REVIEW ARTICLE

Regional Health Systems and non-conventional medicine: the situation in Italy

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Abstract In Italy the different regional healthcare models are structured, in order to provide both a single theoretical framework and to enable direct comparisons. In this paper we examine whether and how the regional healthcare systems include alternative medicines and, if so, whether this can be specifically attributed to the different organisational models in place. This analysis will be preceded by a framework to show how in Italy there is a constant and continuous increase in non-conventional medicine (NCM), determined from a research by citizens of a person-centred medicine and preventive. We shall examine how NCM has been incorporated in the National Health System (SSN) in Italy, from the time the Regional Health Systems were set up, and the factors that have contributed to their inclusion or exclusion. After a brief synopsis of the process of growth, distribution and recognition of NCM in Italy, we shall describe how it has been incorporated and consolidated in the regional healthcare systems.

Keywords Personalised medicine · Complementary and alternative medicine CAM · Preventive measures · Regional health delivery · Dominant health system · Italy

Introduction

Complementary and alternative medicine (CAM) or nonconventional medicine (NCM), as this broad domain is defined in Italy considering that they are neither part of the

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once described as alternative medicines—as opposed to official medicine—then promoted to complementary, and now defined as non-conventional. The definition of NCM is clearly adopted both by the European Parliament ("Resolution on the status of non-conventional medicine", 1997) and by the Council of Europe ("A European approach to non-conventional medicines", 1999).

for a personal rapport with the physician, the special attention given to the individual nature of the patient, the

consideration of the individual as a whole—physical,

psychological and social, the appreciation of an approach

that values a patient's resources, involvement in the process

of diagnosis and cure [2, 3].

In the literature in general [1], and in particular in the field of sociology, there is a growing interest in what were There are many reasons for the appeal of NCM: the need

dominant health system nor included in the mandatory

curriculum for graduation as a Doctor of Medicine (MD) in

Italy, embraces a variety of healthcare cures which are more

and more consolidated worldwide, although varying from

continent to continent and country to country, as do the levels of recognition and degree of regulatory legislation

In Italy the debate on the effectiveness of cures and

This "assimilation" ranges from services that recognise and

The debate does not seem to consider the fact that the

validity of the various NCMs is still ongoing. Despite this,

some Servizi Sanitari Regionali (SSR)-Regional Health

support them as forms and methods of care on a part with

biomedicine, which is the dominant health system in Italy, to

those that do not recognise evidence of their curative value.

public makes constant use of NCM to address their health

problems and that more and more doctors practise and

Systems—use them to integrate biomedicine.

throughout the world.

prescribe them.



NCM is particularly appreciated by those who seek an approach that considers the person as an organic whole. Such a gestalt includes evaluation of organic parameters and the patient"s account of the sickness and case history, while maintaining freedom of choice and treatment.

The growth and spread of NCM/CAM in Sociology in particular, on the other hand, is more complex [2, 4–9]; for some they represent post-modern forms of expression—satisfying a desire for self determination and freedom of choice of healthcare. For others they are harbingers of the decline of the dominant conventional medical ethic, prompting increased individual responsibility for one's own health. For still others [1], they are cultural phenomena, which seek to build a new way of looking at sickness and healing.

The holistic approach and privileged patient-carer relationship constitute the first cultural aspect of NCM. For those who are drawn to these approaches, healing is not a mechanical act but a process that develops out of their own biography. CAM represent a source of knowledge, capable of bringing about healing, of giving meaning to discomfort and disease, of providing personalised responses that also address the need for a social identity.

To speak of "NCM" is to refer to both new forms of treatment and cure, and to a complex process that includes institutional programmes, personalised programmes, the life stories of individuals and their experiences of sickness.

Almost 11 million people in Italy use NCM (a term, along with CAM, that is neither used in the official documents of the Italian National Health System nor by the Ministry of Health) through their treatments and experience, along with thousands of doctors who use them daily.

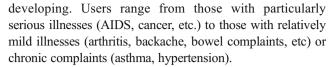
Despite this, their legislative status and degree of inclusion of NCM still varies greatly across Italian Regional Health Systems (SSR).

Taking this as our point of departure, we shall first describe the overall healthcare framework and the characteristics of those who choose NCM. Then we shall look at the level of recognition across Italy, before examining some specific regional cases. We shall see how different regional healthcare models implement different forms of legitimacy for NCM. The regional models considered will be only those identified in the literature [10] as ideal types (in the sociological sense).

We shall therefore examine healthcare in Lombardy, Tuscany and Campania, and their levels of inclusion of NCM. We shall try to establish whether or not there are paths for inclusion of NCM that are the result of the organisational models of the regional healthcare systems considered.

NCM: a growing phenomenon

In this section, we describe briefly how the increasing use of CAM is spreading in all countries, both industrial or



There are many reasons why people, irrespective of social rank and gender, seek unconventional treatments: the need for a new patient-doctor rapport, personalised treatment, a holistic view of the person, and others, but also for preventive action, able to take account of individual needs (person-centred medicine) as we have seen above.

Let us first take a closer look at the incidence of CAM usage.

Over 80% of the worldwide population makes use of traditional, complementary or alternative medicine. According to the World Health Organisation (WHO), half the entire European population has tried a CAM.

Despite the growth of CAM in Europe and worldwide, there are few data available documenting this. In the literature [3], articles can be found outlining a framework of the CAM most used in the different European countries, in Australia, Japan and the USA [11–15], but there is still not a database enabling a comprehensive overview, or even a comparison among different countries and different healthcare systems.

Research conducted in Europe suggests that three out of four Europeans are familiar with homeopathy and, of these, 29% (about 100 million Europeans) use it for their healthcare.

