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Foreword

This document (FprEN 16686:2014) has been prepared by Technical Committee CEN/TC 414 “Project Committee - Services in osteopathy”, the secretariat of which is held by ASI.

This document is currently submitted to the Formal Vote.

Attention is drawn to the fact that in certain countries specific national regulations apply and take precedence over this European Standard. Users of this European Standard are advised to inform themselves of the applicability or non-applicability for this European Standard by their national responsible authorities.

Introduction

Osteopathy is a primary contact and patient-centred healthcare discipline, that emphasises the interrelationship of structure and function of the body, facilitates the body's innate ability to heal itself, and supports a whole-person approach to all aspects of health and healthy development, principally by the practice of manual treatment.

Patients who choose osteopathic treatment must be assured of the quality and the standard of care that they will receive.

This standard is concerned with the provision of osteopathic diagnosis, treatment and care. It aspires to set a standard that provides for high quality clinical practice, education, safety and ethics for the benefit of patients.

This European Standard does not supersede national legislation.

1 Scope

This European Standard specifies the requirements and recommendations regarding the healthcare provision, facilities and equipment, education, and ethical framework for the good practice of osteopathy.

2 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

2.1

care

interventions that are designed to maintain and improve health

2.2

case history

detailed account of a patient's health and disease status and other information provided by them

2.3

clinical record

document which relates to the case history, examination, assessment, evaluation, diagnosis, treatment or care provided to a patient, and any necessary administrative information

2.4

co-morbidities

concomitant but unrelated pathological or disease processes

2.5

consent

acceptance by a patient of a proposed course of action to be taken by an osteopath after having been informed of relevant factors relating to it

2.6

continuing professional development (CPD)

means by which members of a profession maintain, improve and broaden their knowledge and skills relating to that profession

2.7

diagnosis

the development by an osteopath of working hypotheses of dysfunction(s), and recognition of signs and symptoms of illness or disease using diagnostic processes of examination, assessment and evaluation

Note 1 to entry: This definition is being used in this Standard, whether or not the legislation of an individual state prevents such a term being used by an osteopath

2.8

dysfunction

area of the body with impeded biomechanical, neuroelectrical, vascular, biophysical, biochemical or cellular function which is causing a decrease in health

2.9

health

state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity

2.10

healthcare

activity carried out by a professional in the field of the health and/or well-being of the person

Note 1 to entry: This definition is being used in this Standard, whether or not the legislation of an individual state prevents such a term being used by an osteopath.

2.11

osteopath

osteopath (in some circumstances and some countries referred to as an osteopathic physician or osteopathic practitioner) is an individual who has completed an appropriate education in osteopathy and continues to demonstrate the required standards

2.12

osteopathy

primary contact and patient-centred healthcare discipline, that emphasises the interrelationship of structure and function of the body, facilitates the body's innate ability to heal itself, and supports a whole-person approach to all aspects of health and healthy development, principally by the practice of manual treatment

NOTE 1 to term: The terms osteopathy and osteopathic medicine are sometimes, and in some countries, used interchangeably

2.13

patient confidentiality

right of an individual to have information about them kept private

2.14

primary contact profession

profession that a patient may consult directly but does not imply managing the multidisciplinary care of the patient

Note 1 to entry: This definition is being used in this Standard, whether or not the legislation of an individual state prevents such a term being used by an osteopath.

2.15

referral

transfer of responsibility for care to a third-party for a particular purpose, such as additional investigation, care or treatment that is outside the referring practitioner's competence

2.16

treatment

interventions that are designed to improve, maintain and support health, relieve symptoms, or reduce dysfunction and disease

3 Description of Osteopathy

The practice of osteopathy uses osteopathic, medical and scientific knowledge to apply the principles of osteopathy to patient diagnosis and treatment.

The aim of osteopathy is to improve and support all aspects of health and healthy development. Osteopathic treatment may be preventive, curative, palliative or adjuvant.

Osteopaths analyse and evaluate the structural and functional integrity of the body using critical reasoning of osteopathic principles to inform individual diagnosis and treatment of the patient.

These principles are:

- the human being is a dynamic functional unit, whose state of health is influenced by the body, mind and spirit; if one part is changed in the system, the balance of the whole pattern will be affected;
- the body possesses self-regulatory mechanisms and is naturally self healing; the human being always tries to regain its own dynamic balance and establish homeostasis; and
- structure and function are interrelated at all levels of the human being.

The osteopathic approach to healthcare is patient-centred and focused on the patient's health rather than disease-centred.

Scientific rigour and evidence-informed practice are an important part of patient treatment and case management.

Osteopaths use manual contact to identify and evaluate movement in all structural and functional aspects of the patient, identifying alterations of function and movement that impede health and addressing these. The highly developed sense of touch and attention to complex systems as a unit is typical of an osteopathic approach.

Osteopathy is an independent healthcare discipline. Osteopaths should also cooperate with practitioners of other disciplines.

Osteopathy is based on principles drawn from human physiology, anatomy, embryology and other biomedical sciences. In consequence of the complexity of the human organism there are a number of different models that are used in osteopathy.

The models set out in Annex A articulate how an osteopath seeks to influence a patient's physiological responses. These models influence the gathering of diagnostic information and the interpretation of the significance of structural findings in the overall health of the patient. Typically a combination of models will be appropriate for an individual patient and adapted to the patient's diagnosis, co-morbidities, other therapeutic regimens, and response to treatment.

The terms osteopathy and osteopathic medicine are sometimes, and in some countries, used interchangeably.

4 Clinical practice

4.1 General

Osteopathy is focused on the patient's health rather than being disease-centred. Osteopaths shall have an understanding of osteopathic and non-osteopathic models of health and disease and how these inform a critical consideration of practical patient care and management. They shall have a critical awareness of relevant research and of principles and practice of relevant healthcare approaches for adequate referral, cooperation and adjuvant treatment.

