

Communication

## The Process of Integration of Complementary Medicines in Public Healthcare Service of Tuscany (Italy)

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### Abstract

Complementary Medicine (CM) is being increasingly used by European citizens in order to increase their overall state of health and well-being, as well as to treat various illnesses and diseases. The interest for these therapies has progressively risen also in Italy and in Tuscany as well. In response to the increasing demand in the past few years by the Tuscan citizens, the region of Tuscany has started their integration in the healthcare service. Since 1996, the Tuscan Regional Healthcare Plans (RHPs) have been considering the role of Complementary Medicine (acupuncture, herbal medicine and homeopathy).

The aim of this article is to describe the pathway and results of the integration process of CM in the public healthcare service in the region of Tuscany (Italy) lasting more than 20 years.

The RHPs of Tuscany have started to incorporate several types of CM treatments (i.e., acupuncture, herbal medicine and homeopathy) in 1996, as described in their specific chapter. This represents the highest degree of integration of such therapies in the Public Healthcare system in Italy.



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Furthermore, the Region of Tuscany decided to include CM in the Essential Levels of Assistance (ELA/LEA) in 2005. Accordingly, a network of 107 public clinics providing CM health services was built (updated to December 2017) and the relative regulations (i.e., laws, bills, resolutions, etc.) were approved by the regional authorities.

The Tuscan experience has shown the feasibility of CM integration into the Public Healthcare Service. This innovative process, which is characterized by an inclusive, modern and sustainable approach to the healthcare, might pave the way for a platform aiming to build integrated Healthcare Systems at a national and European level.

### **Keywords**

Complementary medicine; integration in public healthcare system; Tuscan healthcare service

## **1. Introduction**

Since 1996, the Tuscan Regional Healthcare Plans (RHPs), which generally last 3 years and serve as the main instrument of planning in healthcare matters in the region of Tuscany, have been considering the role of CM.

In the region of Tuscany, complementary medicines are considered acupuncture, herbal medicine and homeopathy that are the medical therapies most diffused among Tuscan citizens and having a good safety profile and “a sufficient level of evidence”. To date, in order to guarantee a proper integration of such disciplines (i.e., acupuncture, herbal medicine, homeopathy) into the Regional Health Service, all of the recent RHPs have included at least one chapter on CM services on the basis of latest scientific evidence [1].

### **1.1 CM in the Regional Healthcare Plans of Tuscany**

All of the recent Tuscan RHPs have been taking into account the role of CM since 1996. Noteworthy, there has been an increasing interest on the issue of CM and patients’ well-being.

The 1996-1998 RHP, containing only a few references on CM, still defined CM as non-conventional medicines: “[...] enhancing non-conventional medicines [...]”, while the 1999-2001 RHP included a whole chapter: “*Integration of non-conventional medicines into health interventions: established by the Regional Committee for Non-Conventional Medicines; Commitment to promoting research on the effectiveness of non-conventional medicines*”. The chapter in the 2002-2004 RHP: “*Integration of non-conventional medicines in health interventions*” set up three regional reference centers for acupuncture and traditional Chinese medicine (TCM), herbal medicine and homeopathy. In the 2005-2007 RHP, these therapies (i.e., acupuncture, herbal medicine, homeopathy, and manual medicine) were defined as complementary medicines and underwent a complete integration into the Regional Healthcare Service and into the Regional Essential Levels of Assistance (RELA). The chapter in the 2008-2010 RHP: “*Complementary and Non-Conventional Medicine for Integrative Medicine*” aimed at defining at least one CM Center for each Local Healthcare Authority and at creating the Center for Integrated Medicine at the Hospital of Pitigliano. The 2011-2015 RHP discussed the role of CM in various chapters (i.e., “*For Pain*

*Control*"; "The Appropriateness of Complementary and Non-Conventional Medicines"; "For Natural Pregnancy and Childbirth"; "Integration of CM in the Prevention and Treatment of Mental Disorders"; "End of Life Treatment"). The latest RHP is under revision.

### **1.2 The Tuscan Regional Law No. 40/2005: "Disciplines of the Regional Healthcare Service"**

The Tuscan Regional Law (RL) no. 40/2005 (Article 43): "Disciplines of the Regional Healthcare Service" established that the department of CM has been officially included in the Regional Structure of Clinical Governance, together with other health sectors such as the Regional Transplant Centre and the Clinical Risk Management and Patient Safety Centre.

