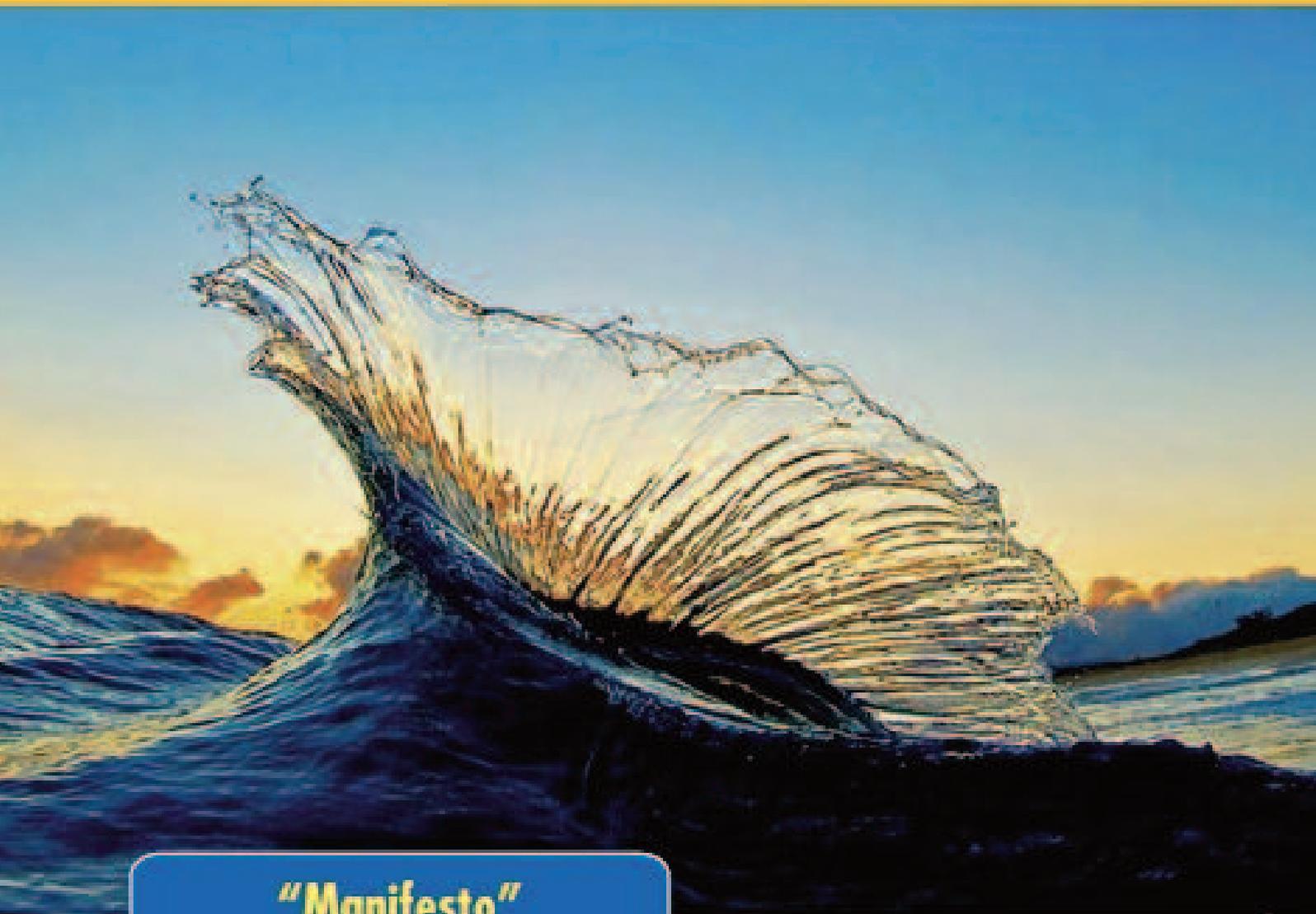


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**HOMEOPATHY  
and Integrated Medicine**



**"Manifesto"  
for Integrated Medicine**

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 and Integrated Medicine**

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## Presentation

This contribution has the purpose to encourage the proposal to combine mainstream treatment, which finds approval in the Western biomedicine, otherwise identified as academic medicine, with the current unorthodox treatment, which nowadays is generally defined as CAM (Complementary and Alternative Medicines): a remarkable number of practitioners and patients believe that CAM can be combined with or replace the orthodox medicine treatment and, in some way, be implemented for recovery in those cases when biomedicine methods have failed or carried out negative results. CAM can be defined as "diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine" (Ernst, 1995; Barret, 2003) and comprise "a range of recovery treatment originated from assessments completely differing from those implemented by Western medicine" (Thorpe, 2002). The pathway to achieve this proposal is hindered through the vagueness of the subject, different way of thinking, party interests, hard-line, different law system and unbiased difficulties due to varied health care directives drafted by each government.

Nevertheless, it is a general opinion that this combination can lead the potential of healing treatment to develop in every field of the human life, regarding not only health conditions, but also the relation with oneself and with the society. Since unclearness in terminology, concept and even in defining the integrated health model is being found among international works, the goal of this contribution is to better identify CAM and its treatment potential within the public health care service. The model of Integrated Medicine currently tested at the Hospital of Pitigliano has been taken as reference by drafting this document.

Simonetta Bernardini, Ivan Cavicchi, Andrea Dei,  
Guido Giarelli, Francesco Macrì, Alfredo Zuppiroli

## "Manifesto" for Integrated Medicine

- Integrated Medicine aims to harmonise the roles of all healthcare resources in a seamless manner irrespective of the speciality, the era and the cultural background in which it operates. The main healthcare resources are actually defined as Biomedicine and Complementary and Alternative Medicine (CAM).
- Integrated Medicine addresses the complexity and the wholeness of the individual. It includes the science behind these important issues and assumes joint responsibility for the care and health of the individual. Disease is viewed as a phenomenon that results from many differing factors; the pursuit of health is a priority.
- Integrated Medicine recognises that the individual is a combination of body, mind and soul as related to his own personal history and to the environment. It considers the current division between various therapeutic models to be an obstacle to be overcome in order to lead to shared care and hence to reciprocal assistance.
- The citizen's freedom of healthcare choice is a right that should be upheld and protected in the setting also of the physician's freedom to advise. The personal, cultural and spiritual beliefs of each individual influence his experience and interpretation both of illness and of healing.
- Integrated Medicine contemplates the meaning of health and healing and the meaning of illness and treatment. Each patient is both the subject affected by the disease and the person who can express his potential to heal himself when guided and supported properly.
- Integrated Medicine promotes research on the effectiveness and safety of healthcare irrespective of the many and varied approaches to therapeutic practice. The disciplines in the Integrated Medicine model must guarantee proper levels of theory and of practical safety and effectiveness.
- Integrated Medicine brings together - integrates - the values expressed by citizens and those professional values of the physician and other healthcare workers in the light of social justice and sustainability in the community.
- Integrated Medicine creates a syncretic forum within the different disciplines in medicine. This is made necessary by the new knowledge achieved in the last few decades about the living organism. The paradigm of Integrated Medicine is based on an interdisciplinary approach to healthcare organisation rather than on a hierarchical approach.
- Integrated Medicine values the wise use of scientific knowledge, understanding of the individual's situation and problems, sensitivity to promote mutual understanding, prudence in deciding upon necessary intervention, responsibility as to the ability to predict the consequences of one's therapeutic actions, the ability to listen, the value of the patient's opinion, recognition that the individual's primary means of expression is through language, responsible and judicious use of technology, the relevance of therapeutic actions affecting the patient's current situation, and the value of experience as well as of theoretical knowledge of all the procedures that might help the patient.

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# Integrated Medicine

## The anatomy of a choice

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Medical sciences are broadly specified by the society which they develop in, and as such, it is defined as a social and cultural expression of thinking, customs, economics, politics and devotion of a human society. Several features set out such expression: decisions related to healthcare politics, industry sector capital and pretensions of the health community and ability of influence of the media.

Through these interconnections the medical sciences represent an utmost complex reality and difficult to be simplified, beyond the needs that are a cornerstone of the social pact which has involved institutions on the one side and the academy and medical associations on the other side in the last one-hundred and fifty years. This pact results in the achievement of orthodox medicine, that is the biomedicine (or academic modern medicine), which basically represents the official culture to work as a medical professional within the National Healthcare Service. This achievement is an obvious result of the social pact, since both the academy and associations, by underwriting it, could only guarantee the cultural legitimacy and not the qualified skills of the own graduates and members.

The main feature of this cultural legitimacy has been to work as a medical professional with a self-evident explanation of a real or questionable scientific support, through which orthodox medicine is used to specifically understand and explain the kind of illness and, consequently, to propose a therapeutic treatment. Since knowledge progress highlighted the overstated feature of the justification in the name of the term "science", it hereafter would have been preferable to talk about explanation on the basis of effectiveness evidence or evidence existence, even though those, who are the less cautious and the most inexperienced physicians are still talking about an orthodox medicine founded on strict scientific principles. This approach successfully led to resolve some pathologies and to develop numerous lifesaving drugs, however, it turned to be insufficient or even ineffective to treat a large number of chronic pathologies.

The so-called evidence-based orthodox medicine is still neglecting this clear failure, by restricting itself to attempting to treat and cure the symptom at the most rather than to finding the cause of suffering conditions. However, this observation did not restrict the attempt to impose common morals, promoting the unexceptionability owned by a cultural model that, by appealing to the support of criteria univocally of a strict scientific method, claims to predetermine and control a complex and difficult reality, as health conditions of the community are,

influencing their choices. This attempt can be explained from many perspectives except one, which is unfortunately the scientific perspective. Moreover, it is important to highlight how this attempt could not be imposed in a veiled manner by convenience, political opportunities, basic connivance or pressure performed by supremacy groups. This paper will not deal with the importance and the influence of these factors, but if we do not mention them it would be a self-deprecation. A sensational example was the invalid announcement by the WHO related to the outbreak of the pandemic H1N1 flu, representing an incredible "own goal" to express such an attempt bringing the "Emperor has no clothes" novel by Andersen back to mind. But much earlier we had experienced another mockery, this time by the evidence-based medicine (EBM)<sup>1</sup>, which we will discuss in a further contribution more broadly. This doctrine has been a plain evidence of a childlike behaviour, praising a paradigm basically founded on the quantification of a series of observable criteria, and thus objective, and at the same time this doctrine has contemplated itself as research for a patient-based medicine (and thus specific and subjective). It goes without saying that this idea leads to diminish, influence and restrict the concept of healing and recovery process as successful result of the physician-patient relationship. Indeed, this view leads to delete and thwart the good and qualified professional physician who makes reflections, assessments, distinctions and responsible decisions according to its own expertise and culture.

Beyond these flaws, the great restriction for biomedicine lies in its definition that, by words of Eric Cassel<sup>2</sup>, encourages to protect the structure of an organism rather than the functionality, to protect the mind rather than the person, and mostly to contemplate both survival against normal health conditions and life-length compared with life quality. This concept has a teleological feature in the orthodox medicine: through science and technology development it will be able to virtually destroy human suffering. In order to achieve this proposal, it aims at forming a strictly controlled discipline performed by high-qualified professionals. However, one forgets the fact that when developing a society which neglects the death and aims to an everlasting well-being conditions, one of the crucial aspects of the human being is left out, that is indeed the suffering.

I am outlining this contribution with a feeling of admiration for all those who in the last 150 years have been engaged in contributing to develop a certain culture and a certain technology, which have deeply marked the mankind history. However, I cannot help emphasizing the

fact that in the last twenty years an increasing number of members belonging to the healthcare community have found appropriate to betray the orthodox medicine, often to their cost, drawing from other therapeutic instruments for their health care. These therapeutic instruments have been developed together with the orthodox medicine by working out some ancestral instruments of the healthcare art, as in the case of osteopathy, chiropractic or phytotherapy; or related to different paradigms as the case of homeopathy, homotoxicology, or anthroposophical medicine. Other instruments have been finally introduced in the Western countries, cherishing the millenary experiences of other civilities, such as acupuncture, ayurvedic and Tibetan medicine. All these therapeutic techniques have been gathered by the Western literature in an individual group and established to be implemented by professional physicians qualified in medical sciences earlier defined as alternative medicine, and later as non-conventional medicine and, in the end, as complementary (CAM), introducing an adjective that entails harmony and not opposition. The latter definition is justified by the fact that professionals using this kind of medicine were in the first place graduated physicians from those universities which practised orthodox medicine, and that many of those professionals were using them as a further therapeutic instrument to that imposed by biomedicine. It is to be noticed that also this latter definition of complementary medicine does not seem to be sufficient, if considering the international literature. Even the label for integrated or integrative that provides the expression of several therapeutic methodologies or the synergy of several professionals qualified in different disciplines is at the present time used inconsistently (see contributions by Bernardini and Giarelli), along with the lacking of a certain cultural development concept.

### *Birth of legitimacy*

It is commonly understood that the approval uttered by the healthcare community towards therapeutic methods which are not taken into account by orthodox medicine is the result of a hopeful less invasive and more customized care system. This is absolutely true and has to be included among the reasons for the success of CAM and of the medicine we have called integrated medicine. Historically this movement developed at the end of the 60s at the San Francisco Bay as corollary of that productive counterculture movement, which was the New Age. Rediscovering values of spirituality, meditation and environmentalism in the name of a protest against political, social and cultural patterns imposed by the political and religious regulations established by Western civilizations, the movement implemented unorthodox therapeutic treatments in the name of an subject-based holistic philosophy. If the crucial features of the movement were social pacifism and eclectic attitude, which implied an insightful exploration of the subject to find the individual spirituality, it is important to mention that those features led the attention and the interest of Western young people towards a world consisting of clearer, more direct and acceptable values, that is the millenary world of Eastern civilizations.

This led to the introduction of Eastern culture elements into the Californian society, including therapeutic practices or life patterns which were unknown or not taken into account due to the industrial and post-industrial civilization. It should be recalled that in the same period Europe was being shaken by other kinds of insurrections, for example the 1968 protest, which the present writer had a direct experience of and not for exciting age reasons, or the Provo protest, whose followers had completely different goals compared with the New Age purposes. The Californian movement firstly spread among Anglophone countries and then among Western countries with different tinges and an increasing number of physicians and hospital nurses approached to that culture which was different from the mainstream culture. From this it resulted a spontaneous, amorphous and uncontrolled movement, as it is used to be, since it derived from a way of thinking which prioritised the subject and not the community. It is proven by the CAM definition, deriving from the compromise between European complementary and North American alternative medicine and the fancy justifications of evidence adopted by professionals who were used to practice these methodologies. This took Paul Root Wolpe, a great personality of the contemporary science as well as a great exponent of the man-science relationship, to argue that CAM is "what sociologists refer to as a residual category" in that it is "defined not by its internal coherence, but by its exclusion from other categories of medicine".

However, the coherence flaw did not restrict the success of CAM. Data reported by trustworthy institutions show that the number of those who are disillusioned by the orthodox medicine is steadily increasing in every Western country, with peaks in Germany and France (75%), in the US, Japan and Australia (50%), in Belgium (38%) and in Italy (20%). However, there is no doubt that the referendum held in Switzerland on May 17<sup>th</sup>, 2009 represents a milestone to make this trend official. In that occasion 67% of the voters were in favour to introduce five complementary medicine, i.e. homeopathy, phytotherapy, acupuncture (traditional Chinese medicine), neural therapy and anthroposophical medicine, into the Constitution of the Confederation, inverting the decisions taken by the Swiss Minister of Health which, by neglecting results of a study called PEK relating to the appropriateness degree of such practices, removed the five aforementioned medicines from the National healthcare system. The approval expression uttered by the population led the five medicines to be reintegrated in the National healthcare system with legitimacy as the orthodox medicine, to be practically refunded, as long as a qualified physician in the specific complementary medicine prescribes them and to be subjects of medicine degree courses at Swiss Universities. It is crucial to highlight the fact that most Swiss citizens do not shy away from the academic medicine, but they have decided to virtually implement therapeutic models, whose effectiveness often lacks of the support the academic medicine believes it has achieved: the present author considers such an opinion as broadly justified at least within the actual knowledge. For this reason, medicine integrated model seems to be a

successful model, according to which a physician, by treating his patient, implements both mainstream medicine and one or more disciplines we roughly call as CAM. All this entails some mandatory observations. The migration by the health community towards CAM does not depend on a flaw of the National Healthcare System, since it occurs at the same degree in several countries, regardless of the planning, through which services are provided. Moreover, it cannot be neither assumed that it could depend on the physician-patient relationship, which is known to encompass a more or less paternalistic and authoritarian attitude of a physician, according to customs and politeness of a nation. Hence, it shall be deduced that such a revolution is something that is deeper connected to the health treatment and it ultimately concerns the medicine essence, therefore the dimension of illness or suffering conditions as they are felt and perceived by a patient is not sufficiently fulfilled by the orthodox medicine. Thus, this shifting shall not be considered as result of an ideological choice, even if it could be in some cases, rather as a pragmatic choice justified by acceptable results. So, the point is: even if CAM does not find any scientific legitimacy as it occurs for the orthodox medicine, they have achieved empiric legitimacy, finding approval among the health community. In this regard the opinion of the present author is clear and simple: CAM and orthodox medicine follow two different paradigms. Even if CAM postulate unacceptable scientific theories, they can be accepted as operational methods, as they virtually follow the same self-protection system implemented by the human organism to protect his own identity. In turn, the orthodox medicine in its therapeutic treatments leaves the presence of this system aside and it is to be emphasised the fact that neglecting it has not been historically a culture subject but often a choice in its full awareness to support the academy model. We are going to go back over this point in another contribution, which deals with hormesis and emphasizes how it decided to neglect the presence of the phenomenon in the 30s and to remove it from the university books, since it confutes the statements of the orthodox medicine. In fact, confronted with the evidence of a stimuli-based effect by a substance at low doses and an inhibitory effect at high doses towards a living organism, it decided to deliberately restrict the scale from a therapeutic perspective to inhibitory-based doses and to codify this choice according to the Food and Drug Administration criteria. The canonization of orthodox medicine occurred and was labelled as "medicine of the anti-drugs".

### Opposition of paradigms

Both orthodox medicine and CAM follow distinguished paradigms, whose features cannot be compared with each other. Even if one were to layout these features, it can be said that therapeutic models can be basically divided into two big categories, depending on if they encompass the (in)existence of a feeling of trust perceived towards the ability of an ill organism to build a self-recovery process. If that feeling exists, the medical act can induce a slight interference fit to encourage this process. Vice versa: if the ability of self-recovery is believed not to be sufficient,

the resulting therapeutic model assumes that the ability can or shall be neglected. In the first case it shall be emphasised the fact that the disease is considered as a general instability state and the self-recovery process is deemed as a reestablishment of the usual balance state. Hence, stimuli-based actions always entail the involvement of the patient, who consciously embraces a mind-body approach towards himself and that approach becomes the main cause for his recovery. Many unorthodox therapeutic treatments make that involvement one of the main pillars of the methodology, even if it shall be accepted the fact that self-recovery abilities are limited, as Hippocrates stated. In the second case the disease is seen as the result of a malfunction of the biological mechanism and the therapeutic treatment aims at inhibiting this mechanism. The latter is the paradigm, which the orthodox medicine is based on and, for this reason, the medicine has been previously defined as medicine of the anti- drugs (anti-inflammatory, anti-biotic and anti-depressing drugs etc.). This medicine does not necessarily encompass an active role of the patient because it is assumed that the biological mechanism inhibitor acts regardless of the patient willingness. This process often implies a high degree of perturbation, which, even if it can help to remove the disease, can cause undesired effects, damaging other biological mechanisms (the so-called side effects). These undesired effects are often irreversible and, virtually, the aforementioned self-protection mechanism comes to being damaged, entailing a long-lasting restriction to protection abilities. This is what Cassel expressed, whose name I mentioned before, and his words specify the determinist and mechanist feature of biomedicine.

### The unusual attractiveness of CAM

At this point the question which occurs is the following: most CAM have a century-old history, indeed, it can be simply said that the introduction of the term *science*<sup>ll</sup>, which occurred at the time when modern Western medicine originated to contrast science against complementary medical sciences, represented a clear profanation, since CAM undoubtedly had a superior status compared to biomedicine from a theoretic and practical perspective. However, in order to discuss about "science"-based medicine it was sufficient that a dentist named Morton discovered the general anaesthesia in 1846 to radically change the surgical world, that Semmelweis formulated in 1847 the antisepsis concept, that suggested washing their hands to limit puerperal fever cases; furthermore, to abandon the custom to pass off very high doses of arsenic and mercury as drugs, which entailed derision and mockery by homeopathy professionals and it was enough to limit the implementation of blood-letting, purgative and induction to emesis as panacea for all diseases. And yet, it is to be mentioned that the term *science* was the strong point to strengthen the privileged status of biomedicine from an institutional and academic perspective, even if being examined by a physician and then following his therapeutic prescriptions in relation with his observations on biomedicine at the beginning of the 20<sup>th</sup> century was, for the patient, an experience which could give him an equal chance of both beneficial or bad results.

In other words the medical act was part of the risk. Therefore the question is: why did that movement, which we are observing at the present time, not take place, but conversely the benefits and contempt of orthodox medicine were accepted with supine resignation by the community? And why now? At present the orthodox medicine has broadened its sphere of knowledge, it can employ extremely advanced and, above all, less invasive technology, it can have more and more powerful drugs: so why do we have to experience an increasing degree of attention and interest by the health community towards medicine models which orthodox medicine has always mocked, fought against and attempted to remove? Likely the answer lies in a string of factors, which led the Western health community to pass inadequacy judgments of the therapeutic model, suggested by several national healthcare services. This has been subject of discussion at many places, and many reasons are brought forward for it.

Many sociologists state that what is occurring is a usual consequence of the globalization period, which dates back to the end of the Cold War. Although this led to a deviation process, since sanctions were imposed on the free movement of capital and of citizens, it allowed to develop a total dimension of health problems. Globalization entails several perspectives and had a severe impact on the decisions made by international organizations because globalization favoured the migration of people and, consequently, the establishment of multiculturalism. I believe that this was one of the factors which determined the choices made by WHO, leading it to formulate three decisions (1972, 1977, 1978) aiming at integrating the different (un)orthodox healthcare systems, as results of both tradition and knowledge progress, in a single medical model consisting of features that can be compared with the healthcare conditions which could have been achieved among emerging countries. This model shall naturally show features where mutual influences of different cultures can materialize in. This fact involves the development of cooperative models, which embody the different therapeutic techniques with the purpose to fulfil the most basic needs of several nations. The establishment of a pluralistic medicine model fully falls under this hope and the technological development of communication encourages this concept, allowing cultures to blend with each other. The decision dated 2002 repeats this concept and demands international organizations to come together and to achieve a legitimated model. Hence, the integrative and integrated medicine development shall not be achieved for a cultural establishment of a movement arisen in the Western countries in an environment where the economic and institutional conditions encouraged it, as sociologists usually state.

In addition, sociologists emphasize how this revolution is related to the increased availability of finance and research for well-being conditions of the health community. The setting of biomedicine aims to remove an anatomic or physiological flaw and recovery is deemed as standardisation of a number of biological criteria. In other words, biomedicine focuses on the disease and not on the subject itself, drawing from the Cartesian doctrine to repair the mechanism.

