

## ◆ REVISIÓN

# Accreditation in digestive endoscopy

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For pharmaceutical treatments, strict licensing and regulatory processes motivate the production of a reasonable evidence base. On the other hand there has been little demand for legislation on interventional procedures and for the production of guidance on their use. This has meant that new interventional diagnostic and therapeutic procedures have often disseminated with a poor evidence base and in the absence of any kind of control or monitoring. The recent trend towards greater international collaboration aims to optimize the quality of the assessment of new procedures and the efficiency of existing systems.

### Development of quality assurance in digestive endoscopy

At first, quality assurance concerned surgery and disciplines involving a surgical option: gynecology and obstetrics, stomatology, ophthalmology, and also anesthesia and reanimation. Then it was applied to disciplines including interventional procedures with a risk of failure or complications, concerning ophthalmology, gastroenterology, pneumology, cardiology, radiology.

During the third quarter of the 20th century, in a period of innovation, pioneers developed endoscopic diagnostic and therapeutic procedures in the digestive tract. At this period, there was no control neither of training and technical capacities of the operator nor of efficacy and risk of complications linked to the procedure. The evolution toward guidance and quality assurance was stimulated by the increasing cost of procedures reimbursed by medical insurances (government or private) and by the multiplication of suits requiring indemnisation for malpractice. Endoscopic procedures are now evaluated on the

terms of cost, efficacy and risk of complications. The evaluation of cost / effectiveness aims to improve methodology, results, and to decrease the risk of complications of established and new procedures.

The development of quality assurance is a major task of the Health Authorities in liaison with experts issued from the respective medical societies. The capacity of the physician in diagnostic or therapeutic procedures is submitted to accreditation based on his previous experience and knowledge obtained in training courses. Quality assurance also applies to the Hospital environment which is submitted to certification, after the report from expert visitors. Accreditation of the physician and certification of the hospital are narrowly connected and periodically controlled.

### Quality assurance and the practitioner

The usual curriculum of a physician endoscopist includes graduation in the specialty gastroenterology and adequate training in endoscopy. In many countries, other categories of physician practice endoscopy in justification of their experience and previous training. This occurs particularly with surgeons but also with internists and general practitioners. In England, general practitioners often perform endoscopy in community medicine and in hospital endoscopy units. Their ongoing competence will be regularly reassessed at 3 years intervals, to ensure that the standard demonstrated at initial accreditation is sustained.

Nurses may practice digestive endoscopy in some countries. In the USA the practitioner nurse receives a specific training and performs procedures while a physician is present in the sector. In England endoscopy is widely practiced by nurses and is not limited to sigmoidoscopy or solely for diagnostic purposes. Most clinicians predict an important but restricted role for endoscopy by nurses in endoscopic services. In this country the endoscopy-nurse receives an endoscopic training similar to that of doctors in

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medicine, and is submitted to the obligation of continuing education. The endoscopy-nurse is responsible for the procedure, including cases of malpractice or complications.

### **Quality assurance and the patient**

The basic requirements from the patient point of view include at first safety and efficacy of the procedure, then a clear result completed by assessment of pathology and a clear follow-up plan. Other requirements include privacy, dignity and the informed consent, which should be referred to in the record of the endoscopic procedure.

### **Quality assurance and documentation**

The endoscopy report of a procedure includes the following statements: date of procedure, patient's identification, identification of the operator and his assistant, a brief documentation of the patient's history, indication of the procedure, medication administered before or during the procedure, type of sedation, analgesia and anesthesia, indication of informed consent, reference of the instrumentation including accessories, and use of disposable material. The record of the procedure describes the anatomic extent of examination, diagnostic findings or therapeutic intervention if any, duration of the procedure, complications occurring during the procedure if any, and notation of fluid or tissue sampling.

Quality in documentation requires the use of appropriate terminology in the record. An international list of terms approved by OMED, ESGE, ASGE, JSGE, is now available in 14 languages. This Minimal Standard Terminology (MST) for Computerized Databases in Endoscopy is available in endoscopy software packages, under the name of Endobase - ESI by Olympus. The endoscopy report recorded in a computerized base or CD, can be transferred to selected sectors such as pathology, radiology, within the hospital. Image filling is another requirement in documentation: images are recorded either as a video which can be transferred to a CD or as selected still images to be printed in the record.