More in detail, CM representatives were elected in every health authority and officially entered the Healthcare Council of each provincial hospital and university hospital, the Regional Healthcare Council, and the Regional Bioethical Commission.

It is to note that, to date, the Regional Healthcare Council is not operative anymore but its function has now been taken by the Tuscan Agency/Body of Clinical Government (OTGC). In addition, CM representatives in the Bioethical Commission have been reduced to 1 member.

### **1.3 Specific Regional Laws Concerning CM Training and Practice**

The 2008 Agreement between the Region of Tuscany and the Regional Federation of the Association of Medical Doctors and Dentists, the Regional Committee of Pharmacists, and the Regional Federation of Medical Veterinarians defined the training procedures for CM professionals, as well as the accreditation procedures of training institutions. Moreover, the lists of CM professionals were defined. So far, six private institutes (five in homeopathy and one in acupuncture) have been accredited.

The 2013 Agreement between the Italian State and the Regions and the Autonomous Provinces of Trento and Bolzano [2] defined the terms and requirements to establish the quality certification of CM training and practice in acupuncture, herbal medicine, and homeopathy (including anthroposophic medicine and homotoxicology) by medical doctors, dentists, veterinarians, and pharmacists. The Agreement originated with the Tuscan RL No. 9/2007 [3], which regulates CM training and practice in acupuncture and traditional Chinese medicine, herbal medicine, and homeopathy. More specifically, it stipulates that the professional associations of doctors and dentists, veterinarians, and pharmacists must draw up lists of professional experts in CM based on the criteria defined by the Regional Committee for CM Training, and issued a specific certification. It is to note that the RL intentionally deferred the definition of the criteria to an agreement with the professional associations in order to overcome the problems arising from the "competition" between the Italian State and the Regions [4].

A third Agreement involving the region of Tuscany and the representatives of the Associations of Medical Doctors and Dentists, Pharmacists, and Veterinarians was signed in March 2015, in application of the 2013 Italian State-Regions Agreement [5].

The Regional Commission for CM Training (updated with the Resolution of the Regional President No. 75/2017) is composed of representatives of professional and CM associations, Tuscan universities, directors of the regional CM centers, and experts appointed by the Regional Health Council. The Bill No. 993/2009 also allowed the accreditation of public or private non-

university training centers. According to the 2013 Agreement, university master courses consisting of a minimum of 2-year course may also be accredited [6].

#### **1.4 The Tuscan Regional CM Reference Centers and the Tuscan Regional Center for Integrative Medicine**

According to a 2017 regional survey, there are 107 public CM clinics in Tuscany, of which 73 have been fully integrated into the Regional Healthcare Service. Among these, 44 offer acupuncture and TCM services, 17 offer homeopathy services, 8 offer herbal medicine services, and 4 offer other non-conventional therapies (e.g., manual medicine) [7]. Such structures perform about 30,000 visits each year.

The Tuscan Network of Integrative Medicine, created in 2007, coordinates the public CM Centers and provides a unified system ensuring integration, good CM practice, and patient safety with the purposes of prevention, therapy, and rehabilitation. It was recognized as a “Regional Structure for Clinical Governance” in 2009 and was then re-named as Tuscan Regional Center for Integrative Medicine (TRCIM) in 2017 [8].

To date, it consists of four Regional Reference Centers: the Fior di Prugna Acupuncture and TCM Clinic, Florence; the Herbal Medicine Clinic of the Careggi University Hospital, Florence; the Homeopathic Clinic of Lucca, Cittadella della Salute-Campo di Marte Hospital; the Center for Integrated Medicine at the Pitigliano Hospital [9]. This last center is specifically dedicated to the activities for hospitalized patients.

