activity. This is not related to casemix, performance or appropriateness of care; there is no financial incentive to improve, and little data on which to evaluate it objectively. Details of services and materials for individual hospital patient episodes are itemised electronically but are not validated, aggregated or analysed to identify patterns of process and outcome, or to define benchmarks and comparisons which could be fed back to managers and to clinicians.

Reform of HIF governance is the subject of another component of the current project. One recent report³ confirms several observations:

- The need to move to case-mix sensitive funding (eg by diagnosis-related groups DRGs) in order to establish a link between performance and payment
- The futility of the current invoicing system
- Publication of targets and an annual report on how the public money is spent by HIF
- The need to clarify explicit clinical pathways, guidelines and referral criteria

Macedonian Medical Association (MMA)

The Association has a voluntary membership of some 90% of doctors, and includes dentists, but not pharmacists. It incorporates many local and specialty-based associations. It supports the principles of self-regulation, CME and evidence-based medicine and is keen to develop as a national resource for education and clinical practice guidelines. The MMA is anxious to play its part in the educational reform process as the professional organisation that should take the lead in setting standards of clinical care and in professional development (doctors, dentists, pharmacists).

As potential host of a national centre, the MMA represents the interests of many doctors, some dentists and few pharmacists. It has few administrative support staff and no permanent manager.

Republican Institute of Health Protection (RIHP)

The RIHP is responsible (article 110 HCL) for advising the MoH on several elements of a national quality system, in particular:

- Collection and analysis of activity data
- Design and planning of health care
- Methodology of health care
- Design and development of information systems

These responsibilities are central to the definition and measurement of health care performance (eg in monitoring access, equity and population health; providing performance data), but are poorly developed for that purpose. In practice, the "design, planning and methodology of health care" are interpreted as referring to public health rather than clinical practice.

Patient-based data from primary care and hospitals are collected and aggregated electronically by regional institutes and passed to the national centre. Although much of the data elements are the same as the HIF, the system is entirely separate, coding and classifications are different, and there is no exchange or cross-validation of data with the HIF.

The missing agency

Larger countries have developed a variety of governmental or independent agencies to promote evidence-based medicine, patient-centred services, organisational development and continuing professional education. Many have established one or more agencies to provide:

- Resource centre for quality improvement standards, methods and experience; a focal point for the collection of information from within the country as well as comparison with others
- Collections of clinical practice guidelines and evidence-based medicine
- Advice on the appropriate use of health technology
- Training in quality improvement
- Collection, analysis, comparison, publication and active feedback of data on performance of providers (quality, quantity, cost and value for money) in conjunction with HIF and IPH
- Development and maintenance of organisational standards
- Independent assessment and accreditation of institutions (as health service providers) which meet published organisational standards.

Such an agency would need substantial professional, governmental and public support – and external technical advice - in order to become established. Central financing would also be needed for at least three years until at least part of the operational costs could be recovered from fees charged to (and budgeted by) the HIF or direct to institutions for services provided. National bodies which oversee and assess both organizational and clinical standards, and which might provide a model for Macedonia, include directly-funded government agencies (ANAES in France, QIS in Scotland), semi-autonomous agencies (NCQA in Poland) and collaborations of independent professional specialties (CBO in the Netherlands).

1.5 What actions are required to achieve these objectives?

National centre

Designate the MMA as the authorised national coordinator for HTA and clinical guidelines and as a resource centre for information, continuing professional development (CPD) and clinical audit.

Expansion of this centre (to include the broader remit of quality and safety throughout the health care system, including the development of organisational standards and institutional accreditation) may be considered at a later stage within the overall national strategy.

Establish an advisory group for this Centre to include stakeholder representatives (eg consumers, professions, academics, managers, funding agencies and government)

Recruit and train personnel with skills and experience in information management, communications, biomedical research, education and general management

Establish relationship with corresponding centres and programmes in other countries

Advice to HIF

Develop a contractual relationship between MMA and HIF for the provision of advice on the purchasing of clinical services, consistent with practice guidelines issued to practitioners.

Clinical information

MMA should be party to the development of a national strategy for the collection, coding, aggregation and exchange of performance data and information, representing the need for practitioners to have accurate, timely, complete and clinically relevant feedback for the purpose of internal audit and professional development.

Establish a library and database of literature on the definition, measurement and improvement of clinical standards, accessible to all practitioners

Professional development

Define, with Chambers and Medical/Dental Faculties, the curriculum and teaching requirements for introducing the principles of evidence-based medicine, clinical guidelines, peer review and performance measurement to undergraduates and trainee specialists.

Design a national curriculum, materials and programme to teach the principles and support the implementation of internal systems for clinical safety and quality (including audit, risk management, the use of guidelines and performance measurement) in every institution.

Develop and publish a technical manual for practitioners and managers on the design and operation of internal quality systems.

1.6 What technical advice, training and goods need to be procured?

External consultancy

- 1.1 Establish principles, policies, procedures and criteria for HTA and guideline development in Macedonia
- 1.2 Develop policies and procedures for the exchange of data and information to support the definition and purchase of services eligible for HIF reimbursement
- 1.3 Develop and implement strategy for dissemination of guidelines to practitioners and public
- 1.4 Advise on the capture, coding, aggregation and feedback of clinical data at local and national level
- 1.5 Draft national curriculum and materials for teaching peer review and internal systems for quality and safety
- 1.6 Assist in developing technical manual for local systems
- 1.7 Evaluate progress, products and impact of the Centre on clinical performance after one year
- 1.8 Advise MMA on policies and procedures for rational drug use
- 1.9 Assist national development and local application of hospital formularies
- 1.10 Provide HIF, MMA and Chambers with technical advice and practical experience from similar centres in neighbouring Balkan states

Internal consultancy

- 1.1 An experienced and competent manager should be designated to detail the terms of reference, job descriptions, contracts and administrative procedures, to coordinate communications and to manage the national centre (one year initial contract, renewable and funded for three years)

1.2 Members of the Advisory Group should be contracted by the MoH for one year, renewable according to fulfilment of responsibilities and conditions previously defined.

1.3 The Centre should be supported by a permanent secretariat to include logistics, records, document handling, book-keeping and communications.

1.4 A respected, qualified and experienced clinician should be appointed to develop the principles, procedures and criteria for “filtering” clinical guidelines and technology assessments into Macedonia; to oversee their application throughout the network; to develop an annual programme of work and to be accountable for the operation of the Centre

1.5 A full-time research officer should be appointed for up to three years

1.6 Allowance should be made to reimburse the direct costs (eg travel) of specialty sub-groups as required

Training

1.1 Induction training for Centre personnel in HTA and guideline development

1.2 Induction training for Centre personnel in teaching and implementing local clinical audit systems

1.3 Series of local workshops on clinical governance and audit for managers and clinicians

1.4 Series of local workshops for prescribers and pharmacists on the use of formularies

Goods

1.1 Design and expand capacity of MMA computing and website

1.2 Establish core MMA library of reference texts and materials

1.3 Extend practitioner access to Internet in all health care organisations

1.4 Publication and distribution of guidelines documents to practitioners and, in simplified form, to the public

2 Continuing professional development

2.1 What are the objectives?

Continuing to update and extend knowledge and skills is an essential feature of maintaining competent professional practice, primarily to support quality services and protection of the public. In many countries professions are considering arrangements for some form of mandatory re-registration or re-validation, or strengthening their current requirements. This is primarily because the “shelf life” of knowledge acquired at the point of initial licensing becomes less each year, with a consequent need for learning support through life. Continuing medical education and CPD systems will need constantly to evolve and adjust to take account of these developments.

