

Nederlandse norm

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(en)

Gezondheidszorg door chiropractoren

Healthcare provision by chiropractors

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ICS 03.120.10; 11.020

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EUROPEAN STANDARD

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English Version

Healthcare provision by chiropractors

Prestation de soins de santé par les chiropracteurs

Bereitstellung von Gesundheitsleistungen durch
Chiropraktoren

This European Standard was approved by CEN on 10 May 2012 and includes Amendment 1 approved by CEN on 12 December 2013.

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Foreword

This document (EN 16224:2012+A1:2014) has been prepared by Technical Committee CEN/TC 394 "Project Committee - Services of chiropractors", the secretariat of which is held by ASI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2014, and conflicting national standards shall be withdrawn at the latest by July 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 16224:2012.

This document includes Amendment 1 approved by CEN on 12 December 2013.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

The World Health Organization (WHO) defines chiropractic as a primary contact healthcare profession concerned with disorders of the neuromusculoskeletal system, particularly the spine, and the effect of these disorders on the function of the nervous system and on general health. Treatment encompasses a wide range of interventions, but emphasis is placed on manual methods of care.

The chiropractic profession has evolved in Europe and occupies an important position in both primary and secondary healthcare provision. It is therefore imperative that chiropractic services are delivered at the highest attainable level.

The principal objective of any standard for healthcare services ought to be that users of any given service can be confident of a level of care that assures reproducible quality throughout the profession. Clinical governance, the determination of monitoring healthcare provision and ensuring maintenance of standards therefore form one of the cornerstones of care.

This standard is concerned with the provision of chiropractic services. It aspires to set a standard that provides optimum levels of patient management, patient safety, clinical and cost effectiveness and ethical practice. It also defines a level of education consistent with producing chiropractors who are competent to comply with the standard. It is not intended to be a guideline, although information contained might inform the development of guidelines for individual nations and national organisations.

Finally, this standard encourages that services provided by chiropractors be subjected to regular review through an evidence-based approach and a commitment to supporting and acting upon clinical research.

This European Standard does not supersede national legislation.

1 Scope

This European Standard specifies requirements and recommendations for healthcare services provided by chiropractors.

2 Terms and definitions

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

2.1

assessment

health professional's evaluation of a disease or condition based on the patient's subjective report of the symptoms and course of the illness or condition, along with the objective findings including examination, laboratory tests, diagnostic imaging, medical history and information reported by family members and other health professionals

2.2

audit

review and assessment of healthcare procedures and documentation for the purposes of comparing the quality of care provided with accepted standards

2.3

biopsychosocial model

model that refers to the interactions between biological, psychological and sociological factors

2.4

capacity

ability of a patient to understand, remember and consider information provided to them

2.5

care

interventions that are designed to improve health

2.6

case history

detailed account of a person's history which results from the acquisition of information through interview, questionnaires and assessment of appropriate medical records

2.7

chaperone

person who is present during a professional encounter between an health professional and a patient

EXAMPLE Family members or another member of the healthcare team.

2.8

chiropractic

health profession concerned with the diagnosis, treatment and prevention of mechanical disorders of the musculoskeletal system, and the effects of these disorders on the function of the nervous system and general health

Note 1 to entry: There is an emphasis on manual treatments including spinal adjustment and other joint and soft-tissue manipulation.

Note 2 to entry: Taken from WFC Dictionary definition [11].

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- 2.9**
chiropractic institution
educational establishment dedicated to the provision of chiropractic education and training
- 2.10**
clinical guidelines
systematically developed statements designed to assist both practitioner and patient decisions about the appropriate healthcare for specific clinical circumstances
- 2.11**
clinical record
document which relates to the diagnosis, assessment and care of a patient
- 2.12**
consent
acceptance by a patient of a proposed clinical intervention after having been informed of all relevant factors relating to that intervention
- 2.13**
continuing professional development
CPD
means by which members of a profession maintain, improve and broaden their knowledge and skills and develop the personal qualities required in their professional lives
- 2.14**
delegation
asking someone who is not a regulated health professional to provide care on a chiropractor's behalf
- 2.15**
diagnosis
identification of a disease or illness resulting from clinical assessment
- 2.16**
diagnostic procedure
structured procedure that exists to enable a chiropractor to arrive at a diagnosis which may include physical examination, diagnostic imaging and laboratory tests
- 2.17**
discharge
release of a patient from a course or programme of care
- 2.18**
evidence-based care
clinical practice that incorporates the best available evidence from research, the expertise of the practitioner, and the preference of the patient
- 2.19**
formal education
educational activity at established recognised formal systems of elementary, secondary or higher education
- Note 1 to entry: Compare with the ISO 29990:2010, definition 2.15 "non-formal education" [4].
- 2.20**
further investigation
additional clinical study which contributes to the assessment of a patient and which may include diagnostic imaging and laboratory tests

2.21**graduate education programme****GEP**

dedicated framework for the continuing education of new graduates of chiropractic institutions during their initial period in practice

2.22**health**

state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity

Note 1 to entry: Specified in the preamble to the "Constitution of the World Health Organization" [6].

2.23**health promotion**

provision of information on healthier lifestyles for patients, and how to make the best use of health services, with the intention of enabling people to make rational health choices and of ensuring awareness of the factors determining the health of the community

2.24**medical device**

instrument, apparatus, appliance, material or other article, either used alone or in combination, including the software necessary for its proper application and intended by the manufacturer to be used for human beings

Note 1 to entry: This definition is in accordance with Council Directive 93/42/EEC [7] and with EN ISO 13485:2003 [1].

2.25**neuromusculoskeletal**

interaction between the nervous system, musculature and skeletal framework of the body

2.26**patient confidentiality**

right of an individual to have information about them kept private

2.27**patient examination**

assessment of a patient with the intention of reaching or reviewing a diagnosis or plan of care

2.28**plan of care**

plan designed to deliver therapeutic benefit to patients following diagnosis

2.29**primary contact practitioner**

healthcare professional qualified to undertake a process of assessment, diagnosis and care in the absence of a formal referral from another registered healthcare provider

2.30**professional development**

continuum of education, embracing undergraduate and postgraduate studies and regular refresher training

2.31**referral**

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

2.32**undergraduate chiropractic education**

acquisition of knowledge and skills by students at chiropractic institutions leading to an accredited qualification in chiropractic

EN 16224:2012+A1:2014 (E)**3 Service requirements****3.1 Clinical practice****3.1.1 Clinical records**

Clinical records shall be maintained in accordance with good professional conduct and shall contain relevant and necessary information about the patient and the patient's healthcare (see also Annex A).

3.1.2 Case history

The chiropractor shall acquire and document current and past information on a patient related to their health (i.e. physical, psychological and social wellbeing) by asking specific questions, either of the patient, responsible adult or legal guardian with the aim of obtaining suitable clinical information useful in formulating a diagnosis and leading to a plan of care for the patient.

