QUALITY ASSURANCE OF CLINICAL PRACTICE
UEMS policy paper, final draft

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 clinical practice. Its aim is to ensure that the quality of healthcare provided by specialist doctors in Europe can be measured and compared, and that improvements can be made based on valid evidence and with appropriate resources.

The UEMS believes 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 medical regulation as quality control.

The paper is addressed to all who have an interest in this area: patients, doctors, medical associations, health service employers and fund-holders, regulatory authorities, national and European legislators. While these groups may start from different positions when considering the subject of QA, the UEMS believes that all can be united by a common agenda.

This can be summarised by:

i) a requirement for all stakeholders in the quality of healthcare provision to accept their responsibilities in ensuring that this is supported and monitored, with a view to its continued improvement;
ii) the achievement of this through the implementation of a QA system that considers all relevant components: the individual doctor, the team(s) within which they practice; and their work environment;
iii) this system being based on the QA cycle: monitoring clinical practice against standards accepted as valid by all stakeholders, introducing improvements that are appropriately resourced, reviewing these changes, and ensuring that the system itself is adequately quality assured.

The following list of recommendations drawn from the text expands the summary and is designed to act as a means of identifying those who can assist with implementation. It also acts as an index to specific paragraphs of the paper.
RECOMMENDATIONS

All stakeholders must acknowledge their responsibilities to supporting high standards of clinical practice (2, 8 - 10, 14)

**Action:** all stakeholders

There is a clear requirement for the continuing development of professional standards to match changing expectations, technologies and resource availability (10)

**Action:** doctors, all stakeholders

Doctors should be able to demonstrate their continuing fitness to practice by engaging in a suitable QA process (12)

**Action:** doctors, medical associations, regulatory authorities

To be effective a QA system must consider all relevant components: the individual doctor; the team(s) within which they practice; and their work environment (13, 26 - 33)

**Action:** doctors, all stakeholders

Standard-setting requires a solid evidence base, is likely to be medically-led, and requires a high degree of consensus to be accepted for implementation (15 - 17, 25)

**Action:** doctors, all stakeholders

QA systems must be designed around outcomes and methodologies that have the confidence of all stakeholders; valid measures of performance – a term that reflects all components of a doctor’s practice – are required for valid quality assurance (18 – 19, 25)

**Action:** doctors, all stakeholders

Appropriate consideration must be given to the potentially significant influences many variables may have on the measured outcomes of medical practice (20 – 25, 32)

**Action:** all stakeholders

External audit by trained assessors working according to defined criteria is a well-validated means of assuring the quality of the work environment and the healthcare team (26 – 30)

**Action:** doctors, employers, fund-holders, regulatory authorities; all stakeholders

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

**Action:** doctors, employers, fund-holders, regulatory authorities; all stakeholders

Risk management systems covering all three functional levels can assist whole organisations to improve their performance (33)

**Action:** doctors, all stakeholders

It is an absolute requirement for any quality assurance system to be supported by appropriate resources, including time, people, money and information technology (34)

**Action:** all stakeholders

Stakeholders have a right to know that QA systems are appropriately funded and are financially accountable (35 – 36)
A generic workable model can be recommended for implementation. This is based on the QA cycle; includes all stakeholders; emphasises the setting of valid outcome measures and monitoring of all three functional levels; encourages developmental interventions whilst ensuring that “outliers” are examined; and is itself subject to regular review (37 – 44)

There is no evidence to demonstrate any additional effectiveness of mandatory systems (45)

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 all EU/EEA states and a number of non-EU/EEA countries. Its activities cover the full range associated with specialised medical practice and are jointly carried out by its Management Council and more than thirty Specialist Sections.

Stakeholders

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

Accountability

3) In modern society there is greater emphasis than ever before on accountability within healthcare. The UEMS recognises that this will require greater openness regarding standards by each of the stakeholder groups. The UEMS believes that this can best be achieved by ensuring that appropriate methods for the Quality Assurance (QA) of clinical practice are implemented.