#### **1.5 The Re-Organization of CMs in Tuscany**

The Resolution No. 1224/2016 [10] reorganized the CM activities, further strengthening their integration into the Public Healthcare Services. In other words, CM has progressively become a key component of the Tuscan Health System as stipulated by the RL No. 40/2005. [11]

This resolution identified “priority areas” according to which Local Healthcare Authorities and university hospitals should ensure access to CM services for all Tuscan citizens. In details, such priority areas are cancer care; pain control; natural childbirth in low-risk pregnancies; gender medicine; prevention and treatment of upper respiratory infections and atopic diseases in childhood and adulthood. They were defined because of the epidemiological relevance of the diseases and of the demonstrated effectiveness of CM.

Its main purposes are: 1) to promote a coordinated reorganization of CM activities; 2) to increase the availability of CM treatments in outpatient and inpatient settings; 3) to optimize the use of human resources without increasing public healthcare costs; 4) to further implement training and professional development into the field of CM in order to guarantee quality and appropriateness in patient care.

#### **1.6 The Interregional CM Group at the National Health Commission of the State-Regions Conference (2007–2015)**

An Interregional CM Group, composed by the majority representatives from the Italian Regions, was established at the National Health Commission of the State-Regions and Autonomous Provinces Conference in 2007. Noteworthy, Tuscany had a leading role. The greatest achievement

of the Group was the approval of the Agreement between the Italian State and the Regions and the Autonomous Provinces of Trento and Bolzano [2] in 2013, which has been already described.

### **1.7 CM in the Regional Tariff Nomenclature**

The Regional Government Resolution (RGR) No. 655/2005, modified by the RGR No. 652/2011, established the role of CM as a new branch in the Regional Tariff Nomenclature, including CM into the Tuscan ELA and specifying the cost of each visit (i.e., 18€; now 24€). The visits were associated with the following code: “CM Visits for Acupuncture, Herbal Medicine, Homeopathy, Manual Medicine”. Furthermore, specific co-payments were planned for these CM services. Exemptions from the co-payment are envisaged only for specific diseases, i.e. cancer patients, and for people with low-income levels.

### **1.8 CM in the Clinical Guidelines of the Regional Health Council**

The Regional Health Council had to edit specific Clinical Guidelines for Tuscan physicians, specialists and other healthcare professionals in which CM was also included. More specifically, the following Guidelines were edited and are available in Italian language at: <http://www.regione.toscana.it/consiglio-sanitario-regionale/linee-guida>; “Pain Control During Labor and Delivery”, no. 54/2014; “Menopause Guidelines”, no. 12/2015; “Back Pain Guidelines”, no. 33/2015; a specific clinical guidance document no. 42/2015; *The Use of Acupuncture and TCM in the Tuscan Healthcare System*”, is available at:

<http://www.regione.toscana.it/documents/10180/12779792/Allegato+parere+n.+116-2014/97f7ab91-89df-4198-8143-dee1a6eebb77?version=1.0>

In addition, to date, a “*Proposal of Insertion of a Section on CM in the Regional Diagnostic-Therapeutic Pathway of Breast Cancer*” (2018) is under revision. Such document takes into account the role of CM as a supportive cancer care issue for reducing the adverse effects of anti-cancer therapy.

### **1.9 Integrative Oncology**

The issue of cancer therapy and patient well-being turned out to be a crucial point for the integration of CM in conventional medical practice in Tuscany. In fact, every Local Healthcare Authority and university clinic now offers “Integrative Oncology” services with the purpose of improving cancer patients’ quality of life and reducing the adverse effects of Chemotherapy, Endocrine Therapy and Radiation Therapy by means of CM treatments. The RGR No. 418/2015: “*Integration of CM in the Oncology Network of Tuscan Tumor Institute*” (TTI, now defined ISPRO), approved on proposal of the Tuscan Institute of Tumors, established the core principles of such integrative discipline [12]. A Regional Work Group, composed by both oncologists and CM experts, was created in order to apply the purposes of the Resolution.

To end with, the “*Bando Ricerca Salute 2018*” (Tuscan Healthcare Research Announcement 2018) was approved in 2018. It contains a specific “CM” subheading in the Line 3 (Oncology), for which 1,000,000€ were allocated [13]. Four research projects concerning the efficacy and effectiveness of acupuncture, herbal medicine and homeopathy were submitted. To date, they are under revision.