3.1.3 Patient examination

- a) Following the taking of the case history, the patient shall be investigated for signs of disease, abnormality or dysfunction.
- b) The chiropractor shall use examination methods that include, but are not limited to, physical examination procedures; orthopaedic, neurological, and chiropractic tests, as clinically indicated.

3.1.4 Further investigation / diagnostic imaging

The chiropractor shall:

- a) identify when further investigations are needed and act on this need in the patient's best interests;
- b) use further investigations when the information gained from such investigations will benefit the management of the patient;
- c) undertake and/or interpret the results or, if this is not possible, refer the patient for appropriate further investigations;
- d) record the outcomes of the investigations in the patient record.

3.1.5 Clinical decision making and diagnosis

The chiropractor shall:

- a) evaluate the patient's health status and health needs from the information gained during the case history, physical examination and further investigations;
- b) formulate and document a working diagnosis and/or differential diagnosis and a rationale for care, based on the evaluation of this information. The diagnosis, or rationale for care, shall be kept under review while caring for the patient;
- c) interpret all of the information available about a patient and then make and record decisions about the patient's health and health needs and how these change over time;
- d) consider the natural history and prognosis of any presenting complaint, or emergency situation that might need immediate action, and the likelihood of preventing recurrences or managing any long-term healthcare needs.

3.1.6 Plan of care

The chiropractor shall:

- a) develop and record an agreed plan of care, taking into account the wishes and preferences of the patient. The plan of care should encourage the patient to participate in improving their own health. The plan of care shall have specified aims and be consistent, appropriate and safe with the patient's identified health and health needs;
- b) be knowledgeable about the underlying theories of the care they provide and be competent to apply that form of care in practice. The chiropractors' provision of care shall be evidence-based. The patient shall have given informed consent to the form of care provided;
- c) review with patients the effectiveness of the plan of care in meeting its agreed aims.

3.1.7 Referrals

The chiropractor shall consider onward referral to another appropriately qualified healthcare professional when it becomes clear that a patient

- a) is not appropriate for chiropractic care, or
- b) requires concurrent or additional investigation or care, or
- c) is failing to respond to chiropractic care, is deteriorating or has developed additional symptoms outside the field of expertise of the chiropractor.

Referrals should be in writing or done verbally and should detail the reason for the referral, the care provided by the chiropractor and any relevant aspects of the patient's health. Referral details shall be noted in the patient record.

3.1.8 Use of equipment

All medical devices used by chiropractors shall be CE-marked [7].

In case of X-ray equipment, management shall fulfil Council Directive 96/29/Euratom [8].

A maintenance record shall be kept for each piece of equipment or device.

3.2 Core competencies

- a) The chiropractor shall have knowledge and understanding of:
 - 1) normal structure and function of the human body;
 - 2) aetiology, pathology, symptoms and signs, natural history and prognosis of neuromusculoskeletal complaints, pain syndromes and associated conditions presenting to chiropractors, including the psychological and social aspects of these conditions;
 - 3) evaluation of the health and health needs of a patient, including common diagnostic procedures, their uses and limitations, and appropriate referral procedures;
 - 4) management of neuromusculoskeletal conditions using manual therapies, physical rehabilitation, general nutritional advice, and the principles of health promotion and disease prevention;
 - 5) scientific methods to provide and understand the evidence-base for current chiropractic practice, and to acquire and incorporate the advances in knowledge that will occur throughout professional life;

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- 6) history, theory, philosophy and principles of chiropractic practice in a contemporary context, including the biopsychosocial model of illness, its limitations, and its role in the healthcare setting;
 - 7) principles of ethics related to chiropractic care, legal responsibilities and codes of professional conduct and practice;
 - 8) nature of professional accountability and duty to protect and promote the interests of their patients, including not abusing their position, avoiding psychological dependence and maintaining patients' trust.
- b) The chiropractor shall have developed the following abilities:
- 1) ability to obtain appropriate consent before assessing individuals and for providing chiropractic care;
 - 2) ability to take a comprehensive and problem-focused case history and perform an accurate physical examination;
 - 3) ability to integrate case history, physical examination and diagnostic imaging to arrive at an appropriate diagnosis and/or differential diagnosis;
 - 4) ability to interpret diagnostic procedures and make an appropriate response;
 - 5) ability to select appropriate clinical skills and to formulate a management plan in concert with the patient;
 - 6) ability to apply appropriate clinical skills in the treatment of a patient, and to provide information and advice for recovery and continued health;
 - 7) ability to communicate clearly with patients, their families, other healthcare professionals, and the general public, and to ensure patients are fully informed of their treatment choices and care;
 - 8) ability to interpret scientific evidence in a critical manner, and to find and use information relating to healthcare.
- c) The chiropractor shall demonstrate the following essential abilities for safe and competent chiropractic practice:
- 1) recognition that the chiropractor's primary professional responsibilities are the health and care of the patient;
 - 2) respect for the values and attitudes of the patient, and a commitment to patient-centred care;
 - 3) commitment to safe and ethical practice, and to maintain standards of chiropractic practice at the highest possible level throughout professional life;
 - 4) appreciation of the need to recognise and work within the limits of their own knowledge, skills and experience and, when a condition exceeds their capacity to deal with it safely and effectively, to refer patients to other healthcare practitioners;
 - 5) appreciation of the need to continually update knowledge and skills throughout professional life, apply continuous quality improvement in their practice, and to contribute towards the generation of knowledge and the education of colleagues;
 - 6) willingness to work in the wider healthcare context, and in a team with other healthcare professionals.

4 Education

4.1 Undergraduate chiropractic education

The chiropractor shall have a formal, comprehensive undergraduate chiropractic education of a minimum of five years full-time or equivalent.

NOTE An example of a suitable framework for undergraduate chiropractic education is provided by the European Council on Chiropractic Education (ECCE) [10]. (See also Annex B.)

4.2 Graduate education programme

The graduate education programme (GEP) normally follows immediately after successful completion of the undergraduate programme and is the period of transition from safe and competent practice to autonomous and independent professional practice. It shall be clinically based and last a minimum of 12 months.

