Building an excellence model for the use of natural drugs: the case of Lombardy Region

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Summary

Indeed, Traditional/Complementary and alternative medicine (TM/CAM) and Conventional Medicine (CM) are two medicines that spring from two different epistemological models. While the philosophy of the CM is based on reductionism, the philosophy of the TM /CAM is based on an holistic view of the man and of the nature. While CM does quantitative evaluations of the biological phenomena of the body and of the mind, TM /CAM prevalently does qualitative evaluations and distinctions. For this reason, the final outcome of these two medical systems is often a description of the diseases and of the therapies that is incomprehensible for the doctors of the two different medical systems and for the consumers also. In a general way the level of information that is present in a developed country market it’s not enough for a safe, efficacious and proper use of TM/CAM by the patient and perhaps also by many providers. Along the experience of Lombardy Region an excellence model for the use of natural drugs and therapies is possible only by involving all the stakeholder that surround the patient that use complementary medicine.

Key words: Traditional Medicine, Complementary and alternative medicine, Integrated Medicine, Patient’s Education.

Mots clés: Médecine Traditionnelle, Médecine Complémentaire et Alternatif, Médecine Intégrée, Education du patient.
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1. Introduction

Even though Traditional, Complementary and Alternative Medicine (TM/CAM) has millenary roots, it is a new phenomenon in the landscape of responses to the demand for health of the population. Given its increasing spontaneous and unregulated use in the Western world, including in Italy and Lombardy, TM/CAM can no longer be considered as a marginal phenomenon. Around 20% of the Lombardy population use habitually TM/CAM. Many medical doctors and providers propose TM/CAM to their patients as a therapeutic opportunity for pathologies, that often are neither mild nor ordinary, but rather pathologies for which there are no other responses or for which conventional medicine responses are not considered satisfying.

Facing this situation, the regional regulatory authorities are obliged to intervene to define a general framework for the use of TM/CAM which would protect the consumer and guarantee the quality and appropriateness of the interventions. As TM/CAM methods are new, it is difficult to find predefined itineraries and therefore it is necessary to find new paths.

In the WHO Traditional Medicine Strategy 2002-2005, WHO has identified a path for the implementation of safety, efficacy and quality of TR/CAM which has been re-endorsed in the document Guidelines on developing consumer information on proper use of traditional, complementary and alternative medicine (WHO, Geneva 2004) finalized by a WHO Consultation in Milan in December 2003.

The document underlines that the following actions are needed to protect the consumer:

- To identify the benefits of TM/CAM;
- To identify the risks involved in the use of TM/CAM;
- To promote information and the proper use of TM/CAM by the consumer, as well as the level of awareness and information of the patient that uses TM/CAM products under self-prescription, in particular in the case of pregnant or breast-feeding women, elders and adults who treat children with TM/CAM products under self-prescription;
- To monitor the safety of TM/CAM therapies and promote a more complete and deeper knowledge of the possible interactions and contraindications of TM/CAM products, as well as interactions between TM/CAM products and conventional products;
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- To promote training, recognition and identification of qualified providers by the public;
- To promote knowledge on the costs of TM/CAM and of possible coverage by insurances.

Many of the actions identified in this document are currently strategic choices of the Lombardy Region also in the management of the conventional health field.

This consideration led the Regional Government of Lombardy to sign a Memorandum of Understanding with WHO in May 2003 for a close cooperation with WHO in the field of the TM/CAM. The aim was to promote health policies which could contribute to cultural, normative and regulatory tools, in order to guarantee an informed, safe and effective access to TM/CAM by the population. It was clear to the MOU’s actors that a joint action by civil society and institutional entities would have been necessary for reaching the final outcome.

1. Objectives of the research

The present work consists in implementing and finalizing the document *WHO Guidelines on developing consumer information on proper use of traditional, complementary and alternative medicine*. Applied to the specific national and regional situation, it could be used as a model of excellence for developing actions for consumer protection.