Research carried out in the USA in 1997 showed widespread use of alternative therapies, with percentages between 32% and 54%, and greater diffusion amongst women. Other research [16, 17] shows that minors treated with complementary and alternative medicine (CAM) represent about 12% of all in the age bracket.

In Great Britain, research carried out on behalf of the Research Council for Complementary Medicine shows that every year 10% of the population consults a specialist in alternative medicine. Some surveys [18, 19] show that 16% of General Practitioner doctors (GPs) practise some form of CAM, and that in 40% of GP surgeries these types of therapies were available. More recently, in England it has been estimated that between 10 and 28% of adults use CAM [16, 20, 21], while the figure for minors ranges from 18% to 37% [16, 17].

In France, more than 49% of the population makes use of some form of complementary medicine [11, 22–24]. The most common CAM are homeopathy, acupuncture, thermal cures, osteopathy and chiropractic. Homeopathy is mainly practised by doctors and at some public hospitals; about 10,000 are practitioners who have attended officially recognised courses. About 46% of Germans and 35% of Britons make use of CAMs.

In Japan, 60% of the citizens of Tokyo claim to use nonconventional treatments, the most important are: phytotherapy (herbalism), acupuncture and shiatsu massage.



A survey carried out by the University of Adelaide and the South Australian Health Commission found that 30% of the population uses natural medicines, the most common being chiropractic, acupuncture, naturopathy, massage, phytotherapy and homeopathy. It was also found that Australian women more frequently use CAMs than men.

In Canada, research carried out at the end of the nineties showed that 15% of the population use CAM.

A more recent study highlighted the multi-dimensional, multidisciplinary roles that traditional medicine and NCM play, and the interest shown in them by international institutions: at the end of 2010 the North Atlantic Treaty Organisation (NATO) set up a research group, the NATO Integrative Medicine Group.

On the basis of research carried out in Italy [25], 13.6% of the population—about 8 million people—stated that they had used some form of CAM in the 3 years preceding the survey.

This confirms a trend already detected in 1999, of a growing acceptance of the validity and usefulness of therapies [16]. Among the various NCMs, homeopathy is the most widely used (7% of the population), followed by manual treatments (6.4%), and physiotherapy (3.7) and acupuncture (1.8%).

These figures have remained stable, as has been documented [26], despite the erosion of purchasing power of the average Italian family, for whom, in most cases, treatment must be self-funded, with the exception of those with private health insurance schemes (managers, journalists).

Women are the most frequent users of non-conventional remedies in general (15.8% women, 11.2% men), as is the case for the specific treatments of homeopathy (8.8%, as against 5.1% for men) and phytotherapy (4.8%, as against 1.5%). Manual treatments and acupuncture are less differentiated by gender. Most users are aged 35–44 years, although users of acupuncture tend to be older.

Managers, entrepreneurs and freelance professionals are the professions that have been the most frequent users in the last 3 years (23.3%), followed by office workers (21.6%) and manual workers (12.5%).

Children aged between 3 and 5 are the highest subgroup using homeopathic cures—10.7% of the total age group. It is not surprising to note that these children frequently come from family contexts in which there is already significant use of such therapies: 31% of infants and children treated with NCM have parents who also use such therapies. In the case of children with just one parent who avails of NCM, it is invariably the mother. This trend is also confirmed by research carried out in other countries [16, 27–29].

Most Italians favour only one type of non-conventional therapy (69.2% of cases), while 21.1% claim to use two (homeopathy and phytotherapy in 35.5% of cases; homeopathy and manual treatments in 30.8%). More women

than men use two or more NCMs in combination—in the vast majority of cases this is one NCM and allopathic medicines (73.5%), in particular homeotherapy and phytotherapy.

The data also shows ever greater awareness of possible and different health and health-related issues, not just confined to NCM, but also in relation to quality of life [30], the environment [29], preventive and personal medicine and health awareness in general.

Despite this, the latest official statistical data of the Italian National Institute of Statistics [25], shows a fall in the number of Italians using NCM—by about a million persons, compared with previous figures. By age group, there are falls among the 25–54 males, the elderly, and among those resident on the Italian islands. Use of NCM by infants and children up to the age of 14 remains stable. The decreased use concerns all therapies considered and, in particular, manual treatments (osteopathy, chiropractic). Acupuncture and phytotherapy remained stable, while use of homeopathy grew [31].

In Italy there are over 20,000 doctors prescribing homeopathic and anthroposophical medicines. About 3,000 practise acupuncture. There are also many doctors and veterinary surgeons who have completed postgraduate studies [25] to acquire specific skills in homeopathic and anthroposophical medicine.

In Italy homeopathic and anthroposophical medicines are available exclusively from chemists and almost none keep them in stock as a matter of course.

There are about 30 businesses in the Italian homeopathic sector, with over 1,200 employees. Spending on homeopathic cures is about 300 million euros per annum. Italy is the third largest market in Europe for homeopathy, after France and Germany, and the sector grows by an average of 6-7% annually.

Despite the widespread acceptance of homeopathy by Italians, a heated debate is still underway among groups of doctors pro and contra.

In Italy, different sources reveal the ever-growing appeal of CAMs, in particular this is shown in Table 1.

The long road from breaking down barriers to legal recognition

The increase in interest and widespread use described above has not been accompanied by a uniform level of formal legitimacy, despite the fact that in public opinion and for many doctors such recognition is now firmly established. This patchwork regime of different official statuses is also found among other European countries and worldwide. In some countries, CAMs are recognised and reimbursed, even if only partially [32–35].