- a) The graduate education programme shall prepare graduates to:
 - 1) maintain and improve on best and safe chiropractic care for lifelong, self-directed learning for continued professional development;
 - 2) further professionalism (i.e., knowledge, skills, attitudes and behaviour expected by patients and society).
- b) During the graduate education programme the graduate should:
 - 1) demonstrate a defined body of knowledge, understanding, clinical and procedural skills, as well as professional attitudes for providing effective, patient-centred care;
 - 2) show that they effectively facilitate the chiropractor-patient relationship and the dynamic exchanges that occur before, during and after the chiropractic encounter;
 - 3) show that they effectively work within a healthcare team to achieve optimal patient care;
 - 4) demonstrate that they are an integral participant in the provision of healthcare;
 - 5) show responsibility to use their expertise and influence to advance the health and wellbeing of individual patients, communities and populations;
 - 6) demonstrate a lifelong commitment to reflective learning as well as the creation, dissemination, application and translation of chiropractic/medical knowledge;
 - 7) show that they are committed to the health and wellbeing of individuals and society through ethical practice, profession led regulation and high personal standards of behaviour.
- c) The graduate education programme should:
 - 1) encompass integrated practical and theoretical instruction;
 - 2) guarantee best and safe care by deliberate practice and valid feedback.

4.3 Continuing professional development

Continuing professional development (CPD) is a process of lifelong learning. As well as enabling chiropractors to provide better healthcare services to patients, it should also help chiropractors to fulfil their potential. The learning needs and interests which individuals identify should be in the context of their own development and the practice/organisation in which they work. The individual chiropractor shall:

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- a) have a minimum of 30 hours learning activities a year, of which at least 15 hours is to be learning with others – colleagues or other professionals; The different forms which learning with others can take include, but are not limited to, courses, lectures, discussions, seminar groups and conferences; being coached or mentored by another healthcare professional and peer group reviews;
- b) maintain their own records of CPD;
- c) be responsible for reflecting on and identifying their own learning interests and needs and how these are met.

5 Code of ethics

The provision of healthcare shall be based on trust, assurance and safety. In society, chiropractors possess a position where they are trusted; this trust is acquired by education and experience and with this trust comes the responsibility to conform to standards of conduct and behaviour. The Code of Ethics sets out the principles and values of chiropractors in their work as providers of professional healthcare. While the Code is written for chiropractors, the public has a right to know what can be expected of chiropractors and the boundaries of their professional practice.

While it does not seek to define scope of practice, it may have this effect by virtue of the limitations it places on types of behaviour and practice. Chiropractors shall act in line with the principle that the wellbeing of the patient is paramount. It necessarily follows that the nature and delivery of chiropractic care shall be consistent with this value.

The Code recognises that chiropractic is practised in a range of jurisdictions, each having different legislative frameworks and regulatory processes. Where a country is regulated by statute, this Code cannot supersede the Codes of Practice and Standard of Proficiency for that nation. In jurisdictions without statutory regulation, it is recommended that this Code be adopted for use to ensure a minimum consistent standard throughout European states.

NOTE See Annex C for further details.

6 Organisation**6.1 Practical organisation of clinic facilities**

Facilities where chiropractic care is provided:

- a) shall be organised in such a way that health personnel are able to comply with their statutory duties;
- b) shall be organised in such a way that systems are in place to detect deficiencies in order to improve quality;
- c) should be organised in such a way that access for the disabled is provided.

6.2 Facility requirements**6.2.1 General**

The clinic in which chiropractors practice may vary considerably in size, position and environ in accordance with national requirements and legislation.

6.2.2 Clinic and hygiene

The clinic provider should ensure that:

- a) the clinic is clean;
- b) hygiene procedures are written down and followed throughout the clinic;
- c) all areas of the clinic have a comfortable working temperature and sufficient ventilation to assure the comfort of the patient;
- d) all rooms have adequate sound proofing, low ambient noise level and good lighting.

The facilities of the clinic should meet professional standards.

6.2.3 Access to the clinic

The chiropractor should be contactable by accepted means of communication. The clinic shall be clearly signed for anyone wishing to access the facilities. It should provide access for people with disabilities.

6.2.4 Reception and waiting areas

The reception and waiting area should have a reception desk and sufficient seats for the number of people expected in the clinic, including those accompanying the patient. The reception area should be designed so that patients are comfortable when giving private information, whenever possible.

The prices for treatment shall be clearly displayed.

A written complaints procedure shall be available for the patient on request.

The clinic shall give access to drinking water.

6.2.5 Toilet

There should be facilities for disabled available, whenever possible.

6.2.6 Consultation and treatment room

The size of the consultation and treatment rooms shall be sufficient to allow the free movement of the chiropractor and patient. There should be a desk, and seating for at least the patient and a companion or chaperone.

The consultation and treatment rooms shall be sufficiently sound-proofed to ensure privacy of conversations.

Rooms for exercise or group activities shall be large enough to accommodate the designated activities.

Any facility for dressing/undressing shall be large enough for the comfort of the patient, with direct access to the treatment room and the privacy of the patient ensured.

A wash hand basin shall be readily accessible.

6.3 Equipment requirements

6.3.1 Equipment

The following pieces of equipment are the minimum required for the proper provision of chiropractic services:

- a) Treatment table: A relevant table with paper or textile cover, which is changed or cleaned for each patient, shall be available.
- b) Equipment for examination:

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- 1) Instruments required for proper examination and treatment shall be readily available.
- 2) Anatomical models and/or other patient education materials should be available.

6.3.2 Maintenance

The chiropractor shall ensure that all equipment (see 3.1.8) is maintained in accordance with manufacturers' recommendations. Maintenance records shall be kept.

6.4 Incident reporting and learning

Where they are available, the chiropractor should engage in chiropractic and/or multidisciplinary patient incident reporting and learning systems.

6.5 Quality assurance

- a) The chiropractor should review the effectiveness of services they provide. This may be achieved by participation in relevant quality assurance programmes.

NOTE References to quality management system standards can be found in the Bibliography [2], [3] and [4].

- b) The chiropractor shall have a written complaints procedure in place in their practice which is easily accessible to patients. Any complaint or claim made by a patient shall be dealt with promptly and fairly. Patients shall be told about their right to refer any unresolved complaint to the relevant authority.

6.6 Insurance

The chiropractor shall hold:

- a) professional indemnity insurance to cover any liability to patients that may arise in connection with the performance of their profession;
- b) employers and public liability insurance to cover their practice, employees and the public in the event of a claim.

6.7 Professional association membership

The chiropractor is strongly encouraged to join a national chiropractic association.

Annex A **(informative)**

Patient records

A.1 Duty to keep patient records

- a) The chiropractor should record information in a patient record for each patient.
- b) Patient records should be written in an official language of the country.
- c) Patient records should be stored by either paper or electronic means and the security maintained such that they are only accessible to authorised personnel.
- d) The chiropractor should ensure that provision is made for the safe-keeping and secure storage of patient records upon ceasing work at their practice address or in the event of their death.

