UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES
EUROPEAN UNION OF MEDICAL SPECIALISTS

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UEMS RESPONSE

to the

CONSULTATION REGARDING COMMUNITY ACTION ON HEALTH SERVICES

Preamble – The European Union of Medical Specialists

The UEMS is the European-level body that represents doctors who have higher specialist qualifications and work as specialists throughout Europe. It has more than 800 active representatives from National Medical Associations from 34 countries (26 EU member states, and 8 EEA and wider Europe), and 37 Specialist Sections and Boards. The UEMS is the oldest European medico-political organisation – it celebrates its 50th anniversary next year – and has offices based in Brussels.

The UEMS has policy on many aspects of the quality, safety and effectiveness of specialist medical care, including: the setting and assessment of standards of medical training, the mutual recognition of specialist qualifications, continuing professional development for specialists, and systems for ensuring the quality of medical care. In accordance with these policies, the UEMS has encouraged Commission officials and Members of the European Parliament to ensure that the highest attainable quality of specialist medical services is provided for patients throughout Europe.

The UEMS therefore welcomes the Commission's public consultation and its invitation to all interested parties to contribute to this initiative. The UEMS trusts that a similarly inclusive process will be followed in the preparation of legislation, and in the continuing development of this initiative.

Introduction

The vast majority of patients want access to safe and good quality medical care close to where they live and work. Hence, as a first principle, any Commission initiative should be used to improve general standards of provision to support this as, in addition to addressing the reasonable expectations of European citizens, this would minimise the need for mobility.

However, when these reasonable expectations – as regards the quality, safety, speed of access, and availability of healthcare – are not readily met, it is clear that patients wish to have access to healthcare further from home, and successive European Court of Justice (ECJ) rulings have confirmed and defined that right to mobility. In certain circumstances, mobility may be clinically helpful, such as in the case of rare diseases, complex or specialised procedures, lack of provision of certain services, or when patients may have to wait an unacceptable time for treatment.

The UEMS is also keen for the Commission to more fully address issues related to the mobility of doctors. Current legislation providing for this right is based on criteria that have little relevance to modern standards of medical practice. For reasons of ensuring the safety of patient care, there is a need to update specific European legislation to provide for the appropriate regulation of doctors who do migrate.

The potential of this initiative for improving equality of access to healthcare services, and for ensuring similar standards of care throughout Europe must also be recognised. While recognising the importance of subsidiarity regarding healthcare systems, the UEMS believes that, in order to enhance the quality of healthcare provided, there is much potential for the advantageous harmonisation of standards.

There is also the potential for economic factors, such as scarcity of resources, to influence decisions in this area. While it is acknowledged that finances are not unlimited, the primary motivation for legislation in this area must be the quality of care for patients. It is patients who have driven legal changes thus far, and it will be patients who will continue to do so if they feel that their reasonable expectations regarding their healthcare needs are not being provided for.

Question 1: What is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

In general, when considered against the total number of requests for healthcare, the number of cross-border consultations is small. However, due to their nature, they may have a disproportionate impact, with an increased requirement for interpretation, patient support and management facilities, and appeals to the Courts when refused.

In some geographical areas, there are longstanding and/or well-established arrangements where cross-border healthcare has been incorporated into the health economies. In others, the pattern of use of healthcare by large tourist populations – while less predictable – can be planned for. A recent phenomenon, related to the expansion of the European Union, has been the mobility of fee-paying patients who seek healthcare in countries where this can be provided at a lower cost.

To date, the less predictable effects of unplanned – and by its nature, unplanned-for – patient mobility have had relatively small effects in terms of direct impact, though clearly the effect of ECJ rulings in this area has been significant. However, it is clear that populations, and individual patients, have increasing expectations as regards the safety, quality and accessibility of their healthcare.

When linked with the well-described pressures on all healthcare systems – of demographic changes, increasing complexity, availability and cost of therapies, and budgetary constraints – the potential for patient mobility to destabilise healthcare economies may be significant. This is most likely to be the case in those countries that spend less per capita on healthcare, as they lose the investment in their own national healthcare economy – through the loss of costs reimbursed – when they "lose" patients who migrate for better, or more complex services.

The UEMS therefore advocates greater investment in healthcare – specifically directed at improving the safety, quality and accessibility of patient care – in order to minimise the need for patients to have to migrate. The UEMS also calls on the Commission to provide the necessary legislative framework to ensure the development and monitoring of the standards required to support improvements in the safety, quality and accessibility of patient care.

Question 2: What specific legal clarification and what practical information is required by whom (eg; authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

Information

High-quality healthcare is highly dependent on the reliable and effective communication of complex information between many individuals. This is as true for the patient who expects a clear explanation of their diagnosis and therapeutic options, as for the doctor(s) who make the diagnosis and provide treatment, and the wider medical teams that provide continuing care. These complexities are multiplied when different languages, cultural traditions and geographical separation play a part, such as in cross-border healthcare.

The UEMS therefore advocates, as an absolute pre-requisite standard – hence justifying its inclusion in legislation – the provision of comprehensive and comprehensible information for the patient, from the time that he/she considers migrating for healthcare, to the provision of treatment and how this will be paid for, to the means of redress should problems occur. This should be the case for all patients, but must be so for patients who migrate.

For the doctor(s) who care for these patients, accurate information on current and previous healthcare problems is essential to their ability to make an accurate diagnosis and to provide safe treatment. It is also essential to ensuring that appropriate continuing care is provided when the patient returns to their home country. Accordingly, the UEMS supports the development of electronic "Health Cards", while noting that it is essential that the confidentiality issues related to these are fully addressed.

The UEMS considers that currently in Europe information systems are insufficiently developed to provide the information that would be required by patients, and their doctors, to make meaningful assessments and comparisons of the quality and safety of healthcare provided in different centres. It is essential therefore that common data-sets are agreed, and that resources are provided for the information technology required to

support such an initiative. The UEMS believes that the Commission could play a major part in facilitating such a development.

There are certain forms of medical intervention where medical specimens or data cross borders for analysis or diagnosis – as is the case in Teleradiology, Telemedicine, or remote diagnosis. The UEMS considers it essential that the practitioners involved in providing these forms of care are appropriately regulated and are able to communicate effectively with their colleagues in the originating country.

In the interests of the safe care of patients, appropriate standards must be set and monitored, in order to ensure that the language and communication skills, availability for discussion, and accountability of practitioners is as effective as for doctors working in the originating country. This is particularly important as there is the potential for these forms of remote analysis and diagnosis to be "outsourced" to countries that are not EU/EEA member states, and where at present it is not possible to guarantee that even the current European standards will be achieved.

Legal clarification

The UEMS recognises the importance for patients – both in personal terms, and as part of the quality of their care – of rapid access to medical expertise, lack of delay in diagnosis, and timely treatment. The concept of "undue delay" has been referred to by the ECJ, but this has not been elaborated. The UEMS believes that this concept is highly patient-specific – individual circumstances have a major impact on what may be accepted as a "reasonable delay" – and will require the expertise and advice of the doctor(s) directly involved in the care of that patient.