4.2 Essential competencies for osteopathic practice

Osteopaths share a set of core competencies that guide them in the diagnosis, management and treatment of their patients and form the foundation for the osteopathic approach to healthcare. The following are essential competencies for osteopathic practice which could be included in all training programmes (see 6.3 below):

- a) osteopathic history, principles, and approach to healthcare;
- b) basic sciences relevant to osteopathic practice;
- c) diagnosis and treatment planning;
- d) knowledge of the mechanisms of action of manual therapeutic interventions and the biochemical, cellular and gross anatomical response to treatment;
- e) ability to appraise medical and scientific literature critically and incorporate relevant and contemporary information into practice;
- f) competency in the palpatory and clinical skills necessary to diagnose dysfunctions of the body, with an emphasis on osteopathic diagnosis (see Annex A);
- g) competency in a broad range of osteopathic skills;
- h) proficiency in physical examination and the understanding of relevant tests and data, including diagnostic imaging and laboratory results;
- i) understanding and expertise in diagnosis and osteopathic treatment using the osteopathic models (see Annex A) and evaluation of the outcomes;
- j) thorough knowledge of the indications for osteopathic treatment, and contraindications to specific osteopathic techniques;
- k) ethical and legal aspects of healthcare;
- l) a basic knowledge of commonly used conventional medicine and Complementary and Alternative Medicine;
- m) a knowledge of practice, financial and data management, and regulation relevant to osteopathic practice; and
- n) self awareness and the ability to be self-critical, and to be able to respond positively to feedback from patients and peers.

4.3 Case History, examination and interpretation of the findings

Osteopaths shall take a case history of the patient and analyse the patient's presenting complaint. They shall be able to interpret verbal and non-verbal information. This information shall be individually recorded and stored safely. Confidentiality shall be maintained at all times.

Osteopaths shall give patients the information they need and in a way they can understand and benefit from. There should be an explanation of benefits and risks and as a result, consent given by the patient for the treatment/procedure.

Osteopaths shall formulate and record a diagnosis or rationale for care or referral, based on the osteopathic evaluation and the case history. The diagnosis and rationale for care shall be kept under review while caring for the patient.

Osteopaths shall select an appropriate course of action based on a rational decision-making process which includes a critical consideration of limits of competence, the likely effects of osteopathic treatment, relevant research and the patient's wishes.

Osteopaths shall demonstrate a detailed knowledge and understanding of human structure and function, with great emphasis on functional interrelation of all the systems of the body. This shall be sufficient to recognise, identify and differentiate between normal and abnormal structures and processes in the living body. Osteopaths consider and recognise through an understanding of the models (see Annex A) and principles that the presenting problem may be caused by underlying health concerns.

Osteopaths shall conduct an effective assessment and undertake a thorough, sensitive and appropriately detailed evaluation.

As well as using clinical skills to evaluate a patient, osteopaths shall also be able to determine whether further investigations are necessary.

Osteopaths shall have a knowledge and understanding of human disease and dysfunction sufficient to inform clinical judgement and to diagnose and to recognise disorders not suitable for specific osteopathic techniques.

4.4 Osteopathic treatment

Osteopaths shall generate accurate, contemporaneous clinical records of the outcomes of the patient evaluation and treatment process.

Osteopaths shall be able to justify how osteopathic treatment is applied to the patient.

Osteopaths shall select, use and modify a wide range of osteopathic techniques and patient management approaches. Osteopaths shall assess the effect of treatment during and after its application, where possible.

The purpose of osteopathic treatment may be preventive, curative, palliative or adjuvant. Osteopaths shall endeavour to help the patient regain as much of their natural structural integrity and function as possible. Osteopaths shall guide the patient to an understanding of the significance of the potential effect of the treatment and enhance the patient's understanding and commitment to individual exercise, preventive measures, adapting lifestyle and diet, as well as making use of healthcare disciplines, as appropriate. Osteopaths shall make clear the importance of these aspects and self-care activities for the patient's health. This includes explanation of its potential benefits, risks and limitations.

Osteopaths shall help patients to make informed choices about their personal healthcare maintenance. The osteopath shall educate the patient in the understanding of their disorders and how to manage their conditions or prevent recurrence.

Osteopaths shall be able to recognise adverse reactions to osteopathic treatment and to initiate appropriate responses, including referral when appropriate.

Osteopaths shall endeavour to work in partnership with healthcare professionals and patients, as effective interaction of all involved provides optimal care.

Osteopathic practice facilities shall meet the need of the patients for confidentiality and optimal cooperation in the treatment process. They shall be hygienic, safe and conducive to the delivery of high-quality healthcare, and adhere to national health and safety standards.

4.5 The osteopathic profession

4.5.1 General

Osteopathy is recognised as distinct from healthcare disciplines that utilise manual techniques and is not limited to the spinal thrust techniques often associated with manual medicine.

To avoid isolation as practitioners, osteopaths are recommended to seek cooperation with other practitioners and to join a national osteopathic association or register, or where no such body exists, work with colleagues to form an association or register. Osteopathic organisations are recommended to work in cooperation with others to promote high standards of osteopathy.

4.5.2 Continuing professional development

Osteopaths shall maintain and develop their knowledge and skills of osteopathic treatment and science through continuing professional development.

Continuing professional development shall maintain, improve and broaden the osteopathic knowledge and skills of the graduated osteopaths and develop the personal qualities required in their professional lives.

Subject to national legal regulations a requirement shall be put in place to ensure the continued formation of the osteopath in practice.

