The European Union of Medical Specialists (UEMS) is a non governmental organization, which consists of all national bodies representing medical specialists in the European Union, the European Economic Space and several associated countries. The physical and rehabilitation medicine (PRM) section of the UEMS consists of three committees: the Committee for Education (European Board of PRM), the Clinical Affairs Committee and the Professional Practice Committee. Quality of care is the core issue addressed by the Committee for Clinical Affairs. The aim of this paper was to present the background to this European approach, our first achievements and the ideas on which our new action plan was based.

A short history of the quality approach

Any human activity starts with a creative phase. Quality is the result of the strong desire to launch a new project and to constantly follow-up its process and its outcomes. When the process becomes mature, the industrial phase is reached. The process can be prolonged, enlarged or replicated. The participants’ motivations may fade, and the provider’s profits may gain priority over the benefits to the customers. The product or service provided may also have to compete with imitations or newly developed systems. This is where the need for a quality approach arises.

The first step consists in setting up official quality standards and eliminating all products and providers not fulfilling the criteria defined. Standards have to be previously defined by governments or professional organizations, in line with the practices adopted in the old days by the guilds to protect themselves from external competition.

During the "scientific management" phase defined by Frederick Winslow Taylor (1856-1915), many industrialists focus on developing production methods involving lower costs and greater efficiency.1 W. Edwards Deming2 applied statistical procedures to improve the production of strategic equipment in the United States during World War II, and these methods were subsequently adopted in Japanese industrial circles from 1950 onwards. This author summarized his theory of management in 14 points, including: 1) creating constancy of purpose toward improvement of product and service; 2) ceasing dependence on inspection to achieve quality; breaking down barriers between departments; 3) instituting a vigorous program of education and self-improvement. Since then, many methods of quality improvement have been applied in all sectors of goods production and service delivery.

The International Organization for Standardization
(ISO) created the Quality Management System (QMS) standards in 1987. These standards are designed to certify the processes and systems used by an organization, and not the product or service itself. ISO 9000 standards do not certify the quality of the product or service.

The Deming Wheel (Plan – Do – Check - Act) (Figure 1) has been adopted by the French High Authority for Health as a model for professional practice assessment. Quality circles and total quality management also feature on the long list of quality management methods available. In each of these systems, the commitment of the participants in the production process is a key issue.

In the early XX century, Dr William W. Mayo and his sons founded the Mayo Clinic and promoted the multidisciplinary approach to health care. The fundamental elements of the Mayo Model of Care are still relevant today: “1) A team approach that relies on a variety of medical specialists working together to provide the highest-quality care; 2) An unhurried examination of each and every patient with time to listen to the patient; 3) Physicians taking personal responsibility for directing patient care in partnership with the patient’s local physician; 4) The highest-quality care delivered with compassion and trust; 4) Respect for the patient, family and the patient’s local physician; 5) Comprehensive evaluation with timely, efficient assessment and treatment; 6) Availability of the most advanced, innovative diagnostic and therapeutic technologies and techniques”.

Since the pioneer times, quality of care has attracted the attention of governments, care payers and care consumers. This led to many organizational and supervision programmes being set up in the USA, Europe and other parts of the World. However, there exist so far no European quality systems addressing the specific features of PRM and focusing on programmes of care rather than on facilities or individual doctors. The only existing procedure meeting those two criteria so far is the accreditation survey, which has been implemented in the USA by the Commission on Accreditation of Rehabilitation Facilities (CARF) since 1966.

The European context

The European Union resulted from a series of treaties. The Treaty of Rome (1957) set the foundations of the European Economic Community (EEC) and proclaimed the right to the free circulation of people and services. Since the Treaty of Maastricht, the European Union (EU) has been ruled by the fundamental principle of subsidiarity. Medical care has remained under the responsibility of National governments and has not yet been subject to European directives. However, in 1997, the Council of Europe issued Recommendation No R(97)17 to member states on the development and implementation of quality improvement systems in Health Care.

