

Synthesis of report 153C:

Acupuncture: State of affairs in Belgium

Belgian Health Care Knowledge Centre
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FORWORD

The news has begun to take notice of China in recent years. The country has come to play an increasingly important role on the international stage. It is experiencing a meteoric rise in its technological power and this is probably just the beginning. However, China has another face. It is also the age-old country of Confucius, Tao and Zen Buddhism, the country of yin and yang, with its traditional medicine and 'barefoot doctors'. Acupuncture comes from that other China, although it is no longer as popular there as we may suppose.

Acupuncture is certainly the most exotic of the four forms of alternative medicine studied by the KCE at the Minister's request. While the rationale and proprieties of acupuncture hark back to traditional China, some currents of thought are endeavouring to integrate it into the Western biomedical model. So what is the role of acupuncture in Belgium's health care system?

Once again, the KCE has chosen to examine this form of medicine from a multidimensional perspective. We have, of course, used the analytical framework of evidence-based medicine. Although, once again, there is little evidence of the efficacy of this form of medicine, it nevertheless enjoys considerable popularity, even within the medical profession to some extent. That is why the current study has also explored the socio-anthropological aspects of this phenomenon. The aim is to provide the legislature with the most relevant advice to enable it to develop an appropriate legal framework. Given the obvious public demand and expectations, the legislature must ensure transparency and safety for users.

Even though this report is unable to satisfy all the demands of acupuncture practitioners, we wish to thank the large number of practitioners who have helped us to paint a clear and balanced portrait of their medicine as practised in Belgium today.

Synthesis

Table of contents

1	INTRODUCTION	2
1.1	CONTEXT	2
1.2	OBJECTIVES AND METHODS	2
1.3	LIMITATIONS	3
2	ACUPUNCTURE IN BELGIUM: USERS, PRACTITIONERS AND PRACTICES ...	4
2.1	NON-CONVENTIONAL MEDICINES: AN INCREASINGLY FREQUENT USE.....	4
2.2	ACUPUNCTURE IN BELGIUM: GENERAL BACKGROUND	4
2.3	WHO ARE THE PATIENTS?	4
2.4	WHO ARE THE PRACTITIONERS?.....	6
2.5	THE PATHWAY OF THE PATIENT.....	7
	2.5.1 Initial access to the non-conventional medicine.....	7
	2.5.2 The consultation.....	7
	2.5.3 Financial aspects.....	9
	2.5.4 Patient satisfaction.....	9
3	IS ACUPUNCTURE CLINICALLY EFFECTIVE?	11
3.1	EVIDENCE IN THE SCIENTIFIC LITERATURE	11
3.2	PATIENT POINT OF VIEW	13
3.3	WHICH RISKS?.....	13
4	TRAINING	14
5	LEGAL FRAMEWORK	15
5.1	BACKGROUND.....	15
5.2	THE COLLA LAW	15
5.3	CONSEQUENCES OF PARTIAL EXECUTION OF THE COLLA LAW	17
6	CONCLUSION	18
7	REFERENCES	21

I INTRODUCTION

I.1 CONTEXT

Acupuncture, chiropractic, osteopathy and homeopathy can be classified under the label of complementary and alternative medicines (CAM). In 2007 the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institute of Health (US) defined these medicines as a 'group of diverse medical and healthcare systems, practices and products that are not currently considered to be part of conventional medicine'. These therapies are referred to as 'complementary' where they are used jointly with conventional treatments, and as 'alternative' where they are used instead of conventional treatment.

The Belgian Minister for Public Health and Social Affairs has asked the Federal Healthcare Knowledge Centre (KCE) to describe the current situation of these practices in order to review or implement the law of 1999 (the so-called 'Colla law').

This alternative medicines project includes the publication of three reports. After a first report on chiropractic and osteopathy¹, this is the second one, devoted to acupuncture. A third report, on homeopathy, will be published later in 2011.