A.2 Content of patient records

Patient records should contain the following information:

- 1) patient's name, address, date of birth, contact details, marital status, gender, occupation;
- 2) if the patient is not competent to give consent, the name and status of the person giving consent;
- 3) notification if treatment or advice is given in contradiction with clinical guidelines;
- 4) advice given to the patient;
- 5) reason a patient has required access to records or required corrections of records;
- 6) information given to or received from other healthcare providers, institutions, laboratories, insurance companies, police, child welfare, etc.;
- 7) patient's general medical practitioner;
- 8) notes on sick leave, reports.

Patient records should be an accurate reflection of each clinical encounter and should include any factors relevant to the patient's ongoing care, including their general health.

All records should be understandable to another chiropractor who may be called upon to assume the care of the patient. Records should be stored securely in accordance with local legislation.

A.3 Correction of patient records

Any errors within a patient record should be corrected by the addition of the correct information without deletion of any previously entered information and noting the source of the correction.

Annex B (informative)

Recommended programme curriculum ¹⁾

B.1 General

A programme curriculum should include:

- 1) curriculum model and educational methods;
- 2) basic biomedical sciences;
- 3) behavioural and social sciences, ethics and jurisprudence;
- 4) clinical sciences and skills;
- 5) clinical training;
- 6) assessment methods and regulations;
- 7) curriculum level, structure and composition.

B.2 Curriculum model and educational methods

The chiropractic institution should define a curriculum model and educational (teaching and learning) methods consistent with the objectives of the curriculum. The curriculum and educational methods should ensure the students have responsibility for their learning, and prepare them for lifelong, self-directed learning throughout professional life.

Curriculum models should include discipline, system, integrated, problem or case-based learning models, using organising principles such as themes and domains.

Instructional methods should encompass teaching and learning methods that, while not neglecting the transmission of factual knowledge and skills, also stimulate enquiry, critical analysis and problem-solving abilities. The curriculum should encourage active participation through the principles of self-directed learning, and foster the concept that the curriculum is not only 'taught' based solely on didactic models.

Teaching and learning methods should be diverse and include a variety of methods, e.g. prosection (or dissection), computer assisted methods, and large and small group classes.

The curriculum and educational methods should foster life-long learning skills and an appreciation of the need to undertake CPD.

The chiropractic institution should describe the content of courses that guide both staff and students on the learning outcomes expected at each stage of the programme, and the level of integration between the basic sciences and clinical sciences and include:

- the theory of chiropractic and the scientific method;

¹⁾ Based on ECCE Standards, version 4, 2011 [10].

- the theory and principles of chiropractic practice, other forms of research inquiry and evidence-based practice, including analytical and critical thinking.

The curriculum should include elements for training students in scientific thinking and research methods.

Theory of chiropractic should include concepts and principles of practice, and the role of empirical evidence in informing chiropractic knowledge.

Training in scientific thinking and research methods should include the use of research projects (or equivalents) to be conducted by chiropractic students.

The curriculum and educational methods should foster the ability to participate in the scientific development of chiropractic as professionals and future colleagues, and to keep up to date with evolving knowledge through an appreciation of research inquiry and the skills to identify, find and critically evaluate information including research evidence.

B.3 Basic biomedical sciences

The chiropractic institution should identify and include in the curriculum those contributions of the basic biomedical sciences that enable a knowledge and understanding of the basic sciences applicable to the practice of chiropractic.

The basic biomedical sciences should include anatomy, biochemistry, physiology, biophysics, molecular biology, cell biology, genetics, microbiology, immunology, pharmacology, pathology and biomechanics.

As basic science teaching is relevant to the overall objectives of the chiropractic curriculum; its relevance should be apparent to students.

Sufficient integration of the biomedical sciences with the clinical elements of the programme should be ensured, highlighting the relevance of the basic sciences to clinical practice.

Basic science and clinical tutors should collaborate in combined teaching sessions based around clinical problems.

B.4 Behavioural and social sciences, ethics and jurisprudence

The chiropractic institution should identify and include in the curriculum those contributions of the behavioural sciences, social sciences, ethics, scope of practice and legal requirements that enable effective communication, clinical decision-making and ethical practice.

Behavioural and social sciences should include:

- 1) psychology, sociology, and the biopsychosocial model of chronic pain and non-specific neuromusculoskeletal pain conditions;
- 2) aspects of patient-centred care models, practitioner-patient encounters and oral and written communications skills, and the transferable skills including IT and reflective practice skills;
- 3) all aspects regulating professional practice including legal requirements, requirements of local national regulatory bodies and codes of ethical practice;
- 4) other areas of professional practice including management and administration issues and current practice models in a multidisciplinary healthcare setting;
- 5) ethical practice including the principles of clinical governance, clinical audit, clinical guidelines, and risk assessment and management.

EN 16224:2012+A1:2014 (E)**B.5 Clinical sciences and skills**

The chiropractic institution should identify and include in the curriculum those contributions of the clinical sciences that ensure students have acquired sufficient clinical knowledge and skills to apply to chiropractic practice in a primary contact setting.

The clinical sciences should include general diagnosis, diagnostic imaging, physical, clinical and laboratory diagnostic procedures, orthopaedics, obstetrics and gynaecology, paediatrics, geriatrics, nutrition, dermatology, pathological anatomy, neurology, spinal analysis including motion palpation, manipulative-, mobilisation- and supportive- techniques, and rehabilitation.

To reflect the most common conditions treated by chiropractors, the curriculum should emphasise pain management, particularly as it relates to neuromusculoskeletal conditions.

Clinical skills should include diagnostic imaging, history taking, physical examination, procedures and investigations, communication skills, treatment procedures, patient care and management, patient advice and education, disease prevention and health promotion.

Clinical skills should include competency in general diagnosis and referral procedures consistent with scope of practice in a primary contact setting.

B.6 Clinical training

The chiropractic institution should identify and include a period of supervised clinical training to ensure the clinical knowledge and skills, communication skills and ethical appreciation accrued by the student can be applied in practice, and so enable the student to assume appropriate clinical responsibility upon graduation.

Every student should have early patient contact leading to participation in patient care.

As an essential component, the curriculum should offer a significant period of time devoted to the students' one-to-one contact with patients. This should be a minimum of one academic year spent primarily in contact with patients. The clinical training period provides the opportunity to undertake the role of primary contact practitioner within a supervised outpatient clinic, and develop clinical competency and clinical judgment.

A minimum of forty (40) complete new patient assessments, of which no more than five (5) may be direct clinical observation, plus a minimum of four hundred (400) treatment (patient) visits and a case-mix of patients should be sufficient to achieve the outcomes of the curriculum, and prepare the student for safe and competent practice as a primary contact practitioner. Above all, this period should develop a level of clinical sophistication to enter practice and a period of postgraduate training.

This period of training should reinforce issues of good record keeping, teamwork, communication with other healthcare practitioners, responsibilities of clinic management, ethics and jurisprudence.