Table 1 The ever-growing appeal of CAMs in Italy

Source	Year	Description
ISTAT	1996-99	9 million Italians use CAMs (15.5%)
ISTAT	2005	8 million Italians use CAMs (13.6% of the population). The most frequently used are homeopathy 7%, followed by osteopathy and chiropractic 6.4%; physiotherapy 3.7%, acupuncture 1.8%
ABACUS	2003	30% of Italians are familiar with the terms "traditional medicine" and "non-conventional medicine"
DOXA	2003	23% of the population use CAMs
ISPO	2003	65% of Italians are familiar with the terms "traditional medicine" and "non-conventional medicine" and understand some basic concepts.
FORMAT	2003	31.7% of Italians have used CAMs at least once; 23.4% use CAMs regularly
CENSIS	2003	50% of the population consider CAMs useful; more than 70% would like to see them reimbursed by the National Health Service; 65% would like to see more controls by the health authorities
Menniti-Ippolito et al.	2004	Follow-up over 3 years of 52,332 families(140,011 persons): 15.6% use CAMs (homeopathy 8.2%, manual therapies 7%, phytotherapy 4.8%, acupuncture 2.9%, other CAMs 1.3%
EURISPES	Italy Report 2006	10.6% of the population choose CAMs
CENSIS	2008	23.4% had used CAMs in the previous year (in particular homeopathy and phytotherapy)
EURISPES	Italy Report 2010	More than 11 million choose CAMs, 18.5% of the population; by region: Northwest 21.9%; Northeast 17.9%; South 5.4%

Source: Istat [25], Irer [45], Roberti di Sarsina [26]

In some countries of the European Union, CAM can be supplied by the healthcare system, are included in training for medical personnel and are found in the private healthcare market.

Some countries have for some time formally accepted these forms of treatment and instituted training courses at university level.

In Austria, for example, homeopathic medicine is recognised by the Medical Association, and homeopathic medicines are reimbursed by the National Healthcare System and by some private health insurers. In Belgium, homeopathic medicine and acupuncture were officially recognised in 1999, medicines are reimbursed in part by the National Healthcare System and by private health insurers. In Finland, provision of CAM is reimbursed by the public healthcare system, where specialised medical staff is in place.

In the USA, in 1991 the Senate established the Office for Alternative Medicine within the National Institutes of Health (NIH), with financing of \$5.4 million, in order to enable evaluation of alternative treatments. Studies and courses have been financed so that specialists in complementary medicine can learn to organise scientifically valid trials.

In France, some complementary medicines, such as homeopathy, are practised by doctors who have attended specific, officially recognised, courses. Acupuncture is taught at some faculties of medicine. Medicines are reimbursed by the healthcare system if prescribed by doctors.

In Great Britain, some hospitals provide non conventional treatments. In 1982 the British Research Council for Complementary Medicine was set up.

In Spain, there are provisions under national legislation for alternative or non-conventional medical professions.

In Russia, complementary medicine has been officially recognized since 1993, legally practised and taught. Also in 1993, the Ministry for Health officially recognised reflexology, chiropractic, massage, homeopathy and the Buteyko Breathing Technique. Some guidelines are obligatory in Russia. The use of homeopathy is permitted in all clinics and hospitals.

In India, homeopathic medicine is part of the National Health System, over 250,000 homeopathic doctors and 75,000 paramedics prescribe homeopathic treatments, about 10% of the population (100 million persons) avail of homeopathy.

The road to the national law to regulate the matter of NCM is longer in Italy. At present there is still no national



legislation on NCM and it is not part of the National Health System, although at regional level there are some clinics at which NCM is administered. Some private insurance schemes reimburse provision of NCM.¹

Education in NCM is not included in the mandatory program for graduation in the Italian School of Medicine, which lasts 6 years.

There has been an indirect recognition of NCM in the Ministry of Health Decree (22/7/96), which includes acupuncture and other therapies among the specialist assistance services provided by clinics under the NHS. A subsequent Presidential Decree (no. 271/2000) included acupuncture among the additional, extramural services carried out by specialists. Presidential Decree 29/02/2001, which defines the Essential Levels of Health Delivery (Livelli Essentiali di Assistenza), that is all those Health Assistance procedures, etc. equally delivered to all the Italian citizens by the Italian National Health System, makes explicit reference to NCM. However, in 2002 the levels relative to NCM were revoked.

In 2002 the Italian National Federation of Councils of MDs and Dentists (FNOMCeO) recognised the social status of nine NCMs (acupuncture, traditional Chinese medicine, Ayurvedic medicine, homeopathy, anthroposophical medicine, homotoxology, phytotherapy, chiropractic and osteopathy).² These NCMs were also recognised as being the exclusive remit and professional responsibility of MDs and Dentists.³

The revised Italian Code of Medical Ethics, in force since 2006, includes a specific article (art. 15) on NCMs, confirming provisions already in place under the previous code issued in 1988.

This once again stipulates that the only professional roles authorised to practise NCM are medical and dental surgeons who have attended specific training courses.

A similar document was issued in 2003 by the Italian Federation of Councils of Veterinarians (FNOVI), with an article (art. 30) in their Code of Ethics reflecting the same stance.

On 5th December 2003, the Permanent Committee of Consensus and Coordination for Non Conventional Medicines was set up, open to all healthcare sectors.

There have been several interventions by the Italian Supreme Court (1982, 1999, 2003, 2005 and 2007), ruling that:

- Acupuncture is a medical intervention
- Homeopathic products must be prescribed by a physician
- Practising NCM without a degree in Medicine and Surgery constitutes abusive practice of the medical profession.

The Supreme Court also ruled that Regions can not legislate on the appointment of professional figures and that the institution of new professional associations is the prerogative of the State [26].