Continuing medical education (CME) and continuing professional development (CPD) are treated together here because, although they aim at different aspects of development (CME broadens or enhances skills, CPD updates existing skills), in practice the dividing line between them is blurred.

Principles for CME and CPD⁴

Current recommendations in the UK are that programmes should:

- Be designed and delivered in partnership with stakeholders so that the requirements of Chambers for re-licensing or re-validation purposes are relevant to the individual's working environment and to the job they actually do
- Be an integral part of the national quality framework and institutional management of quality and safety
- Meet local service needs as well as the personal and professional development needs of individuals
- Be increasingly focused on the development needs of clinical teams, across traditional professional and service boundaries
- Make use of the full range of development approaches and methods, rather than rely solely or largely on formal courses
- Be modular and attract academic credits where possible
- Be grounded in local peer review and draw on clinical audit and evidence-based medicine

2.2 How may these objectives be achieved?

National coordination of the design and delivery of CME for doctors and dentists

Formal definition and recognition by Chambers of taught courses and learning activities for which points can be accrued towards re-licensing

Local access for doctors and dentists to relevant educational programmes

National strategy for learning and development in every hospital and primary care workplace

Internal systems within institutions to integrate and document personal appraisal and development plans with participation in clinical peer review and audit against agreed clinical guidelines

Systematic recognition of learning achievements or academic credit (eg points) for personal development and formal training, explicitly linked to revalidation or relicensing of professional staff

Provision of local facilities (eg access to libraries, information and data), and funding (eg clinical time, course management)

2.3 What is the current position in Macedonia?

The MMA runs an Annual Congress and a peripatetic lecture programme open to all doctors of whatever speciality. The various specialist associations also run their own congresses.

CME for primary care was established under the previous HSTP primary care education project, but provision for many other specialities remains limited to the Annual Congresses and the lecture series of the MMA,

Four CME centres were built in Macedonia, equipped and staffed as hubs for CME in primary care, and include library and Internet access. With addition of appropriate teaching aids, they could also be used for hospital doctors, dentists and pharmacists but the basic funding for CME (2% of the PHC operating budget) ceased two years ago and the buildings now have limited use.

2.4 Which organisations are involved?

Medical faculty

In many countries, CME is based in local Universities which provide outreach programmes to peripheral postgraduate education centres. The universities have either an undergraduate school or postgraduate or both. Larger institutions designate a senior doctor as “clinical tutor” to coordinate the local teaching programme (eg lectures, workshops). Although they are described as “educational”, departmental and team meetings in the workplace for regular review and audit of clinical work are organized within specialties as a part of everyday clinical commitments.

Chambers

The learning activities which would acquire CME points for relicensing in Macedonia would include attendance at conferences and symposia locally and abroad; participation in local association activities; attendance at invited lectures. Informal learning through private study, peer review, local performance appraisal is not currently to be taken into account.

The Doctors' chamber also provides some educational activities.

Macedonian Medical Association

The MMA, as the principal current provider of CME is anxious to take the lead in setting standards of clinical care and in professional development of doctors, dentists, and pharmacists. The CME strategy indicates that, coordinated by the MMA, *“Every society will have to prepare CME annual plans and programs for a given period, whose goal will be to answer the needs of the profession... These plans and programs (including congresses and seminars) should be evaluated, so that the number of points scored in every CME course should be transparent”*

The Association would also contribute to professional development as the centre for training and information on the use of guidelines and clinical audit.

2.5 What actions are required to achieve these objectives?

The MMA

The capacity and governance of the MMA should be strengthened (see section 1 above) to fulfil the recommendations of the 2001 strategy for CME and to design and cost a programme to ensure that all doctors, dentists and pharmacists have access to systematic, formal CME

Joint policies and procedures for CME

In consultation with the medical faculty and the three chambers, the MMA should identify, agree and document common principles for extending the design and delivery of didactic CME to hospital doctors, dentists and pharmacists to include organisational structures (eg local clinical tutors), activities (teaching and learning methods; multidisciplinary and cross-sectoral learning), materials (eg teaching aids), and operational policies (eg programme evaluation, sharing of data, individual participation records).

The provision of continuing education should be clearly separated from the process of its accreditation. The remit of the Chambers should be confined to statutory regulation of the professions through management of the licensing process.

Formalisation and integration of CPD

A joint working group (led by MMA but including Chambers, academics and general managers) should evaluate existing internal structures and activities within hospitals and make recommendations for their adaptation or development to provide an environment for continued learning within the workplace. This should identify the interface, division of responsibilities and arrangements for integration of formal teaching delivered by academic practitioners and local peer group learning.

2.6 What technical advice, training and goods need to be procured?

External consultancy

2.1 Facilitate the development of joint policies and procedures governing the provision of formal CME to doctors and dentists.

2.2 Advise on the development of CPD within hospitals, and integration with the formal programme of CME.

2.3 Provide guidance to hospital managers on the personal development and management of professional staff.

2.4 Evaluate progress in the institutionalisation of CME and CPD and its impact on clinical performance after one year.

Internal consultancy

2.1 A joint working group (led by MMA but including Chambers, academics and general managers) should be funded to evaluate existing internal structures and activities within hospitals and make recommendations for their adaptation or development to provide an environment for continued learning within the workplace.

2.2 The group should be serviced by the manager of the national Centre

Training

2.1 (TA) Consultative workshop for MMA, Chambers, Faculties on principles and practice of CME and its association with re-licensing.

2.2 (TA) Series of local workshops for clinical staff and general managers on the development of CPD in the workplace.

2.3 Rolling programme of “teaching the teachers” and accredited formal events in CME centres and hospitals.

Goods

2.1 Teaching aids for hospital doctors, dentists and pharmacists in CME centres

2.2 Core medical/dental reference and journal library in each major hospital

2.3 Extend practitioner access to Internet in all health care organisations

3 Professional licensing and re-licensing

3.1 What are the objectives?

Procedures for the licensing of doctors, dentists and nurses are prescribed by law in most countries and are delegated to an accountable body (often at the level of state or province) which defines standards and maintains a professional register. Standards for periodic re-licensing and for other professions are more variable.

The purpose of professional regulation is to ensure that the public receives medical care only from practitioners who are competent, up to date, honest and respectful of their patients. The basis is the keeping of a list or register of those deemed to be competent and fit to practise.

The primary focus should be unequivocally the protection of the public. To secure full public trust, appropriate public involvement in the governance and processes is essential. In the UK, this principle was made explicit in the report of a public enquiry into children's heart surgery at a teaching hospital⁵:

'The purpose of the system of regulation must be to assure the public of the competence of healthcare professionals and, when necessary to protect them. As such it needs the widest involvement of professionals, of the principal employers and the public. It cannot achieve its purpose if it is a system that is designed and operated solely by particular professionals for their professional peers.'

