

Ethics in Osteopathic practice and research: the proposal for an Ethical Framework

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Abstract. Actually the clinical and research context in which health care is provided is characterized by new challenges for health workers, researchers and the broader health care of the community who increasingly find themselves confronted with moral questions and ethical dilemmas which are not rare phenomena and thus merit special attention. Clinical ethics is a thoughtful exploration of how to act well and make morally good choices, based on beliefs and values about life, health, suffering, and death. Because of their holistic approach to medicine and as predominantly primary care practitioners, osteopaths may face a wide range of ethical dilemmas. Recently the National Council for Osteopathic Research has produced a document intended to demonstrate best practice in osteopathic research that must be considered when conducting research in an ethical manner. On the other hand, actually, substantive discussion of specific ethical issues is rarely included in clinical research protocols. A framework of ethics analysis geared specifically for osteopaths is needed to highlight the values morally relevant in their clinical and research practice. A preliminary attempt at such a framework is offered in this study with the development of an ethical framework and two practical ethics tool kits serviceable for clinical and research practice perfectly fitted for osteopathic profession.

Key words: osteopathic Medicine, clinical ethics, research ethics

Introduction to Osteopathic Medicine

Osteopathic medicine was founded in the late 1800s in Kirksville, Missouri, by Andrew Taylor Still an American physician and surgeon who viewed the body as having the natural ability to recover from ill health when functioning effectively (1). He focused on developing an approach that integrated manual techniques to affect body function so as to enable the body to restore health and called this system of medicine osteopathy, now known as osteopathic medicine (2).

Since those early days, osteopathic medicine has evolved significantly, informed by experience and research (3), to become an internationally practiced profession, recognized by the World Health Organization and other international bodies (4).

The American Osteopathic Association (AOA) state that the four major principles of osteopathic medicine are the following: i) the body is an integrated unit

of mind, body, and spirit, ii) the body possesses self-regulatory mechanisms, having the inherent capacity to defend, repair, and remodel itself, iii) structure and function are reciprocally interrelated, iv) rational therapy is based on consideration of the first three principles (5).

Authors in the field of osteopathy, argue that the application of osteopathic principles, the structural diagnosis and the use of osteopathic manipulative treatment (OMT) in patient care, is what differentiates osteopathy from other health professions (6).

Diagnostic palpation is an important part of an osteopath's clinical competence profile, and together with the critical evaluation of osteopathic principles, plays a significant role in osteopathic clinical decision-making process. This may be achieved through a multi-stage reasoning process that usually begins with a biomedical approach to identify red flags for serious underlying pathology, and culminates in specific osteopathic diagnostic approaches that include the judicious use of palpation (7-8).

Osteopathic medicine also emphasizes the importance of the patient-practitioner relationship in the therapeutic process and is characterized by person-centered approaches, rather than disease-centered, to healthcare (9). Osteopathic care is centered on prevention, promotion, treatment and support, which are important population health needs. Although these areas are in common with other health professions, mostly in the field of physical medicine and rehabilitation, strong multidisciplinary collaborations between osteopaths and other health care practitioners are required to overcome preciously guarded professional boundaries if the patients' best interests are to be served. Recent systematic review and survey studies reported positive osteopathic patient experience and satisfaction outcomes (10).

Defining competency domains for osteopathic medical practice

Osteopathic medicine has recently been recognized by Law in March 2018 and regulated as a health profession in Italy (11-12). The Italian osteopathic professional profile was established in order to avoid overlapping the scope of practice with existing health professions (i.e., physiotherapists) and/or their specializations (i.e., manual therapy). The Italian law recognizes osteopaths as separate health professionals for interventions concerning prevention and maintenance of health through osteopathic treatment of somatic dysfunctions within the musculoskeletal system.

A panel of European osteopaths involved in clinical and academic practice, research and regulation, present a professional commentary to facilitate a critical discussion on the role, competencies and scope of practice of osteopaths in the light of the recently published Italian osteopathic professional profile (13).

The concept of competence is central to the professional system to ensure practitioners possess an adequate profile that enables them to effectively perform their role. In the literature, there are different definitions of competence, including the commonly cited one proposed by Epstein and colleagues (14) - "*professional competence is the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning,*

emotions, values, and reflection in daily practice for the benefit of the individual and community being served".

The AOA initiated programs to enhance quality for doctors of osteopathic medicine practicing in the

United States and promote the core competencies required in undergraduate and graduate medical education standards. They include osteopathic philosophy and osteopathic manipulative medicine, medical knowledge, patient care, professionalism, interpersonal or communication skills, practice-based learning, and systems-based practice (15).