Further, the UEMS considers that it would not be helpful to define this concept in wider terms, as the setting of a "maximum" permitted delay (or disease-specific ones) may act as a disincentive to those healthcare systems where waiting times are minimal. Instead, the UEMS would support the wider availability (and ready accessibility) of data of current waiting times in European countries, thus permitting European citizens to advocate for better care.

Question 3: Which issues (eg: clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of cross-border healthcare described in section 2.2 above?

As a basic principle, there must be co-operation between doctors and healthcare managers in the originating country and the receiving country. This can certainly be achieved for planned mobility – particularly when formal agreements have been made to achieve this – but this should also occur when it is recognised that significant numbers of patients are choosing to be cared for in another EU member state. This principle is also applicable, though in a post-hoc manner, for those patients who have had emergency treatment while abroad.

This co-operation should cover all relevant medical aspects of patient care, including – but not comprehensively listing: the referral of the patient with details of diagnosis, investigations and treatment plan (originating country); the nature and extent of clinical

intervention (receiving country); hand-over arrangements and plan for continuing care (receiving country); agreement on how best to deal with potential complications (both countries). This co-operation is essential as there are differences between the healthcare systems in Europe, and differences in therapeutic decision-making.

There must also be co-operation at a managerial level, in order to ensure that the commissioning of planned care occurs in an agreed manner, thus ensuring that financial arrangements and accountability are defined. While this should never become a barrier to mobility, this co-operation must be a shared responsibility, with agreement ideally based on the ability of the receiving country to provide healthcare (without this being to the detriment of its own citizens), and the originating country being able to pay for this.

While supporting the principle that the level of remuneration, or contracting, should be at the level applicable in the patient's home country, the UEMS is concerned that this could act as a barrier to mobility for patients who are citizens of less-wealthy EU member states, or where the true cost of medical interventions is not known. This would be particularly disadvantageous for patients needing super-specialist care.

Question 4: Who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

As far as is possible, such matters must have been addressed before patients access cross-border healthcare. While most patients will benefit from uncomplicated healthcare, it is well recognised that problems can occur, even when appropriate precautionary measures have been taken to prevent these. The UEMS believes that it is essential that appropriate planning is made to cover such circumstances. This will ensure that patients (and/or their relatives) do not suffer twice: once, from the healthcare-related problem, and a second time, from an inability of the system to deal with the consequences of this.

The UEMS believes strongly that "prevention is better than cure", hence that the priority should be on ensuring the highest attainable levels of healthcare quality and safety for all patients. The UEMS further believes that the standards required to support this are equally applicable in the context of cross-border healthcare. Accordingly, the UEMS refers the reader to two of its policy papers – both of which are attached – "Promoting Good Medical Care" (on quality assurance) and "Ensuring the Quality of Medical Care" (on medical regulation), that address issues related to the quality and safety of medical care, and the responsibilities of doctors who provide that care.

The UEMS recognises that different arrangements may need to be made for situations when problems have arisen. In some countries, and some well-established cross-border agreements, a "no fault compensation system" applies. While this may be the preferred model, the UEMS recognises that other countries are not willing to introduce such a system. It would be helpful if the Commission could determine whether there would be support for a pan-European "no fault compensation system" to deal with such situations.

In the absence of such a system, the UEMS believes that, as a basic principle, in the situation of planned and commissioned healthcare, it is the responsibility of the originating country to ensure that the medical and financial consequences of healthcare

problems are agreed, though the cost of these may be shared. It is evident that the receiving country has some responsibility; more clearly so when the problems occur in the cases of emergency care, or when an individual patient is treated abroad – though in the latter case, the patient must assume some responsibility for their decision(s).

Part of the redress system must be the means of providing continuing healthcare for the patient. The UEMS believes that, other than in the case of super-specialised care, this would best be achieved within the patient's home country, and suitable medical hand-over, and financial arrangements, must be made in order to provide for this.

Question 5: What action is needed to ensure that treating patients from other Member States is compatible with the provision of balanced medical and hospital services accessible to all (for example, by means of financial compensation for their treatment in 'receiving' countries)?

The UEMS believes that, through highlighting the reasons for their seeking cross-border healthcare – including lack of access to certain healthcare services, unacceptably long waiting times, inadequate quality or safety of locally-available care – patient mobility can act as a potent stimulus for the general improvement in the provision and quality of healthcare across Europe.

However, the UEMS believes that it is essential – in order to fulfil both the preference of the vast majority of patients of being able to access care close to their home, and also in the interests of encouraging greater equality of healthcare across Europe – that originating country healthcare systems are not damaged by the effect of patients seeking cross-border care (by loss of potential investment through funds flowing out of the country), but also that the receiving country is not adversely affected (by the full cost of treatment not being reimbursed).

The potential for both of these scenarios will continue to exist as long as there are significant differences in wealth between European countries – and even within regions in the same country. As general principles, the UEMS therefore advocates that the re-imbursed amount (or contracted fee) should be the cost of that form of healthcare in the originating country, and that management systems and information technology must be developed in order to determine this. Where this would prevent a patient from accessing clinically necessary care (such as in the case of a patient living in a less wealthy country who needs super-specialised care) a pan-European fund could be established to cover the costs of treating the small number of such patients.

The UEMS believes strongly that, where adequate facilities exist in their home country, patients must retain the right to decline to be treated in another country. This will ensure that patients cannot be required to have cross-border care simply because that would be cheaper than in their home country.

Question 6: Are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

It is a fundamental ethical principle that the primary duty of a doctor is to their patients. Indeed, this is the major reason why the UEMS considers healthcare to be different from other services. Hence, in order to ensure the quality and safety of care that doctors provide for patients, the opportunity should be taken to extend and strengthen the legislation that provides the basis for the free mobility of doctors within the EU.

Accordingly, the reader again (see answer to question 4) is referred to two of the UEMS's policy papers "Promoting Good Medical Care" (on quality assurance) and "Ensuring the Quality of Medical Care" (on medical regulation), that address issues related to the quality and safety of medical care, and the responsibilities of doctors who provide that care. The UEMS also draws attention to its work on ensuring the quality of postgraduate specialist medical training (through setting standards for training, and assessment, and through its visitation programmes for training centres).

The UEMS is wholly committed to the principle of free mobility of professionals – and is able to provide ample evidence of having supported the migration of doctors within the EU. However, the UEMS has lobbied consistently for the revision of the Directives (93/16/EC, 2001/19/EC, and currently 2005/36/EC) that provide for the mutual recognition of medical qualifications. This is because the UEMS has long held that – in order more fully to be able to ensure the quality and safety of patient care, and to reflect the complexity of modern medical care – mutual recognition must be based on the demonstrated competence of doctors, rather than on merely the minimum duration of their training.

Legislation of this nature would also have the potential to provide the basis for greater harmonisation of the training of doctors, through defining desired competencies. This would enable patients, other doctors, and potential employers to have greater confidence in the system meant to assure the qualifications and competence of a doctor who has migrated. It would also provide for greater recognition of educational achievements of students and doctors who migrate during, rather than at the completion of their studies.