The UEMS has nevertheless long been well aware of the importance of this issue. The first Charter on Quality Insurance in Medical Specialist Practice in the EU was adopted in 1996. More recently, quality of care was addressed in a set of three position papers: The Basel Declaration (D0120 - 2001) is a Charter on Continuing Professional Development (CPD); Promoting Good Medical Care (D0349) is a policy paper on Quality Assurance (QA), defined as a process of regular review rather than the application of predefined standards of medical care. The UEMS has pointed out that there is no evidence that mandatory systems are more effective than the model described here.

The Budapest Declaration on Ensuring the Quality of Medical Care (UEMS 2006/18) defined UEMS policies on medical regulation. The UEMS recognises that any regulatory system must reflect the context of medical practice, the expectations of society and the resources available for providing medical care.
The European Accreditation of quality of care in the field of PRM

In the UEMS PRM section, the debate about quality of care started in 2001 and this issue was placed under the responsibility of the Committee for Clinical Affairs, chaired by Prof. Bengt Sjölund (Sweden). At that time, quality systems either existed or were being set up in several European countries. But at the European level, the lack of a suitable legal framework and funding systems made it impossible to import a complex system such as CARF accreditation, although several facilities found local reasons justifying its possible implementation. In addition, mandatory accreditation and certification systems were already imposing an increasingly heavy clerical burden on medical staff in many countries.

Despite those objections, the UEMS PRM Section reached the conclusion that a European Accreditation system would be the best way of improving PRM services throughout Europe and raising the corresponding quality standards in all European Countries. This process should not be too time consuming or expensive to run or to comply with. It would focus on Programmes of PRM care. The assessment criteria would not be defined immediately but only after receiving feedback from the programmes run during a pilot phase. The system is to be an Internet based system consisting of a self-assessment self-administered questionnaire submitted to an International Jury consisting of five members.

The decision to carry out this European project was taken by the General Assembly in Dublin on September 11, 2004. A budget of € 5,000 per year was voted to cover the website development, but all the other aspects of this project will depend on the voluntary work of the members of the Committee for Clinical Affairs. Despite this fairly light system of organization, regular progress reports could be issued.

The description of the final features of the Accreditation Procedure and updated information for applicants are available on the www.europrm.org website.

UEMS Accreditation is open to all PRM Board certified specialists. After registration on the accreditation website, the candidate receives a login and a password giving access to the submission area, where a 9-page questionnaire has to be filled in.

The titles of programmes can be chosen from a pop-up list or freely defined in the candidate’s own words. A free description of the programme is then requested: comprehensive information about the programme should be provided to illustrate each response to the second part of the questionnaire, which contains eight parts: 1) aims and goals; 2) location and safety; 3) patients’ rights; 4) PRM specialists participating in the programme; 5) team management in the programme; 6) evidence based medicine (EBM) in the programme – organization and records; 7) monitoring and outcomes; 8) audit spiral.

Targets of the programme have to be expressed in terms of the impairments on which it focuses and the limitations and restrictions involved, using the categories defined in the International Classification of Functioning, Disability and Health (ICF). A link to the ICF online browser is available.

A minimum of three EBM relevant references are required. Links to PubMed or the Cochrane Library meet this requirement, but textbooks do not apply here.

The last page (about the Audit Spiral) is intended to give this quality assessment process a dynamic improvement approach. Three boxes are therefore devoted to the following questions: 1) what are the most positive (strong) points of your programme? 2) What are the weak points of your programme? 3) What action plan are you setting up in order to improve your programme?

The jury is composed of five members from various European countries. The members of the jury and their substitutes are appointed by the GENERAL ASSEMBLY. This same jury is responsible for assessing the programmes of all kinds submitted.

All the data submitted to the jury are made anonymous. The only person who is informed about the applicants’ identities is the Accreditation Manager, who does not participate in the decision-making process, but can supervise it and is responsible for all necessary exchanges of information between an applicant and the jury.

Jurors can exchange comments about each programme using a confidential dialog corner set up inside the Jury’s working area. A summary of the jury’s comments is sent by the Accreditation Manager to each candidate.