4.5.3 Quality management

Osteopaths and their national osteopathic associations are encouraged to develop systems of quality management in accordance with appropriate recognised European quality standards.

In the absence of existing national quality standards, osteopathic quality standards shall include:

- a) access to the practice premises;
- b) the consultation/treatment room;
- c) provision of waiting areas and other facilities for patients;
- d) information provided to patients about their treatment and care, including its price and any reimbursement mechanisms;
- e) hygiene and cleanliness procedures, for personnel, premises, facilities and equipment;
- f) systems and processes in place for managing emergency situations;
- g) security and confidentiality of patient information and other data;
- h) communication with patients including appointments and reception procedures;

- i) assessment of patient satisfaction; and
- j) continuous improvement processes within the practice.

5 Ethics

The osteopath shall provide services with high standards of ethical and professional behaviour. Annex B provides the principles of ethics for osteopaths. The osteopath shall observe these principles in their interactions with patients, prospective patients and other osteopaths and healthcare professionals.

6 Education and Training

6.1 General

An osteopath shall have reached a level of knowledge and skills through education and training that meets the following characteristics.

6.2 Forms and/or categories of education

6.2.1 General

Regulating the practice of osteopathy and preventing practice by unqualified practitioners requires a proper system of training, examination and licensing.

Benchmarks for training have to take into consideration the subsequent items:

- a) contents of the training;
- b) methods of the training;
- c) to whom the training is to be provided and by whom;
- d) the roles and responsibilities of the future practitioner; and
- e) the level of education required in order to participate in osteopathic training.

There are two types of training depending on prior training and clinical experience of trainees:

- a) Type I training programmes are aimed at those with little or no prior healthcare training, but who have completed high school education or equivalent; and
- b) Type II training programmes are aimed at those with prior training as healthcare professionals.

6.2.2 Common features of both Type I and Type II programmes

Osteopathic manual treatment is a distinctive component of osteopathy. It requires both cognitive and sensorimotor skills, and knowledge, and the development of these clinical and manual skills require time and practice.

Osteopathic skills and physical examination training shall be delivered via direct contact. Other academic curricular content may be delivered in various training formats.

Both Type I and Type II programmes shall be externally validated or assessed, with independent and expert osteopathic input.

Providers of osteopathic education and training shall ensure, through documented information, that clinical and academic staff have appropriate professional and educational knowledge, skills and experience, maintained with continuous professional development.

Supervised osteopathic clinical practice is an essential component of the training of osteopaths, which may take place in several formats. The majority of clinical training shall take place in an osteopathic environment. Suitable formats include:

- a) in a dedicated osteopathic teaching clinic, where high-quality clinical support and teaching can be provided;
- b) in medical hospitals or in healthcare establishments, where students are able to observe a wide variety of pathologies and standard medical treatments and to train in inter-professional communication;
- c) in school-approved private osteopathic practices where students are able to observe, diagnose and treat patients under supervision;
- d) in a teaching environment, where students are able to observe how an osteopath/lecturer performs a treatment of a patient and reflects the process with the students; and
- e) in a teaching situation where students may treat patients in front of students, supervised by the lecturer or table trainers and with patient consent.

The student shall undertake supervised osteopathic clinical practice within a dedicated teaching clinic. It is required that in all programmes the student shall perform osteopathic treatments in a dedicated clinic on no fewer than 50 distinct patients in order to be trained in a variety of presentations during their education. This includes taking the initial case history and examination, making a diagnosis, and formulating and implementing an osteopathic treatment plan for the patient.

6.2.3 Type I programmes

A typical Type I programme, as defined by the World Health Organization (WHO) Benchmarks [1], would take 4800 hours, including at least 1000 hours of supervised clinical osteopathic practice and training.

Models of higher education (including definitions of teaching, learning and contact hours) vary across the countries of Europe and the requirements for a Type I programme shall meet no fewer than two of the following three requirements:

- a) no fewer than 4800 hours;
- b) no fewer than 240 European Credit Transfer System (ECTS) credits, with a minimum of 60 ECTS credits at the level of the second cycle;
- c) a Master's level qualification (whether or not preceded by a separate Bachelor's level qualification).

6.2.4 Type II programmes

The length and content of a Type II programme shall be adapted depending on assessment of the prior education, training and experience of the student.

It is required that Type II programmes shall include a minimum of 1000 hours of supervised osteopathic clinical practice. However, this number might be adapted depending on the range of prior training formats as described in paragraph 6.2.2 above.

A typical Type II programme would take 2000 hours over a minimum of four years, including supervised clinical practice and training.

The osteopathic learning outcomes for a Type II programme shall be the same as for a Type I programme.

Type II programmes shall cover osteopathic core competencies including knowledge, understanding and application of the osteopathic models. Regardless of any prior education, training and experience, graduates of Type II programmes shall also demonstrate the same practical competencies of osteopathy, including sensomotoric skills and the application of osteopathic principles in clinical treatment, as graduates of Type I programmes.