Today, professional regulation is no longer seen as an activity which stands alone. Rather it is regarded as an essential part of a wider system of quality assurance and quality improvement that brings together employers' arrangements for clinical governance - and national arrangements for institutional safety and accreditation.

3.2 How may these objectives be achieved?

The general principles informing sound professional regulation include clear standards, sound processes ensuring compliance, appropriate accountability, transparency and fairness. Trust will depend largely on the extent to which such principles are observed.

Registration

Registration provides a nation-wide professional standard. Basic registration - licensure - is restrictive; doctors (and other professionals) cannot practice without it. Specialist certification, achieved on completion of specialist training, is indicative of the field of practice in which the doctor has acquired further competence. Many countries now place a further statutory requirement on doctors to maintain an active license to practise - revalidation. The purpose is to be as sure as possible that anyone actively practising as a doctor has provided up to date evidence of their current competence and fitness to practise.

Standards

The licensing bodies (in Macedonia, the Chambers) are required by law to set the basic professional duties and responsibilities required for practice. These professional standards should represent a consensus statement between the public and the profession, and underpin registration and licensure. They should provide the basic template for all stages of professional education leading to basic qualification and specialist certification. They should be the templates against which practitioners will be assessed for revalidation and should be used as the standard against which to judge professionals whose fitness to practice has been questioned.

Education

The licensing bodies are legally responsible for determining the curriculum for basic clinical education, and for accrediting schools and universities that they approve for providing that education.

They also define the general characteristics of continuing medical education and professional development required for periodic re-validation and thus re-licensing.

Fitness to practise

The fourth function of licensing bodies commonly concerns those practitioners whose professional conduct, performance or health gives cause for concern. The procedures for the investigation of individuals should be quite separate from the decision to withdraw a licence, and there should be a transparent mechanism of appeal, in keeping with current European law on human rights.

3.3 What is the current position in Macedonia?

Collaborative agreement

Agreements were reached in Nov/Dec 2001 between the Chambers of Doctors, Dentists, Medical Faculty and MoH to work together to establish systematic continuing education, and to link this to re-validation of individual competence which would be a condition of periodic re-licensing. Pharmacists were later included, but there is no mention of nurses or other clinical professions. The general aims of this collaboration and proposals are described, at least for doctors, in the Strategy for medical accreditation, 2001. This assumes that there will be organised programmes of teaching, peer review and self-assessment accessible to all practitioners throughout Macedonia.

Practitioner licensing

Statutes of the Doctors', Dentists' and Pharmacists' Chambers are being revised to extend their authority from basic licensing to periodic relicensing (probably every five years) subject to evidence of continuing education. The vision for CME in primary care has been detailed in the strategy for primary care specialist training and agreement had been reached to allocate 2% of HIF funding to cover operating costs.

No detailed programme or funding exists for extending this to hospital doctors, or pharmacists (most of whom are moving from public to private sector) or dentists.

There is no national association of nurses, no chamber proposed, and no register of basic or higher trained nurses.

Practitioner re-licensing

Draft Regulations propose that doctors can obtain extension of their full (in future, five-year) licence if they submit evidence that “in the period of validity of the full licence they have undergone professional development ...and improvement on their own knowledge and skills”. The criteria and the procedure of evaluation of the professional development of medical doctors applying for re-certification of their full licence shall be prescribed by the Re-validation Body of the Doctors’ Chamber. This should also be consistent with the criteria stipulated in the Rulebook on Continuous Medical Education (CME) of the Chamber.

Legislation and regulation

The primary legislation is highly detailed and prescriptive. Current international trends in professional regulation aim to create a framework in primary legislation, which is essentially enabling; important details are promulgated in secondary legislation, or statutory regulations which can be changed more easily when the need arises. Following this route, the Chambers would be constituted as the professional regulator, and would be seen to be properly independent of the Ministry.

The values and principles underlying the legislation are not made explicit. Key concepts such as re-certification, re-validation and re-licensing are not clearly defined or differentiated. Similarly the relationship between CME (didactic learning) and CPD (experiential learning) is not made clear in the context of re-validation and re-licensing.

3.4 Which organisations are involved?

Chambers of doctors, dentists and pharmacists

In keeping with the strategy for medical accreditation, and recent changes in the health care law, the three chambers will be authorised and required to modernise the licensing process, to introduce five year licensing and to develop procedures for subsequent re-licensing. Having embarked first, the Doctors’ Chamber has moved further on this process.

Chambers are established as NGOs under the 1994 HCL for doctors, dentists and pharmacists (but not nurses) “to protect quality of health care, professional interests and performance”. But they are not in a position to protect quality of health care, except with respect to practitioner competence, and the interests which they protect are of the profession and its ethics, rather than of the individual practitioner. There is no stated requirement to protect the patients’ interests or to involve other stakeholders in the regulation of the professions.

The Statute of the Doctors' Chamber of Macedonia (2001), makes clear that the membership and executive exclusively medical; there is no mechanism to represent public and patient interests in the governance of the chamber. It also defines a complex local structure of 30 regional/municipal boards outside Skopje (article 39) and 12 in the capital (article 40)

Macedonian Medical Association

As the principal provider of CME (for doctors, dentists – and maybe pharmacists), the MMA will be directly involved in making didactic learning available to practitioners for their personal development, for the benefit of their patients, and to fulfil the requirements for re-licensing.

Health care employers and institutions

“Internal supervision” of clinical practitioners is required by law (article 165, HCL) and should be able to contribute to the portfolio of evidence which the chambers will need to determine the continuing competence of individuals. But internal systems to evaluate and improve performance either of organisations or of individuals are virtually non-existent. There are no organised programmes of peer review, individual appraisal or personal development for career-grade staff.

Re-validation should begin in the workplace, including systematic review of practitioners (whether employees or independent) against their professional national code of conduct, agreed guidelines for best medical practice, and the published by-laws and rules of the institution.

3.5 What actions are required to achieve these objectives?

Collaboration of Chambers

Establish joint working group of the three chambers to take stock of the existing position, to ensure consistency of purpose, governance and processes, to provide mutual support; this group should include the capacity of the existing internal management, staff and equipment to meet the new demands to review register and introduce re-licensing; report to the strategic JWG with recommendations within six months

Common codes of practice

Each chamber should review the existing codes of ethical practice, and their criteria for accreditation of training in order to reflect the changing environment of clinical work – in particular the “new rules” suggested by the USA Institute of Medicine⁶. This should include clarification of how the interests of patients are to be represented, involved and protected, and how this should be communicated to the professions and the public.

Acceptable evidence of CME and CPD

The Chambers should draw up and publish common agreed principles for the recognition, scoring and evaluation of activities which will be considered as evidence of continuing competence. These should require evidence of active participation in local peer review and “reflective practice” in the workplace.

Personal development in the workplace

The Chambers and MMA should take stock of existing provisions for defining, assessing and developing practitioner competences in the workplace, and make recommendations to the MoH on the policies, structures, mechanisms and resources which managers need in order to strengthen them. This should include the current role and function of local branches of the MMA and the Chambers, and their potential contributions to networks of clinical governance.

