

Non-conventional practice versus evidence-based medicine. A scientific and ethical analysis of the Italian regulation

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Summary. *Background:* The current lack of scientific validation of non-conventional treatments in medicine, whose epistemological foundations lie in scientific evidence and experimentation, raises a significant questions regarding the costs and benefits of alternative-treatment forms. Nonetheless, in the last few decades non-conventional treatments have been increasingly recognised by the Italian medical profession, with one regional healthcare administration adopting some non-conventional practices as part of its conventional healthcare services. *Aims:* The Authors aim to analyse non-conventional treatments in medicine from an epistemological, cultural, ethical, political and economic point of view, in order to highlight criticalities and incongruities, especially when these treatments are approved by a public healthcare system, which should be grounded on the “evidence-based medicine” principle. *Conclusions:* Non-conventional treatments in medicine are constituted by meta-theories, i.e. philosophical, religious and ideological concepts that conflict with contemporary rational, empirical medicine. In the interest of patients and society, the paper stresses the incongruity of a healthcare system which, despite being grounded on the “evidence-based medicine” principle, allows the development of non conventional treatments. Having said that, medical science should address not only the biological domain of illness but also its existential implications. Awareness and respect for the individual experience can undoubtedly lead to a new medical model that allows for a more effective therapeutic intervention. (www.actabiomedica.it)

Key words: alternative medicine, complementary medicine, medical ethics, self-determination, evidence-based medicine, traditional medicine

Introduction

The so-called “non-conventional treatments in medicine” (including homeopathy, acupuncture, herbal medicine, homotoxicology, auriculotherapy, moxibustion, flower of plum therapy, cupping, Tuina, naturopathy, prano- practice, reflexology, shiatsu, yoga, chiropractic, osteopathy) (1) play a decisive role in order to understand our approach to the healthcare system and, moreover, to the world that surrounds us.

Human nature is certainly inclined to believe in the existence of a metaphysical dimension and occult

powers that can be controlled and used for our advantage. Nonetheless, scientific activity, “heretical” par excellence (2), from the seventeenth-century onwards has shown the clear separation between reality (“what actually exists”) and our wishes and faith. The concept of “limit” is inherent within the very definition of “science”: there is something not “scientific”, something which does not meet the requirements of modern science (3). Therefore, interventions and practices exist that we cannot classify as scientific and medical.

Whilst in past centuries non conventional interventions were practiced by medical charlatans, without

any recognition by the medical profession (4), currently, in some cases these treatments are practiced by traditional physicians. In particular, the Italian healthcare system includes these interventions within its own regulation (5-8) at one regional level (9-11) with the compliance both of the national medical association (12) (despite differing approaches in identifying non-conventional treatments foreseen in the regional statement), and large parts of society as a whole.

Nevertheless, the achievement and success of non-conventional practices in medicine within the public healthcare system raises epistemological, cultural, political, ethical educational and economic issues (13).

The epistemological issue

- a) During the 17th century, Galileo Galilei revolutioned the concept of “science”, according to the hypothetical-deductive method of modern science. Starting from a direct study of the phenomenon (“reasonable experiences”), the scientist formulates a rational hypothesis of law, that must be proved by empirical experiment and repeatability (“necessary evidence”). The proven theory acquires a gnoseologic intersubjective value which, as Karl Popper - the point of departure rather than of arrival of contemporary epistemology - pointed out, can be confuted (Popper’s falsifiability criterion) (14). Therefore, knowledge can be evaluated as scientific if it can be proved by empirical experiments and if it can be potentially confuted.
- b) Within the medical healthcare system, a scientific intervention is grounded on scientific evidence (“evidence-based medicine”), with regard to its efficacy (in addition to its tolerability): a medical intervention (even if it is preventive, diagnostic, therapeutical or rehabilitative) is effective if it has the intended effect (the prevention prevents, the diagnosis is right, the therapy cures and the rehabilitation rehabilitates). If medical intervention can be shown to be effective, it can also be evaluated as appropriate in terms of risks and benefits. Of course, the scientific effectiveness (and also

appropriateness) of medicine is “relative”. In fact, some parts of medical results produced by clinical practice do not prove medical efficacy, whilst other parts produced by controlled studies do. Consequently, even though medicine is not included in the so-called “exact sciences”, the presence of a partial experimental framework makes it a scientific field of study.