In addition, the Italian Register of Osteopaths (ROI), the most representative osteopathic professional association in Italy, decided to produce an Italian Core Competence Framework in Osteopathy, based on the Italian health care system (16). According to osteopathic principles, scientific literature and a population needs-based approach, the most important functions of the osteopath are health promotion and prevention, osteopathic care, therapeutic education and scientific research (17, 18).

For the health promotion and prevention, osteopaths must be able to recognize the biopsychosocial context in order to identify risk factors for health and to raise awareness of healthy lifestyles and to formulate health educational strategies and preventive interventions. Osteopaths must be able to promote community empowerment explaining the biological, psychological and social aspects related to pain from a biopsychosocial point of view.

For the osteopathic care, osteopaths must be able to base clinical reasoning on osteopathic principles and models and to collect useful elements for their evaluation and to identify the indications and contraindications for OMT based on the person's needs and expectations in order to guarantee the patient's safety. Osteopaths must be able to identify, through osteopathic tests, alterations of the structure/function relationship according to biomechanical, circulatory-respiratory, neurological, energetic-metabolic, behavioral self-regulation models and then to develop an osteopathic therapeutic patient-centered plan coherent with the clinical context. Delivering OMT safely and respecting the dignity and sensitivity of the patient, monitoring the patient's state of health during treatment and evaluating the outcomes are also important steps for a proper osteopathic care.

For the therapeutic education, osteopaths must be able to educate the patient in the self-management of his/her own pathology and promote patient's perception of his/her own body in order to make him/her autonomous, if possible, in the management of his condition (19). Osteopaths must demonstrate interpersonal and communication skills that enable them to establish and maintain professional relationships with patients, families, and other members of health care teams (20).

Finally, osteopaths should strive to demonstrate the efficacy of OMT using contemporary standards of evidence-based medicine whenever possible. Consequently, osteopaths must recognize the importance of cultivating a research culture as an investment in their future, and need to be involved in a careful process of introspection to determine who they are as researchers and what type of research is important to them (21).

A framework for thinking ethically

Actually the clinical and research context in which health care is provided is characterized by new challenges for health workers, researchers and the broader health care of the community who increasingly find themselves confronted with moral questions and ethical dilemmas which are not rare phenomena and thus merit special attention.

Because of their holistic approach to medicine and as predominantly primary care practitioners, osteopaths may face a wide range of ethical dilemmas. A framework of ethics analysis geared specifically for osteopaths is needed to highlight the values morally relevant in their clinical and research practice and a preliminary attempt at such ethical framework is offered in this study.

Currently professionalism and code of ethics uphold the osteopathic oath in the conduct of one's professional activities that promotes advocacy of patient welfare, collaboration with health professionals, sensitivity to a diverse patient population, and adherence to ethical principles to maintain public trust and confidence in the osteopathic profession (22).

Clinical ethics is a thoughtful exploration of how to act well and make morally good choices, based on beliefs and values about life, health, suffering, and

death (23), and so osteopaths need to know that, for a good therapeutic relationship, clinical care and ethical duties run smoothly together.

Clinical research is the way to learn how to prevent, diagnose and treat illness and its laudatory goal is to advance knowledge to help future patients, but fraught with significant ethical challenges to examine by applying moral principles and codes of professional conduct (24). Recently the National Council for Osteopathic Research has produced a document intended to demonstrate best practice in osteopathic research and considerations for conducting research in an ethical manner (25). On the other hand, actually substantive discussion of specific ethical issues is rarely included in clinical research protocols.

Ethics is an inherent and inseparable part of clinical practice and research and osteopaths have an ethical obligation to benefit the patient, to avoid or minimize harm, and to respect the values and preferences of the patient. Are osteopaths equipped to fulfill this ethical obligation? Goal-oriented clinical ethics and protocol ethics tool kits could improve osteopaths' awareness, attitudes, knowledge, moral reasoning, and confidence about their ethical obligation.

A "Clinical Ethics Tool Kit" for professionals' practice

Clinical ethics is a structured approach to ethical questions in clinical medicine and depends on the larger discipline of bioethics, which in turn draws upon disciplines such as moral philosophy, health law, communication skills, and clinical medicine. Central to the practical application of clinical ethics is the ability to identify and analyze an ethical question, usually a clinical case, and using values, facts, and logic to decide what the best course of action should be.

It was therefore important to think up a Clinical Ethics Tool Kit (CETK), consisting of some serviceable instruments and processes, which might be going to help trainee and professionals to understand the formal and moral domains of communication, informed consent process, narrative approach and osteopathic record management, and furthermore to use an effective model for osteopathic ethical reasoning.