Definition of critical work volume

Within its role as the custodian of clinical guidelines and technology assessment, the MMA should define general principles of the volume of clinical work and current experience, particularly of complex or specialised procedures, which would be considered adequate to support technical competence. This would help to:

- define the appropriate settings (in primary, secondary and tertiary care) for diagnostic and therapeutic procedures
- define the scope and limits of individual clinical specialties
- provide measurable criteria for the chambers to assess continuing competence of individual practitioners

Data collection and management

The Chambers and the MMA share a need to profile individual practitioners and clinical practices. They must define what information they require and be involved in the national specification, design and development of clinical information systems. They also need technical support to specify, procure and maintain their own internal systems.

3.6 What technical advice, training and goods need to be procured?

External consultancy

Professional regulation

3.1 External support to clarify the principles and practice of professional ethics, regulation and re-validation

3.2 Provide Chambers with models of governance and responsibilities of licensing bodies, and examples of infrastructure such as staffing, administrative procedures, register management and specification of data requirements and technical systems

Professional development

3.3 Development of joint procedures for accreditation of CME activities, classification and scoring of CME and workplace activities, and procedures for collecting and verifying evidence and individual profiles for the purpose of re-validation.

3.4 Assist MMA and Chambers to assess the current practices and provisions for defining, assessing and developing practitioner competences in the workplace, and to prepare recommendations on the internal policies, structures, mechanisms and resources which managers need in order to strengthen them.

3.5 Evaluate the current role and function of local branches of the MMA and the Chambers, and their potential contributions to local networks of clinical governance and professional development.

Technology assessment

3.6 Advise MMA on the identification and measurement of technologies whose clinical effectiveness has been shown to correlate positively with volume of individual or team workload.

Internal consultancy

3.1 Establish joint working group of the three chambers to take stock of the existing position, to ensure consistency of purpose, governance, processes and ethical codes, to provide mutual support, and to report to the strategic JWG

3.2 Assign the research officer of the JWG to service this working group of Chambers

3.3 Allow for legitimate expansion of staffing in Chambers in order to meet new demands of legislation, as recommended to and endorsed by JWG

Training

3.1 (TA) Consultative workshop for MMA, Chambers, Faculties on principles and practice of professional ethics, regulation and re-validation

3.2 (TA) Series of local workshops for clinical staff and general managers on the development of CPD in the workplace (see previous section).

3.3 Training for staff of chambers in new principles, procedures and technology

Goods

3.1 (Chambers) Software and hardware to support maintenance of professional registers, and the aggregation, analysis and exchange of clinical data (identifying practitioners, not patients) with health care institutions and regional and municipal branches

3.2 Publish updated ethical codes of the three chambers, distribute to all relevant practitioners and make publicly accessible

4 Institutional infrastructure

4.1 What are the objectives?

Unless local mechanisms for quality are also in place, national “top-down” strategies have limited impact. Most countries’ quality plans begin by linking the initiatives of the ministry of health (as the principal regulator) with the activities of general hospitals (as the principal providers of care and users of resources).

In the past thirty years, one of the key features of national health quality systems has been to replace ministerial directives and statutory inspections (“command and control”) by internal self-regulation and public accountability. There is much evidence that internally motivated self-development is more effective in changing individuals and organisations than any external intervention.

This rationale assumes that, at local level in primary and hospital care, there are institutional structures, processes and resources for the management of quality and safety.

Many terms have been used to describe a comprehensive management approach to quality and safety, and there are many academic arguments about which is best. For the current purpose, an institutional system should focus on patients, safety, improvement, practitioners and managers, clinical teams and the interface between departments and institutions. In management terms that means having an explicit policy, formal structures, effective methods and basic resources.

4.2 How may these objectives be achieved?

Define the values and principles of institutional quality systems within the context of the overall national strategy

Develop awareness among managers and practitioners of the current risks and the potential for systematic improvement

Develop institutional and individual incentives for adopting new working methods

Provide practical training and examples to managers and key clinicians

Practical guidance to managers issued with the commitment of the MoH

Establish external system for assessment of internal systems, in order to support, stimulate and share best practice

4.3 What is the current position in Macedonia?

Policy

The Health Care Law holds institutions responsible for “internal supervision” but there is little agreement on what that means, no formal internal policy and very little action to implement it.

James Cercone’s report of January 2004 on “Improving service delivery” is based largely on a survey of 70% of the 61 public hospital managers. Analysis of these results also draws attention to:

- The need for a comprehensive strategy for quality, safety and performance
- Formal internal structures and mechanisms
- Explicit standards for management and clinical practice
- Valid, reliable, accessible data
- Training for managers in methods for improving quality, safety and patient centredness

Organisation

Doctors accept (according to article 159 HCL) responsibility for the quality of their own clinical performance but have few mechanisms for corporate professional responsibility for their colleagues or for collegial self-regulation. Accountability is strictly hierarchical. No routine reports are required specific to service performance. Professional staff are not visibly accountable and would have real practical difficulty in adopting, implementing and auditing clinical guidelines even if they were available.

Methods

International voluntary programmes

Some international programmes involve hospitals on a voluntary basis. For example, the maternity unit at Strumica is participating in the UNICEF Baby Friendly Hospital Project; since joining the programme, the perinatal mortality has reduced by 30% 100% of babies are being breast-fed on discharge and printed information packs are given to every mother. At the Clinical Centre in Skopje, the Department of Obstetrics participated in the WHO EURO ObsQuid project to exchange data on clinical process and outcome and benchmark with similar units in other countries.

External laboratory standardisation

Until two years ago, biochemistry laboratories took part in an External Quality Assurance programme run from Skopje. Since this ceased there has been no external reference centre to standardise and reduce variation in calibration and assay procedures.

Performance measurement

Without access to reliable and relevant performance data, any review of current practice, activity, safety etc is subjective, anecdotal and of little value for personal learning or organisational development. Many of the controls which do exist rely on someone else eg the sanitary inspection.

Personal development

Clinical appointments are to permanent positions and are not subject to any local review of physical/mental health, participation in peer review, adherence to local rules, fulfilment of employment contract or personal development planning. Clinical personnel are not organised to take professional responsibility for their colleagues, and general managers have little authority to counsel, support, discipline or dismiss poorly performing practitioners. Workloads vary widely between full-time staff in the same disciplines.

Clinical records

Hospital patient records consist of loose papers of varying sizes and uncertain order. Some key information, such as preoperative surgical assessment or consent to treatment, were found to be missing. There are no clear policies on the clinical content, administration or systematic audit and improvement of patients' records.

Patient and staff safety

Awareness and attention to safety is low eg tall gas cylinders are not secured in patient areas, pipes run across doorway floors, broken paving, gratings and steps challenge patients entering the hospital.

Identification bracelets are not used to identify patients in hospital even for transfusion or general anaesthesia (except in maternity for neonates) ; no data are available on the number of incidents involving surgery on the wrong patient or the wrong side, or of medications or transfusions given to the wrong patients.