The jurors can vote either “yes”, “no” or “under consideration”. “Yes” means: “I would accept this programme with no objections”; “no” means: “I would reject this programme, which is not worth being corrected, since its intrinsic value is too low”; “under consideration”
means: “This programme is worth being corrected, and some improvements are required before it can be finally accepted (which may lead to a "yes" vote).”

The votes are automatically processed using the following algorithm:
— one or more “Under Consideration” votes: the application is given “under consideration” status;
— if there are no “Under Consideration” votes (all the votes are either YES or NO):
   a) 4/5 or 5/5 “yes” = accreditation without any further procedure;
   b) 3/5 “yes” votes = under consideration status;
   c) 2/5 “yes” or 1/5 “yes” or 0/5 “yes” votes = refusal

When a programme has been refused, it remains anonymous and the applicant is entitled to resubmit an amended version a second time without having to pay any additional charges.

Accredited programmes are immediately displayed on the home page of the accreditation website.

When a programme obtains the “under consideration” status, the applicant is requested by the Accreditation Manager to repeat the application procedure after improving it in line with the jury’s comments.

After the two-year pilot phase, a set of criteria on which to base refusal or acceptance (Table I) was voted by the General Assembly in Namur on March 8, 2008.

Random control visits will be organized in order to check the veracity of the information given in the questionnaires submitted to the jury. If any false declarations are discovered, the Accreditation will be withdrawn and this information will be published on the UEMS PRM website.

The pilot phase (2006-2007)

During the pilot phase 15 programmes from six different countries were submitted for Accreditation. These countries were: Austria (3), France (3), Hungary (3), Italy (1), Lithuania (3) and Slovenia (3).

The titles of these programmes mostly involved patients with neurological conditions (6), and some of them focused on stroke (3) and spinal cord damage (1). Other titles included walking assessment and the rehabilitation of patients with various conditions (1), elderly people under post-traumatic conditions (1), amputees (1), patients with osteoporosis (1) and cancer patients (1). Three of the programmes were General PRM Programmes, one of which was especially devoted to children. Children were also addressed along with adults in the other two general programmes submitted. Overall, 11 titles from the list of 15 suggested in the pop-up menu were selected by the applicants.

Eight out of the 15 programmes were immediately accredited by the jury, four were given “under consideration” status and one was refused. Among the programmes given “under consideration” status, one of the applicants never replied and was therefore subsequently refused. The other three were eventually accredited.

In the case of the programmes which were refused, all the applicants gave an insufficiently detailed open description and the responses to the questionnaire were inconsistent. This made the interpretation of the questionnaire difficult for the Jury. Problems also

Table I.— Criteria for European Accreditation of Programmes of Care in the field of PRM.

<table>
<thead>
<tr>
<th>Criteria for refusal</th>
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<tbody>
<tr>
<td>— The Programme of Care submitted is not run by a PRM Board Certified specialist</td>
</tr>
<tr>
<td>— Or there is a combination of the following negative aspects: 1) No provision is made for vocational training on the PRM health care programme; 2) No follow up is being carried out on the outcomes of the programme; 3) The scientific bases of the programme have not been specified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criteria for acceptance: the criteria do not all have to be fulfilled, but the following points will be the most important ones taken into account by the jury</th>
</tr>
</thead>
<tbody>
<tr>
<td>— Page 1 - General presentation: 1) Personalized title of the programme; 2) Comprehensive description of the programme, with information corresponding to each part of the questionnaire, explaining the reasons for responding yes or no</td>
</tr>
<tr>
<td>— Page 2 - Aims and goals: Goals must be consistent and should be expressed in terms of ICF categories</td>
</tr>
<tr>
<td>— Page 3 - Location and safety: Safety issues must be addressed</td>
</tr>
<tr>
<td>— Page 4 - Patient rights: Human rights issues must be addressed</td>
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<tr>
<td>— Page 5 - PRM Specialists participating in the programme should be listed</td>
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<tr>
<td>— Page 6 - Team management in the Programme: 1) Adequate staffing (competence); 2) Adequate continuing vocational training for physicians and staff</td>
</tr>
<tr>
<td>— Page 7 - EBM in the programme – organization and records: 1) There should be a clearly presented EBM basis; 2) Clear definitions of admission/discharge criteria should be given; 3) the programme should include properly organized patient records</td>
</tr>
<tr>
<td>— Page 8 - Monitoring and outcomes: 1) there should be appropriate numbers of patients/year; 2) Outcome measurements determined and the audit spiral should be clearly presented</td>
</tr>
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</table>