The Regional Government of Lombardy has introduced TM/CAM in the Lombardy health care system through the following steps, which should be considered as normative prerequisites of this research:

- Deliberation n. VI/48041, 4 February 2000: this act introduces complementary medicine into the activities of the Regional Socio-Health Plan 2002-2004;
- Deliberation VII/13235, 9 June 2003: this act started a series of actions for the assessment and promotion of norms with the aim to identify instructions and boundaries for complementary medicine. In addition, this act also identifies modalities for the training and practice of the providers with the expansion of this sector to the socio-health world;
- Regional Socio-Health Plan 2007-2009 approved with d.c.r. n.VIII/0257, 26 October 2006: this plan provides the continuation of the activities approved by the previous
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deliberations as well as a more careful monitoring and control of policies for integrating complementary medicine, in order to assess the cost/benefit impact on people health and on regional resources.

The objective of the research carried out by the Regional Institute for Research, Lombardy upon request of the Directorate-General of Health, Lombardy Region, is to assess the means by which it is possible to expand the quality level of the Lombardy healthcare system as a whole to the sector of traditional medicine and complementary and alternative medicine (TM/CAM).

With this aim, it is necessary: to identify a model of excellence for the use of TM/CAM, to assess through a statistic survey how the providers and citizens use TM/CAM in Lombardy, to recognize the differences between the theoric model and the actual situation, to define the normative and regulatory interventions needed for adapting the actual use and practice of TM/CAM to the identified model.

At the same time, it is necessary to identify communication tools among various providers, between providers and citizens as between the regulatory authorities and practitioners/citizens.

3. Methodology and structure of the research

3.1 Definition of a model of excellence for the practice and use of complementary medicine

Given the abovementioned prerequisites and objectives, the first step of the research focused on Definition of a model of excellence for the practice and use of complementary medicine in Lombardy Region.

The WHO Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine have been taken as a starting point to identify a model of excellence for the use and practice of complementary medicine. This model should be based on safety of practice and products, quality and efficacy of methods and proper use by providers and consumers.
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As these guidelines contained values agreed worldwide, it was necessary to adapt them to the specific regional context. For this reason, the research started with a wide critical revision of the abovementioned WHO guidelines on the basis of rules, regulations and specific problems or situations characterizing Lombardy.

The outcome of this first activity, therefore, has been constituted by development and application of the *WHO Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine* for providers and consumers in the Lombardy Region.

In order to have a complete definition of the model, it was necessary to adapt these guidelines to the providers that are involved with managing patients’ health in the TM/CAM sector.

In this phase devoted to the definition of a model for the use of complementary medicine, the implementation of the guidelines was limited to the consumers and only to those providers clearly allowed to intervene on patients on the basis of their professional profile: medical doctors, dentists, pharmacists.

While several recommendations of the guidelines for the consumers involve directly and sometimes explicitly the pharmacist, the medical doctor required a specific adaptation of the guidelines. A new profession is starting: the integrated medical doctor. This is a medical doctor who is able to unify the knowledge acquired from his/her experience as traditional medicine expert and as medical doctor *tout court*, with science and conscience, in the interest of the patient, following an informed consensus.

The development and consequences of this type of medical profession, therefore, requested a specific application of the guidelines. This specificity would relate to the behaviour of the medical doctor with patients and colleagues whenever s/he decides to use TM/CAM products, practices or methods in association or not with practices or products of conventional medicine.
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The outcome of this second activity was characterized by application of the guidelines for the medical doctor with the aim to guarantee a safe use of TR/CAM integrated with conventional medicine.

Finally, the work proceeded with the application of guidelines for all mass media operators. Nowadays mass media are to be considered major keystones for having a conscious and informed citizen as the principal actor of his/her health management.

The outcome of this third activity, therefore, has been constituted by the application of Guidelines for the mass media for developing information on the proper use of traditional, complementary and alternative medicine directed to the consumer.