This period of training should reinforce issues of self-evaluation through reflective practice, self-directed learning principles and an appetite for life-long learning.

The importance of tutor role models and the influence of standards in chiropractic practice set at this stage should be recognised in the clinical training facility offered to students.

Close supervision of students, which is of paramount importance at this stage, should include formative and summative feedback mechanisms.

A clinic observation programme should be in place to provide opportunities for students throughout the curriculum to observe clinical procedures in practice, to learn from more experienced colleagues, and to maintain the motivation for becoming a chiropractor.

B.7 Assessment methods and regulations

The chiropractic institution should define and document the methods used for assessment, including the criteria for progression and appeals procedures. Assessment methods should be regularly evaluated, and new assessment methods developed as appropriate.

The definition of methods used for assessment should include consideration of the balance between formative and summative assessment, the number of examinations and other tests, the balance between written and oral examinations, the use of normative and criterion referenced judgements, and the use of special types of examinations, e.g. objective structured clinical examinations (OSCE), and the role of external examiners.

Evaluation of assessment methods should include an evaluation of how they promote learning. Evaluation of assessment methods should include the quantity and quality (reliability and validity) of assessment methods, in particular the reliability and validity of assessments in clinical skills and competencies.

The assessment principles, methods and practices should be appropriate to the educational aims and objectives, and promote appropriate learning practices.

Assessment methods and assessment criteria should be made known to students at the outset of the programme, or course component, and clearly reflect the course objectives.

The number of assessments should not require excessive amounts of learning of detailed information to the detriment of time to reflect and assimilate the material.

The type of assessments should encourage an integrated approach to learning, and encourage material delivered earlier in the programme to be revisited at later stages.

All students should carry out an undergraduate research project appropriate to the level at which the degree is being awarded. This research project should consist of a research enquiry in a specified topic area using either a qualitative and/or quantitative approach. Irrespective of the design of the project, it should show clear evidence of critical thinking and appraisal of the current research evidence and of the findings from the research project.

B.8 Curriculum level, structure and composition

The chiropractic institution should describe the content, duration and sequencing of courses that guide both staff and students on the learning outcomes expected at each stage of the programme, and the level of integration between the basic sciences and clinical sciences.

Chiropractic programmes may be diverse in points of entry reflecting prior learning achievements. The length of the undergraduate programme however, should be a minimum of five (5) full-time (study) academic years. In terms of academic credits, this is equivalent to 300 credits where 60 credits equals one academic year. The clinical training period should also be delivered on a full-time basis.

The duration and modes of delivery of the programme should satisfy national requirements for graduates to practise as a chiropractor.

The integration of disciplines should include both horizontal (concurrent) and vertical (sequential) integration of curricular components. The process of integration can enhance student learning by demonstrating the relationship between programme material and future chiropractic practice. There should also be opportunities to revisit and further develop material covered earlier in the programme.

The curriculum should develop as well as educate and train students through models of self-directed learning, and by presenting them with opportunities to develop in particular areas of interest, e.g. in the research project (or equivalent).

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All courses within the curriculum should have explicit learning outcomes in terms of the level of knowledge and understanding, skills and attitudes expected on completion of the course.

Annex C (informative)

Code of ethics

C.1 Working with patients

C.1.1 Good clinical care

- a) Good clinical care should include the following:
- 1) adequately assessing the patient's condition, taking account of the case history, the patient's views and, where necessary, examining the patient;
 - 2) providing or arranging advice, investigations or treatment where necessary;
 - 3) the chiropractor should not misrepresent the gravity of a patient's condition;
 - 4) referring to another healthcare professional when this is in the best interests of the patient.
- b) When the chiropractor provides care they should do so:
- 1) within the limits of their competency;
 - 2) with regard to the fact that the welfare of the patient is paramount;
 - 3) in keeping with evidence-based care;
 - 4) with a view to improving health and quality of life.
- c) The chiropractor should ensure that their records are accurate, legible and attributable. They should be an accurate reflection of the clinical encounter and should include any factors relevant to the patient's ongoing care, including their general health. All records should be understandable to another chiropractor who may be called upon to assume the care of the patient. Records should be stored securely in accordance with local legislation.
- d) The chiropractor should respect the right for patients to seek a second opinion, either from another chiropractor or from another health professional.

C.1.2 Health promotion and self care

- a) The chiropractor should encourage patients to care for themselves. They should advise patients on appropriate self-help measures.
- b) The chiropractor should support health promotion initiatives that reduce reliance on health professionals. This can include advising patients on the impact of lifestyle choices on their health and wellbeing.

C.1.3 Raising concerns about patient safety

- a) Where the chiropractor has concerns about the safety of patients, they should report those concerns to the appropriate body after having made every effort to ascertain the facts.
- b) If the chiropractor has concerns about the safety of patients, they should document them, along with the steps they have taken to try to resolve them.

EN 16224:2012+A1:2014 (E)**C.1.4 Equality and diversity**

The chiropractor should act in accordance with legislation to ensure fair access to assessment and care. They should not discriminate on the grounds of colour, race, age, disability, ethnic origin, lifestyle choices, gender, sexuality, marital status, socioeconomic status, religion or beliefs.

C.1.5 Keeping up to date

- a) The chiropractor should keep their skills and knowledge up-to-date throughout their professional life.
- b) The chiropractor should be aware of practice and clinical guidelines that impact their work and should apply these in their practice.
- c) The chiropractor should be aware of and comply with codes of practice relevant to their jurisdiction.
- d) To enhance the quality of the care they provide, the chiropractor should liaise with colleagues and patients and conduct clinical and practice audits. They should be prepared to modify their practice where it is clear that any particular intervention is not working.

C.1.6 Teaching, training, appraising and assessing

- a) Where the chiropractor is involved in teaching, training, appraising or assessing they should ensure that the information they provide is accurate. They should be clear when making use of theories which have not yet been verified or subjected to academic or scientific investigation or research.
- b) Where the chiropractor is involved as a teacher, they should ensure that they develop the skills, attitudes and practices of a competent teacher.
- c) When writing reports about colleagues, the chiropractor should be honest and objective. They should not unfairly criticise a colleague nor use language that unjustly casts doubt on their character or integrity.

C.1.7 The chiropractor-patient partnership

In order to optimise the chiropractor-patient relationship the chiropractor should:

- a) be polite and considerate with their patients;
- b) show respect for cultural differences;
- c) treat them with dignity;
- d) treat each patient as an individual;
- e) respect privacy and the patient's right to confidentiality;
- f) support patients in maintaining their health.

C.1.8 Communicating with patients

- a) As clear communication is central to the relationship between the chiropractor and their patients, patients should be involved in their care and the chiropractor should encourage them to take an active role.
- b) The chiropractor should take account of any special needs when communicating with patients. These may include physical or learning disabilities.
- c) The chiropractor should explain clearly to their patients information about what will happen during their assessment and care. They should also tell them about the results of the assessment, their plan of management and when their care will be reviewed.

