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WFITN ethics charter

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Since the foundation of the World Federation of Interventional and Therapeutic Neuroradiology (WFITN) 25 years ago, one of the goals that some previous Executive Committees had on their program was to create an official Charter of Ethics. Nevertheless, multiple attempts to create an Ethics Committee to write a charter have regularly failed. Why?

The origin of this failure could be found in the fact that even if we have friendly close relationships inside our federation, our origins are very various and different, coming from all over the world and from different specialties. Consequently, we do not share the same cultures, the same religions, the same ways of life, the same beliefs . . . which leads to the fact that value of the human life is not appreciated in the same way within our different countries and continents. According to that situation, the solutions we can choose to take a difficult decision are obviously not always identical, which is absolutely normal.

It explains why nowadays, many societies have written their own Charter of Ethics, all of which are often very different.

In 2014, thanks to the dynamism and the energy of Georges Rodesch, President of the WFITN, it was at last decided to dedicate the next annual WFITN seminar to ethics. The seminar was held during the 2015 ABC WIN meeting in Val d'Isère. Professor Felix Umansky, former Chairman of the Ethics and Medico-Legal Affairs Committee of the World Federation of Neurosurgery (2005–2013), was invited to present to us the World Federation of Neurosurgery (WFNS) Ethics Charter and the way his group achieved consensus inside the WFNS. During the same working session, some colleagues coming from different parts of the world have described the main ethical concerns of their countries.

This allowed us to write this draft. We have not only used our own experience based on multiple discussions between us inside our World Federation, but we have also drawn some inspiration from the WFNS charter, which is one of the best ethics charters already published globally. In the months following the 2015 seminar, we have worked to write a proposed charter, taking into account the different points of view that have been collected. This draft has been carefully analyzed, and then modified during the last 2016 WFITN seminar in Val d'Isère under the current presidency of Sirintara Pongpech, thus resulting in this official document.

The WFITN ethics charter is based on evidence, assessments, and questions. It is a document that is intended to be remodeled and to evolve. Nobody indeed owns the truth, and sometimes what we believe to be the truth today can be completely wrong tomorrow.

We must thus be aware that our personal ethics will remain subject to change, and will have to be adapted according to the evolution of the countries and societies in which we live.

Ethics is in the field of doubt.

It explains why our charter cannot be a list of rules applicable to all patients in all countries. Its goal is to indicate some principles, allowing us to think together inside our own teams about how to choose the best, or very often the least bad solution for our patients.

We must remain modest and indulgent. For some very sensitive topics, it was not possible to reach a consensus. Consequently, as for the training recommendations, this charter will certainly be discussed again and modified in the future.

WFITN Charter of Ethics in Neurointerventions

With the Collaboration of:

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1. Introduction

Relationships between patients and physicians are based on ethical principles developed over time for the well-being of patients. However, with the increasingly rapid development of tools, equipment, techniques, and treatment strategies, it is critical to engage in an ongoing process of reflection in order to update these ethical principles in pace with the changes.

Consequently, formulation of this charter was undertaken by the WFITN to help neurointerventionalists, working in either academic or private practice, to confront problems in patient management and research. The charter is intended to present a set of recommended guidelines rather than rigid rules. It is meant to support international efforts to raise the standard of care globally. Clearly, not every situation can be encompassed by any written guidelines, and this charter should be used with flexibility and adapted to the local culture and legal system. Our intent is that reflection on the principles delineated in this charter be an ongoing process, with planned future modifications of the charter as needed.

2. Competence, training, continuing medical education, and certification

2.1. Training

To ensure the best standards of care, training guidelines must be clearly defined and consistently upheld.

Trainees in neurointervention originate from different specialties (mainly neuroradiology, neurosurgery, and neurology), and specific training pathways have been previously elaborated and published by the WFITN (*Interventional Neuroradiology—Training Charter*: *INR 2009; 15: 11–15*).

In order to become a fully trained neurointerventionalist, after completion of background training in neuroimaging or clinical neuroscience, the standards call for two years of additional full-time study in an accredited neurointerventional training program. Comprehensive training, spanning all aspects of relevant basic science and clinical multidisciplinary practice, from treatment planning through complication management, is mandatory. The training program should cover, without bias, all appropriate therapeutic options, such as surgery, endovascular treatment, radiosurgery, medical treatment, or therapeutic abstention.

The training program should integrate the principles of Evidence-Based Medicine (EBM).

Senior neurointerventionalists have the duty to engage in teaching and training postgraduate physicians. They should freely pass along their skills as mentors, in order to raise the standard of neurointerventional practice.