3.2 Building a database to collect evidence available in international literature.

Information is key to the development of a model of excellence for the use of TM/CAM which rotates around a responsible and informed consumer. However, as mentioned in the WHO Traditional Medicine Strategy 2002-2005 (WHO, Geneva 2002), the need to implement efficacy and security of TM/CAM is one of the major challenges for its quality.

In this respect, research in the field of traditional medicine is increasing at the international level, and numerous trials related to this sector can be found in the most popular databases. Focusing on the importance of the research, the Lombardy Region started to promote a campaign on TRM/CAM research in 2000 (deliberation n. VI/48041 of 4 February 2000) which was reiterated in 2003 and it is currently undergoing. Experts from various disciplines were invited to activate a scientific research aimed at finding potential therapeutical resources. Once passed the test for safety, efficacy and cost/benefit ratio, these resources could become resource of the regional health care system.

For the abovementioned reasons, a database consultable by the providers contributes extensively to move forward the aspects of quality, safety and efficacy of the system of TM/CAM care.

Data related to acupuncture, homeopathy and phytotherapy – the most popular disciplines in Lombardy – were collected. The research was conducted on web sites and journals characterized by a referee board, while grey literature was occasionally accepted only when
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the typology of the study and its importance were relevant to the research as a whole. The abovementioned web sites were useful to collect data related to action mechanisms, clinical efficiency and cost/benefit ratio.

The amount of data collected (Tab. 1) allows to invalidate the common prejudice that these disciplines are not supported by basic and clinical researches. If anything, a first evaluation of the data founded in this bibliographic research drives to the conclusion that the quality of this research is medium-low. In the future, it will be possible to expand the research of evidence to other disciplines. The effects related to the integrated use of practices and products of complementary and conventional medicine, as well as the possible interactions between complementary medicine products and conventional drugs, will also constitute a focus.

Table 1

<table>
<thead>
<tr>
<th>Studies on</th>
<th>total items</th>
<th>divided in:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture</td>
<td>540</td>
<td>Acupuncture and its action mechanisms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acupuncture and clinical trials</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ratio cost/effectiveness in acupuncture</td>
</tr>
<tr>
<td>Phytotherapy</td>
<td>559</td>
<td>Phytotherapy and basic pharmacology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Phytotherapy and clinical trials</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ratio cost/effectiveness in phytotherapy</td>
</tr>
<tr>
<td>Homeopathy</td>
<td>67</td>
<td>Homeopathy and basic studies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Homeopathy and action mechanisms</td>
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<tr>
<td></td>
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<td>Homeopathy and clinical trials</td>
</tr>
</tbody>
</table>

Following data collection, a database was developed using “Microsoft Access”, a useful tool both for uploading/recording data and searches. Access joins a search engine to a graphic interface (mask), through which it is possible to record data, according to readable instructions.

Titles and data are in English. English is in fact the official language of the international scientific community. This way it will be easier for the DataBase to be consulted, and it will attract international researchers willing to upload data related to an ongoing research activity.
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By opening the file DBMC (DataBase Complementary Medicine), the initial screen appears. Here the provider can decide whether to upload new data or ask for information. For data entry, there are two pages: Infotext and Content.

The Infotext page collects information on: code, title, name of the journal, year, number of the journal and pages, language, authors, etc.

The Content page contains information related to: the pathology of the study, possible conditions related to the pathology, if the study is of pharmacological type or clinical type and what was the used methodology, etc. It also provides an hyperlink window which allows inserting the Abstract.

The third section Search related to queries for the DataBase. The output of the search is a table including all basic data of the researches/studies as well as the abstracts as an attachment.

3.3 Development of a communication model for updating the providers, informing the consumers and creating an informative feedback

The last element for the development of a model of excellence was planning an information flow for providers and consumers together with a feedback information flow. On one side, this should make accessible the increasing amount of data available in the DataBase. On the other side, the implementation of the guidelines will produce norms and regulations that will be accessible to providers and consumers. A feed back of information from citizens and operators to regulatory authorities will complete the information flow. The model could be managed autonomously by a Regional Observatory as well as by any other entity which could act as Observatory. Otherwise it could be integrated, with adequate treatment, within the already existing regional web site.