In reality, from the patient's perspective the disease is the loss of a personal way of living in the world and interaction with it. Recovery process means to obtain a standard way of interacting again. Hence, diagnosis and treatment cannot disregard to examine what the loss of well-being conditions to the patient means, not to mention that diagnosis and treatment shall not neglect the importance of patient's life experiences, his personal questions and other individual peculiarities. The so-called listening and narrative medicine is crucial to formulate an appropriate diagnosis and to prescribe an adequate treatment, because the concept of recovery changes: achieving a standardisation of a number of biological parameters is no longer the goal, but the aim is to reintegrate the subject into his normal interaction with the world. And this is what patients find in CAM, relying on the availability of finance they had not before had and a higher degree of knowledge on how to keep well-being conditions steady, due to an easier way to gain information, but above all, patients find in CAM outdated values, starting from anamnesis, which was considered by Hippocrates a very important instrument for the treatment, and instead it was neglected by biomedicine. Similarly, factors such as impacts of a trend or rather drop-out reasons are drawn into play, but they seem to me to be less important. Patients obviously are not interested in prioritising a science-based therapy, praised to be focused on the subject, while they have to think how to come out of their pain and suffering, which are factors embodied in the individual by nature. Those who do not have faith find no relief, the same is for the patient: science is a monad that does not give the warmth, comfort and reassurance that he needs. This is also due to the fact that orthodox medicine has often showed its limitations regarding the illnesses, which severely affect the patient. This failure is one of the causes which leads the patient to be attracted to CAM because they encompass therapeutic methods which adapt themselves and follow the natural process, and focus on the patient needs, in order to remove suffering as well as to replace it through well-being feeling. It is obvious that this expectation experiences some limitations and physicians qualified in CAM are the one who are responsible and have the duty to explain the patients the real recovery expectations of CAM, even if this seldom happens.

In addition to the aforementioned reasons, in the last forty years the bioethics development has strongly attempted to refine medicine. The legislation in many countries provides to regulate the patients rights and the introduction of informed consent allowed to refine the physician-patient relationship. At least this is what bioethicists state, but it is also true that bioethicists, with rare exceptions, restricted their actions depending on the orthodox medicine, justifying its choices and, unfortunately, its purposes and above all they refrained from criticising that could have upset the supreme class. For this reason, I find that the contribution given by bioethics for the actual revolution shall not always be considered as meaningful.

I believe, indeed, that one of the main reasons of the attractiveness of CAM is due to the changing relationship

between the physicians, both hospital and territory, and patients. Even though it is true that the medical act could digress into risks, it is also true that it was usual for a physician to spend the night holding the hand of a child suffering from bronchial pneumonia, waiting for the resolution of the crisis or the bad result. That was everything he could do and the family was grateful for it, being aware of the fact that the feeling of confidence conveyed by the doctor through his powers was very different from what a mother or another relative could do. Nowadays physicians formulate diagnoses, just prescribing the usual treatment consisting of antibiotics which allow to remove the infection in a short time. Often he does not need to see the patient again to observe how the treatment is proceeding. This is the power of technology, but this does not encompass the same feeling of gratefulness previously mentioned and, above all, it represents a strong limitation for the pietas that makes medicine the most amazing profession in the world. Technology is developing, observation is being replaced by instrumental analysis, treatment decisions are being entrusted to the sum of individual professionals' opinions: I am sure that all these factors demotivate the health community, which experiences a progressive dehumanization of the process and the loss of pietas conveyed by the individual helping the other one who is suffering. What will happen when a computer will directly manage the medical act? This is not possible with CAM because the mankind represents an intrinsic feature of the therapeutic approach and does not disregard the physician-patient relationship.

The great achievement obtained by CAM is to connect physical suffering with psychological and spiritual factors that are the subject of psychosomatic medicine, which was neglected by orthodox medicine not so many years ago. It is to be mentioned that in the development of orthodox medicine the mind has been conventionally considered as an annoying bug, as proved by the fact according to which the psychiatrist was seen as a strange doctor until the 70s, as if he were a second-class professional. The great difference between CAM and orthodox medicine is not to neglect or underestimate the patient experience, the existence of his real world and above all, sounding trivial, the fact he has his own identity and spirituality. When a patient makes connections between his own health conditions and external exposures due to environment or society, which he lives in, he begins considering his suffering feeling through other perspectives and he understands he can be the key player of his own recovery. This occurs in a more striking way when the patient, affected by various pathologies which require separate interventions performed by several high qualified physicians, figures out that for the CAM practitioner everything can be explained through an accurate diagnosis which encompasses an accurate therapeutic treatment as well. Step by step he understands which factors can cause the undesired illness, for instance a headache, and learning how to avoid it. In other words, this kind of therapeutic approach allows him to learn how to experience a different and more comfortable relationship with his own body and this is achievable by taking advantages of his individual freedom deemed as one of the inalien-

able features of an individual. Figuring out the chance to imagine a scenario, which he is part of, in a different framework, the possibility to have an active influence on it, the chance to choose among different possibilities is one of the most attracting abilities of the human soul. This discovery has ever-lasting effects on the way of life and insurance companies are straight aware of, which through researches they have found out that the number of CAM supporters who stay away from work due to illness is significantly lower compared to the orthodox medicine supporters (about 33% less), beyond the fact that CAM supporters cost less in terms of pharmaceutical spending. These considerations strongly influence the social and economic conditions, as highlighted by senator Moynihan in his well-known article "On the Commodification of Medicine"<sup>3</sup>: his thesis was that health care, being science or non-science, had become a commodity and it had to be analysed in terms of costs/benefits. It surprises that complementary medicine professionals did not realize how this paper damaged the cornerstones of the orthodox medicine and it resulted to be much more efficient compared to their other eulogistic articles enriched by good thoughts.

### *Reaction of the orthodox medicine*

At the present day orthodox medicine and its most fervent followers are still attached to their hardline ideas, speaking out against the triumph of ignorance, the longa manus of the medieval obscurantism, the wave of irrationality and resurgence of superstition as result of false information and artificial messages. They are right: they belong to a host which is regulated, organized and protected by institutions and, if necessary, praised by Big Pharma lobbies. The academy is deteriorating a little bit, this is true, since there are more and more information and training courses about CAM within the framework of biomedical disciplines, but considering the financial crisis experienced by Universities, the need to meet the requirements of the health community is understandable, maybe through courses which are not only specific for physicians. In addition, there was a number of historic judgements, for example the one pronounced by judge Cardozo in 1914 in the Schloendorff case, which established the sanctity of the human being and the self-determination right of the patient, but they had found out how to bypass those judgements. Finally there were bioethicists and their anti-paternalist movement against physicians, but it was sufficient to growl and they became quite again. And that story of the humanity in medicine, good indeed, but it is a waste of time when few tests are able to specify results and therapy with the technology in the 21<sup>st</sup> century: it is sufficient to adopt a possibilist expression of interest to overcome the inconvenience. However, the clouds appearing on the horizon do not allow to lower our guard, even though those clouds brought only few damages. Not least, the medical associations had the chance to strike would-be professionals off the roll but it refused to do it due to indolence or other paltry reasons. The United States experienced that sad story of the XIV amendment, through which those professionals obtained legitimacy, and Italy experienced a self-destruct-

tive, reckless and above all unrequested position taken by the FNOMCeO in a creative moment and remembered as Terni 2002. In such way they dogmatize on magazines or in television the recklessness and the fool prejudices of a community which is expected to be healed through less dangerous drugs or methods they believe to be more pleasant. They are often regretting the period of the American Medical Association, when, in order to obtain the working license it was necessary to endorse the commitment not to implement practices different from those imposed by the orthodox medicine, or else expulsion, forgetting to speak out against the limitations of their therapeutic model, or even the fact according to which their drugs represent one of the main death causes within the hospitals of the Western world (fourth or fifth on the base of statistics). Even because the fact that patients demand to control their health and take independent decision on how to heal and how to feel better seem to them as an outrage to their cultural superiority, since the task of the patient obviously is not to decide how to heal and how to feel better, but it is up to the professional practitioners. When a layperson has the pretension to intervene on the faith and the profane individual has the pretension to intervene on the sacredness, things go bad. However, the social pact between State and biomedicine is to be respected and if sometimes the reasons of the politicians waste the evidence experienced by the science, it is necessary to adapt to the situation.

### ***The open-mindedness of institution and orthodox medicine***

Community requests and observations about cost/benefit can considerably have an influence on a different healthcare services regulation by several Healthcare National Services and that is what WHO expected through its resolution dated 2002. However, before this occurs, it is necessary that CAM provide evidence of effectiveness and safety, which are badly defined by bioethicists as features of benefit and non-benefit which a public institution has the right and the duty to ask for. This is required by WHO through its resolution and it especially stresses on this question in order to obviate the beginning of a dogmatic enthusiasm and uninformed disbelief. This is a cornerstone of the *regulation of globalization process about healthcare*. CAM have been basically accepted because their therapeutic methods were not intrinsically dangerous, even though some certainly not enlightened scientist sometimes needs to claim that, for example, homeopathy is dangerous, not realizing the fact that his statement confirms the discipline. The strength of orthodox medicine, as we already mentioned, lays in its organization and regulation, essentially deriving from its institutionalization. CAM and CAM practitioners are too far away to achieve such a status and they, at the most, vanish into the air citing Hobbes, and stand by, living their migration in silence. However, in order that disciplines are institutionalised, a popular legitimacy is not sufficient, it is at least necessary to synthesize that kind of legitimacy and the scientific legitimacy, as defined by the orthodox medicine: this means the legitimacy shall find approval among a legion of professionals who verify the achieve-

ment of quality control according to a number of reference criteria. And it is absolutely sure that from this perspective the real effectiveness proof of CAM, letting alone the bright support of followers, does not go beyond the evidential reasoning. As it will be discussed in separate contribution, it shall be moreover taken into account that orthodox medicine has not the same reference criteria and generally the legion of professionals often consists of experts who are not certainly known for their unconcern, lack of prejudices and high degree of open-mindedness. At most they can accept the fact according to which orthodox medicine procedures can have a restricted understanding of the kind of illness, but they are sure it is the only source of truth and those who relay on CAM are not certainly heralds of an emancipation message.

It being understood that the institutionalization process of these medical sciences must overcome a number of obstacles, such as legal hindrances, regulations and financial tests, it does not seem that an alternative to their confirmation exists, which represents a compulsory step, and the place assigned to this confirmation can only be a hospital, where orthodox medicine physicians and professionals qualified in complementary medicine have the opportunity to confront each other and to cooperate in order to establish the best efficient procedures. Therefore, it is to be hoped that a miracle takes place in the stronghold of orthodox medicine as supporter of the ideological purity, that is the hospital, where traditionally and for institutional law it is taken for granted and without appeal what science is and what it is not. In turn CAM practitioners, that are those who perform their work and are used to implementing one or more so-called complementary treatments besides biomedicine, are involved to cooperate together with hospital physicians to enhance the procedures and this fact entails a number of problems: first of all to be open-minded towards the other one, avoiding the inescapable collision of paradigms. And this encompasses the need to involve staff nurse who must understand the fact, according to which their expertise is changing and a new kind of organization is taking place, since the staff nurse is much more involved with the patient's healthcare. A new Medicine is about to develop which shall be the endorsed outcome of several therapeutic and healthcare perspectives.

The orthodox medicine reacted differently. The development of Western biomedicine in the last fifty years led to take into account aspects related to healthcare and disease prevention, such as diet, preference of natural products, exercising, environmental aspect which CAM were responsible for. This fact entailed an institutional and academic awareness and step by step many universities and National Healthcare Services centres have developed training courses on *integrative medicine* or *integrated medicine* for physicians and hospital nurses. In addition, it shall be considered that nursing schools were the first ones which requested the opportunity of this kind of training, acknowledging indeed the usefulness derived from CAM as representative for those who had the closest direct relationship with ill patients. As a matter of fact, these training courses are now not anymore an optional serviced provided by universities, but they are becoming

a standard service in the United States, Canada, Australia and New Zealand. The situation experienced in those countries is in contrast with the European experience and, especially, with the Italian scenario. I believe that such a *delay* lays in the fact according to which the adoption of the holistic paradigm was not as successful as it was in Anglophone countries. This cannot be left out for a limited amount of the healthcare community, but the adoption of a holistic paradigm by most of the healthcare community cannot be considered as self-consistent, meaning that the paradigm should entail relational, behaviour and, above all, cultural features which are far away to have a privileged status among our community. The success of CAM in Europe and in a more restricted way in Italy, is more distinguished through cultural traditions, as in Germany and France, and through the disillusion of the individual towards the therapeutic proposal provided by the orthodox medicine. The relation setting of several professional societies implementing CAM has been to accomplish a grid-group contrast politics. The low degree of responsiveness by the Academy and institutional bodies which control the culture development of Italy did not certainly encourage this development. The first master degree in integrated medicine was held in Siena in 2009, where the author of this paper was called to hold a seminar on the first day. I recall when, during the seminar, I emphasized the importance of the event, I realized that nor teachers neither the public were culturally able to perceive the significance of the event. Following the example of the University in Siena, other universities introduced training courses which often did not strictly refer to biomedicine professionals, but I would like to highlight the fact that, unlike to what happened in the United States or Canada, no one considered to introduce official training courses for staff nurse. However, the gap to bridge between Italy and Anglophone countries is huge, even because nor integrative neither integrated medicine have received the essential boost to establish their relating paradigms from an institutional and charismatic perspective. For instance, take into account the difference with the United States, when Bill Clinton sponsored himself to establish a commission responsible for studies regarding CAM, and with England where the Prince of Wales personally promoted and funded a committee of the House of Lords.

In most cases, the expansion of healthcare services has taken place by creating multi-purpose healthcare centres, but if on the one side this fact meets the community needs on the other it does not help the therapeutic model of the Integrated Medicine to develop, and once more it must be mentioned that Integrated Medicine must provide for the cooperation of several professionals into the patient treatment. It is commonly understood that in the Western world this process must encompass (Coulter, 2003) a simultaneous cooperation of four items:

- the addition of CAM to largely hospital-based programs;
- the inclusion of CAM practitioners into procedures normally performed by orthodox methodologies;

- the increasing trend for health insurance companies to provide total or partial coverage for CAM treatment;
- initiatives on the part of the patients to obtain integrative care.

The third and the fourth items belong to institutional healthcare politics. This process is more feasible in Tuscany, since it is provided and covered by public Healthcare Service.

### Dicussion and conclusions

At present the institutional hopes for a legitimated model are quite nebulous, more or less as the WHO resolution in 2002. In other words, they show the state of the art. On the one hand a holistic model is praised and according to WHO it is due to multiculturalism: therefore different models exist depending on both the country and the situation where they have been developed. On the other side prejudices are experienced, which are uttered by those who are used to supporting orthodox medicine, therefore they do not accept, by nature, any other possibility, without even knowing what is been talked about. The only thing WHO is sure of is that this model would be desirable, if it were carried out. There is no escape from the rhetoric of confusion between model and real world and, as in the case of this Manifesto, a justificatory approach can be theorized, but lacking of a descriptive empirical fundamental, any other observation is considered as premature and pleonastic. Insurance companies have a much clearer overview: they are in favour of this model, foreseeing an increase in its turnover.

The proposal of this developing model has been greeted with different feelings and obviously distinctions and doubts were put forth by both sides. However, orthodox medicine did not show hostility towards this proposal and this had occurred not only in small hospitals in the countryside, which had revealed to be conservative, rather than in *cathedrals* referring to orthodox centre that are big hospital centres. There is no doubt that the model proposal has been achieved according to political decisions and pressures performed by superior groups. But the question is: why were medical disciplines, which were until a short time before not mentioned and contested, allowed to belong to the *cathedral*? Why did academy and medical power consider the opportunity of this compromise under a different perspective? The answer lies in the growing success of CAM among the community members, but this does not mean that professional physicians would be welcomed in those disciplines, the physicians who have fought for the development of this new biomedical model. The aberration of viewpoints is obvious.

The establishment of compromise legitimacy among different vultures could encompass the thinking according to which the development of Integrated Medicine is seen as the result of a diminishing arrogance by the orthodox medicine overwhelmed by the success of CAM, as unfortunately some CAM followers' sharp comments show. This means to have a mind like dodo does, a bird weighing twenty kilograms which lived on the Mauritius isles and was proverbially stupid; the last specimen was killed at the beginning of the 18<sup>th</sup> century, representing the first

example of animal extinction due to human beings. Never has orthodox experienced shine for generosity nor abandoned its overbearing and oppressive nature towards any other beliefs because it would neglect its nature, which cannot be possible, since it has self-nominated as the only authentic medicine. The enormous number of religions is an outstanding example for this behaviour. Instead, I believe that a portion of this success is due to the fact that those who specified the social pact being cause of the establishment of orthodox medicine, changed their strategies. Hence, it is true that the strengthening of what we here define as "hope for the establishment of Integrated Medicine model" seems to entail the willingness of a certain academic political choice and the hope for a change in the orthodox medicine. But thinking that this consolidation is due to a relaxation of the orthodox medicine and to a surrendering of related archiepiscopates due to CAM establishment, is the expression of ill and brainless chauvinism, which is still not satisfied for all the damages brought, since short-sighted fundamentalists has always existed.

The point is that any ideological purity, when achieved a superior status, fades as time passes and it is available to openings which do not compromise its status. This fact explains the position taken by most of the professional Associations which accepted physicians practising the so-called integrative medicine or even of those who neglected to apply orthodox therapeutic techniques. In other papers I have already claimed that the position of the latter ones has to be considered as incompatible with the registration to an association which allowed them to take advantages from an institutional revenue. All in all, associations are more liberal than one might think and they have never taken measures towards those who were unwise and deviant, let alone the cases in which their therapeutic prescriptions, neglecting the orthodox, revealed to be causes for self-evident damages. As a matter of fact, this behaviour allows the association to leave heresiarchs aside and emphasizing their insanity allows to negatively justify the orthodox biomedical model itself, with all its limitations and lacks. Hence, it is sufficient to highlight the lack of credibility of CAM and the superficiality of its supporters, mocking, scorning and, in severe cases, cursing them. What is felt is that Western biomedicine plays a subtle game, giving unorthodox practitioners the opportunity to perform within its framework, to co-opt what is good about CAM, and, if necessary, to adapt it and to integrate it as a tool in its own toolbox. This absorbing strategy has been usually adopted by Western biomedicine in the past and, as in this case, every time there was the risk to loose approval among patients attracted

to the unorthodox. It must be mentioned that a kick-off for a hospital centre implementing integrated medicine always entails a disorganization aspect, since a professional mismatch takes place: if a physician follows biomedicine, he strictly applies a codified paradigm, which is being seen as the perfect one, even though patients will not survive. CAM practitioner is not supposed to fail, instead, changing his professional profile from physician into a healer.

The cooptation process improves at its best and more easily when it is possible to use a common language. This is feasible with those physicians who apply CAM as well, since they are doctors as they are, and they have shown their own cultural skills in the same academies. The situation begins to be more difficult when dealing with professionals who intend to achieve goals, eluding their daily procedures. As a matter of fact, the aim is not to draw up the paradigm of Integrate Medicine, but to broaden the health tool range of the orthodox medicine, preserving the strictness of the clique and the superior pontifical state. In other words, believing that the orthodox has degenerated and is willing to share its power is statement of ingenuity. Certainly this is not the utopian message hoped by CAM practitioners, aimed to change the disease approach scenario. However, the biological time of the evolution does not seem to me to allow a different process from the one given through the current situation. From a biological perspective the evolution lasted millions of years within niches, and only in recent years, it started to influence the dimensionality and features of the environment. To me it seems to be a hard challenge, but the attempt must be made in order that the merging of different therapeutic models finally deletes the "integrated" adjective and begins to simply talk about Medicine. Even though the challenge with its idealistic shades will experience a partial success, meaning that patients will take some advantages from it, it will not be a waste of time. ■

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# The question about unorthodox therapy legitimacy

## Antinomy and law of non-contradiction in Integrated Medicine

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Healthcare and its specifications belong to the priorities performed by the State. Since culture and Western religions had an influence on the development of the State regarding the achievement of an extreme rational model, it is commonly accepted that in the Western world the rules, regulations and laws specifying those priorities shall be prompted by a radical rational thinking. Hence, it is not surprising that therapeutic treatments provided by several National Healthcare Services shall be supported by a rational management principle, which is being linked reasonably or not to the so-called evidence assessment within the medical sphere.

Therefore, the guidelines defining these therapeutic treatments, it is worth remembering, should specifically concern the patient, and obtain legitimacy within a National Healthcare Service, following a specific general paradigm. The point is that there are two types of legitimacy: orthodox legitimacy, founded on a claimed scientific nature of biomedical model and defined by particular randomized control or randomized clinical trials (RCT); and clinical legitimacy, based on a number of several methodologies according to many therapeutic models considered as legitimated, even though they are unorthodox, for example CAM therapies. In addition to these two types, there is a third kind of legitimacy, that is the anthropological one, which is founded on completely different requirements, as it will be shown. However, since the approval or non-approval of legitimacy by a National Healthcare Service entails the presence of physicians, practitioners, bureaucrats and casuistical lawyers, who certainly have no experience in anthropology, it all comes down to the problem to establish if a therapeutic treatment could be legitimated or not, following an empirical model in substitution of the orthodox pattern<sup>1</sup>. It is obvious that in a rationalism-based society the orthodox method, theoretically having an undisputed scientific evidence, is intrinsically legitimated due to self-definition. This is not the case of CAM and this fact is the core of the problem about the approval of certain therapeutic techniques within the National Healthcare Service. Surely the problem is the focal concept about the (non)institutionalization of Integrated Medicine.

At the current legislation, every therapeutic technique shall meet effectiveness and safety requirements, which can be proved through scientific experimental methods. From the most integralist perspective this vision originated the evidence-based medicine (EBM). The crucial focus of EBM is that the decisional capability of every medical act is referred to a critical assessment of results which can be founded through scientific materials and this assessment

shall establish which decisions can be adopted in the healthcare of individual therapeutic cases. The point is that the doctrine entails for a diagnostic and therapeutic approach which is not to be linked to the subjective judgement of the single physician, but it has to be an objective approach, as it is determined through empirical results previously collected. The objective criterion represents a huge hindrance for the legitimacy of unorthodox therapeutic techniques, or at least to the most of them, due to a number of reasons which will be discussed next. However, as I mentioned more than once in the past, it is the EBM paradigm itself, despite the appearance, not to meet philosophical and scientific self-consistency rules, which the paradigms has the pretension to be related to. This goes beyond the fact, according to which, I consider it mostly as a result of ascetic approach residing in the Protestant ethics, which remarkably contributed to the guidelines which inspired the actual Western society, for better and for worse.

Fundamentally, the understanding by EBM followers is to be seen as an attempt for rational expression of a complex reality, that is the medical act, despite the social and political implications for institutional convenience. The roots of this attempt lay in the adoption of a logic neopositivism model by the Anglophone culture, that is a philosophical approach developed by the Vienna Circle in the 20s and consequently it spread through its supporters, when most of the intelligent scientists of Central Europe migrated to England and the United States. Philosophers, influenced by the developments carried out by physicians, who in the first decades of the century were able to connect theory and experiment at showing the new principles of the natural reality, believed that the thinking itself as well (philosophy in primis), should be an objective expression, as it were the output of a scientific experiment. This fact entailed that every principle of metaphysics and many of the fundamentals regarding religion and ethics were to be considered as senseless, since they predetermined a purpose by the scientific knowledge. In the following years, the theories carried out by two main philosophers, such as Popper and Hempel, even though they had been formulated in different fields, contributed to a further establishment of the movement, whose cultural prerequisites are being conserved in many institutional directions still today.

The assumption of this thinking movement is to assume the existence of a "science" concept, that could be ideally defined in its abstraction and features. In other words, science shall be defined for its essential nature. This cannot find acceptance for two reasons.