In conclusion, medicine can be intended as a scientific activity, made up at a theoretical level by rationality and related potential falsifiability, whereas at a practical level by experimentation. In other words, the classification of a medical intervention as “scientific” involves rules that must be shared by the international scientific community (15).

If we do not accept the epistemological basis of modern science and of modern medical science in particular, every practice and every medical intervention could be regarded as scientific. With this in mind, what is the difference between homeopathy and a rain dance as a way of curing a disease? Someone could answer that homeopathy boasts clinical results that the rain dance does not have. However, this statement has to be proved. Indeed, if by “efficacy” we mean “experimented”, then neither of these practices can be termed effective and both can be placed on the same non-scientific level.

With regard to homeopathy, the lack of a sufficient level of efficacy trials is universally recognised. In Australia, the *National Health and Medical Research Council* recently published a report declaring that there are no health conditions where reliable evidence exists showing that homeopathy is effective (16).

Supporters of homeopathy and proponents of non-conventional medicine in general contested this conclusion, stating that even if a practice does not have a sufficient level of efficacy trials, it can be still be effective. Such a position recalls the famous logical fallacy of *argumentum ad ignorantiam*, i.e. the truth of a thesis depends on not being able to disprove it. For example, we can state the existence of extra-terrestrial intelligence because no one has proved it does not exist.

However, it is impossible to prove the non existence of something just as it is impossible to prove the non effectiveness of homeopathy. In other words, the burden of proof in support of homeopathy’s effective-

ness (in the form of evidence produced according to protocols agreed on by the scientific community) lies with those who defend it and not with those who don't.

In conclusion, until such proof is provided, homeopathy must be evaluated as ineffective.

In addition, traditional medicine differs significantly from non-conventional treatments thanks to the development of molecular biology, which is accepted by conventional medicine, but not by non-conventional practice. The insights emerging from molecular biology reveal the profound differences exist between conventional and non-conventional practice, differences that should not be minimised.

The problem is that, at present, non-conventional approaches, such as homeopathy, are practiced by many physicians and used by many parts of society. Nevertheless, their apparent popularity is no indicator of their effectiveness. Here we are faced with another logical fallacy, i.e. *argumentum ad populum*. The fact that many believe in something does not prove it is true. For example, the widespread use of a specific drug does not mean it is the best drug on the market.

The cultural issue

In order to understand (not necessarily accept) the diffusion of non-conventional practices, we should address the reasons that foster their dissemination. Only if we identify these reasons, can we promote suitable remedial strategies and protect the principle of patients self determination (17).

Consequently, the professional responsibility of "traditional" physicians plays a decisive role. In fact, the social demand for non-conventional solutions is often supported by the need for greater awareness of the individual in all her complexity, in contrast with a reductionist and mechanistic approach to a patient's illness. Traditional medicine, as a result of the excessive compartmentalisation of practice, runs the risk of losing sight of the individual's psycho-physical dimension.

Undoubtedly, the hermeneutic and anatomic interpretation of sickness (i.e. patient as a flawed machine) conditions not only the "mechanistic" type of therapy (i.e. therapy as remedy), but also the doctor-

patient relationship (a relationship between a technician and a flawed machine). The recognition of more personal and holistic concepts exposes the problems inherent in conventional therapy and the doctor-patient relationship.