In 2006, Italy implemented the European Directive on Pharmaceuticals (2004/27/CE), which includes five articles specifically dealing with homeopathic and anthroposophical medicines. Implementation of this directive meant that homeopathic and anthroposophical medicines existing on the Italian market are legitimate until 2015.

In 2009, the AIFA (Italian Medicines Agency) issued the first guidelines on the quality of homeopathic medicines.

Many other measures have yet to be issued. For example, the administrative procedure for registration of new homeopathic medicines has been on hold since 1995 [26].

Training in Italy still mainly consists of privately run courses—the first school of Homeopathic Medicine was established in 1947 by Antonio Negro.

Recognition of NCM in Italy has been only partial, both because only some NCMs are officially sanctioned and because the NCMs are not included in the range of services offered by the NHS. Nevertheless, the national picture also presents different regional aspects due to the progressive regionalisation of the Italian healthcare system, which we shall examine in the next section.

Purely in terms of the Italian NHS, it seems that CAMs have greater official status in countries like France and Germany, which have social insurance, or mainly private systems, as in the USA, which traditionally are more open to the idea of freedom of choice, to private spending and providers, compared with countries with welfare state-type healthcare services.

NCM in regional healthcare systems

Healthcare systems in the Italian regions

In Italy, one of the principal applications of state policy to devolve powers to the regions is in the case of healthcare, following the lead taken by healthcare systems in other western countries [36]. The slow process was initiated in the 1970s, but concrete changes only began to be seen in the last 15 years [37–39].



For a detailed analysis of the situation of CAMs in different countries of the world, see the article by Paolo Roberti di Sarsina, "The juridical status of non conventional medicine in Italy and in other western countries", published in Antropos & Iatria, no. II, 2003, pp. 72–87

² This recognition follows Resolution no. 75 by the European Parliament (29 May 1997) and Resolution no. 1206 by the Council of Europe (4 November 1999) "On the status of non conventional medicine"

³ Guidelines of the FNOMCeO on non-conventional medicines and practices, Terni 18 May 2002

This was triggered in the mid 1990s with approval of legislative decrees 502/92 and 517/93. These measures established new institutional structures for healthcare in the regions, within a national regulatory system aimed at introducing competition among local health units of the NHS, and within these, methods and techniques of management typical of private businesses.

Regional devolution in Italy, as elsewhere, entailed processes of "privatisation" of the NHS and the adoption of the so-called "administrative competition" style of management [40], subsequently evolving to a form of "administrative co-operation" [41, 42].⁴

The process consisted in transferring powers relative to organisation and management of the healthcare services, within a national regulatory framework, which is still not completely defined, giving rise to a range of different models of governance in the Regional Healthcare Systems.

It is the responsibility of each Region to establish an organisational and regulatory structure for its own regional healthcare services, which leads to a certain diversity, both in the nature of the services offered and how they are regulated.

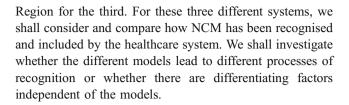
In terms of services offered, the Regions can choose between a high degree of integration between financing and production functions, maintaining both within the ASL (Local Health Authority), or separating the two functions, with the first managed by ASL and the second by the Hospitals.

The Italian healthcare system, in addition to the publicly funded services, also includes a series of accredited private facilities, both commercial and non-profit. All Regions also have limits for spending borne by the NHS [43], and citizens can freely choose the structure they prefer: accredited private or public.

On the basis of these, and other variables documented in the literature [37–39], three models of Regional Healthcare System governance have been identified:

- Competitive model, based on competition among the healthcare organisations, a typical example is the Lombardy Region
- Cooperative model, based on integration between the various healthcare organisations. Found in the central regions and in the northeast (currently undertaking a renegotiated programme)
- Residual-incremental model, which are still based on traditional bureaucratic models of governance to manage systems. This is the case particularly in southern regions.

From these models we shall examine some regional healthcare systems—the Lombardy Region for the first case, the Tuscany Region for the second, and the Campania



The Lombardy model

The Lombardy Region, as early as 1996, opted for a healthcare service model that separates purchasers and suppliers, following the British model. It therefore consists of *Aziende Ospedaliere* (Healthcare Providers), which in addition to the hospital structures themselves, also include most specialist clinics. The ASL (Local Health Authority) should be responsible solely for planning, purchases and control. The system aims to promote competition between public and private players, under substantially equal conditions. Over time, the number of accredited facilities has been increased. The model places particular emphasis on freedom of choice of healthcare structure by the citizen. Suppliers who attract the greatest number of patients are rewarded (money follows the patients).

More recently, the Lombardy Region has revamped the system [10], limiting the number of accredited structures and introducing contractual agreements between ASL and individual suppliers, and spending limits defined for each supplier as in other Italian Regions. In this way, the Region has toned down the element of competitiveness, while still opting for a general orientation towards liberalisation and privatisation of the system.

The Tuscan model

The Tuscany Region follows the model of regional health-care systems based on the principles of cooperation and integration among the various healthcare organisations. The system aims to construct networks of services offered, in which every structure is an essential node of the network, while complementing the other nodes. In this type of system the role played by regional and territorial planning is crucial. Following the logic of rationalisation of offers and containment of spending, it was also decided to establish a limited number of *Aziende Ospedaliere* (Healthcare Providers) [37, 44]. The role attributed to private providers in the public system is regulated, rendering it as functional as possible to the objectives of the public programme.

This model has two variants: the first emphasises the role of negotiated planning (Tuscany, Emilia-Romagna); the second considers agreement and territorial negotiations of less importance, and emphasises regional planning (the Veneto Region).