6.3 Core competencies: the context of osteopathic education

Core competencies in osteopathic education consist of the following:

a) Basic sciences:

- history and philosophy of health sciences;
- gross and functional anatomy, including embryology showing the link to osteopathic understanding and treatment, neuroanatomical and visceral anatomy;
- microbiology, biochemistry and cellular physiology;
- physiology; and
- biomechanics and kinetics.

b) Clinical sciences:

- models of health and disease;
- safety and ethics;
- pathology and patho-physiology of the nervous, musculoskeletal, psychological, cardiovascular, pulmonary, gastrointestinal, reproductive, genito-urinary, immunological, endocrine and otolaryngology systems;
- applied anatomy, neurology and neurophysiology;
- diagnosis;
- radiology and laboratory results;
- nutrition; and
- relevant knowledge of pharmacology.

c) Osteopathic sciences:

- philosophy and history of osteopathy;
- osteopathic models for structure/function interrelationships (see Annex A);
- clinical biomechanics, joint and visceraphysiology and kinetics;

- mechanisms of action for osteopathic techniques; and
 - applied principles.
- d) Clinical skills:
- obtaining and using a patient history;
 - physical and clinical examination;
 - osteopathic diagnosis of the nervous, musculoskeletal, psychological, cardiovascular, pulmonary, gastrointestinal, endocrine, genito-urinary, immunological, reproductive and otolaryngology systems;
 - general synthesis of basic laboratory and imaging data;
 - clinical problem-solving and reasoning;
 - understanding of relevant and current research and its integration into practice;
 - communication and interviewing;
 - clinical documentation;
 - life-support and first-aid care; and
 - osteopathic treatment and osteopathic techniques (see Annex C).

6.4 Osteopathic teaching, learning and assessment

6.4.1 Teaching and learning

Teaching and learning in osteopathy programmes shall take place in a combination of the following contexts:

- a) Lectures: they shall convey and comment upon core subject matter informed by evidence, stimulate critical thinking and debate, and encourage students to extend their own knowledge and understanding;
- b) Workshops and seminars: they may commonly involve small group work, skills development, discussions and student presentations;
- c) Tutorials: they may support the process of self-assessment and tutor guidance and feedback. They may also provide support for individual or group work and for dissertation preparation;
- d) Self-managed or self-directed learning: this is an important part of any programme in osteopathy. It may involve preparation for specific assignments, reflection/discussion, practice of osteopathic techniques, and the use of resource-based learning, including learning resources made available in electronic and other formats. It is important that students are adequately prepared, guided and supported in developing and maintaining effective strategies for self-managed learning.
- e) Production of a dissertation: students will normally undertake their own individual osteopathy related research project or study.
- f) Supervised clinical practice.

6.4.2 Practical skills

The acquisition of practical osteopathic skills requires students to work on peers and, in turn, to experience taught techniques as 'models'.

Palpation and osteopathic technique shall be taught in specialist accommodation utilising appropriate equipment. Provision for students to review and assess their performance of their osteopathic practical skills through the use of regular tutor feedback in this area is ideal and critical.

Teaching and supervision in practical osteopathic technique skills is performed by suitably qualified osteopaths, registered with the relevant national Register or Competent Authority or with a representative association where the former bodies do not exist.

6.4.3 Clinical education

It is essential that clinical learning experience provides appropriate opportunities for students to develop not only patient evaluation and treatment skills, but also the ability confidently to recognise signs and symptoms indicating the need for referral and contra-indications to specific osteopathic techniques.

The clinical learning environment shall be a focus for the integration and practical application of all theoretical, practical, and technical knowledge and skills across the programme. It shall provide the student with a supportive, broad, progressive and well supervised environment in which to develop their clinical skills.

It is expected that students shall undertake substantial supervised osteopathic clinical practice within a dedicated teaching clinic where they can observe senior students and qualified practitioners in the early stages of their training, progressing to take an increasing responsibility for their own patient lists as their experience and knowledge develop.

The following arrangements for osteopathic clinical education are to be expected:

- a) adequate/appropriate learning opportunities for developing professional skills with real patients, paying due regard to case history taking, examination, evaluation and diagnosis, treatment and development of treatment plans, record-keeping, follow-up and referrals;
- b) opportunities to integrate academic and theoretical learning and to develop practical skills within the therapeutic clinical encounter;
- c) adequate numbers for each student of new, returning and continuing patient encounters and exposure to an appropriate range of presenting conditions;
- d) appropriate staff student ratios within the clinical setting allowing for close supervision of patient encounters by tutors, and opportunities for clinical tutorials;
- e) appropriate opportunities for junior students to learn from observation of more senior student practitioners and for senior students gradually to take over responsibility for their own lists and to develop autonomy in patient care;
- f) appropriate settings for clinic education within a dedicated training clinic with adequate treatment and educational accommodation, and appropriate equipment and furnishings for high-quality student experience and patient care;
- g) appropriate clinical administrative infrastructures to support student learning and patient care;
- h) arrangements for on-going assessment and feedback from a variety of clinical tutors;
- i) opportunities to develop practice management skills;

- j) effective mechanisms for monitoring individual student clinical attendance, caseloads, and patient list profiles;
- k) effective mechanisms for ensuring that high standards of osteopathic treatment and the safety of patients are maintained by guiding, developing and monitoring the professional conduct of students treating patients; and
- l) appropriate opportunities to participate in patient reviews with peers under supervision in order to develop peer review skills.

6.4.4 Assessment

Students of osteopathy shall master a wide range of knowledge and skills as indicated above, and they shall be able to demonstrate an ability to integrate and apply their learning as safe and effective practitioners. In achieving this it is also important that empathy with ethical behaviour towards patients, ethical conduct towards colleagues and others, and general behaviour consistent with that of an aspiring professional is demonstrated. In order to ensure that all the required learning outcomes are met and that students progress satisfactorily through the programme, a range of assessment strategies shall be employed.

These assessment strategies should include:

- a) demonstration of clinical competence and practice: including the ability to draw on, synthesise and apply knowledge and skills for safe and effective patient management. Methods of assessment may vary, but should always include the requirement for students to demonstrate skills working with a range of new and continuing patients. So as to ensure comparability of practitioner standards for entrants to the profession, it is essential that external examiners are physically present at some of the practical assessments with real patients in a real clinical scenario;
- b) practical examinations: in which students demonstrate their skills in selecting and performing a range of safe and effective osteopathic techniques;
- c) written examinations: under timed conditions, requiring students to work and think under pressure/usual examination conditions, assessing knowledge-base, understanding and analytical skills;
- d) dissertations or other pieces of extended written work: these are normally related to osteopathic practice and include systematic enquiry, investigation, analysis and evaluation, and shall demonstrate the student's ability to apply appropriate analytical methods, whether qualitative or quantitative, and to plan and carry out a research project.