The first reason lies in the absence of a fundamental truth that can be accessible for the individual, since the individual is not able to distinguish reality from hallucination, due to biological reasons, unless an hypothesis is being carried out. According to the second reason, if it were possible, it could not be used, as science is naturally heterogeneous entailing a several number of disciplines, since features specifying a discipline could differ from those which distinguish another one. At most it can be mentioned that, according to Wittgenstein, most of the scientific disciplines have a number of mutual features, however it cannot be stated that if this set of features is partly available in a discipline, the latter is not a scientific discipline anymore. In the same way, if many therapeutic methodologies are being specified through certain criteria, and other therapeutic methodologies partially meet the same criteria, they shall be considered as therapeutic methodologies.

A possible setting of a theory only specified by an objective evidence based on proper clinical results which do not depend on judgement and prejudice of the scientist, is a precondition for the essentiality of the concept of evidence, as in the case of the science according to Popper which is approved by medical literature (A/N: since Theaetetus by Platon says the same things, it could be sometimes mentioned). Once accepted, it is possible to conceive the clearness of an action performed by the individual, if he accepts to proceed according to objective fundamentals, which univocally are specified through clinical data. This way of thinking is seen as the most reasonable reference of a human action, leading to a growth in terms of reliability. Evidence-based medicine is founded on this paradigm: clinical decisions are to be taken only considering results obtained from the most recent proper scientific studies; each treatment shall be supported through RCT or better SSRCT (Systematic Reviews of RCT), each medical act, in order to be approved, shall entail the opportunity of quantitative measure, the so called protocols shall be avoided, but only the clinical problem shall specify the kind of evidence to be investigated and finally each decision shall be founded on results gained from statistical studies (the so called meta-analyses).

The success of EBM philosophy lies in the basic naturalness to conceive physical and biological reality, specified through a number on linear relations as it were a chess game, where single pieces move through simple rules. Due to this vision of reality, any intuition form originated from skills obtained by a physician during his experience is being criticised. The clinical decision he may take would be subjective and not deemed as the best by objective experimental data and therefore it would be misleading in relation to what the evidence encompasses. In the end, it is to be emphasised the fact that this perspective cannot take into account the patient, only if he is seen as passive role, since his illness conditions can be objectified through a number of criteria and integrated into a predetermined framework. This mechanistic idea about healthcare does not consider the patient, who has the only right to play a passive role. As we discussed in an other paper, it is very likely that this led CAM to success among the community in the last years, as if it were a sort of social redemption.

The non-existence of an objective evidence-based paradigm which refers to RTC the key role in the medical practice, is to be found in the need to decide which objective experimental data could lead to a certain therapeutic decision rather making another kind of choice. This has been the great problem for EBM, since verifiable data could often support several diagnoses and several therapeutic decisions. It is a scenario well known by any physician and from this fact the problem about the decision making arises, which cannot be objective. It is the main cause that demerges the doctrine. And to crown it all, determining the ideal procedure to be followed has always represented a problem, considering uncertainties linked to previous studies and, above all, there is not a criterion to determine the statistical acceptance of meta-analysis process. The aforementioned issues provide for subjective decisions on reliability criteria. In spite of all this, the steady faith in science rationality and objectivity leads EBM practitioners to formulate the following disputable resolution: every time a discussion about therapeutic decision occurs, there will be always a number of neutral data which will be accepted by both parties, leading to a proper objective solution. It is a conventional case which recalls the antinomy "all the Cretans lie" by Epimenides from Creta.

It is reasonable to state that RCTs have been conceived as an instrument to define a direct connection between a specific therapeutic treatment and its chance of success. This virtually represents an attempt to set out a cause-and-effect relationship and it has an undisputed importance from a biomedical research perspective<sup>2,3</sup>. However, it is to be mentioned that this importance is intrinsically limited to the nature itself of the instrument, since a certain number of observable data and their quantitative measure need to be specified, disregarding several criteria which establish (ab)normalities of the single subject. For this reason, RCTs are not consistent with therapeutic methodologies related to principles, which differ from the orthodox medicine. The core itself of many CAMs, referred to the holistic vision on illness conditions and recovery results, virtually represents a limitation, when it is included, for an instrument as RCT is, which draws back to a reductionist paradigm being deliberately founded on some evidence aspects and deliberately disregarding the contemplation of the patient as individual. Procedures adopted by CAM practitioners mostly provide for a physician-patient relationship, which represents a therapeutic instrument and as such is being tailor-made and personalised according to the patient features. In other words, this interaction is idiographic and cannot be specified through criteria, as the nomothetic law of an RCT would hope for. Moreover, it is to be observed that the need for unorthodox therapy mostly concerns chronic disease healthcare or desired prevention, which often represent, unfortunately, causes for failure or unsatisfied results for biomedicine. In this case, CAM procedures often require long periods of time, which is not successfully suited for the implementation of epistemological methodologies; the methodologies provide to set out a cause-and-effect relationship which can play an important role in the physical experiment only if disturbance factors are removed from the relationship.

In the end, a key aspect shall be emphasised, even if it is often omitted. The main feature of unorthodox treatments is based on interpretation philosophical disciplines which differ from the orthodox disciplines by definition. Their great achievement was to develop as an independent medical procedure and as a separate and well-specified therapeutic method with their own tenets and esoteric procedure. Persisting to apply same assessment criteria implemented in biomedicine to unorthodox therapies means to develop the equation CAM = biomedicine, which is not possible to occur without distorting the fundamentals of CAM. This has already happened, for example, introducing acupuncture and osteopathy treatments within some National Healthcare Services. This encompasses, therefore, two main effects. The first effect concerns the partial refusal to the important holistic aspect of CAM; the latter is to necessarily accept the fact to play a subordinate role in relation with biomedicine, since evidence-based assessment criterion of biomedicine will always mark the effectiveness difference between orthodox and unorthodox therapeutic models.

The issue concerning statutory regulation for unorthodox therapies within National Healthcare Services shall not be therefore disregarded to integrate different assessment methods from those which RCT sets out. Before arguing on this issue, I firstly state that this proposal will be always contested, mocked and scorned by RCT followers because they need the tenet to exist. This makes its followers ridiculous, since they behave in a way that does not fit a man of learning, in order to defend both superiority and purity of a scientific method. For the man of learning, the path by definition goes uphill, meaning that a certainty never exists. The most common proposal put by CAM followers is to emphasize therapeutic model variety and to examine its effectiveness through not blind pragmatic trials ("pragmatic" refers to trials carried out under normal and abnormal circumstances). In order to understand the proposal, it is necessary to explain some mechanisms which RCT are based on. Basically the investigation instrument is to compare results obtained through therapeutic treatment applied on a certain group of patients and an experimental control group comprising patients who believe they are undergoing the treatment. The trial is classified as "single-blind" only if patients do not know which group they belong to; "double-blind" means that patients and experimenters as well do not know which group is under treatment; "triple-blind" refers to those who have to statistically analyse data even at the end, are kept far away from information, not knowing who received the treatment to be analysed. However, in the present case, a more advanced RCT version shall be considered, which examines three mechanisms. These mechanisms had been designed to avoid distortion sources as far as possible during clinical trials, forming three or more groups of patients who have homogenous features, if possible. The patient allocation to one of the groups shall be randomized and only members of a group receive the therapeutic treatment to be experimented, but neither them nor experimenters are aware of this, as well as members of the second group which apparently receive the same treatment.

Members of the third are the control group. The difference between the second and the third group allows to specify the "placebo effect"<sup>4,5</sup>, that is the reaction of an organism when it believes to be under a therapeutic treatment which can improve his health conditions. In other words, this effect allows to measure treatment effects, without being associated to the drug pharmacological properties, which are moreover determined through the difference noticed between the first and the second group. Finally, a point must be underlined: the results obtained are to be always interpreted and conclusions could be always invalidated through a specific expectation, bias, wrong assessment of systematic errors, incomplete experimental design. For instance, a negative bias felt by orthodox physicians towards CAM and the positive judgement by CAM practitioners often led to contrasting evaluations. However, it is always to be mentioned that RCTs aim at developing a new evidence and this evidence shall be discussed within a sort of knowledge previously gained. When the theory of this knowledge is not possible from a scientific perspective or at least disputable, for example the case of homeopathy and its conventional theory, the chances to accept the new evidence will be very limited. This cannot be applied to other kinds of therapies, such as phytotherapy and gemmotherapy, which can be fundamentally legitimated through RCT methods and, as such, integrated in orthodox medicine.

The reason for demanding not blind trials (here: in opposition to blind) is now clear: CAM follower wants to sum up both (un)distinguishing effects of a treatment as well as psychic and physiological effects, trivialized as placebo effect. In other words, the placebo effect assumes a stimulus coming from a self-recovery system and, as such, it has beneficial effects and it is remarkably important in terms of therapy. Since this kind of trials does not provide for attempting to mask the nature of treatment, (being a not blind trial, indeed), only two groups of patients are necessary because a comparison between those who receive the treatment and those who do not receive is carried out. The question is that the latter ones know this fact, encompassing an opposite placebo effect rather being beneficial, called *nocebo* or, as it has been suggested more recently, *frustrebo* effect. RCT followers are very critical about this issue: the effect would not approve CAM legitimacy, if it had not been for the *nocebo* effect of the control group, shifting the approval towards the therapeutic treatment effectiveness. Moreover, RCT followers emphasize the fact according to which the nature itself of the trial encompasses cognitive biases risk, whose existence may prior invalidate the legitimacy. Undeniably, this criticism does support the importance of psychological factors for the treatment completion and if these factors are acknowledged to exist and comprise a self-recovery stimulus, it is unknown the reason orthodox medicine on principle decided to diminish and is still neglecting them. The importance given to glorify RCT as instrument aimed to assess the only pharmacological effect of a molecule could suggest, even in a not too veiled manner, the willingness to set out a biomedical model disregarding the patient as a human being as well.

A possible CAM legitimacy is to statistically examine therapeutic treatment results, if success or failure are being referred to a satisfactory degree showed by the patient after receiving the treatment. In principle, this allows to compare the effectiveness of different therapeutic treatments: a comparison only among CAMs or between CAM and orthodox medicine. Statistical analysis allows to properly examine this kind of data and gives the opportunity (not) to propose the legitimacy of a therapeutic treatment as conclusion of the assessment related to different and separate hypothesis, statistically called as "null hypothesis", which is accepted or neglected according to its influence on the rationalization of data collection. The arguing point is the result of a(n) (un)beneficial effect or merely to understand what recovery refers to. For biomedicine, recovery is intended as standardisation of a number of biological criteria, while CAM practitioners consider it as the patient comeback to his standard interaction with the surrounding world, as discussed in other papers. Once again, the attempt to specify recovery conditions from an objective and subjective viewpoint is made. This malfunction cannot be solved because it represents the fundamentals of different visions belonging to therapeutic models and, once again, it opens to mutual criticism to be considered as an example for a statutory regulation by National Healthcare Services. Undeniably, its formulation may be explained both in terms of cost/benefit and referring to the community choice, that is what we defined community legitimacy which is turning, in this case, into empirical legitimacy. This has already occurred in Western countries, as shown by the referendum which has been taken place in Switzerland, even though its implementation and application have always encompassed a number of difficulties and compromises. However, it is understandable to everyone that this kind of legitimacy becomes worthier in respect with the legitimacy related to scientific issues because healthcare choices made by the community, which is ready to pay with its own money to take advantages from therapeutic methods that are different from those provided by orthodox medicine, turn to be prior from a social and political perspective. As a matter of fact, this choice, according to which certain therapeutic models are preferred, whether they are regulated or not, becomes an expression of popular radical change towards the institution which controls the society and towards the orthodox medicine, which the institution referred the authority status and the task to manage the community healthcare to. By definition the State cannot accept the fact to not be taken into account (if it were so, why enacting laws?) nor to see how the community makes decisions on how and where to heal, without reacting, considering the impossibility to avoid their choice which is acknowledged as an ethically proper one. The point is that if community avoids what is provided by the orthodox-based healthcare system, it means that the system does not propose a satisfactory range of opportunities; this problem shall be solved because community protection is one of the principles of the society from an institutional perspective. Therefore, it is likely that this widespread feeling of self-determination compels the system to broaden its healthcare service range, but also to hope for and to support legitimacy criteria re-

garding unorthodox therapeutic models which overcome limitations set out by biomedicine.

According to Ireh Iyoha, and as mentioned at the beginning of this paper, there is another assessment method which disregards the scientific criterion, defined as "anthropological" method<sup>6</sup>. This method generally investigates the observer within the phenomenon chosen to be examined. According to the anthropologists, this method allows to specify some factors that cannot be identified through scientific methods, as randomization or blinded techniques, but merely through an observational and intuitive investigation. These methods emphasize the importance of the relationship between patient and his care provider or, more in general, between patient and the person who has been given the task to solve the patient's illness. In the homeopathic field it has been virtually observed how only the prescription given by the homeopath often turns to be successful to remove a disease, while other prescriptions submitted by other physicians are ineffective. Anthropologists highlight this kind of therapeutic evidence as the result of effectiveness due to a relationship between two different subjects, not depending on the implemented biomedical model. Once again, it has to come to the conclusion according to which feelings, impressions, and previous experiences shall be not neglected when assessing the therapy (in)efficacy and it is not possible to believe to standardize a kind of medicine which aims to eliminate any consideration for human factors, as RCT followers wish for. Mocking physician-patient relationship, human communication and relations because being misleading in the research for a more effective therapy, as the aforementioned followers state in many articles, virtually breaks the essence of a medical act. Furthermore, I say that this should not be stated by those who do not want to recognize the failure experienced by one of the tenets of their orthodox medicine, referring to the fact, according to which the same molecule, assumed to create the same beneficial effects in every organism, if not quantitatively, at least from a qualitative perspective, only partially acts and often gives undesired effects. Neglecting or, worse, disguising this fact, by implementing misinformation campaigns, is not absolutely outstanding.

In my opinion, as non-physician, the diatribe is originated from a basic misinterpretation about the nature of medicine. The steady attempt to understand illness conditions and to explain how to solve the problem, by setting general laws, virtually presumes to assimilate the medical act to an experiment within physics or chemistry field. Consequently, it is expected to follow the same methodological monism, leaving aside the fact according to which medicine is a domain of expression, psychology and human behaviour, beyond being the biological nature of an organism. Therefore any medical act could be allocated to an overall operation framework, however it is crucially important to consider it in relation with its individuality and uniqueness. Hence, the treatment shall take into account the whole psychological framework of the patient, his perceptions, his experiences and his intentions in the future, even because through suffering the feeling of awareness arises, as Dostoevskij wrote. The perspective aimed to form a hyper-rational therapeutic methodology is not able

to envisage this issue because these factors would introduce parasitic and interference effects in the whole perspective, but at the same time it is needed to become aware of the fact that by doing so, the effectiveness of the operation itself is being diminished. Orthodox biomedicine shall acknowledge that the Cartesian *res cogitans* – *res extensa*, which biomedicine is developed through, has undisputed methodological achievements, allowing to frame an analytical approach, but it also shows some limitations and this idea has to be reorganised, as it already happened in many fields of human knowledge. Omitting to cite Feyeraabend and his "Against Method", I recall how this idea has been heavily criticised by Heisenberg, when quantum physics had been developed, and, before him, by Max Weber within the sociological field. On the other hand RCT is a slavish expression of the Cartesian method, with termites living in its roots, and allow to assess only one dimension of a multidimensional society. Becoming aware of this multidimensional aspect is a necessary action, if it is said to act according to a principle of responsibility, as orthodox medicine is used to claiming. Orthodox medicine followers should be humble and take the chance to broaden their own visions, taking advantages from what is offered to them by the enormous cultural legacy of unorthodox medicine, instead of talking about the placebo effect with self-reference and disregard when it is dealing with CAM, as consequent attitude resulting from the nomination of the Cartesian method as tenet by those, I mention again, who need a tenet to exist. But this goes also for a further consideration.

It does not seem to me that in medical procedures there is a clear difference between science and technology. It deals with science in those cases where it is sufficiently obvious that any implemented procedure concerns technology. This is a crucial aspect because each therapeutic methodology, from a technological perspective, can be deemed as an operative method, irrespective of whether the model it is inspired to has scientific features or not, since in this case the goal is not to research what nature hides, but both advantages and beneficial effects. As a result, the physician shall attempt to divide the observation of facts from reliability judgements about a specific model. This is because every methodology aiming to specify the effectiveness degree of a treatment represents the necessary relation with the reference model. A methodology which intends and allows to meet any need the medical discipline would like to fulfil is not virtually available. As many researchers emphasised, I believe this could be achieved, by introducing a pluralist methodology approach, with the

purpose to highlight both RCT limitations in the assessment of unorthodox therapeutic systems and the importance of different cultural beliefs, provided that they are set not in an exclusive manner, considered to contribute to the potential treatment success. This means: on the one hand it shall be aware of the limitations of drug-inhibitor paradigm and Cartesian law, being pillars of the orthodox medicine, on the other hand it shall be acknowledged the impossibility to set theoretic principles that are often to be proved and represent the foundations of unorthodox therapies and, however, they are fundamental for the operative method. From my perspective, the key-issue of the proposal assumes a radical change of the idea of biological organism that cannot be generalized as material reality, considering the fact that its development and its way of being are the result of individual cognitive acts. Therefore, the idea cannot be dealt only at one description layer and if it is applied, to normal conditions, it has to be applied also to abnormal situations, as illness conditions are defined. I believe that this idea, according to which it provides to introduce body-mind relation as inseparable entity, is one of the many possible conditions for medicine to develop in the future and the adoption of what we called pluralist methodology approach could allow its achievement. It virtually encourages the knowledge shifting among different therapeutic methods, allowing the organism to radically change. I believe that the radical change is necessary and is the main goal of the institutionalization performed by Integrated Medicine, focusing on a medical act which not only shows concern for mankind, but also tries to belong to.

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# Homeopathy and Integrated Medicine

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Disregarding how it is read or framed, Integrated Medicine refers to a new understanding of the physician-patient relationship. From one perspective, Integrated Medicine is implemented by providing the patient with a number of therapeutic resources which belong to both orthodox medicine, and complementary and alternative medicine. This implementation comes from the cooperation between medical experts qualified in their specific field, or applied by the same physician with proper professional skills in different disciplines (Integrative Medicine). Through a more sophisticated outlook, there is a need to understand the different features between disciplines, with the aim being to create a scenario where different therapeutic techniques are matched to the situation in order to stimulate patient responses and recovery, achieving good health outcomes. It is in this framework that lays the main difference between the conventional therapeutic model supported by orthodox medicine and the therapeutic model proposed by integrated medicine, therefore creating the concept of New Medicine or Person-Based Medicine.

In addition, this new understanding allows us to overcome several issues that could slow down the integration process. These issues are implied in the physician-patient relationship itself (which is planned to be changed) and are the result of how they have been accustomed, or forced, to live this relationship. Facts show that patients choose CAM treatment for several reasons, depending on the situation. Data from Australian Health Care indicate that the health community choose CAM to:

- help apply orthodox medicine;
- avoid dangers connected with the extended use of orthodox medicine;
- lower the occasions to use orthodox medicine;
- avoid the use of orthodox medicine;
- replace the use of orthodox medicine;
- obtain the highest result implementing both medical sciences.

Three practice styles exist between Integrated Medicine practitioners: the first, (the future objective), is an equal relationship between orthodox medicine and CAM practitioners; the second style refers to the assignment of orthodox medicine physicians to give general guidelines; and the third, is based on collaboration but only regarding the secondary pathology aspects.<sup>1</sup>

However, physicians are approaching the integration process with difficulties; in particular they are not ready

to manage a cooperative relationship with other professionals and are experiencing the increased feeling of mistrust of less known therapeutic models. There is also the unaccustomed nature of sharing the patient and the refusal to bring into question their own therapeutic or diagnostic model. While, in the case of several medical experts involved, it is assumed the need for active collaboration between them, However disposable data does not give pleasing results: a report carried out in Canada assessed the behaviours of general medicine and complementary and alternative medicine practitioners who are operating together in Integrated Medicine settings; the report identified that general medicine practitioners tend to control the patient, to confine colleagues roles and use overly scientific language, while the latter show a more cooperative approach, trying to interpret their own "esoteric" knowledge according to scientific fundamentals, to endorse the scientific language and to improve their own professional qualifications.<sup>2</sup> Such scenarios could become the main reason for internal discussions with the physician, diverting his attention further from the patient who should in fact be the primary goal of the integration process.

The concept according to which Integrated Medicine must achieve the objectives it proposes, setting, if necessary, several mainstream and complementary therapeutic techniques with the aim to stimulate the patient's personal resources to recover health conditions, represents a further step forward. This step is to be made, without doing away with the basic concepts of integration process, which are however essential; it shall be understood that only in this way it will be possible to give a sole answer for several expectations expressed by the patient and to allow a higher degree of tranquillity among possible different therapeutic approaches.

How does Homeopathy tackle the problem? After stating the primary aim of the integration of medical sciences is to stimulate responsive capacities in an organism which is oriented by nature to recover health conditions. As a result, a compulsory step must be made in order to know the patient both in relation to his overall behaviour system, physiological and illness conditions, analysing and identifying in details pathological onsets and symptoms development. According to the first aspect, there is nothing so modern in the study of bio-typological features carried out in Homeopathy. The overall assessment of morphological and functional aspects proclaims studies on clinical genetics and in-depth analysis on the individual genome, formulating hypotheses about pathological aptitude implied in the definition of mi-

asma or responsive model. The patient, classified according to his morphological and functional features, will show pathological conditions with the same features or, with features of the same meaning. Therefore, thoroughly identifying the features of the patient in front of him, the physician is able to foresee what kind of pathological appearances the patient will experience and how each clinical picture will develop, but overall he knows the patient's individual responsiveness degree, linked to the features of his reactive model. Under this perspective the features are even more interesting, since the efficiency level of Homeopathy is ascribed, as it often occurs, to a placebo effect; according to the facts, which have been recently made available, they show that the placebo effect is also related to genetic features of the patient and expressed by the patient himself, due to an abnormal expression of an enzyme which is present in the serotonin metabolism. Referring to the second aspect (the illness phase of the patient), the approach method towards the patient, (which is typical of CAMs in general and of Homeopathy in particular), is based on the collection of spontaneous accounts (narrative medicine) which are especially useful: the way the patient describes his illness symptoms expresses his psychological behaviour towards treatment and recovery itself. An example is provided through the analysis of the exogenous and endogenous illness reading model. In the exogenous model ("Flu caught me") the illness is being linked to negative factors outside the organism; in the endogenous model ("I caught flu") the illness is ascribed to a "mistake" made by the organism itself. It is noted that those who are in agreement with the endogenous model respond less to treatments and believe that recovery, as it is for illness, is an event linked to the functional system of the organism rather than to treatment interventions coming from outside. Moreover, it is to be mentioned that a certain percentage of the therapeutic effect in a clinical setting is connected with how a physician behaves towards a patient and this could account for up to 10% of the total effect (Howtorn Effect). Furthermore, a good relationship between physician and patient encompasses a full understanding of the symptom and it is crucial to emphasize that Homeopathy, according to its widespread meaning, basically implements the diagnosis of the symptom rather than the illness. The pathology in progress is pictured from the diagnostic perspective in order to establish the effective therapeutic possibilities allowed by each medicine that should be used, this represents a further crucial phase for Integrated Medicine purposes. However, the homeopathic intervention is not linked, strictly speaking, to this diagnosis phase if not to facilitate the choice of drugs to use, steering the assessment towards those which result to be the most commonly used drugs for the pathology in progress. Thus, it is about a symptom diagnosis, a kind of attitude that leads to analyse in detail the symptom which is taken into account in every aspect of phenomenological and repertory expression. The symptom should therefore not be blocked, common attitude exercised in orthodox medicine, but followed in its progression, as already claimed by Hippocrates and lived

through its most pragmatic appearance by the shamanism. The mainstream approach is focused on the symptom eradication; the illness, either in a critical or chronic phase, needs to have a multiple prescription, a drug for each existing symptom, often obtaining positive results, sometimes unsatisfactory results, occasionally resolving results, especially in the case of chronic pathologies. The homeopathic drugs available are the result of studies on pathogenesis testing, through which substances (animal, vegetal, mineral) are given to voluntary healthy patients; the symptoms developed in these individuals after the aforementioned administration are the pathogenesis of the given substances which is identified when a significant number of tests are completed and one is able to define the most frequently detected symptoms. Substances (from now on called drugs) can heal those symptoms they cause in the healthy person, if submitted in diluted doses in ill individuals who show those symptoms spontaneously (law of similarity). It is possible to claim that the therapeutic effect is linked to the ability to stimulate internal resources of the organism to recover the biological balance (homeostasis). Clinical application which encompasses the choice for a certain drug is based on several doctrinal interpretations, according to the personal approach of the physician who can follow a repertory model, or a model based on the constitutional study, or on the assessment of the responsive model or sensitive type. Theoretically speaking, disregarding the kind of approach, the therapeutic decision should entail the same prescription, but it is the importance of the symptom assessed in its integrity that could lead to prescriptive differences which perceive the different level of interest the physician can have when symptoms appear. This is a difference which does not entail, however, effective disadvantages, thanks to the reassessment of the symptom which has been modified through the first prescription.