⁴ For a more detailed analysis of the process of regionalisation and the models of healthcare services, see the article by Stefano Neri (ibidem)

The Campania model

The Campania Region, like other southern regions, has opted for a loosely defined model which oscillates, or at least has oscillated for a long time, between the competitive and integration approaches. One study [44] has defined these models as *bureaucratic*, as they rely mainly on bureaucratic and hierarchical models, with poor mechanisms of managerial planning and control, and an absence of contractual agreements.

The Regions that follow this model are at present heavily in debt and have agreed recovery plans to resolve the issue with the government. This feature of the third model has contributed, in recent years, to encouraging Regions to adopt integration mechanisms, similar to those typical of the second model, considered more compatible with rationalisation and containment of spending.

The models described present specific features, regardless of the aspect of health treated. These specific features are also found in relation to NCM, as we shall see in the next section.

NCMs in the regional healthcare systems

The regional position in relation to NCM still varies greatly from region to region.

In Italy, it is the Regions, which, in the absence of any national regulations on NCM and under the reform of Section V of the Constitution, should autonomously stipulate legislation concerning professions, including the recognition and promotion of NCM.

In February 2007, the Committee of Health Chairpersons for the Italian Regions approved the constitution of a "Technical inter-regional group for complementary medicine", coordinated by the Tuscany Region. The group launched a research project promoted and coordinated by the Emilia Romagna Region, and produced a document on the general criteria for training in complementary medicine.

The Emilia Romagna Region, in addition to establishing a control body for NCM, has promoted a proposal for national legislation. There are also plans for financing of experimental projects and training for specific professional roles. The Regions of Friuli Venezia Giulia and Lazio include NCM within the general lines of regional programming. Liguria has regional provisions for bio-natural disciplines. In January 2009 a census was made in Piedmont for 26 services supplying NCM and seven antismoking centres providing auricular acupuncture.⁵

Other regions such as Umbria and Valle d'Aosta allocate financing for experimental projects.

It is Regions such as Lombardy, Tuscany and Campania that approve numerous targets and experimental projects, as well as setting up bodies to oversee the study and control of NCM.

Lombardy—the first model analysed, has an approach to NCM characterised by research activities aimed at obtaining scientific evidence, following rigorous methodology for evaluation of results. This approach can be defined as a science-based model, which while recognising the importance of NCM, invests regional resources so as to provide a highly structured context for healthcare activities involving NCM. This applies both to scientific evidence and recognition of training. NCM can be practised by doctors, at least within the regional healthcare systems, or professionals duly qualified with certified training. In collaboration with the WHO and the University of Milano, the Region promotes clinical studies evaluating non-conventional therapies.

In 2000, CAMs were introduced among the resources under the Regional Plan 2002–2004 and programmes for evaluation were subsequently initiated, as well as efforts to promote legislation, which would define diagnostic conditions and limits for the various sectors of NCM. Procedures were also defined for training and modus operandi of operators involved in the sector and for conventional healthcare operators [45, 48].

The 2002–2004 Regional Healthcare Plan introduced NCM among its innovative projects, with the aim of facilitating the process of integration between conventional and complementary medicine.

A Technical Scientific Committee was also set up, with the aim of evaluating studies of NCM and defining goals for some complaints where NCM are given preference (premenstrual syndrome, anti-tumoural chemotherapy, pains and aches, etc.). In the meantime, the observational studies continue.

A 4-year programme is then envisaged with the collaboration of the WHO [24], on the evaluation and use of NCM—activities which will continue during the 3-year period 2007–2010. Guidelines on the appropriate use of NCM will be drawn up, as well as on evaluation of the effectiveness of homeopathic products, basic training for manual therapies, and finally, guidelines on basic training in safety in chiropractic.

The Lombardy Region approved the programme (decree July 2007), with relative financing, studies, research and clinical trials of NCM, for both public and private providers (Table 2).

In the year in question a total of 102 projects were financed, ranging from experimentation of patients treatments using NCM (homeopathy, ayurveda, acupuncture, phytotherapy) to evaluation of effectiveness, and to experimentation of therapeutic protocols.

Subsequently, in November of the same year, 57 more projects were approved, for shiatsu, shock waves, phytocomplexes and reflexology, mainly proposed by hospitals and also by individual medical studios (at least four).



⁵ Aress Piedmont, ASR census on non-conventional medicine, January 2009, cicl.

Table 2 Subdivision of projects by provider

Provider	Number of projects
ASP (home care services)	6
Hospitals (with a marked concentration in those of the regional capital)	25
Private hospital foundations	3
IRCCS (research hospital) foundations	13
Research hospitals	3
Physician's surgery	1

Source: Our summary of data provided by Lombardy Region (2008)

Financing was also provided for research on CAMs [45], aimed at drawing up WHO Guidelines for consumer protection in Lombardy.

The final report appears to show that one fifth of the entire population of Lombardy makes use of NCM and that in response to this demand, the regional government felt it only proper to put in place rules and regulations, facilitating informed use by the consumer and appropriate use by operators [45].

The Region also elected to define non-conventional healthcare practices with the name MT/MCA⁶ (Traditional Medicine/Complementary and Alternative Medicine), underlining the need to integrate such techniques with the methods of "official" or conventional medicine [45].

The Regional Healthcare Plan 2007–2009 envisaged the creation of a Regional Observatory to monitor and control policies for integration of NCM, enabling a costs/benefits assessment of impact on public health and regional resources.