During the teaching process, the whole team must respect the patient's dignity and confidentiality.

Experienced neurointerventionalists are responsible for deciding when trainees have reached sufficient competence, skill, and clinical maturity to assist in procedures, to practice with supervision, or to perform with relative independence. Tolerance of a rate of complications above and beyond accepted levels of morbidity and mortality for a given procedure in the name of a "learning curve" is not ethical.

Neurointerventional scientific societies and world federations play a central role in the organization of training and teaching, and the societies should be closely involved in setting standards for formal certification.

If financial support for teaching is provided by companies, the content must be independent and free of corporate influence in order to avoid conflicts of interest.

2.2. Training centers

The optimal neurointerventional training center has been described in the WFITN recommendations on practice (*published in Interventional Neuroradiology 2006*).

The director of a training program should be certified in accordance with local regulations. He or she is responsible for enforcing the curriculum, selecting and supervising trainees, and overseeing their interactions with faculty members.

It is the responsibility of the program director to ensure that the program meets the required academic standards.

The program director should seek accreditation of the program by relevant national regulatory bodies.

It is an ethical obligation to help to develop neurointerventions in the developing world through residency and fellowship programs, humanitarian missions, courses, and partnerships with industry in order to allow patients from poor countries to benefit from these treatments.

2.3. Continuing medical education

Neurointervention comprises a dynamically evolving set of treatment strategies, concepts, and equipment, and continuing medical education is mandatory for all practitioners.

Facilitating the maintenance of up-to-date knowledge among practitioners is part of the ethical mandate of the WFITN.

2.4. Certification and recertification

Practitioners should undergo certification as per their national regulations and should recertify regularly in order to maintain their competence.

3. Daily medical practice

3.1. Standard of care

Neurointerventionalists should cultivate a high level of professional dedication in order to provide patient care with compassion and respect.

Patients are entitled to the highest standards of care without attention to race, gender, or financial means.

In time of peace, as well as in time of war or conflict, care should be provided without discrimination.

Medical decision making should focus on medical judgment, taking careful account of the patient's, the family's, and society's norms, without discrimination and without imposition of the physician's own moral judgments or religious beliefs.

Neurointerventionalists must be aware of the limits of their competence, and refer patients to colleagues with specialized expertise more suited to a specific patient's condition.

Each practitioner and each team must perform a minimal number of annual procedures in order to maintain competence. The precise number is subject to local norms and regulations, with reference to standard practice, as previously published.

The decision to recommend an interventional procedure should be predicated on the belief that it will offer the patient substantial benefit, free from financial incentive to the physician.

The realistically estimated risk level of complications must be acceptable to the patient and family members.

3.2. Standards of practice

Standards of practice in neurointervention have previously been published by the WFITN (*Interventional Neuroradiology 2006; 12: 7–8*). Ideally, these include but are not limited to round-the-clock service, admission privileges to an Intensive Care Unit, a full team of trained staff (neurointerventionalist/anesthesiologist/nurse/technologist), and access at all times to relevant neuroimaging examinations.

The neurointerventionalist must remain personally involved in the care of patients for whom he or she has primary responsibility.

Whenever possible, the neurointerventionalist should avoid distant travel during the early postoperative period after a high-risk procedure.

The capacity to offer emergent intervention at all hours, with adequate supervision, is an important part of a neurointerventional service.

Clinical records, with detailed description of operative procedures, medical management, and summaries of discussions with patients and relatives, should be promptly written and consistently updated.

3.3. Material and devices

The neurointerventionalist should strive to ensure that he or she has access to and facility with the most updated and appropriate tools and equipment available in order to provide maximally efficacious and safe care.

Regular maintenance to ensure that all equipment is in working order is highly recommended.

In every case, the device or equipment best suited to the patient's pathology should drive decision making. Conversely, the acceptance of payment for using particular devices or equipment is inappropriate.

3.4. New material, devices, equipment, and procedures

Scientific assessment of the safety, efficacy, and value of all new or innovative technologies is critical. The need for new assessment of a modified device is dependent on the novelty of the modification relative to the prior device. Such assessment may range from carefully monitored observational studies to controlled randomized trials.

New techniques and technologies should not be advocated or advertised before scientific assessment, the results of which should be published in peer-reviewed medical journals.

3.5. Relationships with and attitude toward patients and relatives

The neurointerventionalist should always act fairly and honestly, without making any false claims about qualifications, training, experience, or skills.