3.4 Model for quantifying data related to the use of traditional, complementary and alternative medicine

Once the direction for a model of excellence for the use of complementary medicine was set, it was necessary to assess the current status of TR/CAM use on the ground.
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The development of an interpretative model of a phenomenon starts with the adequate knowledge of the previous or existing situation. In this respect, besides national researches carried out by ISTAT in 2002 and 2005 and certain occasional surveys, a history of monitoring the use of TM/CAM does not exist in Lombardy.

The following five objectives were set for quantifying the data on the use of complementary medicine by the population in Lombardy:

- **ACCS:** the percentage of access to TM/CAM out of the total requests of medical assistance
- **GRAD:** level of satisfaction for the use of TM/CAM
- **PRES:** behaviour of the medical doctor in relation to prescriptions;
- **CONS:** behaviour of pharmacists/herbalists over the counter;
- **AUTO:** diffusion of the practice of auto-prescription of TR/CAM and behaviour of the population in this respect

In addition, a preliminary evaluation was carried out on the possible adverse events related to the use of these methods. It was found out that the incidence was low, in fact lower than 2,3% in the examined group.

4. **Statistic Results**

The statistic evaluation of the current use of TM/CAM in the Lombardy Region has highlighted the difference between the current situation and the model of excellence defined by WHO.

Comparing the current status of the use of TM/CAM with the model of excellence of WHO has allowed the authors to identify the critical points that the regional authorities face.
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and the actions to be taken. Eventually the model of excellence of the use of TM/CAM will be implemented in Lombardy.

By involving all interested professionals – providers, medical doctors, pharmacists and mass media -, the outcome of this process could be the same level of excellence that characterize other sectors of the Lombardy health care model. This process will also protect the citizen that will be enabled to have an informed, safe, efficacious and proper access to the TM/CAM methods.

The data recorded in the recent sample survey show that the use of TM/CAM can not be considered as a marginal phenomenon. This is clear when almost 19,7% of the sample use it “often” to solve problems more or less considered relevant for health and 60,8% of the sample ask for it “sometimes" for similar reasons.

It seems that TM/CAM will continue to have a relevant place in the global healthcare framework in the future. This idea is supported by the fact that 87,8% of the sample think that in the future they will use TM/CAM practices, and 81,9% think that they can suggest it to other persons that might have a similar disturb or disease.

Finally, TM/CAM cannot be considered as a marginal aspect of care. In fact, medical doctors, without any distinction between general practitioners of the health care system and free professional doctors, unexpectedly consider TM/CAM as a resource for the treatment of important pathologies. 54% think it is appropriate for the treatment of chronic-degenerative pathologies rather than for the treatment of mild or temporary pathologies. Only 5,7% use it for light or temporary pathologies.

5. Conclusions

Considering that the Lombardy Region has supported WHO in finalizing the Guidelines on developing consumer information on proper use of traditional, complementary and alternative medicine, it might seem logic that the Region took inspiration from the model of excellence adopted by WHO in the abovementioned guidelines, in order to achieve quality in the use of TM/CAM in Lombardy.
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In this respect the actions that Lombardy Region is undertaking for improving the availability of a safe and efficacious TM/CAM are:

**Identifying the benefits of TM/CAM**

We may confirm that the path taken by the Lombardy Region with d.g.r. of 4 February 2000 has been foreseeing and at the front head. Its value is even higher if one considers that the recommendations have clearly expressed the need to develop studies preferably for pathologies that were socially widespread (e.g. rheumatism) and for which the conventional therapeutic answer was considered unsatisfactory (e.g. child insomnia, with all the problems due to the chronic administration of psychopharmacological drugs to developing human).

**Building a database to collect evidence available in international literature**

One cannot ignore the fact that a revision of experiences and data related to TM/CAM knowledge has been underway for sometime. This work has been carried out through researches based on the scientific model of conventional medicine.