### **1.10 Patient Safety in CM and Regional Pharmacovigilance Procedures**

Tuscany proposed multiple initiatives in order to promote patient safety and to activate pharmacovigilance procedures on “natural” principles, drugs and food supplements. Firstly, herbal medicine phone consultation services (i.e., “*Linea Verde Pronto Salute*”) were implemented for both patients and healthcare professionals at the Empoli Hospital. The service was interrupted after the regional Herbal Medicine Center was moved to the Careggi Hospital and the Homeopathy Center was moved to the Lucca Hospital Information Service. Secondly, the crucial “*Safety Assessment of Complementary and Integrative Medicine*” Conference was held in Empoli in 2003. National and international CM experts participated in the conference. In addition, a specific “*Decalogue*” on CM, promoted by the Italian National Institute of Health, the Italian Pharmacology Society, and the Tuscan Regional Center for Herbal Medicine, was published in 2010 to inform citizens about the safety of CM. Thirdly, the CM Tuscan Reference Centers collaborated with the Italian National Institute of Health and other CM scientific societies in the national campaign: “*Knowing CM to Use Them Best*” in 2009–2010. To end with, a regional educational course on “*Clinical Risk Management and Patient Safety in CM*” was set up in 2009–2010 by the Tuscan Center for Integrative Medicine in collaboration with the Regional Center for Risk Management for Health Professionals [14].

### **1.11 Communication and Information for the Public**

Since the first steps to the integration of CM into the Regional Healthcare Systems, it was very clear the crucial relevance of disseminating scientific results to both healthcare professionals and the public. For this purpose, in 2004 the regional journal *MC TOSCANA* (CMs in Tuscany) was founded. To date, the journal has published 41 issues. The three yearly issues are edited by the Reference Center for homeopathy of Lucca; every issue contains articles concerning legislation and news in the field of CM, as well as scientific studies conducted by the Regional Reference Centers of CM and national and international news in the field of research in CM. Paper issues are sent by mail to about 1,500 readers, and electronic issues are available online at <http://www.regione.toscana.it/cittadini/salute/medicine-complementari>. Information on the main initiatives and steps, which led CM to constitute a core element in Tuscan Healthcare System, are available too.

Another crucial initiative aimed at informing Tuscan citizens about CM is the 2005 Regional Information Campaign: “*Now You Can Choose also CM, if You Want*”. The campaign was launched by the region of Tuscany to inform citizens about the integration of acupuncture, homeopathy and herbal medicine into the ELA of the Regional Health Service.

To end with, the participation to different events and trade shows, both in and outside Tuscany (e.g., the international “*Terra Futura*”, Florence, from 2004–2012; “*Eco & Equo*”, Ancona, 2004; “*Sustainability and Health Opportunities Forum*”, Florence, 2016–2017), represent other important initiatives aimed at promoting a deeper knowledge of CM services among citizens.

### **1.12 Post-Graduate Courses in CMs in Tuscany (2006–2016)**

The issue of high-quality CM training has always been a key point to the region concerning both good professional practice and CM integration into the Healthcare Services in Italy, that is, a country that has never approved a Parliament Act in this field.

All Tuscan universities (i.e., University of Pisa, University of Florence and University of Siena) gave a unique contribution in terms of CM training by providing both Master and Refreshing courses. More specifically, the main educational initiatives promoted by the Tuscan universities are listed as follows:

- Faculty of Pharmacy, University of Florence (2006-2007): level II Master in Traditional Chinese Phytotherapy;
- Faculty of Medicine, University of Florence (2006-2017): level II Master course in Acupuncture and TCM;
- Faculty of Medicine, University of Florence – Empoli Headquarters (2007-2011): level II Master course in Clinical Phytotherapy;
- Faculty of Medicine, University of Siena (2009-2018): level II Master course in Integrative Medicine;
- Faculty of Pharmacy, University of Pisa (2008-2010): level II Master course in Aromatic and Medicinal Plants;
- Faculty of Medicine, University of Florence (2011-2014): Master courses in Natural Medicine and Integrative Medicine (2015-2018).

### **1.13 Private CM Schools Accredited by the Tuscan RL No. 9/2007**

Private CM schools were primarily interested to the promulgation of a law concerning the requirements of quality CM training in order to encourage the accreditation process. In fact, private schools (many of which had a ten-year activity background) proposed various criteria establishing the quality of CM training over time, although they were not recognized neither to a regional nor to a national level.