- d) Prior to commencing treatment, the chiropractor should inform their patients about the relevant risks and benefits of the treatment they will provide, and any other options for care.
- e) The chiropractor should inform their patients how information about them will be recorded and stored. Chiropractors working in jurisdictions where data protection legislation exists should ensure that they are registered with the relevant body and comply with the provisions of that legislation.
- f) The chiropractor should inform their patients who will have access to their records and the measures in place to ensure confidentiality.
- g) The chiropractor should have in place a clearly documented complaints procedure. Patients wishing to make a complaint about their assessment or care should be provided with information to enable them to do so.
- h) Patients should be informed about the arrangements that chiropractors have in place to provide assessment and care if they are unavailable.
- i) Where the chiropractor works with others, patients should be given information on who has responsibility for their day-to-day care and, if this is different, who is accountable for their overall care.
- j) If the chiropractor delegates work to others, they should ensure that patients understand the relationship and the responsibilities of the person delivering the assessment or care.
- k) Patients should be informed about the need for sharing of information to enable effective care to be provided. If patients decline to give consent for information to be shared, they should be informed about the implications of this and how it may affect their care.

C.1.9 Communicating with other health professionals

- a) The chiropractor should share information with the general medical practitioner or any health professional from whom a referral has been received.
- b) With the patient's consent, the chiropractor should disclose all relevant information requested by another health professional.
- c) The chiropractor should correspond promptly with other health professionals when it is clear that onward referral should take place.
- d) In emergency situations, the chiropractor should produce a clear and comprehensive record of events to enable the healthcare team to understand fully the chiropractor's involvement in providing assessment and care and the precise nature of events.
- e) Where further investigations are required, the chiropractor should ensure that all relevant information is provided to those undertaking diagnostic procedures.

C.1.10 Preparing reports for third parties

- a) Where reports are required by third parties, consent should be obtained from the patient for disclosure of information to take place.
- b) The disclosure of information should be limited to only that which includes information requested by the third party.
- c) The chiropractor should ensure that they understand the reason for the request for information and should discuss the request with the patient.

EN 16224:2012+A1:2014 (E)**C.1.11 Children and young people**

- a) Within their practice, the chiropractor should safeguard and protect the health and wellbeing of children and young people.
- b) The chiropractor should act where they think that the rights and welfare of children and young people have been denied or abused.
- c) The chiropractor should consider how information provided to them may be understood and adapt their communication to take account of this.
- d) The chiropractor should identify when there is a need for another person to be present when they are assessing or caring for patients. This is particularly relevant in the case of children and young people, where another person (who may be a parent or guardian) should be present unless express consent is given for the child or young person to be seen in the absence of a chaperone.

C.1.12 Vulnerable adults

- a) The chiropractor should consider whether a patient is vulnerable by virtue of their health and circumstances and take steps to ensure that their wellbeing is safeguarded during the provision of assessment and care. They should also consider the capacity of patients to understand information provided to them and the validity of consent in relation to this.
- b) The chiropractor working with vulnerable adults should consider whether it is appropriate for another person to be present when providing assessment and care.
- c) The chiropractor should not exploit the vulnerability of patients by expressing their personal beliefs, or their religious or political views in any way that might cause them distress or make them feel uncomfortable.

C.1.13 Dealing with relatives, carers and partners

- a) The chiropractor should be considerate to relatives, partners and others close to the patient, and be sensitive and responsive in providing information and support, including after a patient has died.
- b) In providing information, the chiropractor should be mindful of confidentiality and the implications of disclosing information about patients to others.

C.2 Openness and honesty**C.2.1 General**

- a) The chiropractor should be open and honest with their patients.
- b) The chiropractor should not misrepresent the gravity of a patient's condition.
- c) The chiropractor should not withhold information that may influence the patient to decline assessment or care. This may include information on risks or side effects of treatment.
- d) All information provided should be tailored to the patient's specific needs and be delivered in the best interests of the patient.
- e) The chiropractor should recognise when a patient's condition is beyond their scope of practice and communicate this to patients openly and honestly.

C.2.2 Maintaining trust in the profession

The chiropractor should not abuse their professional position to pursue a sexual or improper relationship with a patient or someone close to the patient. Improper behaviour may include words and gestures of a sexual nature.

Where a chiropractor finds they are sexually attracted to a patient or the patient is sexually attracted to them, they should immediately seek alternative care for the patient.

C.2.3 Consent

Consent is an ongoing process, not a one-off event. The chiropractor should ensure that they communicate with patients throughout the clinical encounter and should ensure that privacy is provided to facilitate this process.

The chiropractor should ensure that the patient receives information about the assessment and care that is available to them and that it is presented in a way that is easy for them to follow and use. This allows the patient to be involved in their care and make decisions that are appropriate for them. Consent may not be valid if the patient does not understand the nature of the information given to them about the proposed assessment or care.

The chiropractor should be satisfied they have the valid consent of the patient (or someone able to act on their behalf) before they proceed with:

- examination;
- investigation;
- treatment;
- involving the patient in teaching or research.

The chiropractor should not use their professional position to persuade a patient to consent against their will.

Information to be provided to the patient to allow them to make informed decisions about their assessment and care should include:

- a) purpose of and need for any assessment or investigation;
- b) diagnosis;
- c) proposed treatment or management of the condition;
- d) options for care that are available to them;
- e) likely outcomes with or without care;
- f) any foreseeable risks and likely benefits;
- g) who will be involved in and responsible for the assessment and care;
- h) any reasons for referring the patient to another health professional;
- i) any reasons why another healthcare professional may need to be involved in assessment or care;
- j) whether the care is linked to a research programme;
- k) financial implications of the recommended care.

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The chiropractor should assume that the patient has the capacity and is competent and capable of making decisions unless there is clear evidence to suggest that they are not. The chiropractor should consider any factors that may affect a patient's ability to give informed consent. These may include language issues and physical or learning disabilities.

Unexpected decisions do not prove that a patient is incompetent or lacks the required capacity to provide consent. It may, however, indicate that further information needs to be given to the patient. Capacity is also 'decision-specific'. This means that patients may be capable of making some decisions but not others.

If there is any doubt as to whether a patient has the capacity to consent, advice should be sought from a suitably-qualified health professional.

The chiropractor should exercise their professional judgement in assessing the capacity of children and young people to give consent to assessment and care.

The chiropractor should understand and comply with the legislation in their jurisdiction in relation to issues surrounding consent and young people.

C.2.4 Providing access to patient health records

When a patient requests access to their personal health records, it should not be unreasonably withheld.

NOTE Patient health records are subject to European data protection [9].