I.2 OBJECTIVES AND METHODS

The report aims to respond to the following questions:

1. How effective is acupuncture? What are the benefits and harmful effects?
2. How can acupuncture be defined, and how is it used by the Belgian population?
3. What is the legal status of these medicines and how are they organised in Belgium?
4. How are the therapists trained?

In order to grasp these medicines in their complex and multidimensional nature, a range of methods were used:

- the medical literature was analysed to assess the clinical effectiveness and safety of the therapies under study;
- a telephone survey of the general population gave a view on the scale of the consumption of these therapies;
- a socio-anthropological interview-based survey gauged the perceptions of regular users and therapists;
- an online survey among practitioners describe their characteristics and those of their practices;
- a detailed analysis of the legal and organisational framework helped to understand the Colla law, the hold-ups and issues;
- consultation with the professional associations and experts gave an insight in how these professions are organised and how their practitioners are trained.

Together they draw a picture of the current state in Belgium but they cannot provide a complete answer to the initial research questions because of the limitations of each method and the resulting limitations of the material collected.

In order to give this general overview, we did a triangulation of the results of the different studies.

1.3 LIMITATIONS

Despite the range of methods that were mobilised, this study has several limitations; the most important are listed hereafter.

- The literature search was limited to a review of reviews, i.e. excluding findings from more recent primary studies. The quality of the reviews was variable, but above all, the studies included in the reviews were predominantly of low quality, and very little information on safety was found. Given the focus on systematic reviews, the literature study is biased towards subjects or studies for which a systematic review was published.
- The sociological part is exploratory, and the users survey, focuses on a small purposive sample of regular users, likely to be quite convinced of the value of the therapy and, hence, not representative of the entire user group, and certainly not representative of the whole population. The findings could nevertheless shed a light on the results of the population survey and give indications on the perception of acupuncture and the way consultations take place.
- Likewise, therapists who accepted an interview may not be representative of all therapists.
- The webbased survey among practitioners is only representative of the acupuncturists affiliated to a professional association, which is no prerequisite to practice. But, due to the lack of data on the total number and characteristics of acupuncturists in Belgium, we could not assess the representativeness of the respondents.

Yet, this is the first time a survey tries to draw a comprehensive picture of acupuncture in Belgium.

2 ACUPUNCTURE IN BELGIUM: USERS, PRACTITIONERS AND PRACTICES

2.1 NON-CONVENTIONAL MEDICINES: AN INCREASINGLY FREQUENT USE

The Belgian National Health Survey, carried out every four years by the Institute of Public Health, already highlighted the success of alternative (non-conventional) medicines among the population. In 2001, 11% of those interviewed had consulted an 'alternative therapist' during the past 12 months, and its rose to 12% in 2008².

In a KCE survey in 2009 on a representative sample of Belgian adults, one third of respondents had consulted an alternative therapist at least once during their life, and in the past 12 months 7% had consulted an osteopath, 6% a homeopath, 3% an acupuncturist and 2% a chiropractor. This represents by all means a substantial number of people.