Infection control policies require that the hepatitis status of staff involved in invasive procedures is monitored annually. They also require that clinical waste is separated for incineration ; but the supply of plastic bags is not reliable enough to allow hospitals to follow the colour-coded procedures.

Staff wear radiation dosimeters which are renewed each month but dosage to patients is not recorded. Film reject rates are not routinely monitored to identify patterns among patients, staff, machines or materials, but are said to be low.

Resources

Data

Very few hard data are available to measure performance; those which are available are collected manually and focus on volume of activity and income generation rather than clinical practice, adverse events, complications or desired outcome. Cercone's survey of hospital managers⁷, and Burchfield's report on HIF governance⁸ identified the same issue.

Clinical time

Many clinical departments have no regular opportunity for reflective practice, clinical audit or peer group discussion with clinical colleagues; there is no stated contractual requirement for this, or allowance in personal timetables. Many clinicians hold daily meetings to discuss day to day activity: several have regular multidisciplinary meetings for visiting lecturers or case presentations (often in conjunction with the local medical association); very few have a regular opportunity during working time to analyse clinical policy and performance in a collegial setting. In the UK, 5% of clinical time was estimated to be appropriately allocated to systematic evaluation and development

4.4 Which organisations are involved?

Ministry of health

The Ministry of Health is responsible for three types of institutional assessment, based on inspection against criteria (mostly of resource input and structure) which are defined in the HCL and a variety of other legislation:

- Primary licensing: inspection of plans and proposals for new institution, with report and recommendations to the licensing authority. The licences which are issued have no fixed term (except pharmacies, for five years) so there is no-

reinspection unless significant structural or equipment changes occur. But this would not cover the introduction, for example, of new technologies such as endoscopy.

- Health and sanitary inspection: six-monthly “supervision” of hygiene, medical records, disease registers etc by a team of three inspectors (of cadre of 120) lasting one day, including immediate feedback of proceedings which are followed 5-10 days later by analysis and actions recommended (though these are not automatically followed up at the next 6-month visit). The assessment criteria are said to be transparent in that they are published in the law but there is no simple user guide which would enable institutions to assess themselves, or which might promote consistency (in time and place) between inspections.
- Supervision of professional work: rolling programme of nationwide reviews of clinical specialties (currently psychiatric services) by teams of three eminent clinicians. The priority for reviewing each specialty is set by the Minister, the criteria for assessment are personal to the visiting experts, there is no systematic follow up of recommendations.

Special controls

- Radiation safety: hospitals are visited twice per year by a radiation team from the MoH to calibrate equipment, collimate and measure scatter.
- Medical equipment: there is a bureau to control the introduction of drugs and medical aids, but this does not cover medical equipment and technology for which there is currently no control.
- Medical gas cylinders: there appears to be no legal requirement that compressed gas cylinders are secured to prevent falling and injury to patients or staff; this is not the concern of the Ministry inspectorate

Ministry of Environment

Environmental safety in hospitals (eg water supply, air handling systems) is the responsibility of the Ministry of Environment

Ministry of the Interior

The Ministry of the Interior is responsible for ensuring the construction of fire safety systems, but it is not clear who is responsible for ensuring that these continue to be operated correctly (eg that fire exits are kept clear and in functioning order), or how often inspections take place.

Overall, the criteria for inspection focus on structure rather than performance and are not easily understood by managers of institutions. Responsibility for inspection is shared between several agencies, with some duplication and some gaps. Inspectors receive no initial or continuing training and no practical guidance to promote consistency of assessments and of subsequent recommendations. The flow of formal reports and follow-up of recommendations is not consistent to “close the loop” of improvement.

Macedonian Medical Association

As the national centre for clinical standards and audit, the MMA should have the skills and capacity to help the development of internal systems of clinical governance. At a later stage, it may also take on wider responsibilities for organisational standards and their assessment. Currently there is no national organisation or focus for quality and safety issues which are not related to professional education, licensing or evidence-based medicine.

4.5 What actions are required to achieve these objectives?

Systematic assessment of existing quality improvement activities in Macedonia

A structured audit of a sample of hospitals against established criteria (eg for clinical governance or hospital accreditation) of current structures, activities and opportunities. This would require more detail than the assessment format proposed for the accreditation of training.

Review of international literature

Enable local consultants to access and become familiar with the international body of knowledge and to develop corresponding relationships in other countries.

Provide guidance to institutional managers

Publish general guidance to managers on how to initiate local policies, structures, methods and resources to improve quality and safety

Provide sample documents

Provide examples from other countries of specific policies, procedures and methods

Provide training for quality improvement

Provide training in general quality management and risk management, and in the definition, measurement and improvement of standards related to patients' rights, environmental safety, clinical records, resource utilisation

Develop national IT strategy

Develop a national strategy for information. However the tasks are allocated for measuring and improving quality and safety, those responsible should be major customers of a national system and should be involved its local implementation. Consultant support for the development of this strategy is funded under component 1.2 A of the current Health Sector Reform Project.

4.6 What technical advice, training and goods need to be procured?

External consultancy

4.1 Undertake, with internal consultant, a structured survey of a sample of hospitals and primary care centres against established criteria (eg for clinical governance or institutional accreditation) of current structures, activities and opportunities.

4.2 Assist internal consultant to incorporate findings of the survey with observations of previous consultants concerning hospital and PHC in Macedonia; combine with recommendations on internal clinical governance (section 1 above), continuing professional development (section 2) and re-validation (section 3)

4.3 Assist internal consultant to develop institutional manual for systems to improve quality and safety to integrate and develop existing and proposed strategies, based on evidence from Macedonia and abroad.

4.4 Identify values, principles and priorities for institutional development in order to support current programmes, including hospital performance, professional development and evidence-based medicine, consistent with the overall national strategy.

4.5 Assist in development of training curriculum relative to quality improvement, and assist in delivery of initial training to managers, practitioners and trainers.

Internal consultancy

4.1 Designate, develop and fund (for at least one year, preferably three) a part-time officer, with administrative support (clerical and technical), responsible to the Strategic Joint Working Group (JWG) to help research, draft, consult on and implement a strategy for institutional quality improvement.

Training

4.1 Generic programme for general managers and department heads in every institution

4.2 Specialised courses for quality and safety coordinators to be defined in every institution

Goods

4.1 Computing support for officer, including full access to Internet and facilities for downloading, printing and distributing relevant documents (see list of recommended websites provided)

4.2 Basic library of hard copy reference material, including subscriptions to 2 or 3 leading international journals on quality and safety (full text on-line may be available to Macedonia free of charge)

5 National strategy for quality improvement

5.1 What are the objectives?

Quality and safety are cross-cutting issues which, in any country, relate to every element of the health care system. They cannot be planned, managed and developed within the usual hierarchy of line management for two reasons:

- first, the problems and solutions tend to relate to relationships and communications between managerial and clinical units rather than within them;
- second, effective strategies must actively involve statutory, voluntary, professional and public organisations which represent the stakeholders in the health system.

If individual strategies and initiatives are to achieve optimum benefit at minimum cost, they must be designed, agreed, costed, implemented and integrated within a clear framework of values, priorities and limited resources.