In addition, the increasingly technocratic face of contemporary medicine tends to dominate its anthropological characteristics, as the following examples show:

1) *The prevalence of technology in communicating with the patient both in diagnosis and therapy.*

This approach risks not only undermining the value of hermeneutical reasoning centred on individuality (18), but also of neglecting the beneficial effects that come from the optimization of the doctor-patient relationship, both in terms of diagnosis and clinical therapy.

2) *The increasing specialization and parcelization of scientific medicine.*

This feature certainly satisfies the need of biomedical sciences, where significant advances in knowledge added to the complexity of single areas heightens sectorial competences. However, it is an inescapable need, both from a scientific but even more from an ethical perspective, not to lose sight of the totality and the critical awareness that the single part works for the whole. In this sense, the trend towards medicine that is capable of a personalized, systemic and holistic approach is directed not primarily to fight the pathogenic event, but rather to restore the patient's mental and physical equilibrium by recognising his/her personal values and preserving a harmonious relationship with the surrounding environment. There is also no doubt that a disrupted and altered ecosystem can have pathogenic implications that determine not only physical, but also mental health risks.

3) *The dangerous loss of confidence in medical science, generated also by an ideological (socio-logistic) literature that has acritically questioned its (medical science) effectiveness (19-21).*

4) *The rigid contrast between diagnosis and prevention (22) and the extremist conclusions regarding the healthcare system's limited ability to control*

some serious debilitating and/or deadly diseases (23).

The reduction of the person to his/her biology, the denial of his/her subjectivity and life story are some of the major forces that attract people towards non-conventional treatments, which aim at addressing the person in his/her entirety and complexity, rather than focusing solely on the disorder. In fact, privileging technical skills has led to a neglect of crucial “relational skills” (commitment, attention, listening, concern, empathy) on which the doctor-patient relationship should be grounded. In other words, in daily practice the difficulty is going beyond the boundaries of the concept of *disease* (i.e. the medical concept of pathological abnormality that focuses on disorders of the *corporis fabrica*) to embrace that of illness, where primacy is given to the human experience of suffering and the subjectivity of sickness.

In the face of the predominance of technology, recognizing the need to restore and enhance the patient’s subjectivity and to ground the cure on a relational project means also restoring the importance of the physician, in order to re-evaluate his/her not only therapeutical but also ethical role, with the purpose of improving the entirety of the human condition.

Medicine that not only cures a pathology, but also takes care of the patient means recognising the crucial importance of a physician’s training in the so-called “Medical Humanities” (such as medical ethics, bioethics, history of medicine) (24). In conclusion, society’s demand for non-conventional treatments is in part due to the traditional physicians’ lack of attention to complex human aspects of healthcare, which should mean taking care of the person with health problems.

Information also plays a key role: if incomplete or inaccurate it can on one hand create unrealistic expectations about the real prospects of biomedical sciences and, on the other, determine unjustified denegration that may induce people to make other choices (25).

The political issue

In order to satisfy the growing demand for non-conventional treatments, at present many Italian physicians offer them privately. As already outlined, this

raises questions about the legitimacy of such services from an epistemological point of view. Yet, if non-conventional treatments are not scientific, and they cannot be the result of academic education and training, can a physician, graduated in Medicine and Surgery and a member of the medical profession, provide the patient (albeit in private practice) non-scientific and so non-medical services?

The issue becomes more complex and urgent when non-conventional treatments are offered by the public healthcare system.

This is the case of healthcare in the Region of Tuscany (9, 10). This Region has added some non-conventional treatments among its healthcare services by one agreement with the State (26), another with the Tuscan Regional Federation of Physicians, Pharmacists and Vets (27), as well as by two opinions given by the Tuscan Regional Commission (28).

Therefore, from a political point of view, it is clear how some legitimize non-conventional treatments, without having first resolved the epistemological issue. Indeed, the related “non-scientific” issue seems of little concern: if we cannot call some practices “scientific,” then we will call them “alternative” or “integrated” medicine, when we wish to give them their place at the table alongside medicine *tout court*.