2.2 ACUPUNCTURE IN BELGIUM: GENERAL BACKGROUND

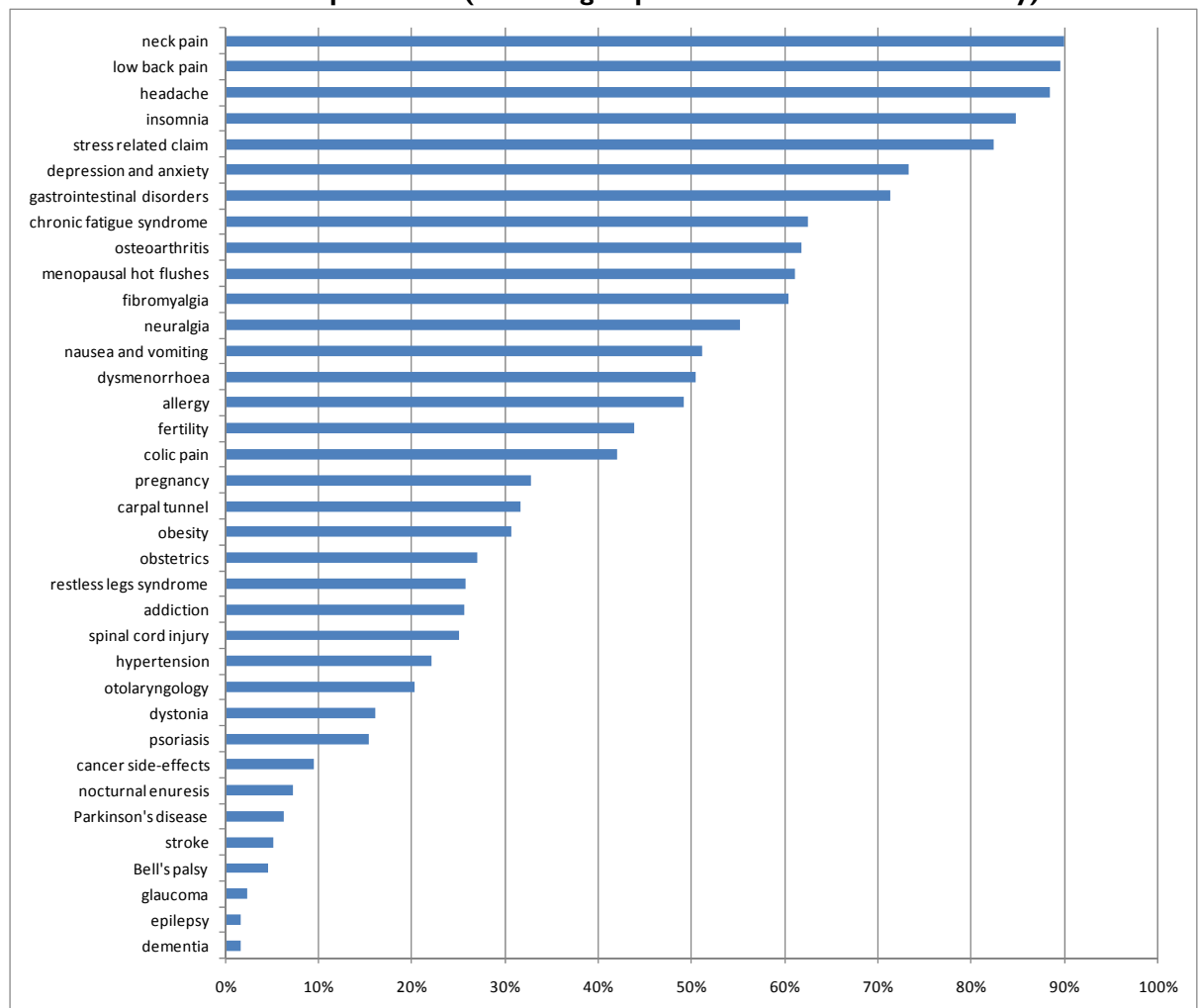
Acupuncture is a medicine of Chinese origin. It got established in Belgium during second half of the twentieth century. 'Western' acupuncture underwent many "translations", both in its content as in its form. The most radical transformations were observed during the 20th century. As doctors got interested in acupuncture and sought to explain its effects in a biomedical model, we saw the advent of a « scientific acupuncture ». Old concepts from Traditional Chinese Medicine (TCM) were gradually challenged by neurophysiological explanations (see below). The meridians, the Qi, the yin and the yang, and other concepts specific to the Chinese philosophical universe, were complemented by or replaced by biomedical concepts from neurology or reflexo-therapy. The strength of this relation to tradition or modernity (scientific acupuncture) partly depends on the acupuncturists' background education (medical or paramedical) (see below).

2.3 WHO ARE THE PATIENTS?

In our phone survey, 2.7% of the respondents had consulted an acupuncturist at least once in the last 12 months. The Belgian National Health Interview Survey had shown that the use of acupuncture remained stable between 1997 and 2008; they found a figure around 1.6%.