With the safety of patient care again emphasised as paramount, and in accordance with its policy paper "Ensuring the Quality of Medical Care", the UEMS also seeks the greater sharing of regulatory information on doctors who migrate. This is consistent with the 2005 Edinburgh Declaration on "Healthcare Professionals crossing borders". The UEMS would also welcome confirmation of the power of regulatory bodies to assure themselves, prior to granting them a licence to practise, of the ability of a doctor to communicate effectively in the language(s) of their patients and colleagues.

The UEMS draws attention to the considerable efforts of the medical profession – at national and European levels – to address all aspects of patient safety and the quality of healthcare. The UEMS calls on the Commission to support these efforts, from seeking the advice of, and working with the medical profession, to framing legislation to deal with the concerns noted above. There is ample evidence of good practice within the medical profession in key areas such as lifelong learning, standard setting and monitoring, and medical regulation; assistance is required to ensure that these forms of best practice become more widely established.

Question 7: Are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States – such as healthcare providers and social security institutions – suggest in order to facilitate cross-border healthcare?

The term "Health Tourism" has been used disparagingly to describe the situation when patients, without prior authorisation, seek healthcare in another country , the inference being that the local healthcare system is being used inappropriately. The UEMS considers that – as the primary responsibility of a doctor is to their patients – where clinical circumstances require, they must provide appropriate healthcare.

However, the UEMS believes that greater clarity regarding the definitions – and effect in terms of reimbursement of costs – of the terms, "emergency", "urgent" and "elective", would be helpful in addressing this issue. The UEMS also believes that this would provide greater clarity regarding the responsibilities of originating and receiving countries, particularly as regards the right to access healthcare services of both temporary and long-term residents (EU citizens but nationals of another EU member-state). This is a particular problem for those countries in which citizens from other EU states choose to retire and, due to the link between older age with increasing need for healthcare services, affect the demographic profile of the population.

As a further means of ensuring that cross-border patient mobility is supported, and is seen in positive terms, the UEMS calls for greater encouragement of the use of the "European Health Insurance Card" (EHIC), and calls for the development of a patient-held health "smart-card" (that potentially could be combined with the EHIC) that would provide, in a standard format, essential medical data, and confirmation of eligibility to access healthcare services.

Question 8: In what ways should European action help support the health systems of the Member States and the different actors within them? Are there areas not identified above?

As has been indicated above, the UEMS believes that this is an opportunity to:

a) set standards that will help to improve the quality of healthcare in Europe;
b) stimulate greater investment in healthcare, in order to ensure that all patients, irrespective of their country of EU citizenship, are more able to access, in a timely manner, effective, high-quality healthcare close to their home;
c) facilitate the development of healthcare information systems that will be of benefit to patients, their doctor(s), health service managers, and commissioners of healthcare services;
d) encourage greater mobility of healthcare professionals, through providing greater regulatory certainty regarding the competence of those who do migrate.

The UEMS calls on the Commission to ensure the development of super-specialised referral centres for the treatment of patients suffering from very rare or complex medical conditions, and to provide – through a fund established on the basis of the principle of solidarity, hence irrespective of the wealth of the patient's originating country healthcare system – for the financial means of providing for the treatment of such patients. Linked

to these referral centres, the UEMS calls for international training programmes to be developed; these would ensure that selected doctors from around Europe (and potentially world-wide) are able to benefit from this specialist expertise.

Question 9: What tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and what through non-legislative means?

The UEMS is concerned that legislation in the area of healthcare has become progressively diffused through different legal instruments, and that the current structure of the Commission means that the healthcare sector is dealt with by different Directorates-General.

The UEMS would welcome an initiative that develops a single, sector-specific Directive that addresses all relevant aspects of the healthcare sector. The UEMS also calls for DG Sanco to be the "lead" Directorate-General, particularly given the emphasis of likely future legislation will be on patients' concerns, and on the mobility of (in this case) healthcare professionals.

While acknowledging the extent of subsidiarity in the area of healthcare, the UEMS calls on the Commission to ensure that greater resources are provided to support the development of initiatives focused on patient safety and the quality of healthcare. This could be overseen by an independent body – comprised of a range of interested parties – that could also serve as a readily accessible means of providing comment on Commission activity in the area of healthcare.

Other issues

As will be evident from the responses to these questions, the UEMS is wholly willing to assist in the development of improved healthcare services throughout Europe, and trusts that, through solidarity between European countries, all patients will be able to access, in a timely manner, effective, high-quality healthcare services, either close to their home or, should they so choose, through cross-border mobility.

The UEMS will also assist in the development – through appropriate standards – of the educational and regulatory structure, necessary in a modern healthcare system, to quality assure the training of doctors and of the centres within which they work, and the basis on which they migrate within Europe.

The UEMS therefore requests that the Commission engages fully with representatives of the medical profession in developing a healthcare system that meets the needs of our patients, the citizens of Europe.

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UEMS 2006 / 18 FINAL

BUDAPEST DECLARATION
on
ENSURING THE QUALITY OF MEDICAL CARE

SUMMARY

This paper sets out the policy of the Union Européenne des Médecins Spécialistes/ European Union of Medical Specialists (UEMS) on medical regulation. This is defined here as the means by which the safety and quality of care provided for patients by doctors is ensured. When implemented, medical regulation should be proportionate as is appropriate for highly-qualified doctors. Accordingly, the UEMS calls on all groups involved in the safety and quality of healthcare to respect the primacy of the medical profession in regulating medical care.

In modern society professions provide an organised and accountable means of delivering key services. Regulation contributes to the relationship between citizens and the state by ensuring that practitioners, who are entrusted with a duty of care by society – and, in the case of doctors, by individual patients – fulfil that trust.

Models of medical regulation can be classified by structure, or by regulatory function. According to structure, five concentric regulatory circles can be identified: personal; peer and team-based; workplace; national, and; international. Classification according to function shows that medical regulation is achieved through: the setting of the standards and ethics for medical practice; the basic, specialist and continuing education of doctors; the accreditation and registration of practitioners, and; intervention when practice standards are not met.

Fundamental features of effective modern regulatory systems are that practitioners are accountable according to defined standards, and that members of the regulated profession, and of society, are involved in the regulatory process. These ensure that the system is appropriately informed of current practice and expectations, and that the members of the profession and of society respect the regulatory structure as fair to both.

The UEMS recognises that any regulatory system must reflect the context of medical practice, the expectations of society, and the resources available for medical care. Accordingly this policy acknowledges the differences in healthcare systems in Europe, and the need for subsidiarity. It is the aim of this paper, through the identification of common principles, to provide recommendations, applicable throughout Europe, that will support the development of fair and better medical regulation.

The UEMS encourages all groups interested in the safety and quality of medical care to support these recommendations. This paper is addressed to all who have an interest in ensuring the quality of healthcare: patients, doctors, medical associations, health service employers and hospitals, fund-holders, healthcare insurers, national and European legislators, and regulatory authorities.