Another favoured route appears to be through governmental intervention, i.e. the inclusion of non-conventional treatment amongst conventional, scientific ones. Emblematic is the case of osteopathy and chiropractic (non-conventional rehabilitation treatments), which are listed as health professions in a proposed Law currently being debated in Parliament (29). However, this reclassification of osteopathy and chiropractic does not solve the related scientific and therapeutic issue. Only the scientific community should solve this issue through research and debate. In other words, politicians should not have the role of deciding what can or cannot be considered a healthcare profession and therefore scientific, but to the scientific community through experimentation. The political world should simply acknowledge and recognize a practice as a healthcare (scientific) profession only if this practice has been already legitimized by the national and international scientific community.

The ethical issue

- a) As can be gleaned from the agreement signed with the Tuscany Region, also before the cited State-Regions agreement, the Italian Federation of Medical Orders (FNOMCeO) has evaluated as medical acts non-conventional interventions (30), as we can find in some resolutions (31) and in the current Italian Code of Medical Ethics (developed by FNOMCeO itself) (12). However, the same Code of medical ethics states the principles of evidence-based medicine and of experimentation as the grounds of scientific medicine (articles: 6, 13, 15, 48, 49, 55, 56, 62, 71, 77). Therefore, from an ethical perspective, it seems inconsistent to provide the opportunity for physicians to “prescribe and adopt [...] non-conventional systems and methods of prevention, diagnosis and treatment” (32).
- b) Moreover, the rule on non-conventional treatments contained in the Code of medical ethics, (article 15) specifies that the physician who performs these interventions, must not, however, “deprive the assisted person of the evidence-based treatments of proven efficacy”. By stating this, however, FNOMCeO is admitting that non-conventional treatments are not scientifically based or effective. Therefore, we ask again on what scientific and medical basis should the physician be entitled to exercise non-conventional interventions?
- c) Another critical issue concerns the medical information on non-conventional interventions with specific regard to the lack of their scientific basis and consequently effectiveness, and also the absence of the physician’s academic preparation in this field of study. On this basis, the patient’s consent to these practices could be judged as not valid (33).

It should be stressed that we are not questioning the principle of free choice in healthcare, i.e. the possibility for the patient to freely choose between different treatment options, including the refusal of therapy or the right to look for it elsewhere. Instead, we wish to

emphasize the need for the patient to be well informed about the limits of scientific knowledge and the professional qualifications of the practitioner in the interests of authentic patient self-determination (34, 35).

- d) Finally, the same ethical rule states that the physician can practice non-conventional solution only after having tried conventional treatments. However, if the evidence-based medicine did not work (and this may happen because medicine is not an exact science), why should we rationally think that what shouldn’t work will?

The educational issue

In Italy the degrees in Medicine and Surgery do not include courses on non-conventional treatments. Consequently, a crucial issue is defining the related professional competences and the operators able to exercise them. The choice to give physicians non-conventional practice has been established both the Tuscany Region and by the FNOMCeO. In fact, the Code of Medical Ethics states (article 15): “The physician ensures [...] the quality of his/her specific education and training when using non-conventional systems and methods”. In particular, at the local level of its organisation, the FNOMCeO assigns itself the task of issuing, through *ad hoc* committees, special educational certificates of other educational institutions and place “competent and capable” physicians in special lists of professionals (30, 31). In other words, since FNOMCeO believes there is a gap in the academic courses in Medicine and Surgery, it, rather than the Ministry of Education, proposes to integrate them.