The RL No. 9/2007 and the 2013 State-Regions Agreement promoted a crucial step for such schools' accreditation process which was completed after an in-depth preliminary investigation by the Regional Departments after the formal approval by the Regional Committee for CM Training and, accordingly, after a Resolution of the President of regional government. In details, the accredited private schools were: 1) the Traditional Acupuncture School of Florence; 2) the Classical Homeopathy School "M. Garlasco", Lycopodium Association, Florence; 3) the Homeopathy School "Effatà", Lucca; 4) the Veterinary Homeopathy School "Rita Zanchi", Cortona (AR), 5) the Classical Homeopathy School "Pieria", Pisa; 6) the SIOMI Homeopathy School, Florence. To date, the new accreditation process according to the State-Region Agreement is still ongoing.

### **1.14 Regional Continuing Medical Education Accreditation for CM Training Events**

Since 2005, CM training events promoted by Tuscan Public Healthcare clinics are accredited at the regional level as Continuing Medical Education (CME) activities.

The exemption from the obligation to collect annual CME credits for students of CM courses by accredited institutes education in acupuncture, herbal medicine and homeopathy for medical doctors, veterinaries, dentists and pharmacists was approved in 2008 at a regional (RGR n.643/2008) and in 2012 at the national level (State and Regions Agreement n.101/2012).

Recently in 2018, a new national regulation for CME has been approved which reconfirmed among its training objectives the evaluation of the effectiveness of the CM in relation to the outcome results and areas of complementarity with the conventional medicine, and extends the

CME accreditation also to CM educational events at all the health professions (paramedical). It also arranges the exemption from the acquisition of CME compulsory credits (150 in 3 years) for students who take the three-year courses of acupuncture, herbal medicine and homeopathy accredited according to the State Regions Agreement of 2013 (Available at: <http://ape.agenas.it/ecm/normativa.aspx>).

### **1.15 Activities within the European and International Context**

The region of Tuscany has always promoted the organization of congresses and conferences in collaboration both with national and European/international institutions. The main initiatives are listed as follows:

- National Conference: *“Non-Conventional Medicines in Hospital”* (Lucca, 2002);
- Organization of the European Congress: *“Herbs, Environment and Citizens’ Health”* (Brussels, November, 2003);
- International Conference: *“European Traditional Medicine”* (Vinci, 2007);
- International Workshop: *“Innovation and Development in Health: Integration of Complementary and Traditional Medicine in Public Health Systems”*, promoted by the ART/UNDP Initiative, UNOPS/UNDP, Tuscan Region (Florence, 2008). Major CM and traditional medicine representatives from different countries (i.e., Afghanistan, Albania, Austria, Bolivia, Chile, Cuba, Ecuador, Salvador, France, Gabon, Germany, Guatemala, India, Iran, Italy, Lebanon, Mali, Morocco, Mozambique, Dominican Republic, Serbia, Syria, Sri Lanka, South Africa, Venezuela) participated in this workshop and approved the crucial declaration: *“Complementary and Traditional Medicines in Public Healthcare Systems: Towards an Integrative Medicine”*. The declaration highlights that Traditional and Complementary Integrative Medicine (TCIM) do represent a key resource to empower Public Healthcare Systems and to improve the quality of services for citizens. Indeed, TCIM may provide a crucial contribution to the socio-economic development of countries and to the preservation of the environment since they protect a thousand-year-old knowledge heritage.
- The 5th European Congress of Integrative Medicine (ECIM) was promoted by the Charité University of Berlin, the Tuscan Region, the Universities of Florence, Pisa and Siena, and the Medical Association of Florence (Florence, 2012). More than 1,200 people participated in the congress; 1033 of whom were medical doctors, healthcare and wellness therapists. Noteworthy, the scientific program included more than 500 scientific papers, 300 oral presentations, and 200 posters, with 90 CM associations as congress partners and about 50 companies as sponsors.
- International Conference: *“New Frontiers in Integrative Oncology”* (Florence, November 11-13, 2016) and International Conference *“Integrative Oncology - Central and Peripheral Brains”* (Florence, March 23-25, 2018). These conferences were organized by the Local Healthcare Authority Tuscany center, the Regional CM Reference Centers and the Tuscan Institute for Tumors (now ISPRO), in partnership with the Association of Research on Integrative Oncology Therapies (ARTOI) and the Traditional Acupuncture School of Florence and were enriched by the participation of at least 1,200 doctors and healthcare professionals including many oncologists.