Other assessment strategies and methods that may be employed include:

- a) portfolios: collating evidence to support claims that learning outcomes have been met. Portfolios may be a means of capturing and giving proper weight to experience, and may be used to document the acquisition of practical and/or clinical and/or affective skills;
- b) essays and other coursework: which enable students to display a broader knowledge of subject matter than in examination papers and test their ability to investigate a topic, to organise their material and ideas to a prescribed deadline, and to critically appraise published evidence;
- c) computer based assessments;
- d) case study presentations and analyses;
- e) oral presentations: testing presentation and communication skills in an individual or group situation;

- f) analytical exercises: including 'paper patient' exercises and Objective Structured Clinical Examination and Objective Structured Practical Examination type assessments.

Quality assurance/control mechanisms for assessment shall ensure external assessor review independent of the educational provider. This will provide a greater likelihood of consistent standards and will deter potential commercial exploitation of osteopathic education and training.

It is important that assessment strategies are regularly reviewed, with programme providers ensuring that best contemporary practice in this area is evaluated and applied where appropriate. The validity and reliability of assessment shall be considered carefully.

6.5 General management requirements

Providers of osteopathic education and training shall develop systems of quality management in accordance with appropriate and recognised quality standards.

Annex A (informative)

Osteopathic models

In 2010 the WHO listed the five models set out below [1]. However, these models are not exhaustive and do not describe fully the different approaches used by osteopaths in the treatment of dysfunction.

Five main models of structure-function relationships guide the osteopath's approach to diagnosis and treatment. These models are usually used in combination to provide a framework for interpreting the significance of dysfunction within the context of objective and subjective clinical information. The combination chosen is adapted to the patient's diagnosis, co-morbidities, other therapeutic regimens and response to treatment.

A.1 Biomechanical Model

The biomechanical model views the body as an integration of somatic components that relate as a mechanism for posture and balance. Stresses or imbalances within this mechanism may affect dynamic function, increase energy expenditure, alter proprioception (one's sense of the relative position and movement of neighbouring parts of the body), change joint structure, impede neurovascular function and alter metabolism. This model applies therapeutic approaches, including osteopathic manipulative techniques, which allow for the restoration of posture and balance and efficient use of musculoskeletal components.

A.2 The respiratory/circulatory model

The respiratory/circulatory model concerns itself with the maintenance of extracellular and intracellular environments through the unimpeded delivery of oxygen and nutrients, and the removal of cellular waste products. Tissue stress or other factors interfering with the flow or circulation of any body fluid can affect tissue health. This model applies therapeutic approaches, including osteopathic manipulative techniques, to address dysfunction in respiratory mechanics, circulation and the flow of body fluids.

A.3 The neurological model

The neurological model considers the influence of spinal facilitation, proprioceptive function, the autonomic nervous system and activity of nociceptors on the function of the neuroendocrine immune network. Of particular importance is the relationship between the somatic and visceral (autonomic) systems. This model applies therapeutic approaches, including osteopathic manipulative techniques, to reduce mechanical stresses, balance neural inputs and reduce or eliminate nociceptive drive. This is sometimes referred to as the cranio-sacral model.

A.4 The biopsychosocial model

The biopsychosocial model recognizes the various reactions and psychological stresses which can affect patients' health and well-being. These include environmental, socioeconomic, cultural, physiological and psychological factors that influence disease. This model applies therapeutic approaches, including osteopathic manipulative techniques, to address the effects of, and reactions to, various biopsychosocial stresses.

A.5 The bioenergetic model

The bioenergetic model recognizes that the body seeks to maintain a balance between energy production, distribution and expenditure. Maintaining this balance aids the body in its ability to adapt to various stressors (immunological, nutritional, psychological, etc.). This model applies therapeutic approaches, including osteopathic manipulative techniques, to address factors which have the potential to deregulate the production, distribution or expenditure of energy.

Annex B (normative)

Ethics for osteopaths

B.1 General

The osteopath shall comply with any regulations or legal requirements in force in the country or jurisdiction in which they practise osteopathy. Any such legal requirements shall also supersede the requirements in these standards.

B.2 Acting in the patient interest

The osteopath shall make their main priority the health and wellbeing of the patients in their care.

The osteopath shall at all times be honest and trustworthy in their dealings with patients, colleagues and healthcare professionals. The osteopath shall not use their professional position to place undue pressure of any kind on their patients.

Every patient shall be treated as an individual and with consideration, dignity and respect; the osteopath shall never allow care to be prejudiced by their views about patients. This includes their gender, ethnicity, disability, culture, religious or political beliefs, sexuality, lifestyle, age, social status, language difficulties or any other characteristic. The osteopath's own values, beliefs and attitudes shall not come before the overriding interest of a patient's wellbeing.

The osteopath shall respect the choice of the patient on whether to consult the osteopath and to accept or decline the treatment that the osteopath recommends. Equally, the osteopath is under no obligation to examine or treat a patient if they do not wish to do so. In the case that an osteopath does not wish to treat or examine a patient, they shall refer to another osteopath or healthcare practitioner.

The osteopath shall maintain clear professional boundaries with their patients and shall not abuse their professional position.

B.3 Working in partnership with the patient

The osteopath shall work in collaboration with the patient, encourage them to voice their own ideas about the cause(s) of their problem(s), and involve them in the decision-making process during the development of a treatment plan.