### **Quality assurance and control of guidance**

Endoscopy involves the use of special skill and each physician will be judged against the standard of

an "ordinary skilled practitioner" having proved that special skill. Accreditation is not always an obligation. Accreditation is an individual initiative occurring on a volunteer basis and is repeated at regular intervals.

Certification applies to all hospital units and is an obligation in many countries. Factors considered in addition to the performance of the endoscopic procedures, are conditions of sedation and anesthesia, safety of gas distribution, material of defibrillation, control of risk of fire, modalities of disinfection of endoscopes and reprocessed material, recording of nosocomial infections, organization of the team of nurses, and care given to inpatients. Certification is a global procedure evaluating the hospital environment and applies to all units and medical disciplines. Certification is delivered for a period of 4 to 5 years after the report of an on-site visit and has to be regularly renewed.

### **Accreditation for digestive endoscopy in some countries**

**USA.** The first national attempt to accreditation was held in 1917 for quality control in surgery, by the American College of Surgeons (ACS). The same College transferred in 1951 its responsibility to Joint Commissions. Since 1987 the Joint Commissions on Accreditation of Health Care Organizations (JCAHO) enlarged their spectrum of activities to home care, nursing home and ambulatory care. JCAHO's governing board includes doctors, nurses, medical directors and consumers. They publish an accreditation manual for hospitals. For digestive endoscopy, a liaison network has been established since 1992 between the JCAHO and medical societies of specialty. The American Society of Gastrointestinal Endoscopy prepares guidelines for practicing endoscopists as a complement to JCAHO.

Periodical controls are required to maintain accreditation of the physician which takes in account the credits obtained on continuing medical education (CME). In the USA, many states require CME for medical professionals to maintain their licenses. Credits apply to such activities as live events, written publications, online programs, audio, video or other electronic media. CME courses are delivered by a variety of professional associations, medical education agencies, hospitals, educational institutions, including universities. Within the USA, CME for physicians is regulated by ACCME (Accreditation

Council for Continuing Medical Education). The ACCME's mission is the identification, development, and promotion of standards for quality of CME used by physicians in the maintenance of competence and incorporation of new knowledge.

**France.** Quality assurance is controlled by a public organism, the "Haute Autorité de Santé" (HAS) which substituted in 2005 to the previous organism named ANAES. The HAS is divided in various sections, corresponding to evaluation (safety and efficacy) of drugs and procedures, accreditation of doctors and certification of hospital units. Each section of the HAS is held by a college of administrators and delegates of medical disciplines and industry. The evaluation of capacity to perform endoscopic procedures and compliance to continuous training is called "Evaluation des Pratiques Professionnelles" (EPP) and is patronized by joint societies EA-HGE ("Evaluation et Accreditation des Hépatogastroentérologues"). The accreditation of the specialist is not an obligation and only a small proportion of the concerned physicians practicing endoscopy comply to this personal accreditation. On the other hand, the accreditation of the hospital environment, which is called a certification, is an obligation. The procedure of certification established in 2002 includes two successive steps: -autoevaluation in the hospital and on-site visit of the hospital by a team of visitors which results in recommendations varying from direct certification, changes requested or suspension. The certification concerns all aspects in the hospital unit and therefore, in addition to the performance of the procedure, the conditions of sedation, disinfection and role of the paramedical staff. The accreditation of the physician performing acts in this specific situation is a consequence of the certification. This certification attributed for a period of 4 years should be renewed after a new visit.

**England.** Since 2004, twice a year in April and October, the practitioner is submitted to a self-evaluation questionnaire called the Global Rating Scale (GRS) system, that was established for digestive endoscopy by Valori since 1964. This GRS is equivalent to accreditation. The Joint Advisory Group (JAG) founded by colleges of specialists issued from the Royal Colleges of Surgeons, Physicians, Radiologists and General Practitioners is responsible for accreditation in digestive endoscopy, which is equivalent to certification. Indeed, the JAG proceeds to the on-site evaluation of the team by visitors, and gives a recommendation with 5-year validity.