It is highly recommended that the Lombardy Region, directly or through a dedicated working group, manage and operate the DataBase developed during this research. This could become a tool for independent information both for providers and consumers. Without any doubt, the DataBase could constitute a stimulation for implementing quality both in practices and products.

Promotion, implementation and update of the DataBase could be a point of reference for the practice of providers in this sector.

A review of the material of the DataBase in view of its dissemination can constitute the basis for more solid information to the public and to the mass media, in order to promote better information and the rational use of TM/CAM by the patients.

**Identifying the risks of TM/CAM**

The risks linked to the use of TM/CAM can be estimated in around 2,3% of the examined group (Research 2007B076) and have such a modest degree that they can avoid being considered both by the subject and by the doctor. The finding of serious cases is occasional. However, a constant monitoring of the possible adverse events should be provided.
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In this respect, we believe that aside the usual control network of the major events which fall under the drug vigilance network, questionnaires should be regularly distributed to significant samples of the population. This effort would help having a total coverage of the possible adverse events.

Promoting information and the proper use of TM/CAM by the consumers, as well as the level of awareness and information of the patient that uses TM/CAM products under auto-prescription, in particular in the cases of pregnant or breast-feeding women, elders and adults who treat children with TM/CAM products under auto-prescription

Achieving this objective is possible only by creating an information network keeping the consumer at the centre. In the research which was carried out, 56.7% of the sample take their knowledge and information on TM/CAM from newspapers and TV, whereas 51.8% derivate their knowledge through people they know and friends. The website that have been built, www.medicomlombardia.it, is strictly monitored for evaluating the achievement of this outcome.

At this point, a sharp action on the structure, efficacy, safety, risks and quality of TM/CAM can be obtained only with activities that involve directly the mass media, by promoting self-regulation codes which take into account the abovementioned guidelines.

Moreover, it would be useful to run campaigns based on the production and dissemination of paper documents through pharmacies and the primary health care centers.

Concerning the use of internet, the only solution seems to create a regional web site with the aim to provide correct and impartial information. This proposal is based on the fact that it is impossible to control the numerous web sites and their content which often have commercial purposes.

Finally, as correct information to the public counts on the participation of both TM/CAM and conventional providers, it is fundamental to plan training courses for updating all providers of the healthcare system. In this way the possible questions and requests could be either answered correctly or at least forwarded to other experts.
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Developing a communication model for updating the providers, informing the consumers and creating an information feedback

This tool, which will need to be managed and implemented continuously, could be looked after by the Regional Observatory for Complementary Medicine mentioned in the Regional Socio Health Plan 2007-2009 approved by d.c.r. n.VIII/0257 of October 2006, as well as by any other entity with TM/CAM monitoring functions, starting from the direct experience of the American National Centre for Complementary and Alternative Medicine (NCCAM). NCCAM has offered in the past years an efficient example of correct and effective information for the public and the providers.

Monitoring the safety of TM/CAM therapies and promoting a more complete and deeper knowledge of the possible interactions and contraindications of TM/CAM products, as well as interactions between TM/CAM and conventional medicine products

Facing this critical point includes joined actions summarized in:

- Implementing consumer awareness and information;
- Implementing awareness and training of the medical doctor/provider facilitating his/her recognition and identification by the public;
- Accessing data reported by the international literature and disseminating them to the consumer and medical doctor/provider with a feedback information flow.

Promoting training, recognition and identification of qualified providers by the public

Qualification and training of providers are with no doubt the crucial points for the proper and safe use of TM/CAM. The Region is called to give its contribution to this work on the basis of subsidiarity, by creating and developing a model for updating/training which would guarantee high quality of the service.

Promoting knowledge on the costs of TM/CAM and possible coverage by insurances

The abovementioned data are an important aspect for promoting access to TM/CAM.

In this case, the collection of data could be carried out with the contribution and participation of professional societies and associations. Posting these data on the regional web site could contribute to protect the consumer. S/he will be put in an informed position to...
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consider autonomously the cost/benefit ratio and the potential economic coverage provided by various insurances.
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