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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.