The following list of key points drawn from the text expands the summary. It also acts as an index to specific paragraphs of the paper.

KEY POINTS

A) Medical regulation – the means by which the safety and quality of care provided for patients by doctors is ensured – requires the setting, assuring and controlling of the standards of care (4)

B) The structures of a modern medical regulatory system comprise five tiers: personal; peer and team-based; workplace; national, and; international regulation (6)

C) The functions of a modern medical regulatory system involve: standards & ethics; education; certification & registration, and; ensuring fitness to practise (7)

D) Combining these structural and functional regulatory elements allows for the development of an effective model, applicable in all European countries (6-8)

E) It is the responsibility of every doctor to practise medicine according to the ethos of their profession, and in accordance with regulatory requirements (11-17)

F) All members of the healthcare team share responsibility for ensuring that safe, good-quality care is provided by that team, and by each of its members (18-23)

G) In addition to their ethical responsibilities to their patients, employed doctors also have regulatory responsibilities to their employer (24-29)

H) Regulatory bodies must develop standards that define what is expected of practising doctors: how they should practise, and how they must not (30-31)

I) The continuum of medical education provides the means, at all stages of a doctor's career, of imparting high standards of medical practice (13, 25, 33)

J) A reliable register must be held of doctors who are permitted to practise (34)

K) When significant problems occur with a doctor's performance, regulatory mechanisms must be able to intervene appropriately and reliably (36-37)

L) The UEMS recommends that greater efforts be made to ensure more effective international medical regulation (38-41)

M) In a modern context, medical regulation requires the co-operative working of representatives of society, and of the medical profession (42-44)

The UEMS considers regulation to be an essential component of an agenda focused on high standards of medical practice. Its policy papers that address the other parts of that agenda are: "The Basel Declaration" (2001) – that deals with continuing professional development as a form of quality improvement, and; "Promoting Good Medical Care" (2004) – on quality assurance.

SECTION 1: INTRODUCTION

The role of the UEMS

1) Established in 1958, the Union Européenne des Médecins Spécialistes/ European Union of Medical Specialists (UEMS) is the representative organisation for specialist doctors from the national associations of EU/EEA countries. Its activities cover all issues associated with specialised medical practice, and are jointly carried out by doctors serving as national representatives on its Council and on its more than thirty Specialist Sections and Boards.

2) The UEMS recognises and values differences in the structure, funding and priorities of healthcare systems in Europe, but believes that the principles required for the regulation of medical practice – which are based on shared ethics – are applicable in all countries. The UEMS accepts that it has a responsibility to encourage good regulation of medicine, and to develop and share policy that will support this throughout Europe.

The quality agenda

3) The UEMS considers regulation to be one part of the quality agenda. In the case of healthcare, while these parts are mutually supportive, they have specific applicability and must be addressed separately. Accordingly, the UEMS has published a policy paper on Continuing Professional Development as quality improvement: "The Basel Declaration" (2001), and one on quality assurance: "Promoting Good Medical Care" (2004). This policy paper completes the trilogy.

The purpose and scope of regulation

4) Medical regulation is defined here as the means by which the safety and quality of care provided for patients by doctors is ensured. Regulation is essential therefore to maintaining public trust in the medical profession, and to confirming that it can be entrusted with the setting, assuring and controlling of high standards of medical care.

5) From a patient's perspective, the system of medical regulation must ensure that their doctor is appropriately qualified, will practise in accordance with established ethical and professional standards, and will provide care that is as safe and effective as is possible. Patients rely on the system of medical regulation to provide the foundations for the building of trust that they have in their doctor(s).

6) The structural elements of medical regulation can be described as comprising five concentric regulatory tiers: a) personal – in which the doctor's professional ethos, shaped by their education, determines their standards of practice; b) peer and team-based – where all team members are responsible for contributing to, and assuring, the safety and quality of care provided; c) workplace – in which the work environment, or employer, is required to achieve defined standards, and ensure that all practitioners fulfil these; d) national – where profession-wide standards for practice are set, assured, and controlled, and; e) international – where harmonisation of these standards may be achieved, and sharing of regulatory information may be required.

7) There are four functional elements of medical regulation: a) agreeing and defining the basis for practice – standards and ethics; b) providing for these to be achieved – through basic, specialist and continuing education; c) recognising who is, hence also who is not, a qualified, and a specialist doctor – accreditation and registration, and; d) when defined practice standards have not been met – fitness to practise intervention.

8) This paper will demonstrate that it is through the combination of these two aspects, the functional and the structural, that an effective modern regulatory model, that will be applicable in all European countries, can be developed.

Interest groups

9) In its generic form, regulation should be as a mutually agreed balance between the interests of three groups: patients, the profession, and society. In the context of healthcare, and particularly when considering the variations in health service systems in Europe, the UEMS recognises that other groups – such as employers, hospitals, and providers of funding for healthcare – also will have an interest in this area. The UEMS invites all interest groups to contribute to a necessary debate on the regulation of the medical profession, and provides this policy paper as the focus for that.

Accountability

10) The UEMS recognises that medical regulation is the key means by which doctors can be held accountable for the standard of their individual practice. It is also the means by which the profession as a whole can demonstrate its willingness to set, and maintain, the standards of medical care expected by modern society. The UEMS calls on all interest groups to support the profession in fulfilling its responsibilities in this area.

SECTION 2: PERSONAL REGULATION

Standards and Ethics

11) It is the responsibility of every doctor to practise medicine according to the ethical standards of their profession. These are learned through medical education and by observing the models provided by their senior colleagues, and are developed further through clinical experience. This ethos should express itself in all aspects of a doctor's practice, such as their commitment to their patients, how they provide safe, good quality care, how they maintain and develop their skills, and their behaviour with colleagues.

12) In accordance with the ethos of the medical profession, every doctor should reflect on their practice, and compare this with the standards set by professional bodies. They also have a responsibility to address any area where they do not achieve these standards. Personal regulation can therefore be seen as the most important regulatory component, through which every doctor provides their own "professional conscience".

Education

13) From the time they enter medical school until the day they retire doctors are engaged in a continuum of education – basic (undergraduate), specialist (postgraduate),

and continuing (post-specialisation). Every doctor has a responsibility to ensure that they are appropriately trained for the care they provide and the procedures they perform, and that they incorporate into their practice effective and proven new developments in their field.

14) While only some doctors choose to take an active role in teaching, it is essential that those who do recognise their responsibility to the next generation of doctors, and patients, and perform this task with diligence. All doctors must recognise that they act as models to students, and to doctors in training, and must set a good example, through their behaviour and clinical performance.

Certification and Registration

15) For patients, confirmation that a doctor is registered with the medical regulatory body is a key part of their implicit trust in the healthcare system. It is the responsibility of every doctor to ensure that they fulfil the requirements for their qualification as a doctor and, later, as a specialist. For as long as they practise, doctors must also ensure that they fulfil the requirements set to maintain their registration.