The main reason why people declared to seek help from an acupuncturist is low back pain. This was confirmed by the survey among acupuncturists and by interviews among regular users. Therapists also mentioned neck pain, and stress-related conditions, including headache and insomnia. Regular users also mention stress-related disorders as a predominant reason, but also wellness.

Figure 1: Frequency of the complaints for which patients often or very often consult an acupuncturist (according to practitioners – webbased survey)



According to our webbased survey among practitioners, most conditions for which acupuncturists are frequently consulted are chronic problems, for which conventional medicine has only symptomatic solutions to offer, and these solutions are generally either of limited effectiveness or bear a number of drawbacks, side-effects or risks. Moreover, many of the conditions also have a more or less outspoken psychosomatic component.

According to the acupuncturists, 10% of the patients consult for preventive purposes, with a majority doing so every 3 months on a regular basis.

Seventy three percent of the acupuncture users in the population survey consult several times per year. In 80% of the cases, this is combined with another non-conventional therapy. This is corroborated by the regular users who report concomitant use of e.g. homeopathy or osteopathy.

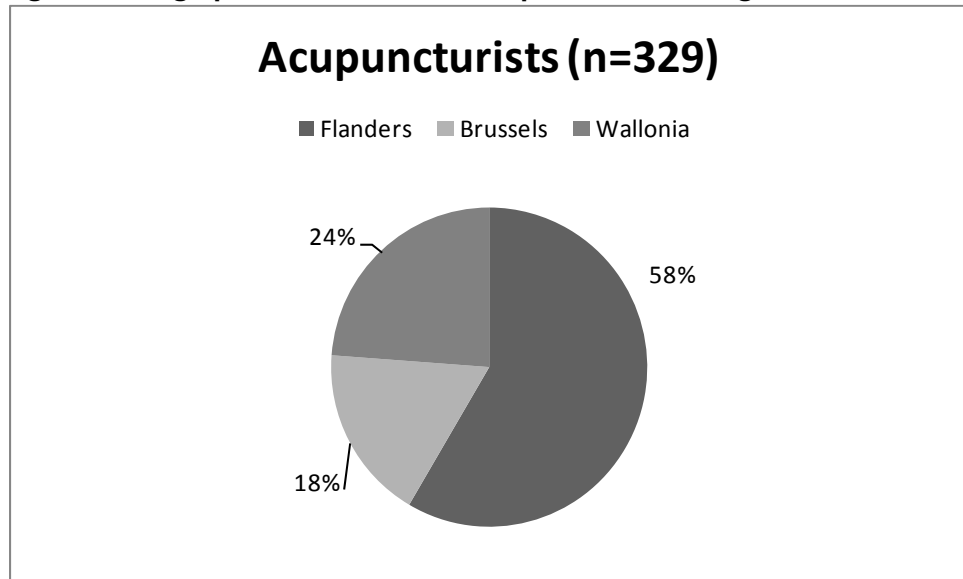
Acupuncturists declare to have a predominantly adult patient population, seeking their help for the above-mentioned reasons (musculoskeletal and stress-related complaints) as well for wellness or relaxation. Less than 20% of them take care of babies (0-36 months) and 30 to 40% treat children or adolescents, although our qualitative interviews reveal an aversion to prick children.

2.4 WHO ARE THE PRACTITIONERS?

Today (early 2011), nearly 600 acupuncturists are affiliated to a professional association in Belgium. The majority (59%) is between 30-and 50-years-old, and almost two in three are men (64%). To a few exceptions they either are kinesi therapist, have a paramedical training (65%) or are medical doctors (32%, or 28% in our sample); amongst them a large majority are general practitioners. The median acupuncturist is in practice since 9 years.

Acupuncturists work mostly at home (73%) or in a separate private cabinet (35%). They are more numerous in Flanders (58%), than in Wallonia (24%) and Brussels (18%).

Figure 2: Geographical distribution of acupuncturists in Belgium



This geographical distribution is very similar to the one observed for osteopathy.