4) For specialist doctors this will entail a greater focus on the quality of their practise; for society and individual patients expectations must be appropriate to what can be provided; employers will need to 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.

The quality agenda

5) The UEMS believes strongly that components of quality management as applied to medical care have specific applicability. Quality Assurance (QA) should therefore be kept separate from Quality Improvement (QI) and Quality Control (QC). 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 believes is limited solely to the field of medical regulation.

6) In the context of this paper the UEMS defines Quality Assurance as the regular review against defined standards of clinical practice. QA makes it possible for the quality of healthcare to be measured and compared, for improvements to be made based on valid evidence, and facilitates greater accountability.

7) This definition should be taken as applicable to all factors affecting healthcare provision hence will have direct implications for each of the stakeholder groups. Factors such as resource availability, practice context, team-working and expectations – both medical and lay – all will influence the outcomes of clinical practice and how these are interpreted.

**Objectives**

8) This policy is intended to assure all stakeholders 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.

9) This is coupled with a requirement for other stakeholder groups to recognise their responsibilities in this area. Each of these must consider the nature and extent of their influence on the quality of clinical practice and acknowledge the need to support high standards by their own actions.

10) It is further intended to provide additional impetus to the development of, and support for, the QA of clinical practice throughout Europe. There is a clear requirement for the continuing development of professional standards to match changing expectations, technologies and resource availability.

11) There is also an absolute requirement for the support of QA by all stakeholders. This will involve information technology and financial resources, time for practitioners to engage in QA activities, and the political recognition of the importance of these activities for all involved in the field of healthcare.

**SECTION 2: THE DOCTOR IN CONTEXT**

**The balance of responsibilities**

12) 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 practice.

13) An appropriate QA system therefore will consider all 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.

**Why quality assurance matters**

14) Each stakeholder 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 to know that they are receiving value for the money they provide for the medical care of the population for whom they have purchasing responsibilities.

**Setting standards**

15) Throughout medical practice there is an increasing emphasis on measures of quality either as a guide or as a point of reference. These have been classified according to the degree to which they are supported by evidence and, in order of increasing validity, are options, guidelines, recommendations or standards. Choices also may need to be made between quantitative and qualitative standards – the former, less valid, tend to be emphasised when resources are limited, there is a more extensive research base for the latter.

16) Standards may be established by a range of techniques. These include: determination by peers based on available relevant information; by comparison with norms of practice such as national procedure databases; by the scientific evaluation of new technologies or medicines; or by an acknowledged panel of experts.

17) There are also some common themes that should be considered. While standards may vary according to national circumstances, in order to be accepted as valid standard-setting requires a solid evidence base, is likely to be medically-led and requires a high degree of consensus. Standards can also be set that are applicable across national boundaries; one example is the use of autopsy for the review of therapeutic decisions as informed by definitive pathology findings.

**Measures of performance**

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

19) There are many ways of setting measures of performance. These may be independent of or informed by established standards. They can be indicators of individual, collective, or global performance, hence reflective of the practice of individual doctors, the team within which they work, or their practice environment. Specific measures of the results of clinical practice – outcome indicators – may also be direct or indirect indicators of performance.

**Influences on outcomes**

20) As with any discrete assessment measure, performance indicators are subject to factors that may affect their validity. It is essential when setting, measuring and considering the results of performance indicators to recognise the potential influence of such factors.

21) These may include the case-mix of patients for whom an individual doctor provides care. 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.
22) 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 healthcare of the elderly physician, whose treatment outcomes are dependant on the rehabilitation teams that contribute to the care of their patients; and the multi-disciplinary teams that influence outcomes for cancer or transplant patients.

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

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

Which outcomes?

25) The UEMS considers it essential that Quality Assurance systems are designed around methodologies that have the confidence of all stakeholders and reflect outcomes that are recognised by all as valid.