The osteopath shall take reasonable care using their professional knowledge and skills to advise and provide appropriate treatment for their patients making it clear to patients, as osteopaths, what they can and cannot offer.

The osteopath shall provide the patient with clear information about the fees or scale of fees that they will be charged for their examination, treatment and any other aspect of care. When known the osteopath shall inform patients about reimbursement possibilities by health public or private insurances.

The osteopath shall listen to the patient and respect their views, values and preferences, encouraging them to take an active part in any decisions about their treatment and ongoing care, including providing advice on self-care.

The osteopath shall explain to their patients in ways that they can understand the reasons for any examination or treatment, the benefits as well as any potential side-effects or serious risks from the treatment.

The osteopath shall obtain consent from a patient before examination or treatment of a patient and where appropriate continues to seek consent as treatment progresses.

The osteopath shall ensure that the patient's modesty is respected.

The osteopath shall make sure the patient is aware of their rights, particularly to stop an examination or treatment at any time and also to be accompanied by a chaperone if they wish.

In states where such procedures are allowed and where written consent is not already required by law, if the examination or treatment proposed is intimate in nature the osteopath is advised to seek written consent.

The osteopath shall comply with any additional legal requirements for obtaining consent for the treatment of children or others who may not be able to give consent.

B.4 Maintaining public trust and confidence in the osteopathic profession

The osteopath shall recognise and work within the limits of their knowledge, skills and competence. The osteopath shall never claim to have skills they do not have and shall refer, where necessary, to a more appropriate health professional.

The osteopath shall ensure that they do not provide an excess level of treatment, treatment that is not required, or in any way put commercial gain above the needs of the patient.

The osteopath shall not make misleading claims about the effectiveness of osteopathic treatment and shall comply with relevant national and EU laws on marketing and promotion.

The osteopath shall act quickly to protect patients if there is good reason to believe that they or a colleague may be putting patients at risk, either by reporting this to an appropriate authority, or in the case of the osteopath themselves ceasing to provide treatment to patients.

The osteopath shall operate a procedure for considering and responding to complaints against their practice and they shall respond promptly and constructively to criticism and complaints.

The osteopath shall refrain, even outside their practice of osteopathy, from any act likely to damage the reputation of the osteopathic profession.

The osteopath shall respect the skills of other osteopaths and healthcare professionals, and communicate and work in co-operation with them for the continuity of care and benefit of patients.

Where the osteopath cannot make themselves available to a patient, they shall ensure, as far as possible, that they have access to another osteopath. The osteopath shall not delegate osteopathic treatment to an individual who is not a qualified osteopath.

The osteopath shall ensure that they maintain personal liability insurance appropriate for their practice.

B.5 Maintaining, respecting and protecting patient information

The osteopath shall make and maintain a full and accurate clinical record for each patient and make appropriate information available to the patient on request.

It may be appropriate for that record to include:

- a) the patient's personal details;
- b) any problems and symptoms reported by the patient;
- c) relevant medical and family history;
- d) clinical findings;
- e) the information and advice provided;
- f) actual advice given to the patient regarding the risks associated with any proposed examination or treatment;
- g) the decisions made;
- h) records of consent and/or consent forms;
- i) the investigation and treatment provided or arranged, and their results;
- j) any additional communication in any form with, about or from the patient;
- k) copies of any correspondence, reports, test results, etc. about the patient;
- l) reaction to treatments/treatment outcomes;
- m) reference to any home/domiciliary visit;
- n) if a chaperone was present or was not required; and
- o) whether a student/observer was present.

The osteopath shall maintain confidentiality about all the information they have obtained in the course of the consultation, examination or treatment of a patient, unless otherwise specified by law.

Confidentiality requires secure retention and storage of information even after the individual is no longer the patient of the osteopath or after they are deceased, in compliance with any existing national standards where these are different.

In states where the sharing of information about patients is not prohibited by law, any such information shall not be transferred to any other person, including another osteopath or any healthcare professional who may be involved in the treatment of the patient or for research purposes (including any staff of the osteopath), without the consent of the patient and having provided them with a clear understanding of the reasons for doing so.

B.6 Working in partnership with healthcare providers

Osteopathy may complement healthcare disciplines. Communication and interaction with healthcare professionals are beneficial to patients and practitioners in particular, and for national healthcare systems in general.

Annex C (informative)

Types of techniques used in osteopathic treatment

Osteopathic treatment may involve a number of different techniques applied in different ways. Some of these different techniques are categorised below. The list does not include all the techniques used by osteopaths. Some techniques may fall within more than one category.

C.1 Direct techniques

These include high velocity-low amplitude-thrust, articulatory techniques, recoil techniques, soft tissue techniques, muscle energy techniques and general osteopathic treatment.

C.2 Indirect techniques

These include functional technique, strain-counterstrain, facilitated positional release.

C.3 Balancing techniques

These include balanced ligamentous tension and ligamentous articulatory strain.

C.4 Combined techniques

These include myofascial release, fascial unwinding, myotensive techniques, Still technique, exaggeration techniques, cranial techniques, visceral and neural mobilisation.

C.5 Reflex-based techniques

These include Chapman's reflexes, trigger points and neuromuscular techniques.

C.6 Fluid techniques

These include lymphatic and visceral pump techniques.

Annex D (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard does not fall under any Directive of the EC.

In the relevant CEN/CENELEC countries these A-deviations are valid instead of the provisions of the European Standard until they have been removed.