- 1) The first argument used by FNOMCeO to justify its decision is that it is consistent with its mission to work “in order to guarantee the dignity of the medical profession”. Why should the medical profession feel threatened by those who operate non-conventional treatments, since there is a clear difference between, on one hand, what is medical science and what is not, and, on the other, between who is a physician and who is not? If anything, a real

threat lies in the confusion generated by the very same representatives of the medical profession when they declare that they alone have the right to offer non-conventional treatments. Whatever competition there is is not within the category of 'traditional' physicians, but rather between those doctors who offer non-conventional treatments and those who don't. Therefore, when the medical profession states its exclusive monopoly of non-conventional treatments, this means that those who offer the same treatments without a degree in Medicine and Surgery (or in a healthcare profession for osteopathy) commit the crime of unauthorised practice.

- 2) The second argument put forward in support of the monopolistic provision of non-conventional therapies is the need to protect the patient's health: "if anyone must do it, it should at least be a physician". However, non-conventional practices are not mandatory and, regardless of the demand, physicians have the right not to perform them (and their decision will be supported by the very definition of medical science). In addition, the fact that an individual's responsible behaviour implies referring to medical expertise to monitor, manage and resolve a clinical case only highlights how non-conventional treatments have no scientific basis. When we state the surgeon performs surgery, it goes without saying that he/she does so in the interests of the patient, whose health would otherwise be at the mercy of "pseudo-surgery" practitioners. If non-conventional practices were experimentally proven to be effective, why in the interests of patient health should we insist that only qualified doctors perform them? On the other hand, as non-conventional treatments are not 'scientific', are qualified doctors necessarily the only people competent to practice them?
- 3) The third argument concerns the desire to protect the quality of non-conventional practices. However, shouldn't the State guarantee the quality of medical education and ensure that specific scientific requirements of healthcare

treatments are respected? In fact, a fundamental related issue is a possible conflict of interests because the physicians themselves (without any specific academic study in this area) become the guarantors of their own education.

- 4) Finally, the fourth argument refers to the intention to offer citizens the widest possible freedom of choice in therapy. But unless FNOM-CeO limits the definition of medical therapy to its scientific features, any intervention risks being considered "therapeutic" and thus included among medical acts.

In agreement with the above arguments, we would add, however, that the most useful way to demystify proposals that conflict with the scientific nature of medicine is not to isolate or ghettoise non-conventional practices, but show their inherent weaknesses (36). Therefore, we would be in favour of including a course on non-conventional practices in a degree in medicine providing the course is part of the syllabus of the History of Medicine and is taught by a lecturer in that subject. This will make it easier to achieve objective, critical analysis and place non-conventional practices in their historical perspective, which in turn will help to understand their origin, meaning and theoretical premises.

The economic issue

Physicians are professionals who require a (suitable) reward. Since the effectiveness of non-conventional practices cannot be proved, the reward for a non-conventional treatment should be judged as illicit. Of course, the charging of fees for non-conventional treatments is not in itself illegal, but it certainly represents a problem area for physicians particularly when information is inadequate (37).

Conclusion

Non-conventional treatments raise many issues that so far have not been solved.

Above all, non-conventional practices lack their own specific definition and so cannot be placed ob-

jectively within a specified list of subject areas. In this way, it is inevitable that non-conventional treatments are compared negatively to medical science. The question “What are non-conventional practices, which ones are not and why” as yet has no clear-cut answer.

The only certain thing is that they are not scientific practices, where a medical-scientific intervention is grounded on the principle of evidence in agreement with the international scientific community; this intervention supported by a rational and consistent framework of principles, has been tested through controlled studies and shared protocols according to empirical methods, in order to prove its effectiveness.

In conclusion, it is paradoxical that, despite the fact that non-conventional treatments are unproven in their workings and effectiveness (and hence not even their appropriateness can be measured) and that they are not part of medicine *tout court*, they are performed by many Italian physicians, backed up by the decisions and Code of Ethics of their Federation (FNOMCeO) and some parts of the political world.

However, there is a point that we cannot ignore and that obliges medical science to take a hard look at itself: the need for an approach that is consistent with inalienable ethical principles that seek to protect the patient “as a person” and so avoid prioritising the objective analysis of his/her clinical condition.

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