**Japan.** Accreditation is delivered to medical doctors after 5-year training in gastroenterology including endoscopy, and continuing education through attendance to meetings. The standards for accreditation are established in cooperation with the corresponding medical societies which are the Japan Gastroenterological Endoscopy Society and the Japanese Society of Gastroenterology. Accreditation of the physician must be renewed at intervals of 5 years. Hospital units are also submitted to certification.

**Brazil.** In this country a National Committee for accreditation of doctors who have a title of specialist has been instituted in 2005. The National Committee is composed of members of the national societies for the respective disciplines. Concerning digestive endoscopy, these societies are the "Sociedade Brasileira de Endoscopia Digestiva" and the "Federação Brasileira de Gastroenterologia". Since 2006, each specialist must apply for an accreditation to be renewed every 5 years after accumulation of 100 points obtained through continuing education, academic or scientific activities. As to physician malpractice, although Brazil has regulations and institutional mechanisms, their application is rather low. A major step toward hospital accreditation in Latin America took place during the Latin America Conference on Hospital Accreditation, held in Washington D.C., with support of the Pan American Health Organization (PAHO) in 1989. A Manual of Hospital Accreditation has been prepared by PAHO experts. In Brazil, hospitals that participate in accreditation programs have been found to implement continuous quality improvement programs. However, the standards of accreditation are only applied in the minority of Brazilian hospitals which received the basic licensure of the "Organização Nacional de Acreditação" (ONA).

### Quality assurance and innovation

Increasing control in the rules of good practice in medicine, leads to regulate any new procedure, through the rules of evidence based medicine. Randomized trials are requested to avoid the bias of prospective studies. The increasing supervision of the procedures impairs innovation because the development of new procedures is linked to transgression of established rules. The task of health authorities is to maintain an adequate balance between quality assurance and transgression of rules. Any new procedure or treatment introduced must be monitored to ensu-

re it provides effective clinical outcomes for patients and does not create additional unacceptable cost pressures. Health authorities may approve the development of innovative or costly techniques only in the centers, showing adequacy for investigation in a specific area. These centers should provide an evaluation of their methodology and results. In France a new legislative text from Health Authorities, published in July 2009 (article L1151-1), states that innovative diagnostic or therapeutic procedures can be authorized in a limited number of hospitals. In England, since 2002, the Interventional Procedures Programme (IPP) of the National Institute for Health and Clinical Excellence (NICE) has had responsibility for assessing efficacy and safety of new interventional procedures and for producing guidance on their use. The policy applies to medical, nursing and professions allied to Medicine.

#### Web-sites

- **USA**  
Joint Commission on Accreditation of Healthcare Organizations (JCAHO):  
<http://www.jointcommission.org>  
American Society for Gastrointestinal Endoscopy:  
<http://www.asge.org>
- **France**  
Haute autorité de Santé (HAS):  
<http://www.has-sante.fr>  
Evaluation de l'accréditation des hépatogastroentérologues (EA-HGE):  
<http://www.ea-hge.org>  
Société Française d'Endoscopie Digestive (SFED):  
<http://www.sfed.org>
- **England**  
Joint Advisory Group on Gastrointestinal Endoscopy (JAG):  
<http://www.thejag.org.uk>  
British Society of Gastroenterology (BSG):  
<http://www.bsg.org.uk>  
Global Rating scale (GRS):  
<http://www.grs.nhs.uk>
- **Japan**  
Japan Gastroenterological Endoscopy Society (JGES):  
<http://www.jges.net>
- **Brazil**  
Comissão Nacional de Acreditação:  
<http://www.cna-cap.org.br>  
Sociedade Brasileira de Endoscopia Digestiva:  
<http://www.sobed.org.br>

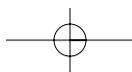
#### • Europe and World

European Society of Gastrointestinal Endoscopy (ESGE):  
<http://www.esge.com>

Minimal Standard Terminology:  
<http://www.omed.org>

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