Ensuring fitness to practise

16) It is an ethical responsibility of every doctor to ensure that they are capable of practising safely; for those who are employed, it is also a contractual responsibility. Doctors therefore must be suitably trained and qualified for the work they perform, up-to-date with current practice, and adhere to relevant standards.

17) Doctors should also be aware of the main causes of potential impairment to their fitness to practise. These can be classified as problems affecting their health, performance, or conduct. It is the responsibility of every doctor – to their patients, themselves, and their profession – to ensure that they seek advice and assistance, should they become concerned that their practise may be impaired.

SECTION 3: PEER AND TEAM-BASED REGULATION

Standards and Ethics

18) Modern medical care relies on doctors from different specialities, and practitioners from other healthcare professions, working together to ensure that each patient's healthcare needs are comprehensively met. Every member of the healthcare team should follow the ethical codes applicable to their profession, but also those relevant to joint working: including good communication, appropriate delegation, defined responsibilities, and maintaining patient confidentiality.

19) Doctors working in teams have a further responsibility – to patients, and to the medical profession as a whole – to ensure that the standards and ethics expected of a qualified medical practitioner are achieved, by themselves, and by their colleagues. It is particularly important that the medical members of healthcare teams develop and support a culture that emphasises the quality and safety of care for patients, and encourage all team-members to work to that goal.

Education

20) Comprehensive care for patients requires a combination of healthcare techniques, performed by a range of practitioners. It is essential that all have an understanding of the contribution that they, and the other members of the team make to a safe outcome for the patient. This can be achieved by training that emphasises the contribution made by all healthcare professionals, but also by teams learning together, or conducting joint audit of their practise.

Certification and Registration

21) In the same way that, for patients, registration confirms the qualification of practitioners, it is essential that all team members know that they can rely on their colleagues to have fulfilled the requirements for skilled and safe practice.

Ensuring fitness to practise

22) It is the responsibility of all team members, should they have concerns regarding the health, performance, or conduct of any colleague, to ensure that these are appropriately addressed. In doing so, they must be mindful of the key ethical principle of protecting patients from potential harm.

23) The medical members of the team have an additional responsibility to identify, and deal with such problems at as early a stage as is possible. This may be through discussion with the colleague themselves, or through being raised with a more senior member of the team. Intervention by peers is an effective early means of encouraging doctors who are developing dysfunction to seek advice and assistance.

SECTION 4: WORKPLACE REGULATION

Standards and Ethics

24) It is part of the ethical responsibility of every doctor to ensure that their practice environment fulfils the healthcare needs of their patients. As highly qualified professionals, doctors are entrusted with clinical autonomy. With this comes the responsibility, in all healthcare systems, of practising with their patients' interests being their primary concern. This includes drawing attention to situations when workplace standards are not being met.

Education

25) It is essential to maintaining existing high standards, and to achieving new ones, that sufficient time and resources are allocated to provide for the education of doctors. In an employed system, this would include funded leave for study and, in a "fee-paying" one, the allocation of part of the practice budget for this purpose. It is in the interests of patients, and their doctor(s), that education is recognised as an investment in safe, high quality care.

Certification and Registration

26) Employers have a responsibility to ensure that the doctors they employ are appropriately qualified and registered. Whether they work in an employed, insurance-based, or “fee-paying” system, doctors should always comply with this requirement.

Ensuring fitness to practise

27) Employers, insurers or organised healthcare purchasers may have systems for ensuring that doctors practise safely, and procedures for dealing with adverse events when they do not. The UEMS insists that such procedures must be fair, based on evidence, and proportionate to the situation.

28) It is essential that the regulatory system is capable of discriminating between systems-caused adverse events, and harm attributable to a practitioner’s negligence or impaired function. Learning from adverse events can reduce the likelihood of their repetition, hence the importance of establishing anonymised, non-punitive reporting mechanisms in all European countries.

29) In accordance with European and national legislation, doctors have the right to have their health and safety suitably protected while at work. Employers, insurers and practice managers should ensure that these rights are met.

SECTION 5: NATIONAL REGULATION

Standards and Ethics

30) In European countries national regulatory bodies have the major responsibility for setting the standards and ethics required of practising doctors. In so doing, they are likely to reflect the context of healthcare in their country, which is a balance between the needs of patients, profession and society. In general there has been a shift, expressed in “professional codes”, to an ethic based on the partnership of patient and doctor.

31) While models do vary, the UEMS recommends the combination of a positive statement (of equivalent status to guidelines) of what it is expected a good doctor should do, and the definition (equivalent to recommendations) of what a doctor should not do in their professional practice.

Education

32) While, in most European countries, medical education usually is delivered at a local or regional level, the setting, monitoring and safeguarding of standards usually is performed by national regulatory bodies. This allows for healthy diversity in delivery, whilst ensuring the maintenance of (near) equality of outcomes.

33) Regulatory bodies must have the authority to intervene when educational standards are not being achieved. There must therefore be a system for the visitation and monitoring of medical schools and accredited teaching hospitals.

Certification and Registration

34) It is essential for patients, practitioners, colleagues, insurers, employers and the regulatory bodies themselves, that a reliable, readily-accessible and easily-understood register is kept of doctors who are permitted to practise. In many European countries, differentiation is made – sometimes with separate registers – of those doctors who hold a basic medical degree, and those who also have a specialist qualification.

35) In general, entry on such a medical or specialist register is based on the achievement of academic qualifications, and the continued fulfilment of good practice standards. In some countries practitioners are required, or will be, by a variety of means, to confirm their continuing fitness to practise.

Ensuring fitness to practise

36) In the absence of any other mechanism, regulatory systems are dependent on complaints or concerns being brought to their attention in order to consider whether a doctor's fitness to practise may be impaired. The number of cases that require investigation and adjudication is a small proportion of the practising population of doctors but, because of the nature of these, media attention may be disproportionately large. There is considerable variation in European countries as to how complaints are dealt with. While the investigation is always conducted by an organisation that includes medical members or advisers, should a case be brought this may be heard by a medical regulatory body, a government body, a special tribunal, or even by a civil court.

37) In order to maintain public confidence, and the support of the medical profession, a robust and fair system must be maintained for dealing with cases of potential impairment of fitness to practise. While terminology may vary, fitness to practise can be impaired by problems of health, or performance, or conduct. There is also variation between European countries as to how these are dealt with, with some emphasising a more rehabilitative approach (such as supervised, or restricted practise), and others a more punitive one (such as suspension, or removal of the licence to practise). A right to public hearing, and a right to appeal are enshrined in European law.

SECTION 6: INTERNATIONAL REGULATION

Standards and Ethics

38) While there is much international agreement on the ethical principles underlying modern medical practice, comparatively little work has been performed on establishing common standards for practice. This may be due to variations in the context of medical practise, or differences in national regulatory systems. The UEMS believes that, with increasing movement of patients and doctors between European countries, greater effort should be made to find common regulatory standards.