Osteopathic Ethical Reasoning model

Some ethical problems are fairly straightforward, such as determining right from wrong, but others can also be more perplexing, such as deciding between two rights or deciding between two different value systems, such as the patient's versus the osteopath's. Making an appropriate ethical decision is the foundation for subsequent ethical behaviors in osteopathic medicine and so to facilitate the development of moral values and professional conduct, a model of ethical reasoning must be used. It has been widely believed that ethical decision-making is a complex process composed of many components and cognitive steps, which help to solve ethical problems and lead to successful ethical decisions (26).

Different ethical reasoning models are reported in literature such as the Four Box model, which break the complexity of ethical reasoning into a series of tasks precisely four quadrants of ethical considerations that must be undertaken to arrive at an ethical decision (medical and osteopathic indications, patient preferences, quality of life, contextual features) (27). This model could be effectively exploited by osteopaths in order to generate a set of hypotheses and to use them to select the optimal or correct ethical decision.

The initial phase of the process includes a statement of the patient's current medical condition. What is the patient's medical problem? Is the problem acute? Chronic? Critical? Reversible? Emergent? What are the goals of treatment? In what circumstances are osteopathic treatments not indicated? What are the probabilities of success of various treatment options? In sum, how can this patient be benefited by osteopathic care, and how can harm be avoided?

The second phase involves discussion of the goals of care consistent with the patient's personal values and beliefs together with exploration of how to best achieve them. Has the patient been informed of benefits and risks, understood this information, and given consent? Is the patient mentally capable and legally competent, and is there evidence of incapacity? If mentally capable, what preferences about treatment is the patient stating? Who is the appropriate surrogate to make decisions for the incapacitated patient? Is the patient unwilling or unable to cooperate with osteopathic treatment? If so, why?

The third phase addresses ethical rather than purely medical concerns, dealing with existing issues related to values, beliefs, and morals and, ultimately, the quality of life. At this stage, potential conflicting values should be identified. What are the prospects, with or without treatment, for a return to normal life, and what physical, mental, and social deficits might the patient experience even if treatment succeeds? On what grounds can anyone judge that some quality of life would be undesirable for a patient who cannot make or express such a judgment? Are there biases that might prejudice the osteopath's evaluation of the patient's quality of life? What ethical issues arise concerning improving or enhancing a patient's quality of life?

Fourth phase in a systematic approach examines the context—that is, taking into account extrinsic influences beyond the confined osteopath-patient interaction. These might include legal ramifications, religious ideology, economic considerations, cultural heritage or customs, dysfunctional challenges within family units, or disparate perceptions between patient and caregiver. Are there parties other than osteopaths and patients, such as family members, who have an interest in clinical decisions? What are the limits imposed on patient confidentiality by the legitimate interests of third parties? Are there religious issues that might affect clinical decisions? What are the legal issues that might affect clinical decisions? Are there considerations of clinical research and education that might affect clinical decisions? Are there issues of public health and safety that affect clinical decisions?

This approach could represent a serviceable Osteopathic Ethical Reasoning (OER) model which well identifies the essential components in an ethical decision making, including the osteopath's knowledge (clinical and ethical), personal, social and moral values, cognitive reasoning strategy (problem identification, decision making, planning and action) and attitudes (empathy, curiosity, respect, sensitivity, trustworthiness, honesty, compassion, caring and humanity).

Narrative based osteopathic medicine

In the last fifty years, there has been a paradigm shift towards the biopsychosocial model of care and its

practical application, known as patient-centered care, which considers the personal meaning of illness in the context of the patient's life crucial in order to alleviate suffering (28). The ways in which patients make meaning within their own context is recognized as a key component of the clinical reasoning processes and is widely documented in contemporary literature, including osteopathy (29). Narrative Medicine (NM) is about incorporating patients' life stories, including their unique underlying value system, into osteopathic treatment options that fit each individual. Patient stories allow making sense of their suffering and how it feels from the inside, they offer a biographic and social context of the illness experience and suggest coping strategies (30).

For osteopaths a narrative approach consists mainly of a specific openness towards patients using narrative skills, such as sensitivity for the context of the illness experience and the establishment of a diagnosis in an individual context, instead of merely in the context of a systematic description of the disease and its etiology. This approach aims to address the relational and psychological dimensions that occur in tandem with physical illness, with the attempt to treat patients as persons with individual stories, rather than purely based on symptoms and in doing this, NM aims not only to validate the experience of the patient, but also to encourage self-reflection in the osteopaths (31). NM could be another potentially valuable ethics tool to increase osteopaths' awareness of the breadth and depth of aspects of lived human experiences and patients' unique ways of making sense of their pain and suffering.