Such national strategies must be developed slowly, carefully and with wide stakeholder consultation and support. They must be transparent in representing the values of the providers, purchaser and consumers of health care to provide a general framework which is sustainable in a changing climate of government and international funding.

5.2 How may these objectives be achieved?

The principles of a national strategy, and many examples from other countries, are provided in the WHO EURO document on national strategies for quality⁹. The four main principles are:

National values and priorities for quality

Principle: The government's values, vision and strategies for quality improvement are comprehensive, consistent and based on evidence and consultation with stakeholders.

- They are explicitly stated and disseminated to the public, providers and purchasers.
- The policy is comprehensive, accessible and consistent with other policies and legislation. It identifies key roles and incentives for quality improvement.

National organisation and institutionalisation of quality

Principle: 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

- Coordination of quality improvement is clearly defined within the ministry of health; there are effective communications with other agencies eg health insurance, public health, finance, information and international
- Accountability and mechanisms for implementing quality improvement are defined throughout the health system

- Support structures, such as agencies, boards, committees and networks (including non-governmental organisations, patients' complaints, training and research institutions, professional groups) are established, publicised and accessible nationally

Methods, techniques and tools for development of quality

Principle: 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 recognised and rewarded in organisations and individuals.

- Statutory mechanisms to ensure the safety of public, patients and staff are established and evaluated. Their regulations, standards, assessment processes and results are accessible to the public.
- Voluntary external quality assessment and improvement programmes are recognised by and consistent with statutory investigation and inspection. Their standards, assessment processes and operations comply with international criteria.
- There are formal mechanisms to define and protect the rights of patients and their families to health services
- Local quality programmes are systematically planned and co-ordinated to meet national priorities and the needs of local stakeholders. They use standards, measures and improvement techniques which are explicit and known to be effective in that setting

Resources for quality improvement

The national programme identifies responsibility for funding and providing the basic knowledge, skills and information required for quality improvement

- Personnel are trained to evaluate and improve the performance of their own work and of their health care organisation
- Personnel have protected time to participate in formal, systematic quality improvement programmes
- Health facilities provide staff with accurate, complete and timely data by which clinical and organisational performance can be measured
- Authoritative information on the theory and practice of standards, measurements and improvement is accessible to all health personnel
- The direct financial costs of the quality programme are realistically identified in advance and allocated to agreed budgets, especially for training, research and information

5.3 What is the current position in Macedonia?

Implied policy

Several documents reflect past and present government thinking, and describe current development initiatives, but there is no explicit overall framework for the institutionalisation of quality improvement. Examples include:

- Health Care Law revised 2004

- Training and accreditation in primary health care:
- Licensing and registration of practitioners
- Continuing medical education strategy

The values which underlie these strategies are not made explicit (that is, what are the characteristics of a “good” health system?); nor are the objectives of the strategies defined in relation to the overall priorities for improving quality and safety.

Conflicting incentives

Current arrangements do not provide financial inducement to improve practice. They even encourage institutions to stay within budget such as by transferring patients without clinical reason, and by retaining excess capacity to safeguard the budget for the following year.

Health care funding, through the HIF, could play an important role in managing change by offering carrots to individuals and organisations to complement the sticks of the regulatory mechanisms. The Fund could, for example, provide data on patterns of care according to diagnoses, treatments, doctors, institutions and communities, and offer financial rewards for:

- Patient management at appropriate levels defined by general policies for primary, secondary and tertiary care.
- Appropriate use of technology
- Efficient use of resources
- Demonstrated improvement of results
- Independent assessment of good organisation and performance eg by external accreditation of institutions and practitioners

If the values of the people of Macedonia were defined and agreed, then there would be a robust basis for defining priorities for reform, and for selecting (from among the wide variety of approaches which have been adopted in other countries) the most appropriate combination of technologies for improvement.

5.4 Which organisations are involved?

In the absence of a national plan, current strategy is in effect driven by the availability of international funding. Key stakeholders have had little or no input to the specifications, scheduling or funding of the health reform project.

All legitimate stakeholders and competent representative organisations should clarify their own expectations (of themselves and of the health care system) and be involved in mapping those expectations, defining current capacities and identifying opportunities and priorities.

Strategic Joint Working Group

This considerable task should be driven by a national working party (“Joint Working Group”) which is realistically funded for at least three years and which represents a balance of stakeholders. These might include consumers, legal, ministry, health insurance, clinical professions, education and training, public health and managers.

Implementation task force

When the strategic framework is clear and agreed, an implementation group should be defined and authorised to design and oversee a plan of action. practical steps to. Some of these are already underway or proposed in Macedonia

5.5 What actions are required to achieve these objectives?

Strategic Joint Working Group

The immediate tasks might include:

- **Analyse current situation** of existing policies, structures, skills and resources for quality improvement: identify issues and opportunities; look at other public and commercial service industries (See WHO profile for self-assessment)
- **Receive, analyse and synthesise relevant reports** drafted by external and internal consultants
- **Specify needs for technical assistance and expertise** (national or abroad): attend workshops, conferences, visits; use libraries, Internet for reference
- **Seek development funding** (internally or overseas) to get a sustainable programme established: budget for transition to operational funding in 3-4 years
- **Draft statement of values and strategic plan:** balance the public, professional and political agenda for quality; make clear that government is committed to transparency, accountability and empowerment of consumers, to leading by example and to keeping quality improvement high on the political agenda; build professional and financial incentives for quality and performance improvement into the health system
- **Inform and consult with the public, professions and paying agencies:** enlist public support for the national strategy, and involvement in defining and assessing standards of service; do not assume that everyone understands what you mean by “quality”; expect managers to have different views from clinicians
- **Identify need for (changes in) legislation:** examine legal opportunities and threats to a quality programme; is new legislation desirable or necessary?

Implementation task force

Some of these tasks are already underway or proposed in Macedonia and should be mapped into the priorities and schedule defined by the national strategy. They might include:

- **Set realistic achievable and sustainable goals**, consistent with time and resources available; choose and prioritise quality values (eg safety, equity, appropriateness), include the cost of time and effort into the basic financing of health care; do not expect quality initiatives to be money-saving in the short term; a quality culture may take years to grow.
- **Identify structures, roles and accountability** for quality: clarify responsibilities and communications for collaboration between government

and statutory activities eg health insurance funds, inspectorates, chambers; define and authorise a competent national agency to advise, co-ordinate and inform; clarify accountability for quality at all levels of the health system; balance top-down control with bottom-up self-governance; define complementary roles of external statutory inspection and voluntary accreditation of individuals and institutions

- **Define and publish the rights of patients:** develop a charter consistent with the social chapter of the European Union and including the issues which commonly appear in national charters in other countries (Access to care, information, empowerment and security)
- **Define and disseminate practical guidance** to clinicians and managers on evidence-based standards of performance and on effective methods for quality improvement. Explore existing international guidance such as:
- **Research and pilot quality projects;** do not expect all imported quality packages to “plug and play”
- **Define a national minimum data set** and criteria for data quality: ensure that agencies share basic aggregated data (eg population-based and patient-based); do not allow non-standard data coding systems. Use comparison among peers benchmarking and feedback for identification of best practice.
- **Develop knowledge, attitudes and skills:** systematically introduce quality into the curriculum and training at undergraduate, specialty and career level; most clinicians have no training in measuring performance; do not assume expert technology to solve behavioural problems
- **Publish an annual account** of the quantified impact and costs of the quality programme

Funding of quality strategy and implementation

Many countries use international loans from national development agencies (eg CIDA, DFiD) to finance the introduction of specific elements of quality improvement. WHO EURO has provided some help with strategy development (Copenhagen Office) and hospital performance (Barcelona Office) through the rolling process of biennial agreements. Most major health care reform projects span 5 years or more; many are funded through World Bank, often including three main elements: development of primary care, reform of health care insurance and development of complementary quality systems.