Hence, the homeopathic drug has features and symptoms of the illness that the drug itself aims to heal, since it is able to cause those same symptoms in the healthy subject. Therefore, in a model which is perhaps not so far from reality, the subject-patient reacts to the disturbing cause, which induced him the illness, through the resources available in his organism: in an optimal phase of biological expression these will be able to recover the health conditions of the body, or however the situation prior to the disturbing event. While in case of lack of responsiveness, they will not be able to impede that the pathological expression permanently establishes. Actually, homeopathic drug re-proposes to the patient its clinical situation but in a different manner, if we want to define it as an artificial one, not connected with the detrimental action strictly speaking, but with the simulation it is able to perform, executing the practice taken place in occasion of the pathogenesis experimentation again. In this case through driven substance dilutions, offering the subject a second biologic chance to react. Hence, we are dealing with two variations comparing with the pathogenesis experimentation: ill subject and not healthy subject, driven dilutions and not ponderal doses. Can these two variations account for the therapeutic effect?

In order to answer this question we can, in the first instance, refer to the theory of hormetic responses established in the last decades of the past century by Townsed<sup>3</sup> and later resumed and broadly developed by Calabrese<sup>4</sup>. According to the theory, substances have opposite effects depending on the dose level they are implemented in: inhibition effects at high doses, stimuli-based effects at low doses. However this theory, supported by empirical data, shows the limitation to establish a range of effective concentrations in the opposite sense, in which infinitesimal doses are not included. There is virtually a model which explains the opposite effect of substances, but it is linked to the applied chemistry laws. An additional step is to study the theory of complex systems.

The complex system is due to the functional interaction among constituent elements of the system; in our case it is about the organism, but broadly speaking the concept can be applied to any functionally active entity, not even a biological one, called knots. Each knot has different possible activity settings and follows that functional combinations of the structure are numerous, also entailing the unpredictability, non-linearity, non-reversibility of the behaviour of the system facing an external stimulus which can be, referring to a human organism, emotional, toxic, infective etc. Depending on the situation, a disturbing act can obviously have both negative and positive effects on the structure, on the base of the functional moment which defines the structure when it is subordinate to the action itself. Nevertheless, the structural stability can change during the different activation steps and, in some of those, the effect of dynamic stimulus on the recovery function of balance state can be achieved through very low intense stimuli, such as those due to infinitesimal substance doses.

Beyond their effective applicability, such hypotheses indicate that only CAMs, homeopathy in particular, have a certain kind of doctrinal structure which is able to be accountable for the opportunity to achieve therapeutic effects, to a greater or lesser extent depending on the situation, physiological and spontaneous abilities of an organism to react during the illness phases, which has been read as lack of homeostatic balance. Therefore, it is also a matter of reformulating the dynamics between mainstream medicine and CAM within the Integrated Medicine project which has approached so far to assign

CAMs a kind of subordinate role. A definition which appeared a few years ago on the BMJ stated: "Integrated Medicine is practising medicine in a way that selectively incorporates elements of complementary and alternative medicine into comprehensive treatment plans alongside solidly orthodox methods of diagnosis and treatment"<sup>5</sup>, almost to officially assert the model of relationships between conventional practitioner and CAM practitioner which naturally, as already mentioned, tends to develop itself, often setting a leadership status by the conventional physician, due to a distortion of cooperative dynamics among several experts qualified in specific subjects.

An issue is not a comparison of the efficiency degree of mainstream medicine with the efficiency level of CAM, according to which conventional medicine would prevail, with the possibility of exploiting the results obtained from the great number of researches carried out in its field, but to set some operational therapeutic strategies which must be related to the equivalence law, since contributions will be based on the mutuality model. Mainstream medicine is able to tackle more efficiently the worsening phases of the symptoms, especially if they show emergency elements, while in the case of chronic development of the illness, its contribution is able to essentially ensure the illness control: it is difficult to identify the picture where the illness chronically develops, in which conventional medicine is able to achieve results besides the well-organized symptoms control system. In the case of chronic illnesses, the goal of Homeopathy medicine is, instead, to finally attain the resolution of the clinical picture, considering an intermediate result as the opportunity to interrupt the conventional therapy. These conflicting results ideally make the integration of two therapeutic systems possible.

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# Integrated Medicine

## Topics and postulates

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### A manifesto

If something can be "touched" (fest) with your hand (manus), then it is "conspicuous". A "manifesto" publicly states the "conspicuous".

### The manifesto

What appears to be "conspicuous" in medical history is a track of adjectives regarding a relation among different specialities due to:

- particular historical, cultural and scientific phenomena;
- different views of the world;
- different theorizing backgrounds;
- different practices of treatments and methods;
- other concepts regarding truth, nature and person;
- other cultural contexts.

### The adjectives of relation

An 'x' medicine (from now on called Mx) is heretical, alternative, complementary, integrable not because it is such but because it is different from another medicine 'y' (from now on called My) which functions as a term of comparison and evaluates. If the adjectives 'add' a quality to the names, which they relate to, assigning some characteristics then "heretical, alternative, complementary, integrable" are qualities which belong to the relation between Mx and My.

### The adjectives of distinction

Differently, if the adjectives of Mx and My respectively should give importance only to the difference, therefore of two sets different only for the characteristics, then we could say: "The adjectives of Mx are... The adjectives of My are...". Therefore there would be two classes of comparable adjectives which together express attributes of merit, determinations, special characteristics, modalities, philosophies, therapeutic theories, that is, different ways to conceive medicine.

### Preconceptions

Due to two different classes of adjectives it could be legitimately said that:

- a drug is predominately relational, biological, personalistic, ecological and anthroposophical, etc.

- other drug is prevalingly unrelated, biological, substantialist, laboratory findings, etc.

But in no case can it be sustained on behalf of My that Mx is automatically heretical, alternative, complementary and be integrated. If that were the case we would have a preconception, a violation of the principles of truth, a falsification of things, a mystification.

### Problems of definition

There are two logical ways to define something: to refer to a predominant meaning as in the case of medicine, the biological meaning or physiological or yet relational, and environmental; to refer, on the contrary, to a set of meanings of the same importance and comparable among them. The former proposes a "closed definition", the latter instead an "open definition".

### Broadening the definition for adjective integration

When thinking that "integrated medicine" is possible, this means thinking of the possibility to broaden the definitions in some way closed. Integrated medicine can not be an open definition of medicine.

The line of argument is simple and as follows: the closed definition is always oriented towards a prevalent or basic variable, (x), therefore the term "medicine" is used as (x) or (y); if (x) is biology then medicine will be mainly conceived as biology; if (y) is the relation it will be basically conceived as relational, etc. The open definition is instead orientated towards more variables (x,y,z...), in this case the term medicine will be used "as x y z...". It is necessary to define Integrated medicine "as x y z...".

### Arguments of definition

The variables x, y, z which define a probable "integrated medicine" are called "arguments": the general definition of medicine changes in "integrated medicine" when integrating the arguments Mx and My, therefore integrated medicine changes the meaning of the word medicine. What is actually integrated medicine? It is the redefinition of different arguments related to different medicines. What is its degree of realism? Its ability to represent, through the arguments, the reality in all its complexity. The advantage for a patient is to have a medicine able to represent at the most its complexity.

### *The advantages of the "demanding patients"*

For people in need of medical care, the demanding patients, it is important and relevant only what is more beneficial for them. What is more convenient is what is better and more suitable for the patients and their situations, contingencies and their social contexts. An integrated medicine has to be a more convenient medicine. Here the meaning of convenient is related to a lot of adjectives: relational, biological, personalistic, substantialist, laboratory-based, efficiency, appropriate, experimental, etc. All the useful, efficient, fine adjectives which work are part of a sole set of properties. It consists of understanding how to organize this set of propriety. There is more than a way to make medicine convenient. The open problem to face is how to reassemble the separated, divided and opposite adjectives.

### *Beyond the "asymptotic" medicine*

"Asymptotic" refers to medical practices and theories which have been divided and differentiated for numerous historical reasons and not only, nevertheless they are tending, at present, to get closer to "something" without reaching it. The "asymptotic" medicines "do not meet" if they are locked in their theory, schemes, in their orthodox ways of thinking, rationalities and doctrines. Medicines can "meet each other" if, on the contrary, they, pragmatically and reasonably, open up to the concrete conveniences of the demanding patients. For the demanding patient, in this post-modern society, for the thousands and thousands of doctors, there are no such things as asymptotic medicines but medicines that should tend to "meet in-opposite" that is, theories which come up ("in") as if they were "opposite" ("against") waiting for the patient's need to question them exactly like when you would question a toolbox. The patient is that "something" and the medical theories must necessarily tend to accept that there are mutual ancillary. Today the patient re-unites, in-tegrates, re-composes, re-links and re-connects. Exactly like a book with a different pagination, the patient re-binds in his primary interest and for his convenience, historically-un-related medicine.

### *Re-binding in a common type*

In order to re-bind, it is necessary to understand why it is unbound, that is, on what issue and why medical sciences have been divided.

The division is the operation by means of which the concept is spread by simply dividing it in several parts. The division of the sole notion of medicine has unbound such notion in several different notions: Mx, My... M is the "medicine" category, "Mx", "My", etc. the types.

The many factors that today bring this dis-integration into question are: social, ethical, cultural, anthropologic, economic, etc. No integrated medicine shall be really integrated unless a way is found to ascribe the numerous types of unbound medicine to a common type at least.

### *Division and complexity*

Today, the division of medical science in different medicines and in different specializations as well denies the complexity of the patient. When talking about rebinding we must remove the antinomy between division and complexity. At the time that everything is divided and this division becomes a problem, everything must be integrated as if by magic. But what comes up and develops as divided can be difficult to compose.

However the complexity of the patient truly exists, and it is undeniable, but what to do? Although the division of medical science is referable to a common type of medicine and this division is an obstacle to the comprehension of the complexity of the patient. How can we render possible not only the coexistence of medicines of a certain category, as this is already in the state of things, but their cooperation and integrated use and exchange in reality?

### *Set*

Today the general notion of medicine M can be represented as a set of different medical sciences, Mx, My, Mz... Should we reinforce this set theory situation, for example shortening the distance between the theoretical views, or should we aim for a process whose final outcome is the overcoming of the set theory situation and therefore another theoretical view?

### *A collection of medicine or something else?*

The set theory, defines the set, as a "collection conceived as a whole of determined objects and separated as well". This means that a likely integration could simply be conceived as a form of unit achieved as a total of the parts, where M is  $Mx+My+Mz...$  However, in this case the use of the expression "integrated medicine" is inappropriate. Firstly, to obtain results of integration it is not sufficient to reconstruct sets although this could bring to an important result. In order to have something really integrated/integrable it is best to put together not only what is divided but to replace what is divided with a model of re-bound medicine.

### *Binding is not integrating*

A problem which arises when integrating different medicines is the adaption to the models. In a certain way the conceptual apparatus of the various medicines should be made available to be reconsidered and redefined in order to favour their category at the expense of their types. In reality, if Mx and My are bound you do not obtain "integrity". The divisions are not overcome if you stay within the logic set theory as explained by Maths. Binding the different medicines only means to place them in another category. Therefore the integrity would be only apparent as it is only the sum of the parts. However, if integrated medicine is a long and difficult change process there is no problem to start from an overall view (to begin with) but important to know that it is a starting point and not a finish point.

### Juxtapositions

If integrated medicine is conceived as a set of different medicines there should be then some juxtapositions among the different medicines. What is a juxtaposition? Juxtapose means "to place close together" "to put alongside" "to move closer to", to indicate a "simple and continuous relation". If we think that integration is juxtapose then it should be known that it is likely to restate differently a historical division of the medicine and excluding a what so ever type of interdependence of theory and practice. "Juxtaposing for integration" is therefore something ambiguous: it is an adequate distance which allows an adequate closeness. But it is also a rationalisation of the existing divisions and a recognition of their coexistence. Thus, if the juxtaposition between Mx and My is a passage in some way obliged in order to start a process of integration, there should be, at a certain point, a way to overcome the juxtapositions to obtain a higher grade of internal interdependence. But what does juxtaposing for integrating mean? Is it a problem of compatibility or something else?

### Compatibility

It is easy to think that integrated medicine is possible only if there are conditions of compatibility within different conceptual apparatus, different treatment practices. But the compatibility between the numerous practices and theories brings up the problem which philosophers define "as incommensurability of the theories", bringing us towards the idea of the adaptation of theoretical bodies to other ones, therefore towards a sort of conformism and homologation of the conceptual apparatus. This makes up to a big problem since an integrated medicine homologating somehow different treatment traditions would be a loss of prosperity, a loss of possibilities, a loss of different types of rationalities.

### Compossibility

Other is to talk about the "compossibility" between Mx and My. Compossibility is when there are no contradictions between Mx and My. Therefore as to integrated medicine it is not about rendering different scientific ideas but compossible, that is, removing the contradictions which contrast them in practice life preserving their precious particularity.

### What intercedes

Once having created some minimal conditions of compossibility between Mx and My it is important to organize "relations" between them. The logic of this relation is opposite to the logic of division and opposite as well as to the asymptotic situations. The meaning of relation is the "non-division", the "non-juxtaposition". The relation connects and interconnects. The relation is the link which connects Mx and My. The relation is what "intercedes" or "not intercedes" between Mx and My. This is always "related" to a patient. Secondly, "related to..." means that organization, knowledge,

professional relationships, tasks, functions, clinical proceedings, depend on the type of relation with the patient. Therefore what type of relation is to be given to Mx and My, thanks to which we could have integrated medicine?

### Correlated and interdependent correspondence

The most appropriate typology of relation to realize integrated medicine and therefore thought for re-binding Mx and My is likely that of the correlated and interdependent correspondence: the relation between Mx and My organizes what intercedes between them, thus their correlativity is important. But what intercedes between Mx and My? Consequently, which correlativity is possible between them? We can identify three types of interdependent correlations when integrating Mx and My:

- the completion correlation, where a drug, either Mx or My according to the patient's needs, is presented in a partial and imperfect way, consequently something must be added to complete it;
- substitution correlation, where a drug, either Mx or My, corrects its own rational organization to offer a more suitable treatment,
- analogical correlation, where a drug, either Mx or My cooperates with an analogical drug in respect to the user, the typology of the intervention and to the needs and necessities, etc.

### Formulary

Most likely in the arrangement of integrated medicine there are problems of completion, substitution and analogy for Mx and My. It is about the research and consideration of the probable practical situations, in which solutions for complementarity, substitution and analogy are set, it is about what are the patient needs. This fact could allow to shift the discussion from fundamentals to real scenarios. It could result as a "formulary of interdependent correlations" in order to direct and to encourage physicians to perform an integrated practice.

### Relationism-relativism

Some supporters of the so-called "scientific" medicine are afraid that discussing about interdependent correlations would lead to relativism. Usually those supporters call for essential principles of scientific nature, that is the principle of falsifiability, assessing, method etc. Those supporters are scientists who talk about humanization, but they actually consider the relationship with the patient and the relationship with other typologies of treatment as a danger for science integrity. If interdependent correlations stand for relativism and not for relationism, the integration of knowledge, of practices, integrated medicine, would be undermined to science sacredness. This attitude theorizes about a specific rationality called "scientific" rationality,

as absolute value which, as such, shall be over and beyond the parts and everything shall be subjected to this value. But an integrated medicine set through interdependent correlations is not possible if we start thinking in terms of upper and lower rationality, absolute and relative knowledge, method as condition for knowledge and relation, as sufficient condition for knowledge.

### **Reasonableness and common sense**

Rationality, whatever it is, does not automatically mean reasonableness and common sense. And not only scientific rationality is often unreasonable. Unreasonable is also the rationality that denies the scientific rationality. Denying a rationality appears to be already an expression of unreasonableness. In order to be reasonable, the rationality shall be ready to face relationships; it shall use relationships to know; it shall comprise in its reasoning the complexity of the person, contingency, singularity, biological and biographical complexity. A hypothetical integrated medicine should be therefore rational and reasonable, be able to consider the patient's ontology as a possible knowledge of the biological, biographical and situational complexity.

### **Relativism-scientism**

Being reasonable could mean that there is a risk where scientists are afraid of slipping into relativism and being unreasonable instead could lead the scientists to slip into scientism. In the medical field, reasonableness requires the refusal of the so-called "strong relativism" and it casts doubt on the value of science, the objectivity of diseases, the substantiality and materiality of patients. Integrated medicine and strong relativism are not only incompatible, but also impossible. On the contrary, a milder and harmless relativism exists which specifies broad fields of contemporary culture by now and which marks the demanding patient, therefore, the society who really wants to dampen the absolutism of scientific rationality, but not running into aporias of unrealistic relativism. This is hoped in medical field. In the medical field, scientism is nowadays as dangerous as relativism: they are the two proverbial sides of the coin. Today, society strongly criticizes medical scientism. However, this does not mean that the critics to scientism stand for relativism legitimization. Today, the dialogue among rationalities is the challenge.

### **Reconsidering the "medical reason"**

What is today "manifesto" – "tangible", that is evident, is a great need of change, so the need to "touch by hand". It is more and more obvious that the demanding patient asks for a medicine to be:

- scientific,
- scientific in other terms,
- but non only.

For this reason, it is necessary nowadays to reconsider the main driving force of medicine, that is the "medical reason".

- To what kind of idea, value, and principle shall the medical reason refer to in order that its way of thinking, knowing, performing are pertinent to the needs asked. Until now the reference idea for scientific medicine has been the scientific nature towards the physical environment of the disease. It is not sufficient anymore, today.

The idea comprising the organic complexity of disease, sick patient, context and situation where the patient lives in is defined as "topicality". It is to consider the topicality as general reference of the medical reason.

- Within a physical, biological and body conception of the disease, the main reference of the medical reason is the "nature". Until now, the attempt to add other social, psychic or environmental conceptions of the disease to the traditional conception has been made; nowadays it is about to reconsider the starting point of such an idea, focusing on it and making it complex. Without this step any serious "humanization could not be possible.
- Since the disease is carried out through the topicality of the patient, the medical reason shall be reconsidered compared to the complexity of the ill patient, as being and person, as body, history and environment.
- In order to know the ill patient's topicality, the scientific and philosophical knowledge is needed, that is, the knowledge allows to reflect on, to understand, to research for everything concerning the topicality of being and of the person, beyond his biological implications, within relationships, contingencies and situations.
- The place, circumstance, occasion, where it is possible to make out the sick person's topicality, where to make use not only of the various knowledge available and which is possible to obtain ontological knowledge from: this is the "relationship" with the patient. Beyond this relationship, any second thought is possible. In order to know the biological aspect of the disease, relationships are not needed, but they are necessary to know the patient's topicality.
- People entailed in relationships firstly express themselves through language, followed by the dialogue, mutual understanding, knowledge delivery, choices and experiences expression. Language is the first crucial reference for relationship; communication is the second step. Language, as predictability, beyond symptomatology, becomes the other knowledge subject for patient and practitioner.
- Clinical rationality is still the fundamental for medical knowledge. However, it deals about improving the clinical rationality making it the most appropriate rationality towards the patient's topicality. Today the challenge is clinical rationality and relationship.
- The outcome resulting from the agreement among medical rationality, topicality, relationship and situa-

tions, is "reasonable rationality". It is a way of strict knowledge in scientific logical thinking, but it is clear from absolute and dogmatic visions.

- Reasonable rationality shall choose the right action to do towards the patient's topicality. How can a decision be made? How can a choice be made? What is the autonomy and responsibility of the person who decides? Topicality assumption necessarily provides that a decision is being made according to the relationship and that the key-actors of the decision are on the one hand the patient and on the other the physician.
- Reasonable rationality would not be as it is, if it denied the incontrovertible reality of its several limitations towards topicality, including the economic ones, which the medical reasons will be more and more exposed to. Limitation is to be assumed as possible.

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## Ethics of integrated care

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«As history taught us that knowing the truth arises chauvinism and that a human being provided with truth represents a potential terrorist, it is obvious to ask: are relativism and nihilism such a real drastic evil that one wants to make us believe? Or perhaps do not they arise the awareness about the relativity of each single perspective, therefore of any religion as well? And conceivably, do they not diffuse the respect of the other's viewpoint and, therefore, the essential value of tolerance? There is something good also about relativism and nihilism: they inhibit chauvinism»<sup>1</sup>.

The statement by Franco Volpi, who passed away too early, helps us to assess the problematic issue regarding the relationship between the so-called "Official or Academic Medicine or Biomedicine" - meaning that scientific medicine, whose established rules and statements are currently subject of the work carried out by most Western physicians and not only, and at present subject of the university educational curriculum - and the so-called CAM (Complementary and Alternative Medicines). As it can be easily noticed, none of these adjectives fully render the sense of Medicine and the following contribution also aims at overcoming the unavoidable limitations showed by the current definitions in order to propose an Integrated Medicine as the outcome of the synergy resulting from the interrelation of professionals in several discipline fields.

In my opinion laity is the only possible and necessary cultural category to accompany us along this hazardous path. First of all any possible misunderstandings are to be avoided and the term is to be cleared out of underlying anticlerical militancy that unfortunately typifies the term in the current debate of the latest years. It is to be reminded that "lay" really means to shy away from dogmatic perspectives, including secularism itself; it means to doubt on, to argue on ideas and facts prompted by reason, logics. It means to be willing to bring our own beliefs into discussion as well, to step back if it helps to understand and respect the rights of our fellow creatures. Being secular means to identify ourselves in the words by Norberto Bobbio: "*Being secular stands for that person who is very fond of his own warm values, such as love, friendship, poem, faith, political planning, but he protects cold values, such as democracy, law, political strategy rules which allow anyone to develop own warm values*". And through this "cold" attitude, Tuscany Region has been taking for over ten years a strict pathway to communicate and to research, keeping the increasing integration of CAM in mind within the Regional Healthcare Service (Servizio Sanitario Regionale, SSR): it is certainly the

most significant experience within the Italian framework, noticing that the right to take health issues into account as a whole has developed in the society by now. On one hand there are treatment limitations showed by Biomedicine towards pathologies which are absolutely not severe compared to the hope to live, but they have a significant influence on the well-being in general; on the other hand there are risks connected to possible side effects caused by drugs and /or medical devices which lead to take a necessary path together, or it shall be considered a further rift of the physician-patient relationship, too often undermined by biological and technical reductionism, which too often has its toll on Biomedicine.