A collaborative consent process

Good osteopathic practice requires obtaining a patient's informed consent (32). It is the responsibility of osteopaths to respect patient's rights, dignity, autonomy and requirements for continuity of care, also respecting a patient's right to refuse treatment.

Informed consent applies to every part of an osteopath's interaction with a patient including case history taking, physical examination, decisions arising from a diagnosis, advice regarding possible adverse reactions to treatment, lifestyle changes proposed, referrals prescribed and further treatments. It is important that osteopaths follow specific guidelines (33) aim to guide

them about the definitions of informed consent and why it is necessary, the important principles and practical steps to obtaining it, what are the elements of full informed consent, how much information is considered adequate, how to explain the proposed treatment and risks to patients, when is it appropriate to question a patient's ability to participate in decision making and how does informed consent apply to children. These guidelines should cover the concept of consent as a dynamic continual two-way process, which must be documented to foster better communication between osteopath and patient, so that patients are able, with their osteopath, to make the best decisions about their osteopathic care.

Prior to attending the clinic, a patient is sent a leaflet describing basic information about osteopathic medicine and OMT, including information about the possibility of having to undress for examination (pre-consultation). During the first visit the osteopath inform patients about the process and specifically that a wide range of health related questions will be asked and that the patient should feel free to ask questions of the practitioner at any stage in the process and then what examinations are proposed, their rationale and that they may provoke some transient pain (first consultation). Verbal consent should be received prior to the examination and then on conclusion of the examination, the findings should be discussed with the patient. Specifically the patient should be informed about their current diagnosis and treatment options and their perceived benefits, but also information about low- grade and rare yet potentially severe risks of treatment is given and patients should be asked if they have understood the risks involved, and be given the opportunity to ask questions. Written consent should be received prior to beginning the treatment and then at the conclusion of treatment, the patient should be offered the opportunity to ask further questions and given information about further treatments. At the beginning of the next visit and as treatment evolves, continue verbalizing actions and their rationale are conducted as part of an ongoing dialogue with the patient and the osteopath reiterate that the patient may ask questions or may halt any part of treatment if they are uncertain or uncomfortable (34).

Patient-centered shared decision-making is a challenge to osteopaths that requires changes in practice and clinicians to gain new skills in order to communicate effectively with patients which include active listening, understand the patients experience and expectations, ability to communicate complex information in non-technical language, tailoring the amount of the information to the patient's needs and preferences, considering the patient's values while weighing choices, creating an environment in which the patient feels comfortable asking questions, giving patients time to take in the information, and checking patients' understanding (35).

Putting ethics into osteopathic records

The osteopathic record is a sensitive indicator of how care is administered, reflecting not only the structure of clinical thinking but also the values embedded in osteopathy practice. Osteopaths are in the midst of a self-conscious reappraisal of how care can be administered more effectively and, at the same time, with more empathy. From this perspective, could be interesting to consider an addition to the osteopathic record with a section called Ethical Concerns (EC), which refers to the deliberations concerning all matters related to the value-based decisions that are constantly made when caring for a patient (36). The moral dimensions of care are constitutive of that care. So why not make an effort to identify how that domain is understood for each patient, and why not explicitly record how the patient as a person (as opposed to a disease) is understood and treated?

In an EC section of the osteopathic record, a synthesis of personal, social, and moral issues related to patient care would expressly address these complex matters. Here, osteopaths would address problems ranging from decision making in crisis and so osteopath's decisions are made and implemented in a moral space of patient values.

Osteopathic records serve important patient interests for present health care and future needs, as well as insurance, employment, and other purposes, but more than a scientific and legal document, it might also become a more comprehensive construction of a person's illness and can be seen as a type of narrative through which tells a story of disease (37).

Osteopaths have also an ethical obligation to manage osteopathic records appropriately and responsibly, all information concerning patients must be kept confidential. The maintenance of strict confidentiality creates an environment that facilitates the privileged and unrestricted sharing of sensitive information between an osteopath and a patient and any breach of privacy will irreparably damage this unique osteopath-patient relationship. In the absence of confidentiality, patients might not fully disclose important facts and might avoid medical and osteopathic care entirely.

Thus, to treat the ethical issues of patient care as a crucial component of evaluating and treating illness, the osteopathic record is the natural home for that evaluation. The obligation to address all the patient's problems, and to enlarge the patient profile in service of treating problems in their full context, serves the goal of being a 'whole osteopath' in service to the 'whole patient'. The osteopathic record must be revised to address this expansion, not only in service to informed consent and protection of patient autonomy and confidentiality, but also to acknowledge the larger ethical dimension of illness (38).