Deviation	
Country Austria	National Regulation Ärztegesetz 1998 (Federal law on the exercise of medical practice) BGBl. I Nr. 169/1998 MTD Gesetz 1992 (Federal law on the regulation of medical-technical services) BGBl. Nr. 460/1992 Ausbildungsvorbehaltsgesetz 1996 (Federal law on the restriction of non-authorized educational institutions in the area of medical services) BGBl. Nr. 378/1996
Clause 3 and 4	§2 and §3 Ärztegesetz und §2 MTD Gesetz According to case law solely medical doctors and physiotherapists, the latter based on a doctor's referral, are allowed to practice osteopathy
Clause 6.2.3	Ausbildungsvorbehaltsgesetz §1 Osteopathic education according to Type 1 Programme is not allowed
Country Bulgaria	National Regulation Naredba N 30 ot 19 juli 2004 "Fizikalna i Rehabilitacionna medicina" (Bulgarian Ordinance N 30 of 19 July 2004 laying down the medical standard "Physical and Rehabilitation medicine") http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=397 Nacionalna obrazovatelna programa po manualna medicina National legislation education program on manual medicine http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=397
Clause 3 and 4	Section VII § 3 and § 3.1 Bulgarian Ordinance N 30 of 19 July 2004 According to the Ordinance only medical doctors who have completed education in the medical specialty of Physical and Rehabilitation medicine are competent and allowed to practice osteopathy. "Highly specialized activities are practiced by medical doctors - specialists in physical and rehabilitation medicine with a certificate of successful completion of a relevant course or program of additional qualification, as follows: 3.1. manual diagnosis and therapy".

Clause 6.2.3	<p>§3 and §4 National legislation education program on manual medicine</p> <p>Osteopathic education according to Type 1 Programme is not allowed.</p> <p>According to the national legislation education program on manual medicine requires at least 11 years of medical education = 6 years of higher medical education (medical doctors) + 4 years clinical specialty "Physical and rehabilitation medicine" +1 year "Manual medicine" in Medical University.</p>
<p>Country Italy</p>	<p>National Regulation</p> <p>[Ref. 1]. Royal Decree 27th July 1934 n. 1265, Titolo II "Esercizio delle professioni e delle arti sanitarie e di attività soggette a vigilanza sanitaria", Capo I – "Dell'esercizio delle professioni sanitarie", Art. 99 (National law on the health professions)</p> <p>[Ref. 2]. Law 1st February 2006, n. 43 "Disposizioni in materia di professioni sanitarie infermieristiche, ostetrica, riabilitative, tecno-sanitarie e della prevenzione e delega al Governo per l'istruzione dei relativi ordini professionali" Art. 5 "Individuazione di nuove professioni in ambito sanitario" (National law on new professions)</p> <p>[Ref. 3]. Law 14th January 2013 n. 4 "Disposizioni in materia di professioni non organizzate", Art. 1 (Provisions regarding not organized professions.)</p> <p>[Ref. 4]. Italian Penal Code "Abusivo esercizio di una professione", Art. 348 (National law on illegally exercised profession)</p>
1 Scope	<p>According to the Italian legislation, healthcare provisions are regulated by Law and can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing a healthcare provision on a person/patient without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
2.1 care	<p>According to the Italian legislation, making "interventions that are designed to maintain and improve health" on a person/patient is a reserved activity which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such interventions on a person/patient without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
2.2 case history	<p>According to the Italian legislation, drawing up a "detailed account of a patient's health and disease status" is a reserved activity which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such activity on a person/patient without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
2.3 clinical record	<p>According to the Italian legislation, establishing and maintaining a "document which relates to the case history, examination, assessment, evaluation, diagnosis, treatment or care provided to a patient account of a patient's health and disease status" is a reserved activity which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p>

	<p>Establishing and maintaining such records on a person/patient without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
2.7 diagnosis	<p>According to the Italian legislation, "diagnosis" is a reserved activity which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing diagnosis without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
2.10 healthcare	<p>According to the Italian legislation, "an activity carried out by a professional in the field of the health [...] of the person" is a reserved activity which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such activity without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
2.12 osteopathy	<p>According to the Italian legislation, a "primary contact and patient-centred healthcare discipline" can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such activity without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
2.13 patient confidentiality	<p>According to the Italian legislation, dealing with patients and managing their private information, whenever finalized to an healthcare provision, can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such activity without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
2.14 primary contact profession	<p>According to the Italian legislation, dealing with patients is a reserved activity which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such activities without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
2.16 treatment	<p>According to the Italian legislation, performing "interventions that are designed to improve, maintain and support health, relieve symptoms or reduce [...] disease" are reserved activities which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such activities without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
3 Description of osteopathy	<p>According to the Italian legislation, "healthcare disciplines" shall be regulated by Law and moreover:</p> <ul style="list-style-type: none"> - performing "patient diagnosis and treatment"; - seeking to "influence a patient's physiological responses"; - "gathering of diagnostic information and the interpretation of the significance of structural findings in the overall health of the patient"; <p>are reserved activities which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p>

	Performing such activities without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].
4 Clinical practice	According to the Italian legislation, "clinical practice" shall be regulated by Law and it is a reserved activity which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. Performing such activities without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].
4.1 General	According to the Italian legislation, to "inform a critical consideration of practical patient care and management" is a reserved activity which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers. Performing such activity without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].
4.2 Essential competencies for osteopathic practice	According to the Italian legislation: - performing "diagnosis, management and treatment of [...] patients"; - performing "diagnosis and treatment planning"; are reserved activities which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. Performing such activities without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].
4.3 Case history, examination and interpretation of the findings	According to the Italian legislation: - taking "a case history of the patient and analyse the patient's presenting complaint"; - to "give patients the information they need and in a way they can understand and benefit from"; - to "formulate and record a diagnosis or rationale for care or referral"; - to "select an appropriate course of action"; - to "evaluate a patient" and "determine whether further investigations are necessary"; - to "inform clinical judgment"; are reserved activities which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers. Performing such activities without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].
4.4 Osteopathic treatment	According to the Italian legislation: - to "generate accurate, contemporaneous clinical records of the outcomes of the patient evaluation and treatment process"; - to "justify how [...] treatment is applied to the patient"; - to "select, use and modify a wide range of [...] techniques and patient management approaches"; - to "guide the patient to an understanding of the significance of the potential effect of the treatment and enhance the patients understanding and commitment to individual exercise, preventive measures, adapting lifestyle and diet, as well as making use of other healthcare disciplines, as appropriate"; - to "make clear the importance of [...] self-care activities for the patient's health" including "potential benefits, risks and limitations";