Words and presentation have a tremendous influence on patients and their families, imparting to the physician the potential power to sway patients' decisions. Consequently, there exists a real medical "Ethics of Language," best learned by experience. What the physician believes to be the truth should be honestly explained, without inducing stress in the patient or family designed to lead to particular decisions by way of emotional manipulation.

Information about benefits and risks, including the operator's own experience and own record of relevant morbidity and mortality, must be offered to patients and families in a manner that is unbiased, clear, understandable, and complete, in accord with the patient's educational level and language ability.

All relevant alternative treatments must be described, and pros and cons discussed.

Where relevant, the cost to the patient of the selected procedure should be explained. Terms for payment should be clearly communicated. The financial resources of the patient should be accommodated to the greatest extent possible; in particular, care should not be denied on the basis of inability to pay.

With the patient's approval, it is recommended that medical information be shared with the patient's family, relatives, or legal representative.

It is recommended that careful records of information discussed with patients and families be kept (in the form of notes, signed documents, videos, etc.), in accordance with local custom and regulations.

The decision to intervene or not and the development of a treatment strategy are often more challenging in the setting of an asymptomatic patient, where treatment is preventive in nature. Particularly in such challenging cases, multidisciplinary consultation should be sought and recorded before making a recommendation to the patient. Various treatment options must be carefully explained to patients and families, thus empowering them to participate in decisions about their care.

The neurointerventionalist should listen to patients and strive to be sensitive to their feeling of vulnerability. All questions should be answered as thoroughly as possible.

A patient always has the right to refuse treatment, and his or her decision must be respected.

In accord with local national legislation, it may be necessary (and it is always recommended) to obtain written informed consent from the patient.

When patients are temporarily incompetent on a neurological basis, treatments that are lifesaving or designed to prevent serious disability should be carried out.

For all elective cases, it is important to provide the patient and family with time to contemplate their decision, between the date of the consultation and the date of the procedure.

Patients' confidentiality must always be respected (e.g., in the sharing of files, images, photographs, or other medical data).

However, in exceptional circumstances, the duty to society may override the patient's right to confidentiality, as in cases where a patient is planning to embark on an activity for which he or she is unfit, and in the course of which he or she may pose a danger to others. Even in such cases, one should first attempt to dissuade the patient and obtain permission for disclosure. When disclosure is legally mandated or required by a court of law, compliance is incumbent on the physician.

Termination of a relationship with a patient should not be impelled by a physician's personal beliefs or attitudes regarding the patient's private life or by the patient's inability to pay. If there is a breach of trust between physician and patient, care should be transferred to another qualified physician without abandoning the patient.

3.6. Standards of personal and professional life

The professional relationships between physicians should be based on the rules of professional medical ethics.

Situations may arise, due to such factors as the age of the physician, injury, illness, sleep deprivation, etcetera, when the technical competence and stamina necessary to perform neurointerventional procedures may decline. It is incumbent on the neurointerventionalist to adjust his or her practice appropriately or to refrain entirely during such times in order to avoid harming patients.

Patient referrals, the particular choice of procedure, and the use of particular devices must not be driven by personal benefit to the physician.

The physician should limit the source of his or her professional income to services that he or she provides, or for which he or she is personally responsible or oversees. Medical fees should be commensurate with rendered services.

4. Research and clinical trials

4.1. Choice of research topics

Given the countless fields of inquiry and limited financial resources, any medical research intrinsically involves a choice of one specific area from among many. Resource allocation should be carefully considered and should take place with the help of scientific bodies, with the best interests of patients and society at large.

Since many conditions treated by neurointerventionalists fall into the category of rare or ''orphan'' conditions, research into such conditions should be supported and not be deterred by small financial returns. Research should be driven by the public good rather than by financial considerations.

Resource allocation for research, including the choice of research focus, will vary by country, depending on the local needs; this is ethically appropriate.

Since angiography suites and devices are very costly, neurointervention is currently a specialty with much greater presence in rich countries, with access more readily available to relatively wealthy individuals. Thus, it behooves us, on an ethical basis, to encourage research aimed at reducing the costs of available treatments, and making such treatment accessible to the largest number of people.

4.2. Management of research

Research must always be conducted in full compliance with national laws and professional regulations, including the Universal Declaration of Human Rights (1948). The ultimate goal of research should be the betterment of humankind.

The potential benefits of any research endeavor should always be greater than the potential risks to the subject.

To ensure maximum patient safety, any study protocol must be detailed, precise, and rigorous, and must be approved by the local Ethics Committee.

The least invasive method of imaging that addresses the research question should always be encouraged in research protocols.