The majority of Belgian acupuncturists practice alone (79%), and, if not, they practice in group, mainly in combination with physiotherapists (kinesitherapists), osteopaths or other acupuncturists.

There are four professional associations of acupuncturists: ABADIC Belgian Association of Acupuncturists graduated from China, BAF (Belgian Acupunctors Federation), EUFOM (European Federation for Oriental Medicine) and UPMAB--BGAB (Union professionnelle des médecins acupuncteurs belges- Beroepsvereniging van Geneesheren-Acupuncturisten van België). They are all registered by the Colla Law, meaning that they fulfil the following criteria: they should have a list of members, agree to participate in scientific research and external evaluation, and have a corporate personality (rechtspersoonlijkheid/personaliteit juridique).

Criteria for membership to an association are: a primary training as described in the Royal Decree 78, a certificate in acupuncture from a Belgian school or a school homologated by one of the 5 Chinese Universities. Only UPMAB-BGAB is more restrictive and is only open to physicians, with an acupuncture certificate from one particular Belgian school (ABMA-BVGA- Association Belge des Médecins Acupuncteurs - Belgische Vereniging van Geneesheren-acupuncturisten- see below).

All the professional associations for paramedically trained acupuncturists view acupuncture as a complementary therapy, in combination with conventional medicine. However, they reject the obligation to work under prescription of a physician, which is interpreted as a lack of trust from the medical world.

This was not only emphasised by the representatives of the professional associations but also clearly appeared from the interviews with practitioners. Moreover, practitioners seem to engage into the study of a non-conventional medicine precisely in order to escape from the framework for conventional medicine.

Besides, they also fear income loss if they would become dependent on the prescription of the GP, as presumably only a minority of GP's will prescribe acupuncture.

ABADIC adheres to the traditional vision on acupuncture, as taught at the Shanghai University. BAF and EUFOM are more oriented towards a European, more medically oriented acupuncture (without rejecting the traditional concepts of acupuncture, though). Since several years, UPMAB-BGAB evolves towards a more traditional approach. Nevertheless, from our qualitative survey it appears that physician-acupuncturists present themselves in the first place as a physician.

2.5 THE PATHWAY OF THE PATIENT

2.5.1 Initial access to the non-conventional medicine

In general, patients use non-conventional medicines as a complement to conventional medicine, whilst not rejecting this last one. From our population phone survey, it appears that 87% of the respondents use both medicines, more often than not for the same medical reason. Eighty percent of acupuncture users also use other alternative medicines.

As for other forms of non-conventional medicine, the primary way to choose an acupuncturist is by mouth to ear referral. This is reported by users and stated by practitioners. A second entry point is via the Internet. We have no precise information how and where Internet is consulted but we know that every professional association publishes a list of their members' addresses on their website. Whilst internet is a modern tool to identify a therapist, the choice is no longer based on the reputation/fame of the practitioner, but only on the 'guarantee' offered by the mere affiliation to a professional association. Unfortunately, this referral modality was not proposed as a choice in the phone survey among general population; consequently, this result could not be corroborated.

According to the practitioners, patients can also be referred by a physician, showing that non-conventional therapies are sometimes used as a complement to a 'conventional' therapy.

Even if it is not possible to fully compare the results because of the different designs of the respective practitioner surveys, it seems that physician referral to an acupuncturist is much less frequent (7%) as compared to the referral to an osteopath (36%) or a chiropractor (42%)³. This could be linked to the higher proportion of physicians among acupuncturists, making direct access easier.

2.5.2 The consultation

First appointment

The first appointment is very prompt: the majority of acupuncturists are able to receive their patient the same day or the day after. When it is not urgent, the delay is 3 days in half of the cases.

Course of a consultation

An acupuncturist's consultation begins with a long anamnesis. Users seem to highly value the fact that they are listened to. Next, the therapist will examine the patient. A traditional acupuncturist will not establish a classic medical diagnosis but he/she will make an energetic report (the so-called energetic diagnosis) and identify the region of the body where the problem is situated and the points to prick. In 'traditional' acupuncture this energetic diagnosis plays an important role, and includes anamnesis, inspection and palpation (including pulse, tongue and audio-olfaction) and a differential diagnosis based on the traditional Chinese medicine references, leading to a traditional Chinese medicine diagnosis.