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In the case of the programmes which were refused, all the applicants gave an insufficiently detailed open description and the responses to the questionnaire were inconsistent. This made the interpretation of the questionnaire difficult for the Jury. Problems also
arose because the rule of anonymity was not complied with in the open questions, and the information provided about the EBM staff involved in the programme, the CME organization, the monitoring of the programme and the number of patients treated per year was not sufficiently detailed.

The programmes given “under consideration” status elicited similar criticisms to the above, but seemed to be better structured. After the additional information requested had been provided by the authors, these programmes were therefore eventually accredited.

The first nine accredited programmes were overviewed by A. Juocevicius and his team. These programmes completely met the following four criteria in the opinion of all the members of the Jury: 1) PRM interventions must be part of the programme; 2) adequate staffing (competence, number); 3) the physicians’ role should be rehabilitative; 4) properly organized patient’s records. The poorest response rates were obtained on the following two points: 1) clearly defined admission/discharge criteria (71 %); 2) clearly presented EBM basis of the programme. (71 %).

Professor Juocevicius’ review method was approved by the General Assembly in Namur and will be used for the regular monitoring of the European Accreditation procedure in the future.

Conclusions drawn at the end of the pilot phase (2008)

Despite the rather small number of applications received so far, it is worth noting that the countries involved up to now were fairly equally distributed between Eastern, Western, Northern and Southern Europe, and that they cover many/most of the aspects of PRM. Upon examination, these applications did not raise many questions about the intrinsic value of the programmes presented but rather as to: 2) how the jury should interpret their content; 2) how the applicants could present the features of their programme more clearly and convincingly. The “under consideration” option was therefore adopted in addition to the possibility of simply voting “yes” or “no” and the system was improved to allow anonymous exchanges of information between the jury and the applicant.

Although the criteria on which their decision was to be based was not defined at the start, the jury’s opinions generally converged. The differences between votes reflected various degrees of tolerance rather than fundamental differences of opinion.

The role of National guidelines and recommendations turned out to be a somewhat controversial issue, although no objections were raised about the need for Scientific Evidence to form the basis of any programme. Of course, the easiest way for an International jury to interpret a questionnaire would be to refer to the references to relevant studies published in English-speaking journals alone, focusing especially on papers indexed in databases such as PubMed and the Cochrane Library. But would this criterion reflect the approach actually used by a PRM team when setting up a programme? Would it not create a bias in a procedure designed to provide objective information about European diversity before trying to harmonize its organization?

We must remember that 23 official languages are recognized in the European Union and that it is stated in the UEMS statutes that both English and French are its official languages. Although English has been adopted as the most suitable working language, no other European language should be ruled out simply for the sake of convenience.

Sackett (Sackett DL) have defined EBM as “integrating individual clinical expertise with the best available external clinical evidence from systematic research”. Besides randomized trials and meta-analyses, tracking down the best external evidence available to answer clinical questions may involve the use of cross sectional studies on patients for developing diagnostic tests, follow-up studies for designing a prognostic approach, and transferring findings obtained in the basic sciences in fields such as genetics and immunology. “Some questions about therapy do not require randomised trials (successful interventions for otherwise fatal conditions) or cannot wait for the trials to be conducted. And if no randomized trial has been carried out for our patient’s predicament, we must follow the trail to the next best external evidence and work from there”.

The availability and the relevance of EBM in the field of PRM may therefore need to be assessed. After an extremely comprehensive study on the relevant scientific databases available, Janet A. Prvu Bettger and Margaret G. Stineman found only 12 systematic reviews, which addressed only five populations: stroke, brain injury, hip fracture and rheumatoid arthritis patients and “older adults”. No systematic reviews have been published so far on several conditions:
Parkinson’s disease, amputation, pulmonary disease, and cancer. The authors of only 8 of the 12 reviews mentioned above made conclusive statements.