Multidisciplinary Scientific Committees, either as part of the Ethics Committee or as an independent body, must validate research protocols.

Ethics Committees must be independent bodies, consisting of healthcare professionals and non-medical members, whose responsibility is to protect the rights, safety, and well-being of human subjects involved in clinical trials. As per local regulation, Ethics Committees must both initially validate protocols and monitor ongoing investigations by way of regular reports.

To protect their safety, dignity, and privacy, patients must be fully informed, in writing, of the purpose and methods of the research in which they are participating, as well as of the risks of complications. They must sign an informed consent, and be made aware of their right to opt out of the study at any point.

A neurointerventionalist who conducts research on behalf of an outside entity may accept reasonable fees, including support for his or her time spent in performing the study. However, he or she should not accept any honorarium that is contingent on the outcome of the study, as this creates a conflict of interest and may lead to bias.

For research funded by industry, protocol development and Data Safety Monitoring Boards should be independently appointed and operated, rather than under the aegis of the underwriting company.

4.3. Randomized studies

Randomized studies entail a comparison between two groups randomly made. Under conditions of uncertainty, the best option for individual patients is participation in a well-designed randomized trial. Despite the fact that some patients in the poorly performing arm may retrospectively feel that they have drawn a short straw, randomization in the setting of uncertainty is the ethical choice for the physician and the genuine best choice for the patient.

4.4. Confidentiality of data, protection of intellectual property, and publication of research findings

All collaborators in research and scientific investigation have the obligation to do their utmost to protect and uphold the integrity of the trial, and to ensure the ethical, scientific, and academic integrity of all aspects of the research process and resulting publications. The need to protect intellectual property may be a major factor influencing the timing of disclosure.

The results of research should not be published or advertised in non-medical media prior to publication in refereed scientific journals or presentation at a medical or scientific meeting.

At the time of publication, data should be fully and accurately disclosed, with appropriate recognition of sources of funding or sponsorship, including nonmonetary resources that contributed to the research undertaking.

Investigators are responsible for ensuring that data analysis, manuscript preparation, and presentations are objective and free of commercial input, influence, or bias.

All results, positive or negative, should be published.

Scientific integrity is of utmost importance; specifically, only one's own work should be published.

5. Conflicts of interest in research and clinical practice

A conflict of interest exists when a physician, an investigator, an author, a reviewer, or an editor has a financial or personal relationship that inappropriately influences or biases his or her actions.

Financial relationships, such as employment, consultancies, stock ownership, honoraria, gifts, and paid expert testimony, are the most easily identifiable conflicts. However, conflicts may also occur on the basis of other factors, such as personal benefit to the operator, personal relationships, academic competition, and intellectual passion.

When companies underwrite medical conferences or lectures, other than those explicitly offered under corporate aegis, or when companies contribute to the publication of medical and scientific literature, responsibility for and control over the selection of content, faculty, educational methods, and materials must lie fully and independently with the organizers and the publishers.

Scholarships or other special funds designed to enable medical students, residents, and fellows to attend selected educational conferences may be permissible, so long as it is academic or training institutions or professional societies who determine the recipients of the funds.

Subsidies from industry that are directly paid to neurointerventionalists to cover the reasonable costs of travel, lodging, or other personal expenses related to attendance at conferences or meetings, or to compensate for the neurointerventionalist's time, may be appropriate. However, further reimbursement, outside modest meals or social events held as a part of the conference or meeting, should not be accepted. A neurointerventionalist who serves as faculty at conferences or meetings may accept reasonable honoraria and reimbursement for reasonable travel, lodging, and meal expenses.

Neurointerventionalists must declare their conflicts of interests at presentations given at conferences or meetings.

6. Advertising

Personal publicity for physicians is typically strictly regulated by the relevant local authorities. In accordance with local norms and regulations, physicians have the right to inform professional colleagues about their particular competence and services offered.

Because of the increasing use of the Internet, public information regarding new procedures and technologies is progressively widespread. Unfortunately, much erroneous information that may generate false hopes in patients is prevalent on Internet sites and social networks. The physician should be sensitive to patients' resulting pre-existing expectations, and understand that there is no realistic hope of preventing the spread of such information. The appropriate response is to engage in detailed discussions with the patient and family in order to clarify misunderstandings and offer realistic assessments.

All communication by physicians through the Internet, TV or newspaper advertisements, or other media must be truthful and utterly free of deceptive or misleading information.

Scientific and medical societies must be aware of the prevalence of false or misleading information available to the public, and should do their utmost to clarify the situation and provide accurate, relevant, and current educational material.