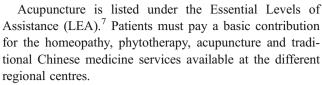
Between 2008–2011 collaboration with the WHO continued to produce guidelines on safety in the use of phytotherapy in conjunction with other medicines; also a review and analysis of the results of the clinical report on NCM: phytotherapy, in order to implement quality of NCM research.

In some structures, both public (Sacco Hospital, for example) and private (San Raffaele Hospital), there are doctors who practise NCM.

Tuscany can be considered the Region best representing the model based on a regulatory approach or at least on the regulation of what can be realistically regulated.

CAMs are formally integrated, promoted and consolidated through measures and financing aimed at providing complementary choices at all Local Health Centres.

The Region has included a specific section on NCM in its Regional Healthcare Plan.



In 2000, a Technical Scientific Committee was set up for evaluation, control, development and verification of projects regarding NCM, and subsequently reconfirmed. There is also a Regional NCM Commission and a Regional Control Centre for NCM.

There is to be a fund to finance integration of NCM in healthcare interventions, in levels of assistance at specialist practices, and to finance projects undertaken by the individual Local Health Centres.

The Tuscany Region [46] has since 1996 begun a process of including NCM in its Healthcare Plans for public structures. At present there are 57 public clinics providing complementary (acupuncture, homeopathy and phytotherapy) and NCM services at health clinics and hospitals. This policy is in line with the principle of freedom of choice as regards therapeutic care, for both citizens and healthcare operators [46, 47].

The Regional Healthcare Plan 1999–2001 includes a specific section on NCM. The special Commission for NCM was set up with the objectives of: identifying strategies facilitating integration of NCM, including the veterinary services; evaluating research proposals; defining, in collaboration with the University and Medical Association, the criteria for accreditation of professional training; promoting the creation of registers or professional associations for NCM.

The commission has carried out research on the popularity of NCM in the Region, the number of services available, and a survey of the opinions of GPs and paediatricians on NCM. Establishment of a fund to finance NCM. The Region has, unlike the national healthcare policies, included NCM in the essential levels of assistance (LEA) and has reconfirmed the LEA for acupuncture, homeopathy and phytotherapy, if provided for under specific projects.

In collaboration with the Universities, specialist training courses and Master's courses (level I and II). A protocol of agreement between the Region and professional associations in the region defines the training paths and accreditation in medicine complementary for operators and training institutes. There are also training courses for pharmacists. Particular emphasis is placed on informing the public about NCM.

A procedure has been defined which Health Centres must follow in setting up complementary medicine services



⁶ Traditional/complementary medicine, the classification includes prescriptive and non prescriptive medicine, biologically based therapies, methods based on the body and therapies based on energy

 $[\]overline{\ }^7$ Essential Levels of Assistance which must be provided by the Regions

within the public healthcare system, after evaluation of doctors' professional experience, the first such in Italy.

A regional law requires that every Local Health Authority should include NCM, listed in the Regional Health Care Range of Fees. The Medical, Veterinary and Pharmacists Association must provide lists of professionals with expertise in NCM, on the basis of requirements defined by the Regional Commission for training in Complementary Medicine.

In 2007 the Tuscany Region approved an experimental medical project for the creation of a medical centre using integrated therapies. The project was begun at the hospital serving the municipalities of Sorano, Pitigliano and Manciano in the province of Grosseto (ASL 9) and integrates bio-medicine, NCM such as acupuncture, phytotherapy and homeopathy, and bio-natural medicine such as craniosacral therapy, shiatsu and naturopathy.

In 2010, a new survey⁸ was carried out on the use and popularity of NCM, the level of awareness of NCM, those who prescribe/recommend them and the structures where they are available.

In regard to availability, the survey considered acupuncture, homeopathy and phytotherapy. The services were supplied in special healthcare centres, mainly private structures (35.5%; 34.7%; 26.7%), followed by public structures (31.2%; 26.9%; 13.3%) and private with public access (29.3%; 16.7%; 15.9%)

Those who recommended NCM were mainly relatives or friends (38.4%), spontaneous initiative (33.8%), GPs (33.1%), specialist physicians (30.5%) and pharmacists (10.2%).

In **Campania** the trend is toward promoting scientific debate, training of operators and informing the public of the possibility of using NCM.

Different decrees have been approved, providing NCM-related support for public and private structures in the territory [49].

Decrees concerning training and financing of projects were passed between 2001 and 2004. In March 2001, a Regional Commission for NCM was established.

Following resolution no. 3589 in December 2003, and policies for division of funding for research and support by the Local Health Authority for private centres in the regional territory, the Region assigned 3 million euros to NCM, later increased to 4 million euros.

Subsequently, with decree no. 190 of 21 September 2004, the Campania Region financed 23 projects relative to NCM (Table 3) for an overall 1,396,966 euros. The projects

Table 3 Subdivision of projects by provider

Provider	Number of projects
ASL NA/1	12
ASL NA/2	2
Hospital structures (Monaldi-Santobono)	2
ASL SA/03	1
ASL CE/1	2
Hospital structures (Rummo)	2
Hospital structures (Moscati)	2

Source: Our summary of data provided by Campania Region (2004)

range from training and updating in NCMs, training of doctors in specific NCM, treatment of patients, as well as raising awareness of schoolchildren on specific themes.

The action taken by the Campania Region may be considered as preliminary to more concrete and intensive distribution of public structures supplying NCM in the territory.

Although the three models considered share some common elements (institution of training projects and financing of experimental projects or use of the various NCM financed by the individual Regions), they each have their own specific characteristics. The Lombardy model aims to validate use of NCM scientifically and within the medical profession (Medical Association, WHO, other medical professions). It promotes the scientific approach, but subject to rigorous control and approval by the regional authority. Aiming to ensure effectiveness, the Tuscan approach to NCM relies on the network model, with close provincial and ASL ties to the Region (creation of at least one centre for NCM in every territorial area). The process of institutionalisation/integration of NCM springs from high awareness at grassroots level and action by local players.