Education, Certification and Registration

39) European directives provide a statutory basis for the mutual recognition of undergraduate and specialist medical qualifications. However, these common minimum requirements – based on duration of tuition, or years of specialisation – have attracted persistent criticism from the medical profession, as they are not reflective of the complexity of modern medical education, nor do they confirm competence.

40) The UEMS has developed a number of initiatives that could contribute to international regulation, including: its visitation and accreditation programmes for teaching institutions; the EACCME system of accrediting continuing medical education, and; its reviews of minimum specialist training durations. It is essential that these, and similar efforts, are developed further in order to ensure a robust regulatory basis for the free movement of patients and doctors.

Ensuring fitness to practise

41) In order to ensure that patient safety is protected, mechanisms are required to ensure international co-operation between regulatory bodies. To facilitate free movement safe-guarded by regulatory standards, the following principles have been accepted by the UEMS: that there should be sharing of regulatory information about doctors; that, on seeking registration in any European country, a doctor must inform the regulatory body of any prior registration in any other country, and of any judgement against them, and; that the regulatory body has the responsibility to inform those other regulatory bodies should an adverse finding at any stage be made against a doctor.

SECTION 7: THE CONSTITUTION OF REGULATORY BODIES

Structure

42) There is considerable variation across Europe regarding the constitution of regulatory bodies. In order to encourage the confidence of all interest groups, there is representation from the medical profession, and from lay members of society. It is important that the needs of society, and the realities of modern medical practice, are considered together when setting regulatory standards.

Process

43) It is essential that the regulation of the medical profession is, and is seen to be: independent; reflective of the needs of relevant interest groups; itself subject to appropriate forms of accountability, and; performed fairly, reliably, and according to valid evidence.

Outcomes

44) Even though it inevitably will be required to take responsibility for difficult decisions, a healthy regulatory system should earn the support of those for whom it ensures control of the quality of professional practice: patients – who rely on its safeguards; the medical profession – whom it should regulate fairly, and; society – that entrusts the system with this independent responsibility.

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PROMOTING GOOD MEDICAL CARE

SUMMARY

This paper sets out the policy of the Union Européenne des Médecins Spécialistes/ European Union of Medical Specialists (UEMS) on quality assurance (QA), which is defined here as the regular review against defined standards of medical care. Its aim is to provide a framework for confirming the good quality of healthcare in Europe and, specifically, of the contribution of specialist doctors. The paper provides guidelines that can be adopted for use in QA systems in all European countries. It will show that this can best be achieved when QA is based on valid evidence, which can also facilitate improvements in medical care and justify the provision of necessary resources.

This UEMS policy paper builds upon considerable evidence of successful, well-established QA systems that are found in many parts of Europe. Fundamental features of these are that they are led by specialist doctors, who control resources allocated solely for the purpose of quality assurance. Accordingly, the UEMS recognises its responsibility to develop policy based on this experience, and invites all interested parties to support this.

The UEMS considers that QA is an essential component of an agenda focused on high standards of medical practice. The other parts of that agenda include continuing professional development as a form of quality improvement – covered separately in the 2001 UEMS policy document "The Basel Declaration" – and its policy, being developed, on regulating the medical profession.

This paper is addressed to all who have an interest in the quality of healthcare provision: patients, doctors, medical associations, health service employers and hospitals, fund-holders, regulatory authorities, national and European legislators. The UEMS considers that, in the context of the QA of medical care, all share the following agenda:

i) of ensuring that systems for assuring the good quality of medical care are appropriately monitored, supported and funded;
ii) of working together, within a medically-led structure, to achieve continuing improvement in the quality of care;
iii) that the means of achieving the above is through the implementation of a QA system that considers all relevant components: the individual doctor, the team(s) within which they practise, and their work environment;
iv) that this system should be based on the QA cycle: monitoring medical care against standards accepted as medically valid, introducing improvements that are appropriately resourced, reviewing these changes, and ensuring that the system itself is adequately quality assured.

The UEMS draws attention to the lack of evidence to demonstrate any additional effectiveness of mandatory systems over the model described here.

The following list of key points drawn from the text expands this summary. It also acts as an index to specific paragraphs of the paper.

KEY POINTS

A) All groups interested in the quality of healthcare must acknowledge their own, and other groups' responsibilities to support high standards of medical care (3, 8 - 11)

B) Professional standards must continue to be revised in order to match changing expectations, technologies and resource availability (9)

C) To be effective a QA system must consider all relevant components: the individual doctor; the team(s) within which they practise; and their work environment (23, 26 - 36)

D) QA systems must be designed around outcomes and methodologies that have the confidence of all interested groups (24 - 25)

E) If they are to be accepted for implementation, the setting of standards requires: a solid evidence base; to be medically-led; and a high degree of consensus (13 - 15, 24)

F) Valid measures of performance – a term that reflects all components of a doctor's practice – are required for valid quality assurance (16 - 17)

G) Appropriate consideration must be given to the many variables that may affect measured outcomes of medical care (18 – 21, 31, 34)

H) All specialist doctors should engage in a suitable QA process, organised by the medical profession, in order to confirm the quality of their clinical care and their continuing fitness to practise (22)

I) The confidentiality of data, personal to patients and doctors, must be respected (25)

J) External audit by trained peer assessors following defined criteria is a well-validated means of assuring and promoting the quality of work environment and healthcare teams (26 – 30)

K) Internal audit and peer review are well-validated means of assuring and promoting the quality of healthcare teams and individual doctors (29 – 32)

L) Risk management systems covering all three functional levels – work environment, healthcare team and individual doctors – can assist whole organisations to improve their safety and quality of care. This requires open reporting in a "no blame" culture (33 - 35)

M) It is an absolute requirement for a quality assurance system to be supported by appropriate resources. These include time, people, money, and information technology (36)

N) QA systems must have a protected budget and be financially accountable (37 - 39)

O) The UEMS recommends a workable model, based on the QA cycle, for confirming and promoting the good quality of medical care. It includes all relevant interest groups; emphasises the setting of valid outcome measures and the monitoring of all three relevant functional levels; encourages developmental interventions, including with regard to "outliers"; and is itself subject to regular review (40 – 47)

P) The UEMS draws attention to the lack of evidence to demonstrate any additional effectiveness of mandatory systems (47)

SECTION 1: INTRODUCTION

The role of the UEMS

1) Established in 1958, the Union Européenne des Médecins Spécialistes/ European Union of Medical Specialists (UEMS) is the representative organisation for specialist doctors from the national associations of EU/EEA countries. Its activities cover all issues associated with specialised medical practice, and are jointly carried out by doctors serving as representatives on its Management Council and on its more than thirty Specialist Sections and Boards.

2) The UEMS recognises and values differences in the structure, funding and priorities of healthcare systems in Europe. These should all support good medical care that is responsive to local needs, whilst encouraging innovation and learning from successful models that represent best practice. The UEMS recognises that it has a responsibility to encourage high quality in the medical care of patients and to develop and share policy that will support this throughout Europe.