The treatment consists of the insertion of needles in the patient's body, at very precise points. This is not painful but sometimes unpleasant. The patient will lie down and stay immobile during 20 or 30 minutes. Disposable needles are used.

Other techniques are also used such as moxibustion (burning of dried moxa plant (*Artemisia sinensis*)), acupressure, etc (see further).

The body is believed to correct its own energy flow and balance after stimulation of acupuncture points and ill health is thought to reflect a disturbance of energy⁴.

The insertion of the needles can occur in a separate room, which allows the practitioner to treat several patients at the time. Music, subdued lighting or incense burning can be used to create an atmosphere favourable to relaxation, which is one of the main intended outcomes.

The practitioner can **combine several therapies** in the same patient, according to his initial or complementary training. 70% of physician acupuncturists combine conventional medicine with acupuncture, and 77% of all acupuncturists report combining acupuncture with homeopathy or oriental medicine. Kinesitherapists and paramedics do so less frequently, because it is not always deemed pertinent or because they have an agreement with the sickness funds to provide only one therapy a time. In contrast, physicians can combine acupuncture with conventional medicine, with reimbursement for both.

The qualitative survey among practitioners indicated that physician acupuncturists' practice varies between two extremes: from a largely biomedical approach integrating some elements of acupuncture as a treatment, based on a classical biomedical diagnosis, using only a small numbers of the 360 theoretical points, depending on patient or indication on the one hand, to a systematically combined practice for every patient on the other hand. The first model could be qualified as a 'modern acupuncture', advocating a critical view of the tradition and a more scientific or reasoned explanatory framework. The second model refers more to a 'traditional acupuncture', characterized by the traditional theories on acupuncture and the functioning of the body.

From the quantitative survey we estimate that 14% of physician acupuncturists present themselves as "western" or modern, 48% as hybrid or mixed and 38% as traditional or "Chinese style". Among non physician the figures are less than 1% modern, 24% hybrid and 75% traditional. These distinctions also reflect themselves in the discourse of the professional associations, as explained above.

Techniques used

Needle acupuncture is used by almost all acupuncturists. More than the half of them also use moxibustion. The third most used technique (often or very often by 44% of the therapists) is ear acupuncture. Acupressure and others point stimulation techniques are less often used. Less than one in four (22%) use Shiatsu (pressure) or ultrasound.

According the acupuncturists we interviewed, they use this therapy for acute pain as it produces 3 types of presumed "morphinic" outcomes : analgesic, anti-inflammatory and relaxing.

Length of the consultations

The first consultation lasts between 30 minutes and one hour among almost half of the acupuncturists or between 1h and 1:30h among the other half. Subsequent consultations are shorter because the anamnesis goes less in depth, and take most of the time 30 minutes to one hour, time spent with the needles included.

Follow up

Forty three percent of the acupuncturist see their patients 4 to 6 times per year and one third of them up to 10 times. From the qualitative interviews we learned that this number of sessions is often judged necessary for curing a specific problem while 'wellness sessions' are rather punctual. Some patients use acupuncture preventively, consulting three or four times a year.

2.5.3 Financial aspects

The first consultation is more expensive than the subsequent ones: 43% of the practitioners charge less than 35 euros, but the others charge 35 and 50 euros, rarely more. Subsequent consultations are charged less than 35 euros by 62% of the therapists. Prices are on average lower than for chiropraxy or osteopathy.

The compulsory health insurance does not reimburse acupuncture as such. Nevertheless, if the treatment is administered by a physician, a 'normal' consultation can be charged and reimbursed.

In addition, the complementary insurance schemes of several sickness funds reimburse 10 to 12.5 euros, up to 5 times a year, for a non-conventional therapy consultation, in so far as the therapist is 'recognised'. Unlike for osteopathy or chiropraxy, the schemes differ between sickness funds, and some restrict their intervention to treatment by a physician.