The Region goes beyond a purely control and legislative function to increase the level of services supplied in the territory.

More in line with the traditional bureaucratic type model of regional healthcare policies, although poorly regulated, the Campania Region follows a model of bureaucratic legitimisation that responds more to top-down directives and circulars rather than assuming an active role on the ground, even while financing specific projects.

The Regions not only present differences in terms of services offered but also in terms of use by the public.

The most recent data supplied by ISTAT [25] indicates that action and/or legitimisation by the Regions in relation to NCM (defined in the research report as non-conventional therapies) is not strictly proportional to the appeal and use of NCM. It is not high consumption that determines greater inclusion of NCM in the Regional

⁸ ARS Tuscany, complementary medicine, bio-natural and wellbeing disciplines in Tuscany, Survey 2009, Archives of the Regional Healthcare Agency (ARS), Tuscany, no. 56, 20011

Table 4 Persons who in the 3 years prior to the survey, have used at least one type of non-conventional therapy, by region and geographical area, 1999-2000 and 2005 (per 100 persons of the same zone)

TERRITORY	At least one type		Acupuncture		Homeopathy		Phytotherapy		Manual treatments		Other non-conventional therapies	
	1999-2000	2005	1999-2000	2005	1999-2000	2005	1999-2000	2005	1999-2000	2005	1999-2000	2005
Lombardy	19.0	18.3	3.6	2.2	10.7	10.2	4.7	4.7	8.6	8.8	1.6	0.5
Toscany	19.3	15.5	3.3	2.5	9.5	7.5	5.6	4.3	8.7	7.4	1.4	0.3
Campania	5.9	4.8	1.2	1.0	2.5	2.0	1.6	1.2	2.7	2.0	0.7	0.1
GEOGRAPHICA	L AREAS											
North-West Italy	20.1	17.9	3.8	2.4	11.4	10.2	5.9	4.7	9.2	8.4	1.6	0.5
North-EastItaly	24.7	21.9	4.0	2.6	13.1	11.4	8.6	6.7	10.7	10.7	1.8	0.7
Central Italy	16.1	13.6	3.0	2.0	8.2	6.8	4.7	3.6	7.4	6.3	1.4	0.3
Southern Italy	6.4	5.4	1.3	1.0	2.6	2.0	1.8	1.3	3.0	2.6	0.6	0.2
Italian Islands	9.4	7.0	1.9	1.0	4.7	3.4	3.0	2.1	4.0	3.0	0.7	0.2
Italy	15.5	13.6	2.9	1.8	8.2	7.0	4.8	3.7	7.0	6.4	1.3	0.4

Source: Our summary of ISTAT data (2005)

Healthcare Systems, but rather general choices of healthcare policies by public decision-makers in favour of models of inclusion.

The Regions in the north of Italy show the highest use, in particular those in the northeast (21.9%), less in the northwest (17.9%) and markedly less in the Regions of central (13.6%) and southern Italy (5.4%). The territorial difference is still more pronounced in the case of homeopathy—11.4% in the north east, 6.8% in the centre and only 2.0% in southern Italy.

Non-conventional therapies are most used in the Province of Bolzano (34.3%), in Valle d'Aosta (24.1%), Veneto (23.4%), the Autonomous Province of Trento (22.1%) and Friuli Venezia Giulia (21.4%).

The three Regions considered here are in line with the trend by geographical area (Table 4).

Users in the south are the most dissatisfied with nonconventional therapies; the most satisfied are those in the Valle d'Aosta, for all the therapies practised (Table 5). Table 5 in general shows that manual treatments appear to be the most appreciated (77.9%), followed by homeopathy (71.3%), physiotherapy and acupuncture.

The three regional models are in line with the national trend (no variance).

The most common usage is traditional medicines but also homeopathic and phytotherapeutic products (44.2%). At a national level, 29.3% of the population uses mostly homeopathic products (Table 6).

Table 5 Persons who in the 3 years prior to the survey, have availed of non-conventional therapies, by number of non-conventional therapies used and benefits users state to have obtained from each type of therapy, by region and geographical area, 2005

TERRITORY	Number of	non-convention	nal therapies used ^a	Benefits obtained from each type of therapy ^b				
	One type Two types		Three or more types	Acupuncture Homeopathy		Phytotherapy	Manual treatments	
Lombardy	68.5	21.4	10.1	64.4	72.1	69.0	81.0	
Toscany	69.0	23.1	7.9	50.3	66.9	71.7	76.3	
Campania	77.1	15.8	7.1	53.1	61.1	56.5	69.2	
GEOGRAPHICAL	L AREAS							
Northwest Italy	67.6	21.7	10.7	63.8	72.9	69.3	79.7	
Northeast Italy	65.9	23.7	10.4	59.5	71.2	72.4	78.6	
Central Italy	71.8	19.8	8.4	63.3	71.7	72.6	78.6	
Southern Italy	77.0	15.6	7.4	51.4	62.8	59.6	70.5	
Italian Islands	74.0	17.5	8.4	67.2	70.5	71.4	74.2	
Italy	69.2	21.1	9.7	61.1	71.3	70.3	77.9	

^a Per 100 users of at least one type of non conventional therapy



^b Per 100 users of individual types of non conventional therapy Source: Our summary of ISTAT data (2005)

An interesting and striking fact is the high exclusive use of homeopathic medicine in the Campania Region (23.7%)—6.7% more than the national average. It should be noted that this Region has long experience of training in homeopathic medicine.