A "Protocol Ethics Tool Kit" for research in osteopathic medicine

Prior to the rise of the pharmaceuticals industry, the growth of osteopathy was largely attributed to OMT and its presumed therapeutic benefits. The licensure of osteopathic physicians in the United States was *de facto* justification for OMT's place in their clinical armamentarium prior to the emergence of rigorous clinical trial methodologies (39).

However, several factors during the latter half of the twentieth century altered this paradigm. First, the growth of the pharmaceuticals industry and the regulatory need for demonstrating the safety and efficacy of new drugs led to the development of and reliance on randomized controlled trials. Second, traditional epidemiologic research methods developed for public health began to be applied to clinical populations. Third, with the requisite methodologies and resources to collect and analyze clinical data widely available, government and other third-party payers increasingly

demanded evidence not only of the safety and efficacy of clinical interventions, but also of their cost-effectiveness. Consequently, in response to these phenomena, there is a present need to demonstrate the safety, efficacy, and cost-effectiveness of OMT.

Osteopathic manipulative medicine traditionally had an empirical basis rather than a research basis and rigorous studies of concept or efficacy for OMT's have not been robust, however, this tradition is beginning to change and the question of OMT safety and efficacy is not the elephant in the room

Effectively research is one of the American Osteopathic Association's top strategic priorities and an excellent way to contribute to the evidence base supporting osteopathic medicine (41).

Obviously, osteopathic research involving human subjects also raises complex ethical, legal and social issues that cannot be ignored. The Nuremberg Code, Declaration of Helsinki, Belmont Report, International Ethical Guidelines and similar documents (42) can be considered the main sources of guidance on the ethical conduct of osteopathic clinical research.

Actually, researchers are moreover faced with very rigorous scientific and ethical expectations as they design and implement clinical protocols (43). Although it is widely recognized that the creation of practical tools to help the development of ethically acceptable clinical research protocols has received little attention and that consequently more intensive efforts to improve ethics education for investigators and institutional reviewers are imperative.

The lack of guidance results in clinical trial protocols that are silent on the ethical issues and the deficiency of their explicit description can result in time-consuming delay, as ethics committees pose questions that the writers must then answer in a later resubmission.

The intent of a Protocol Ethics Tool Kit (PETK) could be to help protocol writers recognize and address common ethical challenges in clinical trials and to help ethics committees review in analyzing protocols in a more efficient, explicit and comprehensive manner. A dedicated ethics section must be included in every protocol to help research teams proactively consider and articulate ethical considerations associated with their protocol and, as a result to improve the dialogue

between ethics committees and clinical research teams and among research team members themselves (44). The process would therefore become more efficient and ethics issues would be addressed proactively, directly from an ethical perspective and more completely.

Based on personal expertise, and informed by the literature (45) and protocol reviews, it was possible to identify some important requirements that should be considered for a discussion in a dedicated ethics section within a clinical research protocol: social and scientific value, scientific validity of procedures, fair and equitable subject's selection, restrictions for research with vulnerable groups or individuals, favorable risks/benefits ratio, informed consent, human rights, data integrity and safety monitoring.

The PETK is not intended to serve as an exhaustive list of ethical issues that can occur in clinical research, and not every requirement is necessarily relevant to every protocol, however, it is recommended that researchers consider all requirements, address those that are pertinent for the particular clinical trial and supplement as needed.

Then PETK should be a multiple-item evaluative instrument, which provides a systematic and methodical approach to address the ethical implications of a planned clinical trial, and which encourage the articulation of an appropriate ethical justification.

Consequently, PETK also emphasize the type of training and skills necessary for osteopaths in their role of investigators. Not only must clinical investigators be skilled in the appropriate methods, statistical tests, outcome measures, and other scientific aspects of clinical trials, they must have the training to appreciate, affirm, and implement ethical requirements, such as the capacity and sensitivity to determine appropriate subject selection criteria, evaluate risk-benefit ratios, provide information in an appropriate manner, and implement confidentiality procedures.

Conclusions

The aim of CETK and PETK is to establish and maintain a recognizable reputation for high quality clinical practice and research, to contribute to the body of osteopathic knowledge, to promote

evidence-informed care and to support the achievement of ethical strategic goals.

Osteopaths have a responsibility to inform themselves about the ethical, legal and policy standards that govern their activities. The values that guide these activities include a commitment to developing an open and honest culture of critical enquiry, scholarship and research, which maintains respect for the heritage and values of osteopathy. The strategies of CETK and PETK aim to promote high quality research and scholarship to support evidence-informed education and clinical practice within the institution and throughout the osteopathic profession.

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