The international, and especially the European, activities promoted by Tuscany also consisted of participation in several initiatives in Brussels, such as the presentation of the Tuscan model of CM integration into the Public Healthcare System at the European Parliament (2009, 2011, and



2013). Moreover, Tuscany participated in several calls (e.g., the European COST 39 project: “*Forest, Trees, and Human Health and Well Being*”, 2008-2010; the 7th Health Framework Program with the CAMPER project proposal, 2009; the collaboration with the WP 3 of the European project CAMBRELLA 7<sup>th</sup> Framework Program, 2011).

Indeed, the participation of Tuscany as an associated member in the European Partnership for Action Against Cancer-EPAAC (2010-2014) at the WP 7 “*Healthcare*”, and the collaboration with the WP6 of the European Joint Action CANCON (2014-2016) deserves a particular attention. The main EPAAC purposes were to evaluate the scientific evidence on the use of CM in cancer care; to propose specific criteria for the dissemination of appropriate information; the mapping of the European use of CM in cancer care by making a survey to Cancer Units of Hospitals across Europe in order to identify the clinical activities related to CM. The results of such work were published online (see [www.epaac.eu](http://www.epaac.eu)) and in the Italian book “*Le medicine complementari per il paziente oncologico*” (*CM for the Cancer Patient*) [15]. The results of the survey were published in the peer-reviewed journal *Support Cancer Care* [16].

### **1.16 International Healthcare Cooperation Activities Supporting Traditional and Complementary Medicine**

Tuscany has a long tradition of international healthcare cooperation activities by means of the Global Healthcare Center, which promotes healthcare projects in several countries e.g., Albania, Kosovo, Bosnia Erz., Bolivia, Nicaragua, Lebanon, Palestine, Senegal, Burkina Faso, Ethiopia, Libya, Mozambique, Uganda, Sudan, Tunisia (<http://www.centrosaluteglobale.eu/>). Some projects, in particular, concerned the integration of CM practice into the Public Healthcare Systems of several southern countries. [17]

Among them, the *Decentralized Cooperation Project: Development of Natural and Homeopathic Medicine in Cuba* (1996-2008), which was promoted by the Municipality of Viareggio, the Province of Lucca, the United Nations Office for Projects Service (UNOPS) and the United Nations Development Programme (UNDP), deserves a particular attention. In the frame of the project, multiple initiatives were carried out in Santiago de Cuba, Pinar del Rio and in two headquarters of La Habana (i.e., Habana Vieja and 10 de Octubre), such as the implementation of CM courses for doctors, pharmacists and veterinarians, homeopathic pharmacies, a production and distribution Center for homeopathic products, and the restoration of the Traditional and Natural Medicine Clinic of La Habana.

Furthermore, the Homeopathic Clinic of Lucca collaborated with the DEMHOS Association of Pisa and with the UNOPS Association of Rome to carry out the project: “*Development of Natural and Homeopathic Medicine in Saharawi Arab Democratic Republic*” (1997-2009), while the Fior di Prugna Acupuncture and TCM Clinic of Florence collaborated in the project: “*Fight Against Maternal-Infantile Mortality in Senegal: Acupuncture and Moxibustion in Fetal Breech Presentation*” (2006). Another important project: “*Integration of Complementary Medicine in the National Health System of Serbia*” (2005-2015) was also initially supported by the UNOPS – City to City Programme, which included the Institute of Public Health of the University of Belgrade among its partners.

Beyond such international healthcare cooperation projects, multiple initiatives and congresses were also organized by Tuscany (e.g., the International Workshop: “*Innovation and Development*

in *Health: Integration of Complementary and Traditional Medicine in Public Health Systems*, Florence, 2008; the International Workshop: *“Traditional Medicines in the Health Priorities of Developing Countries”*, Lucca, 2003, co-promoted with the Educational Orientation Center the Italian Ministry of Foreign Affairs).