Private insurances can also occasionally intervene, depending on the cover, and in general also restricted to treatments under medical prescription.

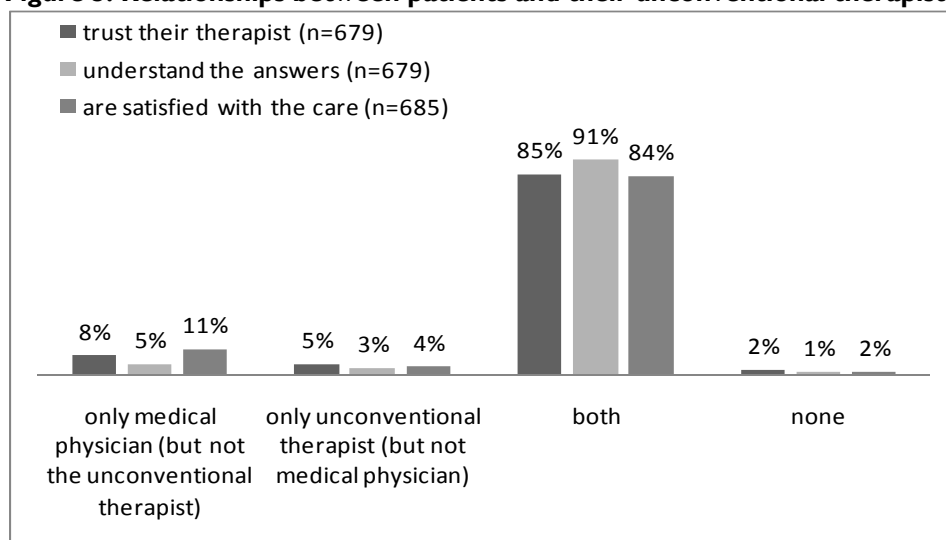
Incidentally, a patient consulting a physician acupuncturist could benefit from a double reimbursement (regular consultation of a physician (compulsory health insurance), plus intervention for the acupuncture session (complementary or private scheme)).

Still, the major part of the cost is borne by the patient, and the telephone survey showed that 12% of the respondents would never consult a non-conventional practitioner because this is considered to be too expensive.

2.5.4 Patient satisfaction

Answers to phone survey showed that patients are satisfied with their non-conventional therapist (in general). They have confidence in him/her and think they understand well the information given. They are also satisfied with the treatment they have received. Their attitude towards the non-conventional therapists does not differ from the one towards their conventional physician: most patients are satisfied (in the broad sense) with the care they received.

Figure 3: Relationships between patients and their unconventional therapist



Regular users of acupuncture particularly appreciate the fact that their acupuncturist listens to them. This is enhanced by the fact that the patient is lying on a table during the insertion of the needles. They all describe a relaxation effect of the treatment, and this effect is clearly also aimed at by the therapists.

In the perception of the patients, acupuncture acts as well on their physical health as on their mental health and emotions. Several users relate the quality of the treatment to the quality of the relationship with their therapist. If this last one is not satisfactory, it could jeopardise the result of the treatment.

Table 1 : The consultation by an acupuncturist

Organisation of the practice	79% solo
Basic training of the acupuncturist	Medical doctor: 32% Physiotherapist (kine): 54% Nurse: 11% Other: 3%
Other activities	Acupuncture + medicine : 29% Acupuncture + kinesitherapy: 42%
Waiting time	The same day or the day after : 84% (new patients) and 89% (already known patient)
First consultation duration	46%: 30 minutes- 1 hour 30
Follow-up consultation duration	77%: < 1 hour
Number of patients per day	58%: <5
Main techniques used	Needle acupuncture : 96% Moxibustion : 55% Auricular: 44% Acupressure: 24%
Type of acupuncture	Classical: 64% Mixed: 31% Modern: 4%
Fees	35-50 €
Reimbursement by health insurances (compulsory, complementary or private)	Consultation by GP partially reimbursed by compulsory health insurance. Up to 5 session per year (any CAM, depending on the therapist's training or affiliation for some sickness funds)
Number of sessions per year	43% : 4-6 sessions 33%: 7-10 sessions