Against a "secular" approach to the awkward issue regarding the relationship between Biomedicine and CAM, such as the experience held by Tuscany Region, vibrant critiques against everything that is not "scientifically proven or provable" regularly appear on newspapers, but sometimes also in scientific journals, expressed by strains which can lead to a heedless envy by the religious fundamentalisms. These "philosophers" feel like being champions of scientific truth and they tackle with all that could be a threat for their reassuring and paradigmatic certainties. A symbolic example for a sectarian and prejudice-based view has been recently delivered by an article published in *Bioethics*, a journal with a good cultural level: "Against Homeopathy"<sup>2</sup>, the title says it all. As a matter of fact, precautionary censures are not the tools to undertake for the difficult path of knowledge, where it is necessary to step in with modesty, deep respect and lay curiosity. If the author in question had those gifts, he could really think about the term used in the first paragraph - *Paradox* - and he would find out that theoretical underpinnings of homeopathy turn to be unacceptable because they defy his epistemological paradigms. Nevertheless, consideration can be stimulated also through the paradox because we are faced with the weakness of our intellectual tools. The pathway of knowledge is winding, it is not linear and therefore it is not possible to get rid of the water memory theory only because it is not based on any "*known* chemical or physical law", mocking the lacking of "*physiological chaos*" which should take shape every time we are drinking a glass of water. Furthermore, according to an essential intellectual honesty, it is preferred not to consider results carried out by research and studies in favour of the homeopathy efficiency as "*false positives*" only because they could occur in any study: then, why do we accept "*other*" studies irrationally? At the end, a research trial within the homeopathy field cannot be assessed as "un-

justifiable" only because homeopathy is based on "fundamentals which do not suit the current scientific knowledge". Through these preliminary remarks, our knowledge, despite its endlessly low degree, would have developed just a little and, in this context, Einstein's words are always valid: "*Truth is what stands the test of experience*". Moreover, in the aforementioned article, the Author labels as "ethically unacceptable" the fact according to which homeopathy professionals, and more in general those who perform CAM, do not act with neutrality, but they "suggest" their own treatments. Do only homeopathy professionals err on the side of self-reference?

### The experience of Tuscan Region

Leaving aside aprioristic and fideist views, we ought to absolutely underline that Medicine is ONE and that in perspective of different medical practice models an improbable harmonizing process cannot be pursued, given paradigms which are often irreducible from a theoretical viewpoint. Only through a lay and pragmatic, and at the same time, strict and responsible approach by all the factors involved could the latest goal of Medicine be achieved, that is, to promote the patient's Health. If it is true that any human being can and must have an active role to treat his own health and not only be a mere passive subject of surgery or a consumer who is not aware of the drugs or cure, regardless any kind of medicine model involved, it is to be remembered that an organism is supplied with weapons to protect his own health and to recover and this potentiality can be stimulated through proper treatment resources. In order to achieve these objectives, the following four pathways are to be taken:

- freedom for patients to choose their own treatment is a right that shall be asserted and preserved, along with the acknowledgment of the freedom of healthcare for physicians;
- treatment appropriateness and efficacy shall be ensured, above all for those treatments supplied within the public service;
- treatment sustainability shall be pursued and choices for healthy life styles shall be encouraged, in order to promote both individual and population health;
- overall approach is necessary towards the person needing to be cured, therefore the centrality of the person and his experiences shall be enhanced during diagnostic-treatment pathways.

Even at a first reading, it is obvious how four key-points, which cannot be exclusive prerogative of a Medicine compared with another medicine, are dealt concerning essential main points of any good healing method, regardless the specific typology at issue. These are the four fundamentals which represented the basic main points to lead the pathway taken by the Committee during the drafting process of the document approved on 13<sup>th</sup> November, 2009<sup>3</sup>. Since the essential bioethical aspects shall be emphasised in our journey towards Integrated Medicine, a further number of principles are to be mentioned, which comprises four basic categories

representing the principle of each argument about ethical fallouts experienced by the Medicine. It is about the four famous principles of Bioethics: non-maleficence, justice, beneficence and autonomy. The good Medicine is the medicine which attempts to highly satisfy both the first and the second group of four principles.

*"Emphasising the unique feature of medicine, and above all of good medicine, the Committee strongly believes that the several existing models of medical practice are not be compared from a theoretical viewpoint, in order to unlikely harmonize paradigms which are often irreducible, but from a practical perspective, that is, at the bed of the patient suffering from a particular disease, whereas the physician, in order to perform a good act for the patient's sake free from prejudices and according to his proven scientific beliefs, assesses these paradigms to search for the most effective remedies, taking charge even of unorthodox choices which are to be left aside when dealing with situations needing necessary well-established and effective treatments"*<sup>4</sup>.

Under this perspective, transparency and intellectual honesty are crucial and shall involve any actors (community, healthcare providers, information). In this context, "*Therefore, if on the one hand Tuscany Region could experience an increasing application of CAM within several healthcare fields, on the other hand public service is asked to cooperate in order to strictly verify quality, efficacy and appropriateness of the offer and to boost researches at issue and continuous supervising of unwanted effects. According to the Regional Committee for Bioethics, this perspective shall represent the principle for any possible integration among medical approaches... Again: the parameter shall be only one and applied to any kind of medicine, which must be subject to an equality principle concerning both criteria for a proper allocation of public resources invested in the supplied services, especially for CAM (not finding full support by efficacy tests collected through methods widely applied by the medical scientific community), and criteria for prescription drug coverage of each CAM treatment for patients who apply for it*"<sup>5</sup>.

Tuscany Region has found inspiration during its pathway regarding CAM through statements and recommendations uttered by important supranational organizations<sup>6</sup>. In this last indication a feeling of need is comprised which the Committee for Bioethics also believes to be essential: integration process shall constantly be combined with requirements concerning quality, efficacy and safety of any treatment pathway, therefore also of CAM, and through ethical goals for a proper healthcare policy, even in the perspective of an equal distribution of healthcare public resources, as we have already mentioned. Since 2002 the Italian National Association of Medical and Dental Doctors (FNOMCeO) has been taking the same path and in the Guidelines about unconventional medicines and practices<sup>7</sup> it reasserts that: "*The application of the above mentioned unconventional medicines and practices is to be considered as a medical act at all effects; hence it shall be taken into account that:*

- medicines and practices can be respectively performed and managed - as medical act - exclusively by physicians and

- dentists in patients who are susceptible of taking advantages after being properly informed about it and after acquiring an explicit aware consent;*
- *the physician and dentist are the only healthcare actors able to identify patients who are susceptible to beneficially implement these medicines and practices, since surgeons and dentists are the only professionals who are qualified for diagnostic acts, which allow to properly distinguish usefulness and advantage of aware recourse from unconventional treatment;*
  - *according to this approach the physician and dentist are the only professionals able to avoid that unconventional medicines and practices be proposed and prescribed to patients having no chances of advantage, taking them away from scientifically reliable treatments, the only two professionals shall always be kept up to date through ECM;*
- ...
- *it is strongly asked, in order to balance the huge demand for unconventional medicines and practices, for a coherent development of systems to preserve efficiency and safety, the establishment of a National Agency comprising institutional actors, such as the Ministry for Healthcare, Regions, MURST (Italian Ministry for University and Scientific and Technological Research) and FNOMCeO. Among the main tasks to be assigned to this Organization, which could be articulated with similar regional structures, it is to be expected: ... to promote basic and applied researches, according to the rules of good clinical practice, within exclusive and above all integrated fields, encouraging the knowledge of fundamentals and the proper implementation of unconventional medicines and practices in the medical culture, making use of own financing resulting from public and private subjects at national and European level".*

## Information

Medicine can be identified as a perfect metaphor of the current society where the "market" won and the focus on economic fallouts has turned from tool into purpose. Under this fact there are economic reasons: the society enhances much more technology than the ability to listen to or the willingness to give advice. When of a patient suffering from anxiety, the choice immediately goes to prescribing a drug: this is time-saving, moves the drug market... it is about a completely different pathway from the attempt to determine that anxiety feeling, to interpret the importance and, after a proper period of time, to apply healthcare strategies. For instance, it is known that, regarding consumptions of some healthcare performances such as minor surgery, less informed patients are those who are mostly under procedures<sup>8</sup>. Therefore, clinical situation is not the only factor which drives to consume in medicine (it would deal with appropriateness, but also ignoring the existence of alternatives, even the more efficient ones, and good health conditions can be achieved without "consuming" a specific diagnostic or treatment procedure.

In this context, emphasising the high degree of responsibility we have to properly inform our patients, we

should always bear in mind, and discuss about it each time with the patients, that *"Doing more does not equal to doing better... A mere medicine encompasses the ability to act moderately, gradually, essentially and to properly apply available resources without waste... Medicine shall respect values, expectations and desires of people who are different and inviolable. Every human being has the right to be who he wants to be and to express what he thinks... A proper Medicine... overcomes treatment fragmentation and encourages exchange of information and knowledge among professionals"*. These are some of the most significant statements contained in the Manifesto for Slow Medicine<sup>9</sup>, illustrated on June 29<sup>th</sup>, 2011 in Ferrara (Italy), promoting concepts which are not exclusive for a specific "type" of Medicine, but they concern the whole treatment practice for health, whether it be CAM or biomedicine.

About the awkward issue regarding information, it is appropriate to go back to the document drafted by the Regional Committee for Bioethics of Tuscany Region: *"Towards a proper public action in the field of CAM, some prerequisites are further necessary concerning information quality which shall be supplied to the community by institutional bodies: information shall be true and not propagandist (based on real indications and natural limitations) and on the other hand information shall guarantee equal access through promoting the knowledge of pathways. Based on the Alma Ata Declaration (1978), WHO identified in the community and in the civil society empowerment an essential tool to promote health: only a conscious citizen, meaning that he knows why he has been informed, he is able to improve his own knowledge and to take part in decisions about him, is under the best conditions to efficiently choose what is more appropriate for his health. Therefore, it is crucial that people are informed about the principles CAM is based on and about the peculiarities of CAM compared to the so-called Biomedicine. In order to avoid the chance that CAM application turns to increase healthcare consumerism process whose outlines we already know, it is finally important to explain that at least some of the big medical systems carried out earlier and developed along with the Western Biomedicine set their own assumptions on the theory according to which it is possible to encourage to recover good health conditions starting from a self-recovery reaction, otherwise called biological recovery. Beyond the essential difference of paradigms, it is therefore important that the patient develops the feeling of awareness according to which, beyond the fact to be healed through drugs, it is possible to protect his own health changing lifestyles; it is useful that when health is compromised, it is possible in some cases to help the healing process through other recovery tools. Hence, the task of each proper social and healthcare information is to build up in each individual the feeling of awareness according to which each human being can and shall play an active role to promote his own health and in recovery pathways; each individual shall not be only a passive actor subordinated to interventions or an unaware consumer of drugs and treatment, regardless what kind of medicine they come from. Integration practices between Biomedicine and CAM essentially entail a comparison among reference medical paradigms. Under this direction, at least*

two concepts are to be considered as an important resource which strictly belong to CAMs, but they are also applied by the Western Biomedicine and shall be a specific subject of each informative message:

1. the awareness according to which an organism is able to protect his own health and to heal (using words mentioned above) and this potentiality can be stimulated through proper treatment resources;
2. close caring of the person, his experiences with the illness, his choices and his values, the consideration of the significance of his own personal story, even for the purposes of the real efficiency of treatment (concepts recently reused by Narrative Based Medicine)<sup>10</sup>.

The well-chosen definition "Narrative Based Medicine" does not betray: for a long time Medicine has been questioning on the limitations led by the biological reductionism. Diversity cannot be equalized to illness, the anomalous factor to pathological factor, medicine is dynamical, ambiguous, necessarily obliged to use taxonomies, explanations and general protocols to treat the patient, but at the same time it is wary against the risk to absolutize them as it were about immutable meanings. So, Disease cannot conflict with but only integrate with Illness and Sickness, according to a lay perspective, where patient's agenda represents an occasion to enhance the relationship with care providers and it is not a flag to be waved as an alternative to medicine. Warnings uttered over a century ago by the great Italian physician Augusto Murri come to our assistance: "...give me a small bottle of urine, let me do a blood culture and I will tell you the diagnosis: pathetic demands for their ignorance"<sup>11</sup>. Even literature delivers a confirmation through the words by Marguerite Yourcenar, when she puts clear words into Hadrian's mouth, resulting evident that even in those times the physician focused his attention on objective and biological aspects, while "human" dimension was on the background: "It is difficult to remain an emperor in presence of a physician, and difficult even to keep one's essential quality as man. The professional eye saw in me only a mass of humours, a sorry mixture of blood and lymph"<sup>12</sup>.

## Research

According to dogmatic and fundamentalist perspectives, researches within the field of Complementary Medicine cannot be carried out, they are even useless and harmful, while according approaches based on modesty and willingness to knowledge it is necessary that researches investigate CAM through empirically proven efficacy and safety tests, especially if CAM treatments are to be integrated in Public Healthcare Services. Against the close-minded viewpoint of the National Committee for Bioethics, which points out in its document (2004) that "if the patient freedom to choose the kind of treatment is undoubtedly an essential value that is universally acknowledged by bioethics and if the freedom of scientific research shall be preserved at any case, treatment freedom shall not disregard scientifically gained and confirmed knowledge, without which it is not possible to properly preserve the pa-

tient's health, ensuring the spread of information towards a feeling of consent"<sup>13</sup>, there is the opposition by the laity of the Regional Committee for Bioethics of Tuscany Region<sup>14</sup>, "being aware to subject the assessment about CAM efficacy and safety to scientific criteria, it tackles with the difficult problem to specify how CAMs can be subjected to parameters which have been typically set for the peculiarities of Western academic medicine. As a matter of fact, the most frequently asked question, and much is being done to find an answer on the international level, does not concern the chance to empirically test CAMs, but to research standard criteria which, even though they do not fully meet parameters set out by the evidence-based medicine (EBM), are proper to guarantee to scientifically randomize CAMs, in respect of the peculiarities each typology of CAM is made of. In turn, the issue regarding the lacking of EBM parameters to assess specific medical fields does not only or mostly arise due to CAM, but also to assess the efficiency degree of some biomedical fields, such as those regarding palliative treatment.

Within this field, the Regional Committee for Bioethics has found a perfect chemistry among its different elements, starting straight away to condemn any behaviour of preconceived refusal without reason, both not considering CAM as possible option, and those who do not accept to subject CAM to a scientific examination, taking as excuse a presumed measurelessness of medical paradigms and, therefore, impracticality of scientific research in this field. Instead, the Regional Committee for Bioethics believes that this pathway shall be recommended, stimulated within an overall framework of ethical commitment by public resources in the healthcare field and conceptually supported by the establishments.

CAM researches should be focused on several kinds of trials, beyond observational researches where they can be applied:

1. randomised clinical trials to assess CAM efficacy and safety comparing with placebo;
2. randomised clinical trials to assess CAM efficacy and safety comparing to corresponding allopathic drugs (it is obvious that these trials can be carried out concerning those fields where efficacy of conventional treatment has not been clearly proved, where contra-indications for conventional treatment exist or the pathology at issue has little importance from a clinical perspective);
3. randomised clinical trials to assess the additional value, in terms of efficiency, of CAMs which has been integrated to the corresponding official treatment: this is the kind of trials the Committee believes should be mostly pursued, where CAM has been added to the mainstream treatment and compared with the official treatment + placebo. As a matter of fact, through this perspective it is possible to establish the added value of CAM integrated in Biomedicine, as it is pursued by the Tuscany model.

However, CAM testing shall provide to be ready to partially reconsider both criteria and models suggested for evidence-based Medicine practices, which could be partially adjusted to the peculiarities of paradigms suggested by each CAM discipline. It is to be noticed that this does not mean to define different criteria or a softened rigidity to research efficacy and safety evidence for CAMs, since the need to adjust a

model, in respect of rigidity and scientificity of the method suggested for the whole research activity, turned to be useful and necessary not only due to the willingness to make trials on CAM possible through well-established criteria, but to all similar needs coming to the surface of important Western medical fields which hardly befit to priorities of EBM. Such standards, commonly approved by scientific community, despite the fact that they can be always changed and improved, are pertinent to some specialities of CAM, but they result not to be proper for other ones. Efficiency and safety assessment of phytotherapy, for instance, is similar to Biomedicine assessment, so that in this field it is not only possible to collect randomised clinical trials and meta-analysis studies through conventional methods, but also to carry out a phytosurveillance, as it occurs in the Tuscany region. Regarding homeopathy, instead, evidence-based medicines face more difficulties: the model structure which EBM is based on is not proper to collect stimulating effects on vital functions induced by submitting substances at low doses. In addition, there are determined obstacles specified by features of some CAM practices: for instance, in acupuncture it is not possible to carry out double-blind empirical tests and the comparison with placebo entails a large number of problems, even for all authorised uses".

Actually, as it is for researches in biomedical field, the Declaration of Helsinki shall be considered also within CAM practices, especially when "medical research is only justified if there is a reasonable likelihood that this population or community stands to benefit from the results of the research" and "in medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests"<sup>15</sup>. CAM should not experience any difficulty to meet these basic requirements, since CAM is distinctively focused on individual illness experience and on care-based approach rather than healing the disease.

### Clinical risk

Treatment quality depends more and more on the promotion of patient's safety. Speaking of CAM, it appears immediately obvious that there is a risk for the patient to experience a state of underground, where healthcare providers ignore themselves in most cases, they do not know each other and they do not want to get acquainted with each other, they do not relate or they do not want to relate with each other, they work in closed fields, which mutuality cannot pass through. And in this scenario, who will be running the highest risk? The patient, of course. "Official" physician is not often interested to know and he does not want to be involved to listen to the patient's choice, then through a lacking professional relationship there is the risk that the patient partially reports "to the other" physician his own clinical history. Instead of building a dialogue which could bring only beneficial effects on patient's safety and health, the patient himself is divided into two monologues, which results can be likely harmful rather than effective. It is about the existence of a risk that has been highly emphasised by the National Committee for Bioethics<sup>16</sup>:

*"Beyond the duty of the physician to deliver the patient all*

*the necessary information, so that he can make his own decisions, there is, as it is known, the burden of the patient to deliver the physician all possible information to ensure a proper diagnosis and an appropriate treatment. Within the field of CAM, the patient's duty is crucially important regarding any possible interactions between substances prescribed according to CAM paradigms and those prescribed according to scientific medicine protocols: such interactions can prevent physicians from carrying out a proper diagnosis and pointing out the perfect therapy for the patient. It often occurs that the patient tends to underestimate the duty to deliver such information because he ignores possible effects of the drugs (which he sometimes takes without being controlled by the doctor) and because he has a certain type of undue modesty, that sometimes cannot be overcome, to tell his physician his own (sometimes occasional) consent towards a medical model which is not shared by the physician. Based on reliable investigations, it turned out that specially those patients who use legally prescribed anti-depressive drugs, take the initiative, often adding alternative coadjutants, ignoring the fact that natural products for anxiety and depression could have harmful effects if they are taken with other drugs at the same time. The National Committee for Bioethics, being aware of the dimension of this issue, stresses the importance for the community to understand the need to build up physician-patient relationship based on mutual and honest information as essential component to achieve a real "treatment alliance".*

Unfortunately, a heavy narrow-mindedness is experienced about CAM application, that is CAM treatment is allowed in case of little disorders, verbatim "in case of disorders of slight importance or hypochondriac patients or under a palliative treatment", but CAM practices are to be refused when the situation is getting worse. Especially, regarding infant or incapable patients, it is stated that "...the impossibility to gain or to consider as valid the consent to these practices by those patients should lead physicians to always suggest treatments scientifically confirmed". In this context, according to a clever annotation: "If the physician... take trusts on CAM, why can it not be admitted that CAM is also applied to children? Thinking over this point, I ask myself why do they not have also the right to take advantage of the medicine their parents have trusted on and see their parents making use of the medicine? One of the complaints towards CAM is not to have scientifically proven foundation. But, in order to have scientific foundation, researches and any financial supports are needed, from private sector to National public bodies, which CAM has so far had a limited access to. Children consider as valid (good) only what they see their parents do and, even being capable to have their own informed consent, they act like their parents and accept with higher degree of trust CAM practices that they have seen their parents use and not those which are prescribed by a different physician, even if they are "scientifically" valid<sup>7</sup>.

Therefore, if the patient's freedom to choose the kind of treatment must be protected, there is a risk of him choosing also the most appropriate solution to his problem, therefore delivering the patient the power to decide. A patient is not an autonomous subject full of aprioristic rights: he shall be trained in his relationship with suffer-

ing and disease. It is known that clinical pathways are often specified through the kind of institution he goes to, and not, instead, through his real clinical needs. Therefore, the chance that an event occurs has been already decided by the patient's first choice. And how can we be sure that the choice taken by the patient is the proper one and not fixed by trends, habits or current facts? In addition, disregarding the initial choice, how can we ensure that the next pathway to be taken is the most appropriate and the most effective path for the patient's clinical needs, if physicians he addresses to do not know each other, identify with each other, rather they are opposed to each other? Many people talk about community empowerment, but this concept should be extended to all of us who are working in the Healthcare field!

Unfortunately, Karl Popper's words are not always remembered: "*Physician must however persuade himself submissively that yet, he keeps on performing his work under probabilistic conditions, because all scientific knowledge is hypothetical or conjectural. What may be called the method of science consists in learning from our mistakes systematically: first, by daring to make mistakes, and secondly, by searching systematically for the mistakes we have made*"<sup>18</sup>. In this context, a unique opportunity to improve the quality degree of our treatment is given by informed consent. Beyond the fact that it has been diminished to a bureaucratic event, when it is reduced to a formal practice along with invasive procedures, its true and deep meaning is to share between physicians and patients what is known and what is ignored about the topic at issue. In many cases, the healing path shows different options which shall be discussed together with the patient in order to take the best choice in that specific situation. Otherwise, we are stuck in paternalism, where the patient has a passive role about choices imposed by the professional authority of the physician.

There are several patients since there are several social, anthropological, cultural fields they live in. According to Rousseau, diseases do not exist, only sick people exist, and each sick person is unique in his vision about health and disease, therefore about healing. Thus, some people will approach, for instance, to homeopathy because they need a healing and health model which cannot be found in Biomedicine and he/she feels it more appropriate for him/herself. If it's up to the patient to decide among the different options, not only within a Medicine model but also among several models, we must create the situation that enables him/her to choose through clear and comprehensive information. It is known, for instance, that in Tuscany CAM is increasingly applied to patients thanks to the improvement of educational level, resulting to be significantly higher among graduated people than others, and the role of the general practitioner, whose importance is also increasing, represents only a third of the information cases regarding CAM, after personal sources such as relatives/friends and several mass media. And how could we properly inform the community, if we, as professionals, are ignoring in most cases the meaning of CAMs? Starting from university courses, education is still an impermeable environment, unfortunately,

and the risk for the safety of the patient consequently increases. It goes back over the laity that always represents as source of inspiration for us: the more qualified we are, the more we will be able to take a step backward standing before a certain clinical case, acknowledging the fact that "another" typology of Medicine could result more appropriate and more effective in this case. If Biomedicine is too often suffering from standardization, CAM is suffering from an extreme individualisation, lacking of an inter- and intra-disciplinary comparison. If we absolutely have to adapt to multiculturalism, due to political and social developments, this is also applied to several medical cultures. *Therapeuo* means in Greek "to serve somebody", the therapist works to serve another person. Hence, it is necessary to know and to acknowledge more and more the "other" person, whether he/she is a patient who wants to make choices that we do not share or he/she is "another" professional practitioner. In this context, Hospital Medicine has a privileged status because physicians work more and more in team, with several professionals, and together contribute to heal the patient. Now we have to overcome barriers which are still too high and exist in many facilities where Medicine is performed outside the hospitals!