Interest groups

3) The UEMS believes that six broad interest groups have a legitimate interest in ensuring that the highest standards of medical care are achieved. These groups are: society as a whole; individual patients; the professionals who care for them; health service employers and hospitals; providers of funding for healthcare; and regulatory authorities. Due to differences in the health service systems in Europe, considerable variations exist as to the relationships between these groups.

The quality agenda

4) The UEMS considers strongly that components of quality management as applied to medical care have specific applicability and must be addressed separately. The UEMS has published a policy paper on QI – "The Basel Declaration" (2001) on continuing professional development – and is preparing one on QC, which it considers is limited solely to the field of medical regulation.

5) In the context of this paper the UEMS defines Quality Assurance (QA) as the regular review against defined standards of medical care. QA makes it possible for the quality of healthcare to be measured and compared, for improvements to be made based on valid evidence, and it facilitates greater accountability regarding all aspects of healthcare delivery. Factors such as resource availability, healthcare context, team-working and expectations – both medical and lay – all will influence the outcomes of medical care and how these are interpreted.

Accountability

6) In modern society there is greater emphasis than ever before on accountability within healthcare. The UEMS recognises that this will require openness regarding standards by each of the groups interested in the quality of healthcare. The UEMS considers that this can best be achieved by ensuring that appropriate QA systems are implemented for confirming and promoting the good quality of medical care.

7) Accordingly, society's and individual patients' expectations should be appropriate to what can be provided; specialist doctors should be willing to demonstrate openness regarding the quality of their practice; employers and hospitals should take greater responsibility for those they employ; funders of healthcare for the extent to which resources are made available; and regulatory authorities must ensure that appropriate structures are in place to achieve these goals.

Objectives

8) This policy is intended to confirm for all interested groups that specialist doctors collectively and individually accept their responsibility to demonstrate that they are committed to the delivery of high quality care for their patients. It also requires all relevant interest groups to recognise their own and others' responsibilities in this area. Each of these must consider the nature and extent of their influence on the quality of medical care and acknowledge the requirement – by their own actions – to support high standards.

9) It is further intended to provide additional impetus to the quality assurance of medical care throughout Europe. There is a clear requirement for the continuing development of professional standards to match changing expectations, technologies and resource availability.

10) There is an absolute requirement of all interested groups to ensure that resources are made available to support QA. This policy will justify the provision of information technology and financial resources, time for practitioners to engage in QA activities, and political recognition of the importance of these activities for all involved in the field of healthcare.

SECTION 2: THE CONTEXT OF QUALITY IN MEDICAL CARE

Why quality assurance matters

11) Each interest group will recognise the importance of assessing and assuring the quality of healthcare. Patients consult doctors to have their health problems dealt with in an effective, safe and timely manner; practitioners want to know that when they prevent, cure or palliate illness, they are improving the health of their patients; regulatory authorities and employers want to be assured that the specialists in their clinics and hospitals are providing appropriate and high quality healthcare; and fund-holders want beneficial outcomes and value for the money they provide for the medical care of the population for whom they have purchasing responsibilities.

12) The UEMS believes that these aims can best be achieved by a system based on a QA cycle that begins with the setting of clinically relevant standards, against which can be measured performance in the delivery of medical care, the results of which may be assessed, and used to justify recommendations for beneficial change and for the setting of future standards.

Setting standards

13) Throughout healthcare there is an increasing emphasis on quality. Measures of quality may serve as a guide or as a point of reference, and may be classified according to the degree to which they are supported by evidence. In order of increasing validity, there are options, guidelines, recommendations or standards. Choices also need to be made between quantitative standards – that tend to be emphasised when resources are limited, and qualitative standards – that are more comprehensive and have been validated by a more extensive research base.

14) Standards may be established by a range of techniques, such as: local standards agreed following informed debate by practising colleagues; speciality-specific standards (such as the use of autopsy for the review of therapeutic decisions); standards established by comparison with norms of practice (such as national procedure databases); standards based on the scientific evaluation of new technologies or medicines; or those set by consensus amongst an acknowledged panel of experts.

15) Some common themes can be identified. In order to be accepted as valid, standard-setting requires: a solid evidence base, a high degree of consensus, and to be medically-led. While standards justifiably may vary according to national circumstances, it is also possible to set standards that are applicable across national boundaries.

Measures of performance

16) Performance is a term that reflects all components of a doctor's practice. It therefore incorporates the term competence which only refers to the knowledge, skills and attitudes that a doctor possesses. In its simplest form competence refers to a doctor's abilities while the broader term performance indicates how the doctor applies these in their practice.

17) Measures of performance may be independent of, or informed by, established standards. They may be indicators of the practice of individual doctors (individual), the team within which they work (collective), or their practice environment (global). They may also be classified according to whether they are direct or indirect indicators of performance.

Factors that may influence outcomes

18) As with any discrete assessment, measures of performance are subject to factors that may affect their validity. The case-mix of patients for whom a specialist doctor provides care may influence his/her outcomes. Practitioners vary in their degree of practice specialisation, and patients vary in the extent to which they present with more advanced or complicated disease. Valid comparison of outcomes will only be possible if standards reflect these and other factors.

19) The influence of other team members also must be considered. Examples include: the influence on the results of a surgeon's practice by the anaesthesiologist(s) with whom they work; the availability of rehabilitation teams for elderly patients on the outcomes of physicians; and the multi-disciplinary teams required for the management of cancer or transplant patients.

20) The environment within which specialist doctors work is equally important. Factors such as resource availability, the numbers of patients and their expectations, all will have a significant influence. The extent to which recognised safety standards are applied may vary significantly between institutions and healthcare systems. This may also have a major impact on the nature, extent and quality of medical care.

21) When developing or monitoring a QA system it is essential to ensure that appropriate consideration is given to the potentially significant influence these variables may have on the measured outcomes of medical care.

The balance of responsibilities

22) The UEMS accepts the principle that doctors should be able to demonstrate their continuing fitness to practice by engaging in a suitable QA process. However this can only correctly occur if a system of QA looks at doctors in the overall context of the health care system within which they practise. By comparing themselves against accepted professional standards QA allows individual doctors to demonstrate the quality of their clinical performance. It should also assist them in confirming their continuing fitness to practise.

23) A QA system should consider three relevant functional levels: the individual doctor; the team(s) within which the doctor practises; and their work environment. It is only by assessing all of these, and considering the influences of each, that valid assessments can be made.

Which outcomes? Whose data?

24) The UEMS considers it essential that QA systems are designed around methodologies that have the confidence of all interested groups and reflect outcomes recognised as valid.

25) Access to medical data is a sensitive issue that is subject to legislation in some European countries. It is an inviolable principle that personal confidentiality must be maintained – whether for patients or for doctors. Direct information should only be accessible to those about whom it refers and those who, with their permission, are required to deal with it. Beyond this, information should only be available if it has been anonymised and/or pooled. Only patients and their direct carers should have access to their personal information; for audit purposes the individual patient should not be identifiable. This principle is equally applicable to doctors. Only individual doctors and those directly assisting with their QA should have access to their confidential information.