Where statutes include provisions for access to medical records, the chiropractor should ensure that they are familiar with relevant legislation and comply promptly with any requests for access.

C.2.5 Confidentiality

The chiropractor should respect patient confidentiality at all times. This includes their personal details, information about their health and healthcare needs, their management and any information disclosed to the chiropractor during the course of their assessment and care.

The chiropractor should not employ any style of practice that may compromise the duty of confidentiality. Where circumstances exist in which confidentiality cannot be assured (for example, on the sports field) the chiropractor should confirm with the patient that they are content to undergo assessment or care.

The chiropractor should ensure that information contained on paper or electronically is kept secure and that access by non-authorised personnel is prevented.

NOTE There are exceptions to the rule of confidentiality. These include:

- a) where disclosure is required by statute;
- b) where disclosure to the appropriate authority is clearly within the public interest;
- c) where the patient or others are at risk of death or serious harm;
- d) where an official with power to order disclosure makes an order.

Where disclosure takes place, the reasons for the disclosure should be recorded, as well as the nature and extent of the disclosure.

C.2.6 Discharging patients

The chiropractor should not treat the patient unnecessarily and should be able to clinically justify decisions to continue care.

When care can no longer be justified on the basis of clinical need, the chiropractor should discharge the patient without delay.

When the chiropractor discharges the patient, they should explain the reason for them discontinuing care. The chiropractor should not discharge the patient purely on the grounds that they have raised issues about their care or have complained about their chiropractor; however, in some circumstances such complaints may render the ongoing chiropractor-patient relationship unworkable.

Unless a programme of care has ended and the patient is being discharged on clinical grounds, the chiropractor should ensure that, where it is practicable, information is provided to the patient about where care may be continued. This may involve referral to another healthcare professional (who may be a chiropractor).

The chiropractor should document their reasons for discharging the patient.

C.3 Working with colleagues

C.3.1 General

- a) Where the chiropractor works in a team, either with other chiropractors or with other health professionals, they should respect the skills and contributions that others bring to the care of the patient.
- b) The chiropractor should communicate effectively with colleagues inside and outside of the clinical team.
- c) The chiropractor should support colleagues who have problems with performance, conduct or health.

C.3.2 Colleagues' conduct and performance

- a) Where the chiropractor has concerns about the conduct, performance or health of colleagues they should act without delay to address these concerns so that patients are protected.
- b) If there are no local systems in place to report or address concerns, they should be addressed to the regulatory body. Where no regulatory body exists, concerns should be addressed to the relevant national association.

C.3.3 Respect for colleagues

- a) The chiropractor should treat colleagues fairly and with respect. They should not unfairly criticise them or discriminate against them. In particular, the chiropractor should not engage in behaviour that undermines patients' trust in the care they receive or in the judgement of those treating them.
- b) The chiropractor should not allow their personal beliefs to affect their professional relationships with colleagues.

C.3.4 Sharing information with colleagues

- a) Where appropriate, information should be shared with other health professionals. This is important for safe and effective patient care.
- b) When a patient is referred to another health professional, the chiropractor should ensure that all relevant information is provided to the health professional receiving the referral.
- c) Consent should be sought from the patient to provide this information.

C.3.5 Delegation and referral

If responsibility is delegated, the chiropractor will remain responsible for the overall management of the care of the patient. The chiropractor should ensure that the person to whom care is delegated possesses the

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qualifications, experience, knowledge and skills necessary to provide the care. Information should be provided by the delegating chiropractor to facilitate effective delegation.

Any person to whom a chiropractor makes a referral should be accountable to a regulatory body.

C.3.6 Honesty and trustworthiness

- a) The chiropractor should never abuse the trust of a patient.
- b) A chiropractor who has been the subject of criminal convictions or who has received a caution or has been refused membership of any other professional body should report these facts to their national association and statutory regulator where one exists.

C.3.7 Providing and publishing information about chiropractic services

- a) If the chiropractor publicises their practice, or asks another person to do so on their behalf, they should ensure that the materials that are used are honest, decent, legal, factual and verifiable.
- b) The chiropractor should not market their practice in a manner that undermines public trust and confidence in the profession.
- c) No claims about treatment or outcomes should be made that are unjustifiable. There should be no guarantees of a cure.
- d) No pressure should be placed on people to use chiropractic services, for example by arousing ill-founded fears about their current or future health.
- e) The chiropractor should not use any title in a way that might mislead the public as to its meaning or significance.

C.3.8 Writing reports and giving evidence

- a) The chiropractor should respond promptly and courteously to requests for information from other health professionals and third parties. They should seek the consent of the patient for the information being provided.
- b) Where the chiropractor has been asked to give evidence or produce statements they should be honest in all spoken and written testimony. Where matters are outside the scope of practice or competence of the chiropractor, they should declare this.
- c) In writing reports, the chiropractor should mention all relevant facts and only provide their opinion on matters that are within their expertise.

C.3.9 Research

- a) The chiropractor who is involved in research should always prioritise the interests of the research participants (who may or may not be patients of the chiropractor).
- b) Research design should be consistent with accepted scientific and ethical principles.
- c) In conducting research, the chiropractor should act with honesty and integrity and should not misrepresent the findings of research. The chiropractor and their staff should carefully comply with procedures detailed in the research protocol.
- d) The chiropractor should keep the identity of research subjects confidential and should at the outset of research obtain their informed consent to be part of any trial or experiment.
- e) A patient should be informed of their right to withdraw from the research at any time.

C.3.10 Financial dealings

The chiropractor should be open and honest in their financial arrangements with patients. In particular:

- a) the chiropractor should make clear to the patient information about their fees and charges;
- b) to avoid dependency, prepayment programmes should not be utilised;
- c) the chiropractor should not exploit the vulnerability or ignorance of a patient about chiropractic care when making charges for care;
- d) the chiropractor should not encourage a patient either directly or indirectly to give or bequeath gifts or money for personal gain;
- e) the chiropractor should be open and honest with employers, insurers and other organisations or individuals;

C.3.11 Conflicts of interest

- a) The chiropractor should always act in the patient's best interest when making referrals and providing care. They should not ask for nor accept any inducement or gift that may affect or be seen to affect the way the chiropractor treats or refers a patient. The chiropractor should not offer inducements to colleagues or other health professionals.
- b) The chiropractor should make clear to the patient any financial or commercial interests they have in recommending products or services.

C.4 Health and safety

C.4.1 General

- a) The chiropractor should manage and deal with risks to health and safety in the work environment and comply with any health and safety legislation.
- b) The chiropractor should have in their practices contingencies for managing emergency situations involving either patients or hazardous materials.
- c) In terms of controlling and managing infection risk the chiropractor should have systems in place to protect the health and wellbeing of their patients, employees and visitors to their place of work.
- d) The chiropractor should comply with legislation relating to the use of ionizing radiation. In particular, the chiropractor should not employ any technique or practice that requires the routine use of X-rays.