### Conclusion

We, healthcare professionals and community, must have the courage to walk together and be aware that expectations of a ill person not always correspond to his rights (nor those of the professionals'...) and that pernicious market logics at times expand the needs circle to the desires circle, until the whims circle. "*Medicine, like science, is a way of power*"<sup>19</sup>: it is very difficult, but we shall not lower our guard. Therefore, we have to discover traps set towards National Healthcare Services and, in general, to Welfare systems, we have to report the almost complete lacking of public bodies to promote research, regardless market influences, we have to fight back the widespread researches focused on market profits in clinical tests and physician training courses, we have to be against a kind of communication that is more or less consciously manipulated, being understood as mass media communication and as communication between physician and patient, we have to withstand the influences by the big industries, not only the pharmacological or electro-medical ones, but also the chemical and agricultural and food industry; we have to fight against the harmfulness of working places; we have to adjust social disparities towards morbidity and mortality; we have to protect environment and ecosystem, therefore, our health, against the increasing injuries... Biomedicine and CAM ought to be allied in this ethical explosion of civilization, rather than being "alternative"! Being Medicine engrossed in the Market, there is the risk to speak only the language of (false) rights, while we have to find the courage to talk also about duties concerning health. Especially, the first duty is to acknowledge the rights of the "others", therefore, to acknowledge the "border" where we have to and we can act, depending on the lay spirit of tolerance, of enhancement of different identities, not "against", but "towards" the other.

If we are able to combine rights and duties which concern all of us, no one excluded, according to the rules of mutual respect, we will make a breakthrough in our pathway towards higher levels of ethical behaviour. ■

*Not everything that can be counted counts,  
and not everything that counts can be counted.*

*Albert Einstein*

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# Hormesis and Integrated Medicine

## Synonymy of a paradigm

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The term *hormesis* means stimulation and I personally find such a definition rather belittling if we take into account the overview which its understanding allows to encompass<sup>1</sup>. This term briefly indicates that the reaction of a living organism to an exposure coming from the external environment qualitatively differs, according to the degree of this exposure. Within the goal of this contribution, this means, for instance, that the effect resulting from an ingestion of a toxic substance depends on its quantity: in small doses a modest stimulation of the organism functions is observed at low doses, while high doses, in turn, lead to an inhibitory effect. This behavior pattern is related to the kind of nature of the living organism and the number of examples depicted suggests that this behavior represents a general biological law. Personally I have always supported the obviousness of the latter thesis and I have always observed hormesis with a certain degree of indifference, considering it as natural, as if it were almost a lemma belonging to the phylogeny and the ontogeny of any living organism. However, it still does not find complete recognition by the scientists community, even though, as we are going to show, the process is easily understandable from a thermodynamic perspective and, openly, the debating on it only seems to be due to preconceptions. Indeed, the great achievement of hormesis is to emphasize the inadequacy of pharmacological and toxicological models postulated by the orthodox medicine.

The lack of respect towards the Academy is always a serious negligence especially when orthodox medicine assesses its successful results following its specific established criteria, but it turns into a capital crime if health is considered as goods in a development economy. Therefore, hormesis history in the 20<sup>th</sup> century represents an extraordinary example for a cultural imposition by the Academy community, which had attempted to neglect and to leave behind the phenomenology, being in opposition with its own advantages and partisan interests. However, if this commodification has led to a critical period for Western medicine, as it has been highlighted in other contributions of this paper, I personally believe that the revaluation of hormesis and of all the teaching suggested by this phenomenology towards our consideration allows to embrace new perspectives in the conventional pharmacology field and to conceive a more natural therapeutic model differing from the one provided by biomedicine in the 20<sup>th</sup> century. In this context, hormesis becomes a crucial pillar of Integrated Medicine, through which we can obtain a rational and often rea-

sonable basis of some features of therapeutic techniques not belonging to the biomedicine sphere. However, in this case as well, the *intelligo ut credam* principle for qualified professional practitioners of these techniques is often to be subordinated to the *credo ut intelligam* fideist principle and it is not surprising that the hormesis concept has been often opposed by those who should have found the keystone of their therapeutic tenets.<sup>2-8</sup> The mere description of the dose-response pharmacological relationship and its foundation, however, gives cause for reflection in order to guide the future medical developments.

### Dose-response relationship

As a rule, the task of pharmacology is to qualitatively and quantitatively understand the influence of a drug molecules on the physiology of the organism. In practice, pharmacological treatments aim at inducing a measurable stimulus or an inhibition of biological mechanisms as a result of the interaction with a drug. The goal of the studies is, therefore, to establish the exposure process of the molecule and to develop, in concert with chemists, other molecules which are able to induce more convenient exposures. In biomedical field this perspective derives from the expectation according to which the indisposition factor is caused by the presence of a key-mechanism that does not work properly as it should. Hence, the inhibition or, at least, the restriction of this mechanism gives the opportunity to remove this indisposition state. For this reason the crucial concept of the academic pharmacology is linked to the research of the drug-receptor connection in order to specify the treatment effectiveness, determining the best drug concentration both in plasma and tissues. The purpose of this kind of studies is therefore to specify the dose-response relationship.

This perspective results from the assumption according to which the response of different individuals to the pharmacological treatment should be almost similar, if not the same, since it refers to the same biological mechanism. Therefore, the existence of an approximate relationship between the number of exposing molecules (dose) and the induced inhibition level (response) is postulated. Since a linear relationship between both quantities at application level is sought, as this relationship helps to obtain a more direct assessment on the therapeutic treatment effectiveness, an attempt is made to use molecules which bond with a certain receptor in a specific way, so that this specific interaction leading to build

a drug-receptor interaction becomes a predominant mechanism. When it happens, the dose-response relationship is described through acid-base balance

$$A + B = A-B$$

where the invariable is defined in pharmacology as  $K = \frac{[A][B]}{[A-B]}$  (according to mutual thermodynamic value).

In this expression [A] is the free drug concentration, [B] is the concentration of unbound receptors and [A-B] is the concentration of drug-receptor interaction. It follows that the pharmacological activity is linked to the fraction of bound receptors  $\frac{[A-B]}{C_B}$ , where  $C_B = [B] + [A-B]$ . A more precise description should entail both an eventual presence of cooperative effects and kinetic observations and, above all, it should be taken into account the biological effects induced by the interaction of the molecule with the receptor, distinguishing among agonists and antagonists. However, for our purposes, this mere thermodynamic model gives the opportunity to specify biomedicine philosophy through a curve showing the development of response according to the algorithm of drug concentration. The expected curve is sigmoidal, starting with the assumption according to which the inhibitory effect is nearly none at low doses and it becomes significant above a certain value (called threshold-value), it increases as drug concentration raises to a saturation limit value which equals the total receptors occupancy. Once defined ED50 as dose value that produces 50% receptors occupancy, it can be shown that in the interval  $\log[A] = \log ED50 \pm 1$  the relationship is linear, if there are no cooperative effects. This concentration interval and the one considered as useable from a therapeutic perspective. In other words biomedicine takes into account the physiological exposure induced by a drug in an interval of three or four logarithmical units, assuming that concentrations under threshold-dose are irrelevant, and harmful or even lethal when the concentrations are too high.

### Shortcoming of the conventional model

The great achievement of the conventional model lays in its simplicity and this is the reason for its success in biomedicine from the 20<sup>th</sup> century. It is necessary to emphasize that this model has strongly restricted pharmacology development, meaning that, given a drug-receptor system, an interval of concentrations is predetermined to be researched on and, therefore, the drug dose to be consumed. In addition, it is to be taken into account that the conventional model led the biomedicine to suggest drug doses which contained an amount of molecules incredibly higher than the number of receptors with which the drug was designated to interact. For instance: an aspirin contains an amount of molecules that is a hundred million times higher than the cell of a human organism and if you would like to give an amount of drug molecules that is equal to the amount of cells, it should be limited to approximately a billionth gram. However, the great shortcoming of the model is another. Indeed, even starting from the assumption according to which the reaction for any individual is the

same at the biological level, the responses observed virtually differ from individual to individual and what is worse is that responses have damaging effects, beyond providing beneficial influence. In practice, the effectiveness of a drug rarely goes over 60% and the beneficial effects are often followed by undesired effects. In other cases, there is no reaction or there are only undesired effects. It is estimated that about 5-10% of hospitalizations is due to these latter effects.

It is reasonable to think that the partial failure of the model is due to the inadequacy of the initial assumption. The interaction between drug molecule and receptor is only the first of many instances occurring in the cells. The biological activities of the cells do not follow a linear development and, therefore, even the responses resulting from the interaction of the drug with the receptor can be non-linear. In practice, the adduct structuring is followed by a string of catalytic and self-adjusting processes which occur according to a plurality of steady flow pathways determined by the mechanism that causes homeostasis. Since this is the central point of the genetic code, it is sufficiently evident that individual responses can differ from one another. In conclusion, there are several evidence according to which many responses of the cell cannot be changed in a certain interval, but they often have to be described as on-off responses, as if the cell could be present in two states only (*quantal description*). This is not only the case of replication or apoptosis, but also the activation process of groups of genes or the promotion of positive feed-backs mechanisms. Hence, the failure of the model lays in assuming linearity in the dose-response relationship. The result is that many drugs cause undesired effects due to immunosuppression or immunostimulation leading to severe damages for the patient's health, even though orthodox medicine often denies this fact.

### Nonlinear dose-response relationship

In standard pharmacological studies researchers do not examine the concentration interval near the threshold-value because it does not belong to the values complex considered as useable at therapeutic level. Instead, it is to be taken into account that in this zone the drug causes an opposite reaction compared with that reaction that can be observed at high concentrations. In other words, the organism response is not conventional but according to the concentration two kinds of effects can be observable: stimuli-based effect at low concentrations, inhibitory effects at high doses. This behaviour can be summarized, stating that the curve has a J-shape rather than being sigmoidal. On the whole, the stimulatory effect is modest and often difficult to be measured accurately because of the signal-to-noise relationship. In addition, the effect is based on time factor and at the beginning it has an inhibitory effect, followed by a stimulatory effect. In any case, from the perspective view of the conventional pharmacology it represents a problem because it requests to introduce a further mechanism to the operative one at high concentrations. For such reason, this fact is being overlooked or called "paradoxical

effect", as it were not a relevant factor, however. It is to be pointed out that it represented the basic principle of the Arndt-Schulz law a hundred years ago and it was labelled under the name of "hormesis" sixty years ago, even though many books on pharmacology did not deal with it anymore.

A methodical study carried out by Ed Calabrese in the last fifteen years has showed that the "paradoxical effect" is a rule rather than an exception.<sup>9</sup> Once its crucial importance had been verified at toxicological level, even pharmacology could not allow itself to neglect this phenomenon anymore. Nowadays, available empirical techniques gives us the possibility to start a journey into the reign of micro-doses.

### The experimental evidence

Over the last years several papers have been published reporting a series of experimental results supporting unambiguously the hormetic reactivity model. The articles are mainly related to environmental toxicology, growth problems, anti-age therapies, immune responses, ionizing radiation effects and the correlation between the hormetic model and homeopathy. The common denominator of these studies is the complexity of the identification and interpretation of the biological mechanisms underlying the phenomenology observed. It is important to note that many of the data examined is limited by the sensitivity of the surveying techniques used which have severely restricted the dimension of the studies. Personally, all modesty aside, I consider that one of the most significant studies was the recent one published by a research group of the University of Florence where I was involved as coordinator; the research carried out enabled to study at a molecular level the effect of a chemical agent in an interval of concentration never studied before.<sup>10</sup>

The study concerns the effect of diluted solutions of cupric ion on the DNA gene expression. The study carried out using the technology of microarrays allowed the comparison of the gene expressions dealt with copper solutions in variable concentration between  $10^{-6}$  e  $10^{-17}$  M (i.e. between 0.06 mg/litre and 60 billionth of billionth of a gram per litre) with those of the genes treated with water lacking of copper. It has been noticed that numerous groups of overexpressed genes become underexpressed when the concentration varies and viceversa. Therefore the production of other metallothionein is stimulated at high concentrations ( $10^{-6}$ - $10^{-9}$  M) while it is inhibited when low, whereas the production of other metallothionein is stimulated only at low concentrations ( $10^{-13}$ - $10^{-16}$  M). This variation of expression obeys the hormetic model.

The study suggests that at least four groups of genes show a significant variation of activity depending on the number of copper ions present and how such activity is modulated by a number of incredibly low exposure of agents, as it is suggested by the fact that the number of over- or underexpressed genes at low concentrations is always considerable (3-4 %).

### The origin of hormesis

Every living organism is describable thermodynamically as an open system in a non-equilibrium stationary state. Since the state of equilibrium is the most stabile state, each system in non-equilibrium spontaneously tends to reach this state, but taken into account that it coincides with the death, the vital process consists into trying to oppose the achievement of the winning goal. The genes, true and almost immortal masters of the body, employ themselves cooperatively to promote the opposition in three ways: a) trying to hold the non-equilibrium stationary state, b) adopting themselves to the environmental changes and c) reproducing. The stationary state is held by the continuous exchange of material and energy in the interaction with the environment which surrounds it.<sup>11</sup> These interactions always imply structural variations of the system and in this sense it is said that they are a constant source of damages that alter the original communication system. To preserve the stationary state the organism therefore reacts to or repairs the damages or activating alternative pathways able to substitute the damaged mechanism. In any case when, due to interaction with the external, the system is moved from its stationary state, *it tends to react in the sense that it opposes the variations induced by the interaction with the environmental agent to restore the original stationary state.*

The principle key is that the system reacts in such a way to keep its identity unchanged, or rather its structural organization.<sup>12</sup> The expression of this self-reference is given by homeostasis, which is simply a self-protection system from the interaction with the environment. However, to better understand the living organism it is necessary to remember that it is always a result of an evolution which is defined by the interactions with the surrounding environment. This leads to the origin of the so-called biological plasticity or rather the mutation of a phenotype due to the environmental agents, implying a constant increase of the possibilities to elaborate the information of the environment. In other words the mechanism of the system is not fixed as in our computers, but, following the concept of Alan Turing, it is able to modify according to the problems it faces. The consequences can be limited to an only organism during its existence or be brought to a genetic variation, with transmission of reproduction. Moreover, it must be highlighted that the structural variations induced by the environment can be different from organism to organism since they depend also on the variations underwent previously. In this context life is a constant learning process and each interaction is therefore elaborated differently from the single living organisms, inducing often autonomous responses.<sup>12</sup> This concept is extremely important at therapeutic levels.

This view finds its rational support at different levels: at the thermodynamic level with the principle of negative entropy introduced by Schrödinger who sensed the existence of a genetic system devised with his beautiful oxymoron of "aperiodic crystal", at the information theory level in Brillouin's formulation, at the biological level with the concept of organization as a result of "case and

necessity" introduced by Monod. The synthesis of this teleonomic view is found in the concept of organism expressed as "self-organizing dissipative system far from the equilibrium" by Ilya Prigogine<sup>11</sup> and "autopoietic system" by Maturana and Varela.<sup>12</sup> In practice all these analysis bring to the same conclusion: life is given by the existence of an organized collaborative system which loses spontaneously its ordered character with time or under the effect of an external exposure, unless the organism is not able to use the energy and material available to restore such character. In that case, besides protecting itself it is able to develop new procedures to contrast the exposure which jeopardizes the functioning or the existence (evolution). The units restoring such system (i.e. cells) must satisfy two requests. The first one is that they must hold inherently the same mechanism as the others (i.e. DNA) which supplies all the information that they need and the second is that they must be able to convey their activity which is carried out following the chemical and physical information of the surrounding cells (cooperativeness).

As we have already said, every interaction with the environment always implies structural variations. This occurs when breathing oxygen, taking in food, interacting with antigens or simply as an interpretation of a cognitive function. Nevertheless the response is strongly correlated to the intensity of the exposure. Weak exposures such as breathing or temperature changes from cold to hot produce small damages and the original order is then restored using appropriate defence mechanism. From a thermodynamic point of view the disorder caused by the exposure is cancelled giving origin to an exothermic process towards the environment with the elimination of discarded products. If these damages are not restored quickly, it is possible to verify irreversible processes and all the cell system changes slowly and in general it is followed by a loss of the biochemical reactivity of the cells. These irreversible processes are the cause of ageing.

The system devised of defensive mechanisms is more efficient when there is a slight increase of the exposure, for instance when the cell system interacts with a small quantity of xenobiotic particles (i.e. extraneous particle). We have already mentioned that from a thermodynamic perspective view the reaction of the system is to oppose against the variation induced by the environmental exposure, but this goes beyond that. Since its mechanism is planned to maintain itself according to the environmental conditions, the system does not limit to cancel the exposure, but it prepares itself to a further interaction strengthening the defensive mechanisms, which imply the repair of the damages which they underwent. The efficiency increase is almost always given stimulating the entire group of cells to favour the production of ATP. ATP is a source of free energy and if the excess of ATP is not used for a new exposure, the cell system uses it to carry out other types of repair with a consequential beneficial effect on the entire system. The stimulatory process is the origin of hormesis, which on the basis of the considerations exposed beforehand it can be described as *adaptive response induced implicating an over-expression of the genes designed to the reparation of the*

*damages and elimination of the discarded products.* The result is that in these conditions life is longer as showed recently with the clear mechanism of the mitochondrial hormesis (cytochrome-oxidase stimulation).

This beneficial effect is overcome if the exposure is too high. In this context of contribution in order to simplify I will merely consider that this happens when the quantity of xenobiotic particles is so to inhibit or limit a biological process. In that case the level of damage to the genetic system increases and the risk of irreversible changes of the entire cell system becomes vast. The system tries to react activating alternative mechanisms to those limited or inhibited from xenobiotic and, if the repair of the damages occurs quickly it is possible to go back to the original stationary state with the release of entropy production. But if this does not occur the excess of entropy produced is not exported and stays within the cell system. Since an increase of entropy means a more or less ordered system, in this case there is an alteration of the entire system with less ability of reactivity and production of entropy. This means that its defence is reduced exactly as the ability to repair damages has, the system adapts to a new stationary state, but it is necessary to highlight that the genes system has less efficiency and its ability to response has been irreversibly reduced. In this case the probability of apoptosis increases and it is normal a premature senescence (in the English literature SIPS, Stress Induced Premature Senescence). All these considerations explain the large probability of collateral effects when adopting therapies, which exploit the inhibition effects, and therefore they must use a relatively high number of pharmaceutical particles.

In conclusion when the xenobiotic quantity is too high, the damages induced can not be restored anymore, the system is not able to reach a new stationary state and it sets towards the state of chemical equilibrium of the system which implicates the death of the organism. There is therefore the cell death for necrosis.

### Discussion and conclusions

Observations above described result to be the direct consequence to the scientific development in the fields of thermodynamic, biology and information science which occurred in the second half of the twentieth century. Their great achievement is to completely specify the living organism and its development and to merge into one general concept a variety of phenomena, such as ageing, hormesis, biological plasticity, material and cognitive stress effects, SIPS and so on. Life extension as a result of caloric restriction and the negative effects deriving from the disuse syndrome both at cardiovascular and nervous system level become lemmas of a theorem which had been perceived by human knowledge ages ago, but it has never been expressed clearly. The basic problem is still the quantification of the statement because it is not yet possible to foresee why and how a cell alteration caused by interactions of an organism with the environment or merely by spontaneous decay of molecules due to ageing could originate the end of life process. Likely the answer is that at the present day we have not under-

stood nor the reason for the cell presence neither the reason for that special structure we are observing in different living organisms. I record here that Kant has already emphasized this second issue, but it does not seem to me that it has been taken into account as it should have.

It is clear that these observations should represent the crucial pillar we have to refer to in therapeutic medicine. Unconsciously many therapeutic models rediscover themselves in such a general framework, even if they are observed from a completely different perspective. I leave the work to specify distinctions and to emphasize disapprovals, dissensions and disagreements in regard to their professional truisms to the experts of these models. I merely emphasize the fact that from this framework the biomedicine pharmacology paradigm results to be limited per se, on the base of giving sub-lethal doses of molecules in such specific quantities often to cause irreversible alterations in the self-defence system of the organism. With this I do not sympathize with the thinking according to which biomedicine led to increase suffering or to treat diseases that would not have broken out without a previous operation. I merely criticize the paradigm inadequacy and the arrogance by the Academy which reasonably explains the aggressiveness, claiming to be the author of a better way of life. What we have stated until now suggests to propose a less aggressive therapeutic model entailing to review the principles of the art of healing. I merely observe how the therapeutic acceptance of the hormesis concept shall involve the complete review of the pharmacological science. According to this concept, the progressive molecules deletion of a drug, given at concentrations that are considered as beneficial ones, provides to cause opposite effects at low concentrations. At the end of World War II it realized that as doses for penicillin decreased, pneumonias worsened because low doses of penicillin stimulated the development of pathogen bacteria. More recently, numerous cases have shown the production of cancerous cells which have been induced when anti-tumour drugs were given.<sup>13</sup> On the base of these and other observations the continuation of the study on hormesis can allow the research of a new category of drugs which have more appropriate pharmacokinetic features and, above all, allow to formulate microdose pharmacology, which could rep-

resent a conceptual revolution of extraordinary importance for future medical developments. In conclusion, the new perspective on the nature of the organism entails a new vision of medical profession. By using the J-shaped hormesis curve of the dose-response relationship, it is sufficient to highlight how the physician can assess if the diagnostic moment and clinical observation suggest the prescription of an inhibition or stimulus-based treatment as more appropriate.

In this context, even leaving aside any prius posterior argument, suggested by a principle of logical causality, I believe that the Integrated Medicine model we are proposing on these pages is to be defined.

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# "Integrative", "Integrated" or New Medicine?

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The conventional healthcare model provided by several National Healthcare Services is experiencing a new shaping process. The sociological and economic reasons encouraging this process of renewal have been outlined in the foregoing contributions and, even though this shift shows features which strictly depend on the specific situations occurring in different States the models that are being conceived provide for a regular implementation of new therapeutic techniques in addition to those techniques already existing.

These new models are, therefore, defined as expression of integrated healthcare models (IHC models), a term introduced in the United States and in England where this process had started out before spreading throughout the Western countries. Within the IHC model the healthcare service differs from the conventional model implemented in the West where biomedicine specifies and encodes, from its predominant status, methodology and practice to be followed in the treatment pathway. Critics consider the conventional model to be extremely reductionist and mechanistic because of its need to be too rational and scientific, prioritising toward a general and approved treatment model, which, due to its kind of nature, tends to smooth the diversity of patients who need to be treated when diagnosed of the same disease. This operating philosophy is valid when the "operation time" feature is significantly crucial for the patient to survive, but it cannot be extended within a paradigm that specifies a biomedical model. The previous contributions emphasised the importance of the mind-body connection both in health and disease conditions: unfortunately one of the limitations of the biomedicine is to neglect this connection, providing to divide these constituents. On the other hand, CAM practices are based on the holistic principle of non-divisibility of the mind-body system both in well-being and suffering conditions and, even adopting treatment techniques which require more evidence in terms of scientific standards and effectiveness, they find approval among the increasing number of patients, especially if they suffer from chronic illness, and for which biomedicine is not often able to propose proper treatment methods. As mentioned in the previous contributions, these observations are considered to be the cause of the proposal for a new therapeutic model comprising both philosophies, which is what we define Integrated Medicine (IHC).