It seems clear that use by individual citizens has not been a factor in the inclusion of interventions by the various Regions, rather the public decision-makers seem to act in accordance with the individual model of Regional Healthcare System in question, also as regards inclusion of NCM.

Thus the Lombardy decision-makers play a major role of control, in line with the model of management in the Regional Healthcare System. The Tuscan counterpart functions more as a promoter, in keeping with the network model. Decision-makers in Campania seem more inclined to respect bureaucratic procedures (compliance with EU directives, and/or with the Committee of Healthcare Chairpersons).

Conclusions, recommendations and outlook

Despite growth in popularity of NCM, compared with other European countries Italy is considerably slower in recognising and legitimising NCM. Nevertheless, there are local healthcare systems that have experimented with and formally accepted such practices in hospitals, centres and regional structures. Certainly it is the case that recognition is still not an integral part of the National Health Service.

As has been noted [50], Italy is among those countries in which there is highly restrictive legislation of the "exclusive

monopoly" type, which considers the practice of medicine by non-qualified personnel as illegal.

The overall picture of the development and process of inclusion of NCM in the Italian Regional Healthcare Systems appears to be still highly fragmented and varies greatly among not only the regions in general but also within the three models of healthcare systems analysed. The absence of national legislation that clearly recognises and endorses NCM in the NHS and in regional healthcare services continues to hamper the process of legitimisation of NCM, also in the choices made by the regional healthcare services discussed.

The analysis of the three regional healthcare systems seems to show that the basis for choices made by regional decision-makers is not the universalist principle of guaranteeing medical care, including NCM, but rather by following a selective principle.

The different options that emerged from the analysis of the three models of regional healthcare systems exemplify the sometimes radically diverse approaches between Regions. The fact is that such approaches seem to be influenced by the different position of associations of medical professionals and scientific research institutes, whose mere presence, even if only indirectly, could in some measure "condition" choices made by decisionmakers.

One example of this type of "conditioning" can be seen in the model of inclusion found in Lombardy, which relies heavily on "traditional" clinical validation of NCM, defining guidelines in collaboration with traditional organisms representative of the orthodox medicine. In fact, Lombardy is not only a region with a large number of

Table 6 Persons who in the 3 years prior to the survey have used homeopathy or phytotherapy, based on use in the last 12 months of homeopathic products, phytotherapeutic products and traditional

medicines, by region and geographical area, 2005 (per 100 persons of the same zone who in the 3 years prior to the interview used homeopathy or phytotherapy)

TERRITORY	Only homeopathic or phytotherapeutic products	Mainly homeopathic and phytotherapeutic products but also traditional medicines	Mainly traditional medicines but also homeopathic and phytotherapeutic products	No use of homeopathic or phytotherapeutic products	Total
Lombardy	17.5	27.2	45.6	9.7	100
Toscany	13.0	26.0	49.6	11.4	100
Campania	23.7	24.4	38.0	13.9	100
GEOGRAPHICAL A	AREAS				
Northwest Italy	18.0	28.7	44.8	8.4	100
Northeast Italy	14.2	31.6	47.0	7.3	100
Central Italy	17.3	27.3	44.0	11.3	100
Southern Italy	23.3	28.2	34.3	14.1	100
Italian Islands	16.6	27.5	39.3	16.7	100
Italy	17.0	29.3	44.2	9.5	100

Source: Our summary of ISTAT data (2005)



pharmaceutical manufacturers [51] but is also home to many pharmacological research centres, such as the Mario Negri Institute, whose managers miss no occasion to state that NCM are "poorly effective". Tuscany, on the other hand, has some leading manufacturers of homeopathic or natural medicines, and its politicians (Health Chairpersons) have made clear decisions in favour of NCM.

Certainly the type of organisational orientation employed by the different regional systems is important. A network model for the various healthcare resources, as in Tuscany, is more likely to be open to innovation and diversity.

Concerning the Campania Region, more than a programme to include NCM, it is a case of a bureaucratic route to NCM, in compliance with outside indications and without strong internal feelings pro or contra, as we have seen in the other two regions considered.

Even if the choices made by Regional Healthcare Systems in regard to NCM are still tentative, it must be emphasised that it is precisely at this level of government, and regardless of the organisational model involved, that institutional legitimacy for NCM is being created.

Tuscany is not only more open to NCM, but also to encouraging important local trials, both at ASL and hospital level. The Lombardy region is more inclined to treat NCM as an experimental option, initiating projects at ASL and hospital levels, but with the objective of defining protocols for evaluation of results.

In Campania, despite specific regional financing, the road to experimentation and also validation still seems to be uphill, or in any case lacks the political willpower and relies solely on the bureaucratic apparatus to achieve progress.

Concerning Italy as a whole, it is a case of a slow process of inclusion, preceded by a phase of domestication, as pointed out elsewhere, with once again the scientific medical community legitimising those who can practise NCM—typified by the Medical Association, but also by the rulings of the Constitutional Court, which accepts some NCM only if practised by medical professionals.

The picture that emerges shows that Italy and each region, despite some resistance, will only be open to NCMs, including them in performance in favour of citizens. Many of the requests for preventive interventions and greater attention to the person will be satisfied with the active role of NCM.

⁹ Mara Tognetti Bordogna, "Non Conventional Medicine and medical pluralism. Prospectives and ambivalence in integrated medicine", report presented at the Regional Seminar *The Emilia-Romagna Regional Programme for integration of non conventional medicine*, Emilia Romagna Regional Authorities ASRE, Bologna 8 July 2005, published by the Regional Healthcare Agency, CAMs Observatory, Report 2005



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