C.4.2 Evidence-based care

- a) The services provided by the chiropractor should be consistent with evidence-based care. The chiropractor should have an updated knowledge within the field of chiropractic research as well as research within the neuromusculoskeletal area in general.
- b) The care delivered should comply with what is expected of a reasonable and competent chiropractor, and should be based upon the best available evidence.
- c) Recommendations from appropriate national and/or international clinical guidelines within the neuromusculoskeletal area should be incorporated in the clinical procedures.



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 France	National Regulation Code de la santé publique art. L. 4130-1 ² (CSP) Code de la santé publique art. L. 4161-1 ³ (CSP) Decree 2011-32 dated 7 January 2011 on chiropractic procedures and practising conditions ⁴ Law 2002-303 dated 4 March 2002 ⁵ (ART 75)

² <http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000020890163&cidTexte=LEGITEXT000006072665&dateTexte=20130513&fastPos=1&fastReqId=885215953&oldAction=rechCodeArticle>

³ <http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000021709047&cidTexte=LEGITEXT000006072665&dateTexte=20130513&oldAction=rechCodeArticle>

⁴ <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023387301>

⁵ <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000227015&fastPos=1&fastReqId=625181647&categorieLien=cid&oldAction=rechTexte>

<p>Subclause 2.8 chiropractic</p> <p>health profession concerned with the diagnosis, treatment and prevention of mechanical disorders of the musculoskeletal system, and the effects of these disorders on the function of the nervous system and general health</p> <p>Subclause 2.16 diagnostic procedure</p> <p>structured procedure that exists to enable a chiropractor to arrive at a diagnosis which may include physical examination, diagnostic imaging and laboratory tests</p> <p>Subclause 3.1.2 Case history</p> <p>The chiropractor shall acquire and document current and past information on a patient related to their health (i.e. physical, psychological and social wellbeing) by asking specific questions, either of the patient, responsible adult or legal guardian with the aim of obtaining suitable clinical information useful in formulating a diagnosis and leading to a plan of care for the patient.</p> <p>Subclause 3.1.4 Further investigation / diagnostic imaging</p> <p>The chiropractor shall:</p> <ol style="list-style-type: none"> identify when further investigations are needed and act on this need in the patient's best interests; use further investigations when the information gained from such investigations will benefit the management of the patient; undertake and/or interpret the results or, if this is not possible, refer the patient for appropriate further investigations; record the outcomes of the investigations in the patient record. 	<p>CSP L4130-1 stipulates that the role of primary contact healthcare professional concerned with the diagnosis, treatment and prevention of disorders and the effect of such disorders on general health is assigned by law to medical practitioners, specifically the general practitioner.</p> <p>CSP L4161-1 specifies the cases of illegal practice of medicine (diagnosis, treatment): anybody who is not a physician medical practitioner cannot establish diagnosis and provide treatment (in writing, by oral examination)</p> <p>Law 2002-303 art 75: Chiropractors have a title for a professional use, it is not a qualification for a healthcare profession.</p> <p>Therefore, French regulations clearly stipulate that practitioners merely holding a recognised chiropractor qualification cannot act in a medical capacity.</p> <p>Decree No. 2011-32 Art 2: Practitioners which are not qualified physicians themselves (not medical practitioners), are required to refer the patient to a physician (medical practitioner) in case of symptoms requiring medical diagnosis or treatment.</p> <p>Therefore, in France the obligations of the Code de la Santé Publique and of the French Decree 2011-32 shall be followed instead of the sections of EN 16224 itemized in the left hand column of this table.</p>
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EN 16224:2012+A1:2014 (E)**Subclause 3.1.5 Clinical decision making and diagnosis**

The chiropractor shall:

- a) evaluate the patient's health status and health needs from the information gained during the case history, physical examination and further investigations;
- b) formulate and document a working diagnosis and/or differential diagnosis and a rationale for care, based on the evaluation of this information. The diagnosis, or rationale for care, shall be kept under review while caring for the patient;
- c) interpret all of the information available about a patient and then make and record decisions about the patient's health and health needs and how these change over time;
- e) consider the natural history and prognosis of any presenting complaint, or emergency situation that might need immediate action, and the likelihood of preventing recurrences or managing any long-term healthcare needs.

Subclause 3.2 Core competences

- b) The chiropractor shall have developed the following abilities:
 1. ability to obtain appropriate consent before assessing individuals and for providing chiropractic care;
 2. ability to take a comprehensive and problem-focused case history and perform an accurate physical examination;
 3. ability to integrate case history, physical examination and diagnostic imaging to arrive at an appropriate diagnosis and/or differential diagnosis;
 4. ability to interpret diagnostic procedures and make an appropriate response;
 5. ability to select appropriate clinical skills and to formulate a management plan in concert with the patient;
 6. ability to apply appropriate clinical skills in the treatment of a patient, and to provide information and advice for recovery and continued health;
 7. ability to communicate clearly with patients, their families, other healthcare professionals, and the general public, and to ensure patients are fully informed of their treatment choices and care;
 8. ability to interpret scientific evidence in a critical manner, and to find and use information relating to healthcare.

Bibliography

- [1] EN ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485)*
- [2] ISO 10001, *Quality management — Customer satisfaction — Guidelines for codes of conduct for organizations*
- [3] ISO 10002, *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations*
- [4] ISO 29990, *Learning services for non-formal education and training — Basic requirements for service providers*
- [5] prEN 15224:2011, *Health care services — Quality management systems — Requirements based on EN ISO 9001:2008*
- [6] CONSTITUTION OF THE WORLD HEALTH ORGANIZATION. Available from: <http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf> [viewed 2011-07-15]
- [7] Council Directive 93/42/EEC of 14 June 1993, Article 17. Available from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF> [viewed 2011-07-15]
- [8] Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. Available from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1996:159:0001:0114:EN:PDF> [viewed 2011-07-15]
- [9] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. Available from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML> [viewed 2011-07-15]
- [10] EUROPEAN COUNCIL ON CHIROPRACTIC EDUCATION (ECCE). Accreditation Procedures and Standards in Undergraduate Chiropractic Education and Training, version 4, 2011. Available from: http://www.cce-europe.com/downloads.html?file=tl_files/documents/downloads/Accreditation%20Procedures%20and%20Standards%20-%20November%202011%20-%20Version%204.pdf [viewed 2012-05-10]
- [11] DICTIONARY W.F.C. World Federation of Chiropractic, 2001. Available from: http://www.wfc.org/website/index.php?option=com_content&view=article&id=90&Itemid=110&lang=en [viewed 2011-07-15]