By nature the IHC model cannot be unambiguous, often drawing back on the attempt to merge or to simply bring biomedicine and conventional therapeutic methodologies of a community together. Hence, pro-

posals and implementations vary depending on the situation in which they occur. For instance: in the United States, where direct payment for services is implemented, this model takes place for profit reasons, while in China or in India the model aims to bring conventional medicine and biomedicine together, since both treatments are financially supported by the State. The number of medical sciences and disciplines complementary to biomedicine that can be integrated into treatment pathways is high, just as wide as the range of application is: from preventive medicine to promotion of health practices, managing chronic and critical illness and palliative treatments.<sup>1</sup>

Integration of treatments belonging to unorthodox disciplines related (and not) to the medical field had spread at the end of the 80s: at that time first contributions regarding this phenomenon had been published in the scientific literature. From then on as the number of healthcare facilities providing therapies, defined integrative, increased, many authors wrote observational papers on this issue. Nevertheless, there is still today the attempt to define this phenomenon, in anticipation to finally clarify the requirements necessary to organize an integrated or integrative medicine setting. After all, experiences of integrating CAM into national healthcare services have been set especially since the end of the 90s until today.<sup>2</sup> From a cultural perspective it is well-grounded to believe that time is still not enough ripe to come to internationally shared observations and thus applicable according to an operating standard. In addition to this, there are complicated regulatory implications which imply the different attitude of healthcare governments concerning investment and facilities provided and they are the result of the cultural substratum of each community. Even not lingering over this topic, since it goes beyond the objective of this contribution, it is necessary to emphasise the fact that among unorthodox disciplines, aiming to be a component of the contemporary medicine, there are differences regarding evidence for effectiveness, especially if they are to be considered according to the principles established by the evidence-based medicine. Therefore, it is no accident that homeopathic medicine is mostly developed in South America (Argentina and Brazil) or in the East, in Pakistan, India, while it is scarcely developed in North America where few hospitals provide homeopathic services (e.g. the New York Presbyterian Hospital and the Philadelphia Jefferson University Hospital). Similarly the traditional Chinese medicine and the acupuncture have mostly developed in China and the Ayurvedic medicine in

India. Homeopathy is more widespread in Europe, especially in England, Austria, France, Germany and Italy, particularly in the region of Tuscany. Moreover, on closer examination, many initiatives for treatment integration into healthcare services are spreading, but rather being related to the great medical systems (Homeopathy, TCM, Ayurveda), they are related to the well-being disciplines (Yoga, Tai Chi, Qi Gong, Reiki etc.) and to acupuncture, mainly provided outside its application context and consequently it is demerged from the complex methodological approach encoded in the Traditional Chinese Medicine. It is plausible to assume that this approach is connected with the difficulties the orthodox medicine has faced not only with other treatments, but with other medical notions built upon different epistemological and methodological assumptions compared with the principles conveyed by the Academy. Consequently, it is understandable that it is easier in the biomedicine to give the way to practises not performed by physicians, and therefore subject to the control of doctors themselves, rather than to start a cultural exchange process in the medical field that is a precondition of the interdisciplinary approach to treatment and of the integrated medicine, at least in the broadest sense given by our scientific Society.

Regarding the reasons for the spreading of the openness (or pseudo-openness) between conventional medicine and CAM, typical of the latest two decades of the medicine history, it seems likely that there is no clarity nor sharing of objectives among the key players of this phenomenon. Indeed, taking into account what has been written and published in the scientific literature, it seems there is the chance to talk about a phenomenon barely outlined, in which the effort ultimately aims to conceive definitions, to establish some guiding criteria that allow the orthodox notion not to "get lost" in this attempt towards openness, to be still able to be in the driver's seat, rather than aiming to identify clear areas of operation, therapeutic complementarity, mutual development perspectives, sharing of objectives which strive for a univocal healing pathway. The evidence is the method itself implemented to provide evidence for effectiveness. Indeed, the objective of clinical studies is not to examine the highest effectiveness of integrated treatment pathways, rather to assess the effectiveness degree of an individual complementary technique.

But what are the reasons that convinced conventional medicine to open towards CAM? According to our perspective, there are two reasons.

### **Communiti demand**

In 2009 more than a third of the US hospital facilities added CAM to their conventional services. According to a survey carried out among hospital facilities, 87% answered the question why they decided for this resolution, saying that the first reason for this shift was driven by the community demand<sup>3</sup>. The pressure applied by health consumers has highly taken its toll in the United States, given that the American health care system is a private and competitive system. It is well-grounded to

think that the spreading of centres for integrative medicine in the US hospitals meets the healthcare system needs. The groundbreaking healthcare service offer is already well established in the US public services and has been able to plan around itself important CAM supporting facilities until to shape a real network of initiatives connected together that are coordinated and standardised regarding both university education and healthcare services, which in fact are rather similar and iterative in several hospitals. In the United States the key actors of the collaborative network built upon CAM and treatment integration missions are the Consortium for Integrative Health Care (CAHCIM), The Bravewell Collaborative Organization and, recently, the Academic Consortium for Complementary and Alternative Healthcare (ACCAHC). The amount of work carried out is enormous and the objectives are not certainly hidden. Indeed, the mission has been clearly stated on their websites: "working in order to transform the healthcare system and to improve the health system in the United States, by fastening the adoption process of integrative medicine into the American healthcare services and by facilitating the achievement of a new health and well-being attitude in the United States".

### **The awareness of the inefficiency of the conventional medicine**

The awareness of the inefficiency of the conventional medicine to manage chronic illness combined with the issues linked to the chemical drug overdose, often as origin of iatrogenic diseases and increasingly considered as cause for suffering which, equal to the same diseases physicians intend to heal, compromise the life quality of the community eventually.

What is the attitude applied by orthodox medicine to open up towards non-conventional therapies which are not assigned equal dignity, since CAM is not acknowledged a cultural equivalence because of the lack of evidence testifying their effectiveness? Professor Daniel Hollenberg, from the University of Toronto, was the first person to shed light on concepts on CAM, integrative or integrated medicine and he studied the phenomenon drawing from Karl Emil Maximilian Weber's closure theory: how specific social groups achieve and maintain their privileged status in the society.<sup>4</sup> This theory explains the subordination process that occurs when a group of professionals monopolizes the privileges closing this opportunity to another group, considered to be inferior. This process can be performed through a series of patterns, such as exclusionary, inclusionary and demarcationary closure. For a long time the orthodox medicine has been attempting to exclude the complementary medicine from the official treatments, while the complementary medicine has been trying, on the contrary, to be included into the authority area of the medicine. This attitude has failed, more or less throughout the world and the next strategy has been the demarcation, through which the closure process has taken place to limit the sphere of competence of professionals. As a matter of fact the closure theory clearly defines relationships that

can specify the oppositions between the two professionals working at the hospital facilities where integrative therapies are implemented; as we are going to see, they belong to the healthcare service offer which, yet today, represent the phenomenon of integrative medicine rather marginally. By implementing exclusionary closure, orthodox medicine practitioners hold their reference and coordination position of the therapeutic approach, praising the culture of professionals. It is beyond question that the objective strategy is to protect this exclusive superiority status. Therefore, the coexistence of these two figures leads to establish demarcation limits, defining the sphere of competence for physicians and CAM practitioners. Despite the introduction in hospital facilities the opportunity for the patient to select a therapeutic technique, the freedom to express his preferences and above all to be included into the examination of his disease conditions which represents a crucial breaking-off of the pillars of the orthodox model, we feel at the present day to deduce that the attitude of orthodox medicine towards complementary therapies is nothing more but a consumerist implementation of these therapies.

Completely different is the integration pathway of CAM in the contemporary medicine. In practice we are making use of everything that can help to meet the specific needs of the community, proposing a competitive and innovative offer in the health care field, as well as to fulfil the need of the orthodox medicine to search for therapeutic techniques useful to minimize damages related to drug. If all this is about the phenomenon of the expansion of healthcare offers that more or less simultaneously had spread throughout the world at the end of the 90s, and if it determined a sort of "modernization" process of medicine, it has very little to do with the renewal process of medicine. Therefore, looking at the phenomenon more carefully, it is hardly surprising that the most diverse definitions are embraced to define a phenomenon, which fundamentally has neither structural clarities nor clarities of objectives: "integrative", "integrated" and even "integral".

If words are holders of ideas, the ideas defining what IHC are not yet structured properly. I personally find that this operating process, tending to be more introspective rather than affirmative, is however very positive and it is a necessary transition. In any case the pathway demonstrates that orthodox medicine is experiencing a critical period, whether it is agreed upon or not. But CAM is experiencing a critical period as well. As a matter of fact, as it is coming out and tackling the orthodox thinking, it jeopardizes to lose its orthodox feature, since it is constrained to face the rules, principles and certainties it believed it developed, as typical of every thinking built up in its environment and always enriching inside itself through its usual mainstay. From my perspective, the challenge growing in the coming years concerns not only orthodox medicine, but also CAM. Progressively the orthodox medicine will have to reckon with CAM, it is not important if it is evidence-based or experience-based CAM, since just demanding the evidence for effectiveness according to the evidence-based model (EBM) will not be sufficient.

Indeed, this warning was not enough to control the progressive increase of the complementary medicine and well-being disciplines implementation at the healthcare facilities. Citing the words of Marc Cohen, author of a study on treatment integration in Australia, they "are CAMing" to the National Healthcare Services.<sup>5</sup> I believe that this phenomenon not only will be a one-way path, but it will also experience an exponential increase.

However, when CAM claims to share the therapeutic potential with the orthodox medicine, it is unimaginable that they not share with them the typical game rules of the medicine of our times, both for better and for worse as well. Hence, if we accept that the notion continuously grows, among successes and perspective mistakes, if we demand from the orthodox medicine to bring its certainties into discussion again, the same we have to demand from CAM. In my perspective, the final product today is unpredictable. However, I do not see this as a limit, since it is a precondition for any evolution process.

In my opinion integrative or integrated medicine is a transitional step, but the real challenge is the ability of the medicine thinking to change, and deeply as well, giving birth to another medicine as a result of a paradigm exchange, of a merging or an extension of concepts bearing the complex of knowledge applied to the complexity of the issue on health, and psychological, physical and environmental well-being in each individual. And if the revolution shall appear like this, there is no hurry, if we consider that only twelve years ago a work published on BMJ was still notable, which simply dealt with the definition of CAM, entitled "ABC of complementary medicine"<sup>6</sup> and, if it is true that ten years later a further consideration on this topic coming from the Canadian integrative therapy centres was presented with an important title: "Integrative medicine: a tale of two clinics"<sup>7</sup>, through descriptive overtones reporting the physicians' opinions on integrative medicine programmes existing at the St. Michael Hospital of Toronto and the Stollery Children's Hospital in Alberta. After all, up to now, most physicians of the orthodox medicine do not show the curiosity towards treatment systems which they consider to be at least second class, if not even to be real tinsels that only annoy the orthodox medicine and to be considered at most as analogous and, eventually, ignorable. An overview of the proposals for integrative medicine services at the international healthcare service facilities leads us to deduce that the integration process is at the beginning and, actually, it is assigned to very few modern facilities and, at the present time, they are far-seeing to work.

In order to understand this observation, I believe it is useful to go back to the concepts as integrated and /or integrative medicine to examine the meaning assigned to these definitions in the several health care systems in the world. This observation could help to understand why the renewal process of the medicine, according to the content that we prospected, is at present a phenomenon in embryo development.

As a general rule the so called integration process is ex-

pressed in two ways: 1) through the coexistence of CAM services within public services; 2) through the existence of services only provided by complementary medicine, acknowledged by national healthcare governments.

Model no. 2 is the most developed in the East, in the two biggest countries, such as China and India. In China the traditional Chinese medicine (TCM) is extraordinarily deep-rooted, in spite of the contemporary availability of the western medicine. However TCM is provided in separate facilities and taught at TCM universities. Therefore, an integration process does not actually take place. The AYUSH Indian Department (Ayurveda, Yoga, Unani, Sidda, Homeopathy) of Ministry of Health protects conventional medicine, however, also in this case, the numerous Indian clinics for homeopathy or ayurveda are separate facilities and are not integrated into facilities where physicians practise Western medicine techniques. Currently conventional medicine (ISM, Indian System of Medicines) are being taught at universities in an analogous degree course to the western medicine course and many Indian physicians have decided to take part in both training courses, both in western biomedicine and Indian conventional medicine. University teaching programmes focused on ISM comprise connections with the western medicine, even if training in biomedicine is not compulsory to work as traditional doctor. Therefore it is evident that, even if the huge number of services provided helped CAM to integrate among communities living in strongly privileged territories through a different and beneficial cultural substratum compared to the West, this model as well can be included within the cohabitation system, while very little has been done for a possible cultural exchange among medical sciences. It is hard to think that these experiences can originate the renewal process of medicine as we defined it above and, based on a deeper analysis, CAM may be more isolated within its own territory among the communities compared to the West.

According to model no. 1, which is applied in the United States, Canada and in some European facilities, CAM services are provided as practice performances within the healthcare centres where orthodox medicine is implemented. However, in this case as well, orthodox medicine and CAM, beyond sharing the same place of supply, achieve a cohabitation process rather than an integration process. In Europe, in addition to CAM services provided in some hospitals and university facilities (Germany and the Netherlands) there are hospitals (Royal London Hospital for Integrated Medicine, Glasgow Hospital for Integrated Medicine) which fully perform complementary medicine services. Orthodox medicine is implemented in these hospitals, CAM practitioners are primarily trained in biomedicine, therefore patients keep undergoing conventional therapies, when it is necessary. Hospitalization is also possible at Glasgow Hospital, but this requires a team entirely made up by CAM professionals caring for the patient. Hence, if the precondition of integrated medicine, at least as we would like to propose it, is the cultural exchange and the interdisciplinary discussion on the treatment pathway, not even this most developed healthcare model can meet the

necessary features for an integrated medicine setting. It follows that the scientific literature aimed to analyse the aspects of treatment integrated systems and integrated healthcare, from public healthcare services as well, has examined up today a hypothetical integration model that has been not yet achieved. For instance, in the article "Integrative Medicine and systemic outcomes research", from the Program in Integrative Medicine of the University of Arizona Colleges of Medicine and Pharmacy, it is stated that "Clinicians and researchers are increasingly using the term integrative medicine to refer to the merging of complementary and alternative medicine (CAM) with conventional biomedicine". However, the Authors fairly emphasize that "combination medicine (CAM added to conventional) is not 'integrative'. Integrative medicine represents a higher-order system of systems of care that emphasizes wellness and healing of the entire person (bio-psycho-socio-spiritual dimensions) as primary goals, drawing on both conventional and CAM approaches in the context of a supportive and effective physician-patient relationship. In this view, health is an emergent property of the person as a complex living system. Within this conceptualization, the whole may exhibit properties that its separate parts do not possess". We share this definition about the complexity theory which, from our point of view, focuses a crucial concept: the merging among disciplines belonging to medicine automatically redefining the medicine itself. In this context the integration process becomes, or better, it would become, the precondition for the birth of that new medicine which is only in an embryo phase at present.

In order to understand the meaning of integration, we can make use of a vocabulary. Indeed, integrating means both combining with something else and embodying into a broader unit. It is absolutely plausible that the combination between CAM and orthodox medicine entails the merging of unequal components, since complementary medicine within the predominant medicine system represent a field of minor importance. Hence, CAM risks much more than the orthodox medicine regarding the merging process, since it could be partially integrated and, as a result, its identity could be demerged. As a matter of fact, it is likely that orthodox medicine avails itself of CAM, for example in order to fight the negative aspects of pharmacological treatments in chronic illness, as highlighted above. However, this procedure of simply absorbing treatment resources represents, once again, a consumerist attitude of CAM which has nothing to do with the integration. However, this coexistence and cohabitation factor among medical sciences has been necessary for the survival of CAM in the contemporary medicine thinking, determining the current supply conditions of CAM in many healthcare services. Hence, the need to underline that this can not be the object to be achieved does not imply that this paper diminishes the importance of the phenomenon which we have witnessed to date.

In conclusion, we can state that CAM history to date has evolved, drawing away from the clear opposition with the orthodox medicine. Conventional medicine, in turn, experienced two phases. The first phase was char-

acterised by an essential detached attitude towards other treatment resources. In that period orthodox medicine was able to build its modern establishment, obtain its outcomes, and astonish for the plentiful treatment instruments it was able to produce. In the second phase the limits of this therapeutic system came to surface, despite it continues to be doggedly supported by a dense confluence of opinion leaders belonging to the predominant medicine thinking developed and protected by the Academy. However, the refusal to scientific medicine became bigger until to jeopardize the entire system and the key actors of this critical period were really the consumers of that medicine. By using the words of Ivan Cavicchi, the second and current phase is the post-modernity step. The thinking, as it appears, is decaying and needs a renewal. In this second phase, CAM accomplished to be taken into account not only by the patients, but also by both healthcare governments and physicians themselves.

For the reasons mentioned earlier, an afterthought in the medical field is underway throughout the world and treatment reconsideration is at the beginning. New concepts, such as treatment integration and therapeutic offerings enhancement as a result of the use of other instruments, whether they are needles for acupuncture, herbs for ayurveda, Chinese or Western phytotherapy, homeopathic drugs, or instruments belonging to well-being disciplines, such as Yoga, Tai Chi etc. are beginning to be taken into account. Even if the experiences, more or less similar in every country, are coordinated by boarder initiatives within a geographical area, it does not imply that they are in turn coordinated internationally. It is sufficient to think about the deep-rooting of TCM in China and about the demerging of TCM in its Western version, in which only acupuncture has found its application until now. Although acupuncture has been applied in very important hospitals we can not say the same for TCM. As a matter of fact, WHO is making a distinction between conventional medicine and CAM. Grasping everything that can be considered as medicine, interpreted as an instrument useful for man's health, in which the terms health and man have a global understandable meaning in our times, we are experiencing anyway a parcelling phenomenon further to which a single aspect of medicine and treatment can be accepted by the orthodox medicine. As we have argued, even though scientific literature and authors attempted to define the integration process of treatments, by using terms like integrated medicine or integrative medicine, actually, what happened until today is something else. It was about the demerger of some treatment instruments and their introduction into the Western medicine, which decided to make use of them, without however bringing itself in discussion. These instruments are therefore accepted according to the typical view of the orthodox medicine, nothing more than further treatment resources to be ranked next to medicine with the risk to simply develop a further consumerist attitude in the health care system, as already underlined above.

If the orthodox medicine is suffering as a result to this cohabitation process perceived by many as threat against

its unquestionable power, this threat is nothing compared to the process we hope it could characterize this new phase of medicine. The interdisciplinary approach to treatment is indeed something really different from the experiences set up until today. The interdisciplinary feature implies a high effort, that is to accept different perspectives in the medicine field that are as many as the components of integrated medicine settings are (conventional physicians, homeopathy, acupuncture and phytotherapy practitioners and professionals of well-being disciplines), taking into account the fact that the settings can be different from the others, depending on what is to be integrated and on the basis of the cultural substratum, in which coexistence and collaboration are taking shape. As a matter of fact every key actor has its own philosophy regarding the concept of health and treatment; the consideration of the treatment focus is different, while it is illness for the orthodox medicine, for the holistic disciplines, instead, it is the patient perceived as a whole in a social, environmental and cultural dimension that influences his capability to react against the disease. Not only, he who is an illness object for the orthodox medicine, is at the same time a recovery subject for CAM. In other words, two different methods are compared, but not for this reason they can not be integrated. According to the orthodox method, the purpose of the treatment is to destroy the illness; the second method aims to implement self-recovery resources, self-repair of the ill patient. In principle, there would not be any obstacle for the merging of the two therapeutic patterns. However, the comparison between the two therapeutic approaches tends to necessarily reduce the trust in the conventional medicine that is not the unquestioned main focus anymore and is, instead, reconsidered in the light of cultural content of CAM<sup>10</sup>. Furthermore, since the precondition to the integration process (and not to the cohabitation) is represented by the shared respect, it follows that the formal hierarchy becomes worthless when the concept of mutual trust and respect among all members is accepted. Therefore, the autonomy of the conventional physician decreases together with its predominant role, the structured system creaks towards concepts as disease and therapy and they are replaced by other concepts as ill patient and treatment which approach forward. Attempts for exclusion and demarcation fail and a new way comes to consider medicine within the merging of treatment systems. On the other hand, the structure of conventional medicine gave its best in emergency and urgency pathologies, but it showed its weakness in chronic illness, where, not accidentally, both CAM and the interdisciplinary and integrative model of treatment have established themselves.

#### *Requirements for an Integrated Medicine Setting and the Centre for Integrated Medicine of Pitigliano*

Although the integrated and integrative medicine is by now an international movement and the literature is debating about it, as extensively as described above, I have tried to highlight how it is not implemented in reality yet. The most important examples such as CAM services

provided at Mayo Clinic, New York Sloan Kettering Center, Boston Dana Farber Hospital, Royal London Hospital for Integrated Medicine, Glasgow Center for Integrative Care of Glasgow, Strasbourg Hospital, and Karolinska Institute are just some of the healthcare facilities among the most famous centres which also implement CAM. They pertain to the possibility to dispose of other therapies, belonging to the wide field of CAM services, in regard of the conventional medicine which they are ranked in, according to a model that does not jeopardize the superiority position of the orthodox medicine and does not involve physicians into the most complex system of the interdisciplinary approach towards treatment. As emphasised above, the integrated medicine model is something else and it provides the possibility for a cultural exchange between medicine and disciplines. In this model it is necessary that the key actors can debate on and share the therapeutic approach, according to an interdisciplinary pathway of operating process, in which the pillars of CAM and of orthodox medicine are compared in order to reconsider both health and illness from more perspectives.

### Requirements for Integrated Medicine setting

#### *Culture Exchange*

Since the conventional medicine physicians often have no notions of CAM, it is important that they have interest to learn this discipline. A great part of work to be done regards the possibility to involve the orthodox physicians through information and professional training. CAM practitioners must invest much time and energy to prepare events aimed at providing information regarding CAM to conventional doctors. Accuracy and appropriateness of terminology are the important supporting instruments as to information and training of the orthodox physician. In fact the teaching programmes must be suitable to the knowledge needs of the physician who is not qualified in CAM but would like to know more about the matter. As to language adaptation in the information and homeopathy training of the convention physicians SIOMI (Italian Society of Homeopathy and Integrated Medicine, Società Italiana di Omeopatia e Medicina integrata) has dedicated energy during its twelve years in Italy aimed at the communication and sharing information about homeopathy medicine culture to the National Healthcare physicians. We believe this effort fundamental. Indeed, if the orthodox medicine physicians do not have any knowledge of CAM, if they are not able to understand the value of the individualism of the cure, if they do not know the substantial differences regarding health concepts and typical diseases in CAM visions compared to the orthodox medicine, the only possible objective in the best of cases would be to acquire acceptance on behalf of an increasingly high number of doctors as for the possibility to consider additional therapeutic practices, but never to share them. The patient, although the same, would be simply the object of further non-shared therapeutic proposals.

It is evident that the information and training in CAM should be provided firstly in Medical school courses and

in other professions in the healthcare field.

Therefore, training line guides are needed and they should be handled by universities on the wake of the American model The Consortium of Academic Health Centers for Integrative Medicine which have joined up 50 medical Schools in USA. Actually, unfortunately, a pre-graduate education is not yet present in Europe but the establishment of a post-graduation education through Masters degree courses concerning CAM practices is recent and sporadic. It is worth to mention the first Master in Integrated Medicine at the Medical School, University of Siena, in 2008 where lectures are aimed not only at giving students a broader vision of human health and disease through notions of philosophy of medicine, sociology, physo-neuro-endocrine-immunology but complementary medicine (homeopathy, phytotherapy and acupuncture) is taught as well and recognized by the Tuscany region as medicine of the regional healthcare service (Law no.9, 2007).