Authors have often emphasized how difficult it is to compare results, due to the great differences existing between the conditions involved. Randomized control trials (RCT) may not be appropriate and are sometimes unethical in the case of patients with evolutive conditions. The best approach may be: 1) to perform prospective or retrospective studies the real clinical settings using nonrandomized designs, and making appropriate adjustments to compensate for any selection bias; 2) using non randomized designs in future research, after identifying the target populations and defining appropriate outcome measures. Efficacy studies involving the use of RCTs could then be used, especially to analyze specific components of rehabilitation treatment. Detailed guidelines on non randomized studies can be found in the Transparent Reporting of Evaluation with Nonrandomized Design (TREND) statement.18

But do EBM data cover all the aspects of good clinical practice? Scientific evidence brings to light the most universal features of medical interventions, whereas studies in the national context have to take into account patients’ cultural and religious beliefs and taboos, the manpower and equipment available, the way the work of health professionals is organized, and the interactions between health professionals and patients’ associations, governmental policy, and public and private funding (Table II). Applying EBM requires much more complex competences and skills than just the knowledge listed in the EBM literature. It is important: 1) to ask the right questions about individual patients’ problems; 2) to obtain the appropriate evidence and to critically assess it before using it; and 3) to perform regular audits on the outcomes.

Should all these aspects be immediately covered in the accreditation questionnaire? The Clinical Affairs Committee concluded that the Internet based accreditation procedure would continue to be used as a simple screening tool, which is not to be regarded as a final goal but the starting point for further efforts.

The action plan

The resulting action plan of the Clinical Affairs Committee was subsequently approved by the UEMS PRM Section General Assembly in Namur, on March 8, 2008. The aims were as follows:

To pursue the efforts made to set up a European system of Accreditation of the PRM programmes of Care.

To review and classify all the European resources available for Good PRM Practices.

To open on our websites (www.europrm.org and www.eurp-prm.org) a new space for resources promoting good clinical PRM practices. A member of the Clinical Affairs Committee and a member of the European Society of PRM (ESPRM) will be jointly responsible for managing this space.

To define what resources should be mentioned in the PRM care programmes submitted for UEMS Accreditation by establishing a follow up and review process.

To foster further research on the effectiveness of PRM in the context of a European network for the

<table>
<thead>
<tr>
<th>Disease</th>
<th>PRM intervention</th>
<th>Scientific evidence</th>
<th>National and local context</th>
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<tbody>
<tr>
<td>— Individual</td>
<td>— Diagnoses</td>
<td>— Sensitivity</td>
<td>— Cultural and religious beliefs and taboos</td>
</tr>
<tr>
<td>— Screening</td>
<td>— Population</td>
<td>— Specificity</td>
<td>— Manpower and equipment available</td>
</tr>
<tr>
<td>— Curing</td>
<td>— Feasibility</td>
<td>— Predictive value</td>
<td>— Modes of organization/communication among health professionals</td>
</tr>
<tr>
<td>— Preventing</td>
<td>— Evaluation</td>
<td>— Efficacy and effectiveness</td>
<td>— Interactions with patients’ associations</td>
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<td>— Caring</td>
<td>— Analysis</td>
<td>— Risks</td>
<td>— Governmental policy-makers</td>
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<td>Impairment,</td>
<td>— Functional, behavioural, environmental assessments</td>
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<td>— Public and private</td>
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<td>— Dysfunction,</td>
<td>— Therapeutic methods: drugs, injections, surgery, orthotics and prosthetics</td>
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<tr>
<td>— Handicap</td>
<td>— Rehabilitation, training and education</td>
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For making assessments
Scientific literature

National guidelines and recommendations

Table II.— EBM and national guidelines in good clinical PRM practices.
Quality of Care and at International and National Congresses.

Conclusions

Quality of care in the field of PRM is a fascinating but highly complex issue. Rather than prolonging an endless discussion on the ideal principles which should be imposed at the European level, we have decided to adopt a “learning by doing” approach, based on the information provided about “real life” situations all over Europe.

References