

UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES EUROPEAN UNION OF MEDICAL SPECIALISTS

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D 0349 final

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;
- 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.

President : Dr. Hannu Halila Secretary General : Dr. Bernard Maillet Treasurer : Dr. Vincent Lamy Liaison Officer : Dr. Leonard Harvey

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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)

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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.

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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.

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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.

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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.

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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.

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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 cooperation 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.

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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.