The collaboration with the IDEASS (Innovation for the Development and Cooperation among Southern Countries) also deserves attention. The IDEASS constitutes an important initiative, promoted by the United Nations and other international institutions, which lead to the realization of the brochure: *“Moxibustion to Correct a Breech Presentation of the Fetus”*. [18]

## **2. Discussion**

It is not easy to explain how the above-mentioned processes were carried out over a period of more than twenty years at the regional level as it happened in Tuscany.

The national institutional framework, that is, the Constitutional Law no. 3/2001, which reformed part of the Title V of the Italian Constitution by introducing a form of “Federal State”, played a key role. In fact, according to such reform, the State defines the fundamental principles in healthcare, and each region is allowed to decide how to apply them and, consequently, to organize its own Regional Healthcare Service in line with its political and social perspectives.

Another key element was the decision of the regional political authority to respond to the widely diffused use of CM by Tuscan citizens (i.e., about 16% according to the Survey of the Health Regional Agency of Tuscany, 2009) and therefore to regulate it [19]. The support of the regional medical associations, as well as the positive synergy with both Tuscan Universities and healthcare professionals also played a crucial role. The integration in the Public Healthcare Service of the most diffused CM (i.e., acupuncture, herbal medicine and homeopathy) has progressively become the common aim of these stakeholders and led to the development and strengthening of a network of activities and experiences in the field of CM.

The present directions consist of developing the projects on Integrative Oncology, pain control, atopic diseases, childbirth and gender medicine, which were recognized as priority areas for ensuring CM services to Tuscan citizen. Such projects will be developed with the aim to increase the integration with conventional medicine treatments, in order to guarantee patients the best resources for their overall health and well-being.

## **3. Conclusion**

This article describes in detail how the process of integration of CM was developed in the public health system of Tuscany. This integration process is first and foremost the response by the regional health institutions to a strong demand from Tuscan citizens. Although this innovative process should be evaluated thoroughly with the adequate research methodology, this type of assessment was not the purpose of this report.

However, some elements allow to evaluate, although in a non-systematic way, some aspects of positive impact that regional integration policies had on citizens and on the health system, such as economic savings both at general level [20] and in specific disorders, such as respiratory diseases [21] and women diseases [22]. The integration of CM in oncology has contributed to improving the quality of life of cancer patients as some studies have documented [23, 24, 25, 26] and also in palliative care in advanced stages of illness [27]. This is accompanied by a general positive trend of

acceptance of new and innovative approaches to health and disease by patients, the cultural exchange among healthcare personnel, the interdisciplinary approach to treatments particularly in specific integration projects such as the issue of the birth and integrative oncology.

In conclusion, we can say that the main result of the process of integration of CM in the regional health service is not much the realization of single, relevant experiences, but of a system of inclusion and integration of these medicines in Tuscan health policies. Over time, their presence is being progressively considered as "normal" and their contribution has been taken in account in every area of regional healthcare both for citizens/patients and for doctors and healthcare personnel.

The Tuscan experience has demonstrated the feasibility of CM integration into the Public Healthcare Service. At least in Italy, it is an innovative process in the definition of inclusive, modern and sustainable approaches to the healthcare involving many different actors/stakeholders. It might pave the way for a platform aiming to build innovative and integrated Healthcare Systems at both national and European level.

### **Author Contributions**

All Authors equally contributed to the present study.

### **Competing Interests**

No conflict of interest. The Tuscan Public Healthcare System supported all the costs for the present study.

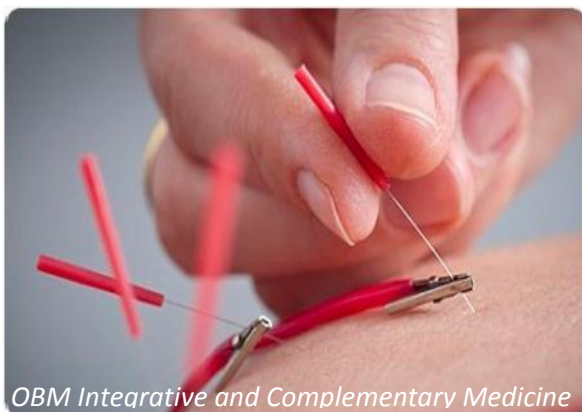
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