SECTION 3: CURRENT QUALITY ASSURANCE SYSTEMS

The working environment

26) Well established systems exist in many European countries for the inspection and accreditation of healthcare institutions. These may act through governmental organisations, professional associations or independent inspecting bodies. Good examples also can be recommended for the most appropriate means of funding these programmes. The UEMS itself, through its Specialist Sections and Boards, has visitation programmes of training institutions that have assisted in the assurance, and further development of high standards throughout Europe.

27) The best developed, and well supported model, is that of external audit by peer review, in which a team of visiting specialists – drawn from either a national or international pool of trained visitors – assess an institution according to defined criteria. These standards typically will cover practice facilities, the provision of resources, and the management of these, collated outcomes of clinical practice, and teaching facilities. Increasing emphasis also is being placed on local QA initiatives, such as standard-setting and the analysis of healthcare processes.

28) The support of practitioners by their employing institution is a further important standard. Criteria frequently include the provision of resources for continuing professional development, teaching and research. The inclusion of specialist doctors in all aspects of the institution's function, most notably their involvement in the maintenance of high standards, also is important.

The healthcare team

29) Inspection by outside visiting teams is a well established method for the QA of care provided by teams. In addition to the factors referred to above, good communication and team-determined outcomes are frequently emphasised criteria. By structuring their assessments according to these and other standardised criteria (as are set out in the UEMS Visitation Charter), visiting teams reliably can assess the extent, function and quality of local peer-review and QA methods.

30) Most notable amongst these is the use of internal clinical audit. Audit has been defined as the continuing formative review of clinical practice against defined standards. While specific methods may vary, it has been implemented widely throughout Europe, with well-established systems at local, regional and national levels and a comprehensive supporting literature.

The individual doctor

31) While individual doctors should always be considered within a broader practice context, methods exist for assuring the quality of their own overall performance or separate components such as knowledge, skills, behaviour and engagement in CPD. Individual outcomes can be considered by methods such as audit of individual practice and review of performance with peers.

32) Some models emphasise developmental and supportive review, others a more summative approach. When considering measures of an individual specialist's performance, the UEMS recommends that due recognition must be made of the professional nature of specialised medical practice. Accordingly, only specialised doctors who will understand the nature of this practice, have had suitable training for this purpose, and who have the confidence of their peers should be employed for reviews of this nature.

Methods common to all three

33) There has been a growing awareness of the importance of risk management and the influence of this on the quality of healthcare. Many QA systems already incorporate methods such as confidential incident reporting, or active patient safety programmes based on the review of audit results. Evidence that whole organisations can improve their performance has been a major stimulus for better error avoidance and prevention. Much can also be achieved through education and by informing practitioners of the relevance of their practice to safety outcomes.

34) Whether for the work environment, healthcare team or individual doctors, one of the mechanisms for improving practice is through the closer examination of "outliers" – those whose performance lies outside the normal distribution of comparable peers. There may be many valid reasons for this; availability of resources, workload and case-mix are a few. Much can be learned from those who perform particularly well; poor performers should be encouraged and assisted.

35) The development of "no blame culture" is crucial to the establishment and maintenance of a healthily-functioning incident reporting and management system. It is better to know of, and learn from incidents than to allow these to be repeated through lack of information.

SECTION 4: THE NEED FOR RESOURCES

The nature of resources required

36) It is an absolute requirement for any QA system that it is supported by appropriate resources. The nature and amount of these will vary according to the system that is established, but include: time, for practitioners to engage in all aspects of the QA cycle; people, to staff the QA system; money, to provide for all necessary components; and information technology, to assist with the collection, collation and analysis of results.

Financial resources

37) Any such system of quality assurance must be funded openly. Ultimately it is patients who pay for this – whether directly, as in "liberal" fee-paying systems; indirectly, through healthcare insurers; or as taxpayers. As interested parties they have a right to know that QA systems will be suitably funded and financially accountable. A similar degree of transparency is required by practitioners who have a right to know that the services they provide, and the quality assurance of these, will be funded appropriately.

38) It is essential that resources provided for quality assurance are used only for this purpose. Whether in a “liberal” or an employed system, finances must have a designated, protected budget.

39) The UEMS considers strongly that wherever a quality assurance system is established, it is the responsibility of the organisation or body that has required this to ensure that adequate funding is provided at all stages.

SECTION 5: A WORKABLE MODEL

The UEMS proposal

40) The UEMS considers that, building on the experience already gained around Europe, a generic workable model can be recommended for implementation. This may itself provide a standard against which further systems could be compared. This model is based on the QA cycle: of standard-setting, monitoring of existing practice, the review of results, seeking improvement by feedback and other changes, and the setting of new standards for the next cycle. The UEMS considers it essential that a QA system similar to or at least as effective as that described here is implemented in all European healthcare systems.

41) Such a system can be established at any level of function: whether individual, team, departmental, cross-speciality or even hospital-wide. It is essential also to ensure that this system itself is subject to regular external assessment and review. Accordingly the UEMS recommends that the structure and function of such systems themselves are inspected regularly.

42) The principle of confidentiality requires that, according to whether it is individual doctors, healthcare teams or the work environment, only they and the assessor(s) should have access to direct information. For all other uses information should be anonymised and/or pooled.

43) In the context of specialist medical care, the development and functioning of such systems must be medically-led. Where appropriate there should also be consultation with patient representatives and regulatory authorities in the setting of standards. In employment-based systems hospital managers and fund-holders will also be important to the implementation of recommended change.

44) The monitoring of medical care must be valid and proportionate in order to maintain the co-operation of all interested groups. Non-medical interest groups will have little confidence in systems that do not address relevant matters according to accepted standards, or fail to introduce improvements where necessary. At the same time, professional groups require support for, engagement in, and ownership of a system that they recognise as integral to their practice.

45) All parties must recognise that – other than in the rare situation of when major problems are identified – feedback should be constructive and developmental. It is more important to maintain long-term confidence in good quality assurance mechanisms than to lose this by inappropriate intervention.

46) In addition to their defined role of confirming the extent of good practice, QA systems will also identify practice that lies outside recommended and accepted standards. Ideally it should be from the commencement of QA monitoring that mechanisms are established to ensure that such “outliers” can be examined in greater detail. In the case of excellent practice, potentially to provide an example for others to follow; in the case of poor practice, to ensure that this is examined fully and addressed. It is essential, in all cases when doing so, that all aspects of healthcare delivery are considered – work environment, healthcare team, and not just the individual doctor.

Other mechanisms

47) Other mechanisms have been suggested, and in some areas established, that are based on ensuring the compliance of practitioners. Examples within Europe include the recertification of their practice privileges by insurers or admitting rights by hospitals, or by the revalidation of their registration to practice as doctors. The UEMS believes strongly that it is inappropriate to focus on only one component of a multifactorial system and draws attention to the lack of evidence that demonstrates any additional effectiveness – beyond that achieved by the structures recommended above – of mandatory systems.