The achievement of an integrated medicine model provides that each key actor of the health service system receive information about CAM planned to be integrated in a therapeutic pathway and that each practitioner is trained according to his own particular skills. It is necessary, therefore, that the Academy engages in this training and in addition to training programmes for physicians, pharmacists, dentists, information/training courses for nurses, obstetricians, physiotherapists, nutritionists and, more in general, for the entire healthcare personnel. The University of Siena has therefore arranged a second 1st Level Master's Degree course for healthcare personnel starting from 2012 that will give information regarding basic principles and therapeutic potentials of CAM not only concerning complementary medicine, recognized in Tuscany, but also regarding some well-being disciplines (Shiatsu, yoga, Tai Chi, Qi Gong, etc.) which have been set by the Region of Tuscany into a further legislative acknowledgement process (Law no. 2 dated 2005). The Medical school at the University of Florence provides training courses about alternative natural medicine within the teaching programmes for physicians and healthcare personnel. Further initiatives are brought on by universities in Rome, Milan and Bologna. Therefore, CAM training courses are structured in post-graduate courses in our country, at least. Yet, Italian education lacks the partaking of teaching programmes so that each university can foster its own initiative. It is a result that students obtain a different training qualification depending on where they attend these courses, and often these training programmes are different from one another with different contents. Furthermore, it is to notice that it is difficult to implement these skills in the Italian healthcare system which does not provide CAM integration in public healthcare services, except in occasional cases: Tuscany is one of these. In this region it was necessary to establish a Master's degree course in integrated medicine when the health care project of the Centre for Integrated Medicine in Pitigliano had been drawn. Once started, the Master's degree course would have provided practical training, which is a necessary feature of any training core curricu-

lum in medicine.

In addition to university training, the Centre for Integrated Medicine in Pitigliano has arranged CME training events both for physicians within the territory and for healthcare personnel of the Hospital. The training courses concern the basic principles of the three complementary medicines provided in Pitigliano: homeopathy, acupuncture and phytotherapy.

However, beyond information and training initiatives that are necessary when the aim is to build an integrated medicine setting, the experience in Pitigliano as first hospital in Italy providing CAM also for in-patients, allowed to highlight the requirements necessary to start a project that could be in reality aimed towards integrated medicine. Therefore, I am going to outline the requirements of such a model that, given the unquestioning innovation, is gradually taking shape and whose experimentation could provide useful information regarding both structure, feasibility and usefulness of this healthcare project for those who would like to organize similar integrated medicine services in the future.

The healthcare project of the Centre in Pitigliano has experienced a long preparation process before being practically implemented. During the two-year-period preceding the starting phase, a scientific committee worked on the drafting of the project to be submitted to the Regional Healthcare Department of the Region of Tuscany. The difficulty to structure a healthcare project that could not relate to any similar experiences in the past is deducible. However, the collaboration with the Italian Local Healthcare Center 9 (ASL 9), which the Centre in Pitigliano refers to, together with the Regional Healthcare Department of the Region of Tuscany, the Faculty of Medicine of University in Florence and Siena, the medical association of Florence and Grosseto, the pharmacist association of Florence and Grosseto, the regional committee of bioethics and bioethics committee of Grosseto, a qualified and specialised physician of forensic medicine, research scientists, epidemiologists and the consultation by Peter Fisher, Director at the Royal London Hospital for Integrated medicine and David Reilly, Director at the Glasgow Hospital for Integrative Care, the Italian Society of Homeopathy and Integrated Medicine (Società Italiana di Omeopatia e Medicina Integrata) allowed to outline the requirements needed for legal, social, healthcare, cultural and organisational perspectives necessary to achieve this project. The Centre for Integrated Medicine has been working since February 2011 and the current ongoing experience allows to draw up today an initial assessment about the main potentials and the main critical issues of a model entailing a high innovation degree for the healthcare system.

Since this contribution is not dedicated to the experience of the Hospital Centre, the concepts herewith outlined will refer to those useful to depict the proposal for an integrated medicine setting according to the experience resulting from a model during its practical application phase. As mentioned in another passage of this contribution, we share the observation that the precondition

for a healthcare initiative aimed to integrate treatments is trust and shared respect among orthodox medicine and CAM professionals. However, this precondition is not obvious, since the orthodox medicine has grown within the Academy and has structured and developed through the approval of the establishment of the predominant thinking in medical field, while CAM implementation is still excluded by many at the present time. It follows that trust and shared respect represent values to be achieved rather than acquired preconditions. The first step to build up this feeling of trust is to know and be aware of the complementary medicines. For this reason, we have made reference to providing CAM information and training.

#### *Relational Exchange*

The second step is, in my way of seeing, the direct and progressive acquaintance among the health professionals who offer their service in the territory within which operates a structure of integrated medicine.

For such reason, the Centre for Integrated Medicine of Pitigliano has promoted numerous initiatives aimed at meeting the physicians of the territory in which the Centre of Pitigliano itself makes reference to and setting up a procedure of relation through meetings with physicians and family paediatricians and hospital doctors, in addition to activating a mailing list to exchange information between the Centre and the territory or activating a call service via phone or email of CAM medical experts in the Centre to all the Italian physicians whose patients make reference to the ambulatories in Pitigliano, and furthermore through delivery of letter of resignation drafted by the Integrated Medicine team and addressed to the family doctor of the patient who received integrated healthcare in the hospital ward or ambulatories of the Centre.

#### *Time factor*

In our view, the mutual acquaintance and the availability to dialogue represent a primary importance for the realization of Integrated Medicine setting. In such way there should be adequate time to analyze the perplexities which are more than obvious and legitimate of our colleagues in orthodox medicine and adequate time required for project maturation.

Another valuable factor is represented by the compliance to forecast errors and eventual changes of treatment and to support the typical frustrations of the process certainly difficult as it is recent and innovative.

On the other hand the awareness to be part of an emerging healthcare project could be a sufficient reason to encourage responsibility, curiosity, modesty and the enthusiasm of the principal actors of a new prospective in medicine. Indeed, if Integrated Medicine is an emerging model, it is also the resulting of an effort process and as things are today it will be defined in the practical development not being able to be issued from similar experiences.

*Mutual trust*

After having highlighted the preconditions, the integrated medicine model is defined on the way throughout the clinical path realized abreast in a hospital ward. The scenario which is outlined in Pitigliano is a small-dimensioned hospital unit and therefore, in our opinion, particularly adapt to the planning of a report which has a strictly collaborative task among the doctors. The principal presence in the unit of patients affected by chronic pathologies is the ideal substratum for this integration practice of medical care. Integrated healthcare in the rehabilitation institutes in Manciano is, instead, provided both to patients with motor and neurological difficulties resulting from incidents, particularly ictus, and to patients in orthopaedic rehabilitation consequent to surgery. Once and again it is about pathologies which are apt to the integrated approach. In both healthcare groups the entire staff of the hospital is called to debate the clinical cases together when complementary medicine is put side by side to conventional therapy.

*Interdisciplinary activity*

As yet, we have focused our attention on the process of collaboration between expert CAM practitioners and orthodox medical colleagues as a fundamental element of an interdisciplinary approach project to medical care. Nevertheless, we should not overlook the concurrent presence of expert practitioners in different CAM fields which allows another level of integration as well, or rather the interdisciplinary approach within the complementary medicine. This model is not only the collaboration between orthodox doctors and expert CAM practitioners, but it includes physicians expert in different complementary medical areas as well. It is common for patients who live in Pitigliano to undergo both homeopath medical and acupuncture or phytotherapy examination and both therapeutic treatments are actuated. This model of integration, which contemplates the possibility of use together with more CAM resources, is rather new and it is still not treated enough in literature, although it is already available in Europe in other medical centres which host CAM such as The Royal London Hospital for Integrated Medicine and Glasgow Center for Integrative Medicine where other different disciplines of complementary medicine is integrated, for instance, psychotherapy and meditation techniques. It is incredible the lack of information regarding the topic in literature although the cultural exchange among alternative medical systems is definitely easier from the moment that few methodologies preconditions, believed as indispensable in this typology of setting are normally present already, in particular I am referring to the involvement of sharing among the CAM operators of items such as: the global vision of the person, the individuality of the therapeutic approach, the trust in the systems of self-recovery of the body, the research of a strong human relation between patient and physician and the belief in the professionalism of each operator. In our opinion the little literature available regarding not only the integration between CAM therapy and orthodox medicine, but also

among the disciplines belonging to CAM therapies is a further confirmation of the yet embryo phase of the comprehension of the international definition proposed of integrated or integrative medicine.

*Healthcare instruments*

The presence of expert practitioners in CAM and orthodox doctors in the hospital entails the joint use of the medical records reserving a space detailing the medical history of the patient, the medical examination and the therapy performed according to CAM norms. The filing system of the medical records must provide the entry of the specific codes related to integrated medicine. This is obviously not possible where healthcare service, through appropriate government provisions, does not recognize CAM therapies.

**Conclusions**

The realization of Integrative Health Care is an extraordinary complex issue. Indeed a system of this type has not yet been realized despite the matter is handled by more authors, especially by those with experience obtained in North America. The definition given by Schroeder and Likkel<sup>9</sup> in 1999 is, by our means, correct and it refers to the necessity of health operators trained with different backgrounds to work together for the patient's benefit. This basic concept, as focused by Daniel Hollenberg of the Department of Health Sciences at the University of Toronto, was interpreted and expanded in several dependent formulations by the Public Health system resulting in a set of integrative health services between biomedicine and CAM determinable as "collaborative practices", "inter-professional approach to healthcare", and "integrative medicine". Although the aim is to combine both CAM and orthodox medicine, few have operated a further distinction, and among these there is SIOMI, between a model of integration where CAM therapies are encompassed in the orthodox medicine in order that the physician has the control of the therapeutic course, and an ideal model where it is thought to achieve the fusion of medicine and CAM in a new health paradigm. This entails the expansion of the biomedical model of illness focalizing on the holistic, global and complex aspect which implies the inclusion of the mind-body-soul aspects in the process of healing. The relation between different healthcare professionals, including orthodox doctors, does not provide, in such case, any hierarchical scale of competence, instead reciprocal respect as well as trust and harmonious collaboration is given to this relation, trans-disciplinary and inter-disciplinary collaboration where a set of therapeutic resources belonging to biomedicine and CAM are offered. It is understandable how this model may not be fulfilled nowadays and that this lack of achievement depends not only on the cultural, geographical and legislative factors but also on the necessity that CAM therapies most demonstrate their utility in terms of improvement of citizens' life quality as well as public health, and saving healthcare costs. There is no doubt however that, in case this model could fully be achieved, it could completely

redesign medicine both from a training point of view and from a methodological approach to the disease and consequently of the therapy.<sup>11</sup> If the culture project proceeds towards this direction we could not define this medicine as "integrated" or "integrative" since it is a new medicine resulted from the alliance between the different thinking supported originally by different paradigms merging in a totally renovated methodological approach. With the proposal of the present manifesto we hope to have suggested an instrument useful for the development of the medical thinking in the direction of a New Medicine.

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# Floating between ideal and reality

## An international monitoring unit of Integrated Medicine

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### A controversial ideal

The starting point to be taken cognize of is the inexistence of univocal perspectives, convergence or consent to the "Integrated Medicine" issue: the challenge begins with the definition itself of the object, which is mostly defined as "Integrative Medicine" in the United States, while the term "Integrated Medicine" is used in Europe.

Some experts believe that integrated medicine (or integrative medicine, according to the North-American definition) is a type of *selective absorption* of components belonging to complementary and alternative medicine within a strictly evidence-based orthodox biomedicine. It is about a *co-optation* [Kelner et al., 2004] or *subordinated inclusion* strategy [Colombo and Rebughini, 2006: 72-75], as it is defined by others, which does not absolutely bring the mainstream knowledge and biomedical clinical practice into question and which confines complementary and alternative medicine as complementary tool of biomedicine [Giarelli, 2005: 247].

Others believe that integrated medicine is completely different and essentially in opposition to the foregoing definition: instead of being merely a selective absorption of components belonging to complementary and alternative medicine within an evidence-based orthodox biomedicine, integrated medicine represents the opportunity to deeply reconsider and to bring knowledge and biomedical clinical practice into question which entails the approach itself towards the patient, his role and the therapist's role as well as the nature of the treatment.

The first definition of integrated medicine does not seem to raise any particular issue for biomedicine because it basically leaves everything as it is: strengthening instead the monopoly control on the national health care system, consolidating and protecting its strategic interests; while the second definition becomes a really great challenge for biomedicine which reshapes the boundaries [Maizes e Caspi, 1999].

As a matter of fact, while the first definition is inclined to confine integrated medicine as a problem of *rationalization* and *assimilation* [1] of complementary and alter-

native medicine to language and biomedical *modus operandi* – that is, deep down, depreciating integrated medicine – the second definition considers integrated medicine as a result of a syncretic and, as such, basic creative process. The fact is that integrated medicine is not only about, according to this definition, complementary and alternative medicine, as if any facing problem was only focused on that issue and biomedicine was deemed to be considered as it is; or, and this is worse, as if integrated medicine had the special right to impose some conditions to access "the exclusive elite" of medicine considered to have scientific and legitimated features valid for its performance. The way for a real integration goes, what we believe is, to the questioning of the three key points of the integration process itself: that is, the political issue, the organizational issue and the epistemological issue.

### Three main issues

First of all the political issue recognizes the essential difference of legitimacy and, therefore, of organizational opportunities, as specifying component for biomedicine compared to complementary and alternative medicine: if the first one results yet to have a monopoly control on healthcare systems, even though it is experiencing a more or less deep crisis, on the other hand CAMs experience a shift between the past margining illegitimacy and the possible inclusive legitimacy in the system. Only the overcome of this liminality condition for complementary and alternative medicine (or as more likely for at least some of them) can represent the fundamentals for a non-subordinated integration process: however, this implies to resolve those issues regarding regulation, self-regulation, accreditation, training, and professional organization which are nowadays very controversial, should there be no responses, they could trigger an endless vicious circle.

The organizational issue is the translation, from the organization of services perspective, of the responses provided for the political issue, indeed, biomedical monopoly on health care systems is reflected at an orga-

[1] Colombo and Rebughini [2006, 69-72] analyze some of the most popular assimilation strategies: "translation" into the biomedicine language of CAM practices and concepts (such as acupuncture, osteopathy, phytotherapy and many massage techniques), "redefinition and downgrading" of a medicine system into a mere complex of specific intervention techniques which can be removed and used without any other reference to the original cultural context (for example acupuncture, but also other Chinese traditional medicine components such as pharmacopeia, shiatsu, tui-na or yoga within ayurvedic medicine).

nizational level in the conventional hierarchical structure of health care work founded on medical dominance [Freidson, 1970]. Historically the organization of services foresaw two solutions for non-medical healthcare practices: the paramedic model and the "allied health professions" model. The first model is based on a hierarchical-vertical distribution of work and has been implemented for hospital nurses, physiotherapists, obstetricians, radiology and laboratory technicians and dieticians: to this day it seems that it reintroduces itself when it deals with complementary and alternative medicine for those who are not medical professionals, such as chiropractors, masseurs, herbalists, or naturopaths who, according to this model, would not be legitimated to set out the diagnosis and to prescribe the related treatment, but apply their own treatment techniques only if they are given a prescription and under the supervision of a physician. Therefore, the physician shall be a supervisor, holding his diagnostic power and deciding if the patient needs a CAM practitioner or not [Barrett et al., 2003; Kelner, 2005].

In turn, the "allied health professions" model has been historically applied for in the case of pharmacists, psychologists and dentists, where a "functional dominance" process [Tousijn, 2000: 186] has been established; this dominance is not hierarchical, but functional-horizontal, based on the different professional qualification. In the case of complementary and alternative medicine this model seems today to be reintroduced, when the physicians are the ones who perform this type of medicine and their skills in complementary and alternative medicine (for example acupuncture and homeopathy) tends to be confined as a mere different skill performed aside and added to the high number of specialties that the field of biomedical knowledge is full of.

Both of these models appear to be simply inappropriate to ensure a syncretic integration process focused on the patient [de Bruyn, 2003]: indeed integration should entail a comprehensive and holistic approach which questions the conventional model about the organization of work, based on the hierarchical-vertical and functional-specialist medical dominance in order to build up horizontal cooperation structures, in which several professionals work together through equal and integrated methods at disciplinary level [Giarelli, 2005: 168-172; Leach, 2006]. In addition, different types of multi-professional and interdisciplinary research teams can adopt several active methods depending on what kind of situation is treated and on the organization contexts, collocating itself along a continuum between merely consultative-cooperative typologies and actual typologies of interdisciplinary integration [Boon et al., 2004].

Finally, the third integration issue has epistemological features and refers to the (sometimes deep) difference of paradigms which specifies complementary and alternative medicine in comparison with biomedicine: a real integration process can not pretend that this difference does not exist, or even hiding it under a visible convergence of objectives for the patient's sake or swapping it with something of a higher approval by medical *estab-*

*lishment*. Otherwise, we could really face a "wasted opportunity of knowledge communication" [Secondulfo, 2005: 196-199] which can not be trivially limited to the difference between scientific knowledge and other kinds of knowledge, but between two (or more) different concepts of science concepts and, consequently, of medicine. Biomedicine is based on the Cartesian, mechanistic and reductionist paradigm while complementary and alternative medicine is set against, on different levels and with different shades of meaning, a holistic, systemic and connectionist paradigm which aims to open new horizons even in certain fields of natural and social sciences [Koestler e Smithies, 1969; Capra, 2002; Laszlo, 2002].

Hence, integrated medicine is asking for a real paradigm shift, if its aim is not to be a mere validating and depreciating standardisation process [Secondulfo, 2005: 198], whose development can only be marked through complex scientific discoveries [Kuhn, 1969]. Along with the aforementioned organizational and political change, these are the three focal points, where it is possible to check, in the next following years, if and in which direction the process of integration is really taking place. As it can be easily foreseen, it is a difficult path with plenty of risks, forerunners of possible deviations with no return.

### **From Integrated Medicine to Integrated Health care**

The implementation of complementary and alternative medicine (CAM) in Italy as well as in other industrial developed countries has increasingly become legacy and daily practice not only of the patients, but also of health care professionals (physicians and non-physicians) who are more and more interested in the holistic nature, based on the health concept as well-being, in the healing process as experiential pathway which is personally managed by the patient and in the systemic, complex, multi-factorial aetiological concept of health-disease [Giarelli, 2003].

Hence, an increasing number of different integration practices is spreading in several health care fields: in geriatrics through the establishment of multidisciplinary teams and the achievement of end of life integrated programmes to improve the remaining life quality in the hospital health care; in psychiatrics through the creation of health care pathways encompassing social networks and emphasizing the role of the patient who is responsible for his own mental health; in pain therapy through analgesic integrated treatment aiming at improving patient's life quality; in general medicine to especially prevent against the disease and to improve the physician-patient relationship; in internal medicine through the implementation of integrated health care programmes for patients, who suffer, for example, from diabetes and arthritis, whose objective is to encourage self-healing and treatment efficiency [Bell et al., 2002].

In all the situations mentioned above it is difficult to merely talk about "integrated medicine", since we are confronted with real integrated health care typologies which entail not only physicians, but also hospital nurses,

physiotherapists, social workers, psychologists, psychiatrists working in multidisciplinary and multi-professional teams who plan the complete health care pathway of the patient and treatment programmes provided: this also leads to integrate hospitals, community care and health visitor services for the patient as well as community and health care services, between professionals' formal service networks and caregivers' informal networks and of other community subjects entangled in the patient's network (friends, colleagues, neighbours etc.). Certainly it deals with a dynamic process and yet too far to be specified, but the need to merge areas of theory and practice which were apparently distant before, such as the integrated medicine and integration area about hospital-territory or community-health care, seems to be increasingly obvious. Hence, it is not possible to take into account any practice of integrated medicine without considering it within the context of the organizational model in which it occurs and how much of this model results to really belong to the integrated health care.

### A model of analysis

Starting from what Boon et al. [2004] suggested, the attempt to set out a model of analysis can be made in order to assess how much an ideal integrated health care really takes place in the realistic spreading practices. There are four key-components to be taken into account:

- *philosophy and values* of each practice regarding integrated medicine/integrated health care as basic components to understand the underpinning vision and the assigned mission to the integration within the context of social and healthcare service systems;
- *structure* of the applied healthcare integration, in terms of constituent and connective components which reports of the integrated healthcare model used;
- *integration process* which encompasses both interaction methods between patient and professionals, and interaction dynamics among professionals themselves;
- *results* in terms of *outcomes*, essential and important changes in the patient's health conditions.

For each of the key-components indicated as model components it should be possible to identify a number of indicators which allow to assess the implementation level of the several methods specific to each practice regarding integrated medicine/integrated healthcare. So that it should be possible to accomplish to:

- specify the different existing models of integrated health care (which include CAM) in terms of philosophy, *vision* of reference institutional context, *mission* of different CAMs provided in each practice regarding integrated medicine/integrated healthcare;
- identify organizational, professional, financial, cultural or any other typology of factors which represent, in the different integrated healthcare models, constituent and connective components which report the integrated healthcare model used;
- outline interactional dynamics of the integration process which specify both professional-patient relationships – including implemented methods of in-

formed consent, information and protection for the patient – and relationships among professionals themselves within the different integrated healthcare pathways;

- assess outcomes obtained through integrated healthcare pathways which have been identified in terms of actual efficacy and appropriateness regarding clinical services provided, as well as in terms of equity and quality perceived by the health care community.

### The reason for an International Monitoring Unit

In order to apply this model of analysis to different practices regarding integrated medicine/integrated health care and to compare them, it is necessary to create a national monitoring unit in the Italian regions (at national level) and in countries where important practices have been taking place for ages (the United States, Canada, Great Britain, Israel etc.) which have been standing out in these last years aiming at studying their peculiarities, emphasizing strengths and weaknesses, contributing to an actual upgrading of the controversy regarding the importance and the goals of integration process.

Hence, the Monitoring Unit will be able to carry out research, monitoring and assessing tasks of the actual practices regarding integrated medicine/integrated healthcare in relation with a theoretical reference framework and a model of analysis which aims at identifying the three main level-issues of integration process [Giarelli, 2005: 246]:

- *clinical dimension of integration* (at micro-social level) allows to reconsider the same treatment approach with its most established features: from diagnosis methods to treatment pathway, from physician-patient relationship to *malpractice* issue and clinical risk management;
- *organizational dimension of integration* (at meso-social level) allows to deeply review the conventional hierarchical health care work: indeed, broadening the continuum health care it is possible to include non-biomedical and non-professional health care work typologies which were excluded before, according to a new multi-professional and interdisciplinary functional logic;
- *structural dimension of integration* (at macro-social level) allows to question about the new interaction methods implemented by several actors involved – health care professionals, State, community, health care-industrial field – within a medical care system which seems to show again pluralistic features, even though in a different way compared with the past when biomedicine had the monopoly control during the 20th century.

The Monitoring Unit could avail itself of a Scientific Committee composed by National and International experts of integrated medicine, beyond representatives of Italian regions, National Healthcare Service professionals, CAM and integrated medicine scientific societies. Furthermore, the Monitoring Unit should work in close relationship with other existing monitoring units (epidemiology, social and healthcare policies etc.) in order to include spe-

cific data of own interest which have been identified within the broadest development of social and healthcare service systems, which appears to be more complicated in complex societies due to a number of challenges, integrated medicine could try to find an answer for.

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