	<ul style="list-style-type: none"> - to “help patients to make informed choices about their personal healthcare maintenance” and “educate the patient in the understanding of their disorders and how to manage their conditions or prevent recurrence”; <p>are reserved activities which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such activities without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
4.5.3 Quality management	<p>According to the Italian legislation:</p> <ul style="list-style-type: none"> - the “provision of [...] facilities for patients”; - providing “information [...] to patients about their treatment and care”; - dealing with the “security and confidentiality of patient information and other data”; <p>are reserved activities which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such activities without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
5 Ethics	<p>According to the Italian legislation, “interactions with patients, prospective patients and other [...] healthcare professionals” is a reserved activity which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such activity without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
6 Education and Training	<p>According to the Italian legislation, “education and training” of healthcare providers shall be regulated by Law according to [Ref. 1, 2 and 3]. For the time being, osteopathy is not recognized as a healthcare discipline.</p> <p>Performing such activities without having a relevant legal recognition or legal authorization by the competent authority can lead to a legal challenge according to [Ref. 4].</p>
6.2.1 General	<p>According to the Italian legislation, establishing:</p> <ul style="list-style-type: none"> - “system of training, examination and licensing”; - “benchmarks for training”; - “roles and responsibilities of the future practitioner”; - “level of education required in order to participate in [...] training”; - different types of training “depending on prior training and clinical experience of trainees” <p>shall be regulated by Law according to [Ref. 1, 2 and 3]. For the time being, osteopathy is not recognized as a healthcare discipline.</p> <p>Performing such activities without having a relevant legal recognition or legal authorization by the competent authority can lead to a legal challenge according to [Ref. 4].</p>
6.2.2 Common features of both Type I and Type II programmes	<p>According to the Italian legislation:</p> <ul style="list-style-type: none"> - establishing “clinical [...] skills” and undertaking “supervised [...] clinical practice”; - providing “clinical training” and “clinical support and teaching” in “medical hospitals or in healthcare establishment”; - “diagnose and treat patients under supervision”;

	<ul style="list-style-type: none"> - performing "treatment of a patient"; - "treat patients in front of students, supervised by the lecturer or table trainers and with patient consent"; - "taking the initial case history and examination, making a diagnosis, and formulating and implementing a [...] treatment plan for the patient"; <p>shall be regulated by Law and they are reserved activities which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopathy is not recognized as a healthcare discipline.</p> <p>Performing such activities without having a relevant legal recognition or legal authorization can lead to a legal challenge according to [Ref. 4].</p>
6.2.3 Type I programmes	<p>According to the Italian legislation, "supervised clinical practice and training" shall be regulated by Law and it is a reserved activity which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopathy is not recognized as a healthcare discipline.</p> <p>Performing such activity without having a relevant legal recognition or legal authorization by the competent authority can lead to a legal challenge according to [Ref. 4].</p>
6.2.4 Type II programmes	<p>According to the Italian legislation, "supervised osteopathic clinical practice" and performing "clinical treatment" are reserved activities which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Performing such activities without having a relevant legal recognition or legal authorization by the competent authority can lead to a legal challenge according to [Ref. 4].</p>
6.3 Core competencies: the context of osteopathic education	<p>According to the Italian legislation, the application of the following knowledge/competencies to patients:</p> <ul style="list-style-type: none"> - "a) Basic sciences": <ul style="list-style-type: none"> - "gross and functional anatomy, including embryology showing the link to osteopathic understanding and treatment, neuroanatomical and visceral anatomy"; - "microbiology, biochemistry and cellular physiology"; - "physiology"; - "biomechanics and kinetics"; - "b) Clinical sciences": <ul style="list-style-type: none"> - "models of health and disease"; - "pathology and patho-physiology of the nervous, musculoskeletal, psychological, cardiovascular, pulmonary, gastrointestinal, reproductive, genito-urinary, immunological, endocrine and otolaryngology systems"; - "applied anatomy, neurology and neurophysiology"; - "diagnosis"; - "radiology; laboratory results"; - "nutrition"; - "relevant knowledge of pharmacology"; - "c) Osteopathic sciences": <ul style="list-style-type: none"> - "clinical biomechanics, joint and visceraphysiology and kinetics" - "d) Clinical skills": <ul style="list-style-type: none"> - "obtaining and using a patient history"; - "physical and clinical examination";

	<ul style="list-style-type: none">- "diagnosis of the nervous, musculoskeletal, psychological, cardiovascular, pulmonary, gastrointestinal, endocrine, genito-urinary, immunological, reproductive and otolaryngology systems";- "general synthesis of basic laboratory and imaging data";- "clinical problem-solving and reasoning";- "clinical documentation";- "life-support"; <p>are reserved activities which can be only performed by professionals having legal recognition according to [Ref. 1, 2 and 3]. For the time being, osteopaths are not recognized as healthcare providers.</p> <p>Applying such knowledge/competences to patients without having a relevant legal recognition can lead to a legal challenge according to [Ref. 4].</p>
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