Even with WB funding, the local Ministry of Health usually pays a share (eg 13%) of the grant money. During this early development phase, plans should be made to ensure that the scheme is fully operational within the timescale available, and to transfer continuing costs from overseas loans or donations to the revenue budget; if this is not done, the country is likely to end up with an unworkable programme, unaffordable staff and a large debt. How these commitments are funded long-term depends on their nature; elements which are clearly retained within the MoH, are directly funded, but “stakeholder” non-governmental agencies are often funded by

HIFs as part of the development and control system to oversee quality, safety and efficiency – and value for public money. For example, HIFs may directly fund a national agency for accreditation of hospitals (service performance, not training), or may do this indirectly by allowing hospitals to pay the Agency for services provided on an item for service basis.

If there is a severe restriction on funding available for development, the best investment may be in defining the strategy for Macedonia (this section) and institutional infrastructure before pursuing further implementation. This would make subsequent bids and proposals more authoritative and acceptable to all parties.

A second priority would be to take stock of the legal responsibilities placed upon national statutory, professional and voluntary agencies by the current Health Care Law and to ensure they have the organisation, resources and skills to fulfil these and to remain within the intent of the law.

5.6 What technical advice, training and goods need to be procured?

External consultancy

- 5.1 Advise and assist JWG in mapping the existing strengths, weaknesses, opportunities and threats to quality and safety of health care in Macedonia
- 5.2 Assist the JWG in applying and interpreting the WHO self-assessment programme for national strategy
- 5.3 Assist the JWG in the structure and content of a draft national strategy.
- 5.4 Assist the JWG to present the draft strategy for consultation and to revise it in response to that consultation
- 5.5 Assist the JWG in developing an action plan and schedule for implementation.

Internal consultancy

- 5.1 An experienced and competent manager should be designated to detail the terms of reference, job descriptions, contracts and operating procedures of the JWG
- 5.2 Members of the JWG should be contracted by the MoH for one year, renewable according to fulfilment of responsibilities and conditions previously defined.
- 5.3 The JWG should be supported by a permanent secretariat to include logistics, records, document handling, book-keeping and communications.
- 5.4 A full-time research officer should be appointed for the duration of the JWG

Training

- 5.1 Members of the JWG should be formally briefed as a group on the background to this report, on the political, legal and financial constraints, on their terms of reference and operating procedures, and on the principles of corporate working.

Goods

- 5.1 Office equipment and supplies, including full access to Internet and facilities for downloading, printing and distributing relevant documents (see list of recommended websites provided)
- 5.2 Basic library of hard copy reference material, including subscriptions to 2 or 3 leading international journals on quality and safety (full text on-line may be available to Macedonia free of charge); these should be shared with provisions in section 4 above

Specifications of technical assistance

Principles

The aim is for the external advisers to provide local personnel with the skills, knowledge and technical resources to develop the programme – not to do it themselves. The primary product is the transfer of skills rather than writing documents. Participants should evaluate all training provided.

Scheduling

In general, each advice package could consist of four one-week visits over a period of one year (as in example below):

- Initial assessment, scoping, planning
- Development activity
- Dissemination and consolidation
- Completion and evaluation

Table 1: Schedule for external consultant eg HTA, guidelines

Month	Tasks	Days on-site	Off-site, travel
0	Preparation	0	2
1	Visit 1: Initial assessment of roles, structures and activities Meet key personnel Draft initial recommendations and action plan Provide examples of policies, procedures and products Consultative workshop with stakeholders Agree future programme Provide inception report	5	3
3	Visit 2: Evaluate progress Assist in drafting operating policies, procedures and contracts Assist in developing communications and dissemination strategy Technical workshop for MMA personnel Agree future programme	5	2
6	Visit 3: Evaluate progress Further technical assistance as required Workshop for clinical teachers in four centres	5	2
12	Visit 4: Evaluation of progress, MMA, HIF Advice, teaching, consultation as required Provide final report	5	2
Total		20	11

Some of the activities requiring local personnel (eg working groups) would have a defined life span, but many should be assumed to be permanent and to last at least three years. If these costs are to be funded initially with international aid, there must be explicit plans for how the posts will be evaluated during this time and for assessing the financial implications of transferring them to general revenue, and the functional implications of abolishing them.

Scheduling of activities, especially of external consultants, should be consistent with the logical sequence and interrelationships between specialist themes, and with the capacity of the JWG to receive, analyse and internalise their message.

Skills required of external consultants

The skills and experience required for this highly specialised advice are more likely to be found in individual experts rather than professional consultants. General personal criteria might include:

- Registered medical practitioner with specialist accreditation
- Relevant experience of teaching and research
- Experience of developing and managing similar systems
- Relevant publications in peer reviewed journals or recognised institutions
- Work experience within the EU and/or accession states
- Fluent in English or Macedonian

More specific criteria are offered in the spreadsheet of consultant tasks.

Appendix: Websites related to quality in health care

Membership organisations

Table 2: membership organisations

Title	Website	Founded
European Society for Quality Healthcare	www.esqh.net/	1996
International Society for Quality in Health Care	www.isqua.org.au	1985
International Society of Technology Assessment in Health Care	www.istahc.org/	1985
World Organisation of Family Doctors	www.wonca.org/	1972

Cochrane Collaboration

The Cochrane Collaboration developed in response to a call by the late Archie Cochrane for systematic, up-to-date reviews of all randomised controlled trials relevant to health care. The first centre was set up in 1992 in Oxford, England to prepare and maintain reviews of controlled trials in pregnancy and childbirth; Oxford also produces a regular review *Bandolier* which is widely distributed in the UK and is available online at www.jr2.ox.ac.uk/bandolier. It is now an international organization that aims to help people make well informed decisions about health care by preparing, maintaining and ensuring the accessibility of systematic reviews of the effects of health care interventions.

Table 3: principal Cochrane websites

Australia	http://www.cochrane.org.au
Brazil	http://www.epm.br/cochrane/
Canada	http://hiru.mcmaster.ca/cochrane/default.htm
China	http://www.cd120.com/cochrane
Denmark	http://www.cochrane.dk/
Germany	http://www.cochrane.de
Italy	http://www.areas.it/index.htm
Netherlands	http://www.cochrane.nl
South Africa	http://www.mrc.ac.za/cochrane/cochrane.html
Spain	http://www.cochrane.es/Castellano/

Other centres

Dutch Institute for Health Improvement/CBO, The Netherlands

As a WHO collaborating centre for quality assurance, CBO (www.cbo.nl) has developed links with several other countries, and provides technical assistance and training, particularly in central and eastern Europe (with the European Commission) and in South East Asia (with WHO and World Bank)

Institute for Healthcare Improvement (IHI), USA

The Institute for Health Care Improvement (www.ihl.org) has been set up in the USA since 1991 and has now established with the British Medical Journal a series of international conferences or "Forums".