SECTION 3: CURRENT QUALITY ASSURANCE SYSTEMS

The working environment

26) In many European countries systems have long been established for the inspection and accreditation of healthcare institutions. Many models exist: from organisations established by governments for this purpose, professional associations and independent inspecting bodies. The UEMS itself, through its Specialist Sections has active visitation programmes in many speciality areas that have assisted in the assurance and further development of high standards throughout Europe. Guidance is also available on the most appropriate means of funding these programmes.

27) The best developed and 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 will 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. Greater emphasis increasingly is being placed on local quality assurance initiatives such as standard-setting and healthcare process analysis.

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 employees 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 also is a well established method for the assurance of the quality of care provided by teams. In addition to the factors referred to above, the form and nature of communication and a greater emphasis on team-determined outcomes are frequently emphasised criteria. By structuring their
assessments according to these and other standardised criteria, visiting teams can provide a reliable means of assuring the extent, function and quality of local peer-review and quality monitoring methods.

30) Most notable amongst these is the use of internal audit by a clinical department or speciality team. Audit has been defined as the continuing review of 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 overall performance or separate components such as knowledge, skills, behaviour and engagement in CPD. Individual outcomes can be considered by methods such the audit of individual practice and review of performance with peers. More recent innovations have included surveys of patients and colleagues regarding their experience of a practitioner’s work and review of performance within multi-disciplinary teams.

32) A wide variation exists as to the manner in which these measures of an individual specialist’s performance are considered. Some models emphasise developmental and supportive review, others a more managerial approach. The UEMS believes that due recognition must be made of the professional nature of specialised medical practice when establishing quality assurance systems that focus on individual practitioners.

Methods common to all three

33) There has been a growing awareness of the implications of healthcare quality and the importance of risk management covering all three levels of assessment referred to above. This has led to its inclusion in many QA systems through methods such as confidential incident reporting or more active patient safety programmes based on reviewing audit results. Evidence that whole organisations can improve their performance also has been a major stimulus for better error avoidance and prevention. Much can be achieved through education and informing practitioners of the relevance of their practice to safety outcomes.

SECTION 4: THE NEED FOR RESOURCES

The need for resources

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

The source of financial resources

35) Any such system of quality assurance must be funded openly. Ultimately it is patients who pay for this – whether directly, indirectly through healthcare insurers, or as taxpayers. As stakeholders they have a right to know that QA systems are appropriately funded and are financially accountable. A similar degree of openness
is required by practitioners who have a right to know that the services they offer, and the quality of these, will be funded appropriately.

36) The UEMS believes strongly that if a quality assurance system is established, it is the responsibility of any organisation or body that has required this to ensure that adequate initial and ongoing funding is provided.

SECTION 5: A WORKABLE MODEL

The UEMS proposal

37) The UEMS believes that, building on the experience already gained around Europe, a generic workable model can be developed and recommended for implementation. This would itself provide a standard against which further systems could be compared.

38) An essential concept is that of the quality assurance 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.

39) Such a system can be established at any tier 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.

40) Ideally, in the context of hospital medical practice, the development and functioning of such systems should involve more than one stakeholder group. Patient and public groups may be represented where appropriate in the setting of standards; regulatory authorities often will have contributed to this process; employers and fund-holders will be important to the implementation of change following the review of results.

41) The monitoring of clinical practice must be valid and sensible in order to maintain the co-operation of all stakeholder groups. Non-medical stakeholders will have little confidence in systems that do not – or are not seen to – address relevant matters according to accepted standards, and introduce improvements where necessary. At the same time, professional groups will need to feel engaged in a system that they recognise as relevant to their practice and that they are supported in this in an appropriate manner.

42) 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.

43) 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 resolved.
44) The UEMS believes it the responsibility of all stakeholders that a QA system is implemented in all European healthcare systems similar to or equally effective as that described here.

Other mechanisms

45) Other mechanisms have been suggested to ensure the maintenance of high standards of medical practice. Systems have been suggested, and in some areas established, that are based on ensuring the compliance of practitioners. This may be either by 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 that it is inappropriate to focus on only one component of a multifactorial system and notes that there is no evidence that demonstrates any additional effectiveness – beyond that achieved by the structures described above – of mandatory systems.

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