Quality Assurance Project (QAP), USA

The Quality Assurance Project (www.qaproject.org/) was initiated in 1990 to help lesser-developed countries to institutionalise quality assurance. It works with the University Research Corporation (URC) to provide technical support for quality improvement to service delivery institutions, Ministries of Health, USAID Missions, and field-based cooperating agencies.

International journals

Table 4: some international journals related to quality in general

Title	Affiliation	Since	Publisher	Website
J on Quality Improvement	JCAHO	1974	JCAHO	http://www.jcrinc.com/journal.htm
J of Quality in Clinical Practice	ACHS, AMA	1981	Blackwell	http://www.blackwell-synergy.com/
Int J Technology Assessment in HC	ISTAHC	1984	Cambridge	http://www.journals.cup.org/
Int J HC Quality Assurance		1987	MCB Univ Press	http://www.mcb.co.uk/ijhcqa.htm
Int J Quality in HC (was Quality Assurance in HC)	ISQua	1989	Oxford	http://www3.oup.co.uk/intqhc/
Quality, Safety in HC	IHI	1992	BMJ	http://www.qualityhealthcare.com/

National executive agencies

Table 5: examples of national executive agencies

Country	Founded	Title	Function
Finland	1994	STAKES www.stakes.fi	National care registers, quality indicators, patient satisfaction databases, HTA
France	1997	ANAES (was ANDEM) www.anaes.fr	Accreditation, clinical guidelines, HTA
Netherlands	1979	IHI/CBO http://www.cbo.nl/	National organisation for QA in health care; technical assistance to hospitals, training, research and development, information exchange
UK	1999	Quality Improvement Scotland	Standards, assessment and accreditation of clinical services

Indicators and data systems

Many countries have sought to aggregate routine activity and outcome data as objective measures of quality and performance (Table 6). The aims and priorities of indicator development vary between internal self-assessment and governance, and external evaluation, accreditation and control. Indicators for external comparison and benchmarking between institutions or countries are more feasible and common in countries with well-equipped and established national data systems and are often a by-product of funding systems which pay health care providers according to case-mix.

Table 6: examples of data systems for QHC

Country	Website	Title
Australia	http://hna.ffh.vic.gov.au/ahs/strategy/app4.htm	State of Victoria: hospital indicators
Australia	www.achs.org.au/open/clin_ind_main.htm	ACHS clinical

		indicators
Canada	www.cchsa.ca/perfind/pimenu.htm	Canadian Council on Health Services Accreditation (CCHSA): indicators
Denmark	http://www.sst.dk/	National Board of Health databases for clinical quality, 1995
Europe	http://www.who.dk/hosmgt/20030224_2	WHO, Barcelona: hospital performance measurement 2003
Europe	www.leeds.ac.uk/nuffield/infoservices/ECHHO/home.html	European Clearing House on Health Care Outcomes (ECHHO)
Finland	http://info.stakesfi/nettihilmo	STAKES: National care registers
Sweden	www.sos.se	National Quality Registers
UK	www.doh.gov.uk/nhshlpi.htm	DoH high level indicators 1999
UK	www.doh.gov.uk/indicat.htm	DoH clinical indicators
USA	www.ncqa.org/pages/policy/hedis/hedis.htm	National Committee for Quality Assurance (NCQA) performance
USA	www.ahcpr.gov/qual/conquest/conqfact.htm	Conquest database of individual indicators
USA	www.jcaho.org/trkhco_frm.html	Joint Commission (JCAHO) indicators

Clinical Guideline and health technology assessment centres

Agency for Healthcare Research and Quality (AHRQ), USA

The Agency supports the development of evidence reports through its twelve [Evidence-based Practice Centers](http://www.ahrq.gov/clinic/epc/) (<http://www.ahrq.gov/clinic/epc/>) and the dissemination of guidelines through the Agency's National Guideline Clearinghouse.

The Agency sponsors the CONQUEST database (COMputerized Needs-Oriented QUality Measurement Evaluation SysTem) for collecting and evaluating clinical performance measures. CONQUEST and the User's Guide can be downloaded online at <http://www.ahrq.gov/qual/conquest.htm>.

Canadian Medical Association (CMA) clinical practice guidelines

The CMA website includes a searchable database of some 2000 guidelines which have been produced or endorsed in Canada by a national, provincial or territorial medical or health organization, professional society, government agency or expert panel.

Center for Health Quality, Outcomes and Economic Research, USA

The Center for Health Quality, Outcomes and Economic Research (CHQOER) is one of 11 Centers of Excellence within the Veterans Administration Health Services Research and Development Program in the USA. The Center's research concentrates on health quality assessment, outcomes measurement, and health economics.

Scottish Intercollegiate Guidelines Network SIGN

The Scottish Intercollegiate Guidelines Network (SIGN) was formed in 1993 to improve clinical care by developing, publishing and disseminating guidelines for good clinical

practice. SIGN selects guideline topics on the basis of the burden of disease, evidence of variation in practice and the potential to improve outcome. Over 40 guidelines have been published or are in development

Table 7: examples of reference centres for clinical guidelines and HTA

Country	Title	Website
Austria	ITA (HTA Unit of the Institute of Technology Assessment- Austrian Academy of Science)	www.oeaw.ac.at/einheiten/ita
Canada	CCOHTA (Canadian Coordinating Office for Health Technology Assessment)	www.ccohta.ca
Canada	Canadian Medical Association	www.cma.ca/cpgs/index.asp
Denmark	DIHTA (Danish Institute for Health Technology Assessment)	www.dsi.dk/
Finland	FINOHTA (Finnish Office for Health Care Technology Assessment)	www.stakes.fi/finohta
France	ANAES (L'Agence Nationale d'Accréditation et d'Evaluation en Santé)	www.anaes.fr
Germany	German Scientific Working Group of Technology Assessment in Health Care	www.epi.mh-hannover.de/
Netherlands	TNO Prevention and Health	www.tno.nl/instit/pg/index.html
New Zealand	NZHTA (New Zealand Health Technology Assessment)	http://nzhta.chmeds.ac.nz
Norway	SMM (The Norwegian Centre for Health Technology Assessment)	www.sintef.no/smm
Sweden	SBU (Swedish Council on Technology Assessment in Health Care)	www.sbu.se/sbu-site/index
Switzerland	Swiss Science Council/Technology Assessment	www.ta-swiss.ch
USA	National Guideline Clearing House	www.guidelines.gov
USA	AHRQ (was AHCPH) includes CONQUEST indicators database	www.ahrq.gov
USA	Center for Health Quality, Outcomes and Economic Research (CHQOER) Veterans' Administration (VA)	http://dcc2.bumc.bu.edu/
USA	Institute of Medicine Publications available to read and download eg quality of long-term care, behavioural health, strategy	www.nap.edu/books

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