3 IS ACUPUNCTURE CLINICALLY EFFECTIVE?

3.1 EVIDENCE IN THE SCIENTIFIC LITERATURE

We performed a literature search to document the effect of acupuncture for all conditions for which we could find at least one systematic review. We concentrated on reviews of randomised controlled trials. We included all interventions related to acupuncture, i.e. based on more or less the same concepts, including acupressure and electro-acupuncture.

Acupuncture is proven to reduce pain, although for most indications the clinical relevance can be questioned. For low back pain in particular, there is stronger evidence that the short term effect may be clinically relevant. In addition, sham acupuncture was shown to be effective in comparison with no acupuncture, indicating that the exact location of the needles is not important, which puts into question the underlying theories underpinning acupuncture.

Some studies show a significant effect on the success rate of vitro fertilisation: acupuncture would result in more pregnancies but also in more live births. In addition, the effect of acupuncture seems to be independent of the control group that was used, i.e. sham or no intervention. There is debate about the possible role of the placebo effect. Some argue that placebo effects are unlikely as the outcome (live birth) is not prone to subjectivity while others state that this cannot be excluded, e.g. because patients are more relaxed.

The placebo effect has indeed also its use, a.o. owing to the fact that, for indications like low back pain and neck pain, conventional medicine only proposes treatments of limited proven effectiveness. Consequently, patients do not obtain a satisfactory answer. In such circumstances the power of a placebo effect has been proven, in particular when the person has high expectations on the treatment.

For most other indications, the evidence in the literature is either inconclusive or absent, not in the least due to the overall poor quality of the published research.

Table 2: Summary of the efficacy of acupuncture for several conditions

Indication	Intervention	Compared to	Observed result	Outcome
Addiction				
Cocaine craving	Auricular acupuncture	Sham	Craving	One small study (n=30) shows an effect
Tobacco cessation	Ear acupressure	Advice	Cessation at 6 weeks	One outcome in one study (n=120)
Breast cancer				
Hot flushes as consequence of the treatment	Acupuncture	sham	Frequency of flushes	Small effect not sustained after the acupuncture was stopped.
Pain				
Pain relief	Acupuncture	Sham / No acupuncture	Pain relief	Effect
Tension-type headache	Acupuncture	<ul style="list-style-type: none"> • Routine care • sham 	Number of headache days	<ul style="list-style-type: none"> • Reduction • mixed results
Migraine	Acupuncture	Routine care/drug treatment	<ul style="list-style-type: none"> • Number of headache days • Migraine attacks • Headache intensity 	Reduction
Back pain	Acupuncture	Waiting list	Pain relief Functional status	Short term effect
Neck pain	Acupuncture	Multiple control groups	Pain intensity	Mixed results (immediately after treatment or short term)
Myofascial trigger point pain	Acupuncture	Standardized care / placebo	Pain intensity	Small clinically non significant effect
Knee osteoarthritis	Acupuncture	<ul style="list-style-type: none"> • Waiting list/usual care • Placebo 	<ul style="list-style-type: none"> • Pain • Pain and function 	<ul style="list-style-type: none"> • Effect • Clinically irrelevant short and long-term effect
Fertility and pregnancy				
Pain during labor	Acupuncture	Sham	Pain intensity	Mixed results (but methodological issues)
In-vitro fertilisation	Acupuncture	Sham/adjuvant	<ul style="list-style-type: none"> • Clinical pregnancies • Ongoing pregnancies • Live births 	Possibly an effect
Gastro-intestinal conditions				
Irritable bowel syndrome	<ul style="list-style-type: none"> • Acupuncture + psychotherapy • Acupuncture 	<ul style="list-style-type: none"> • Psychotherapy alone • Herbal therapy 	Improvement in symptoms	Short term effects
Postoperative nausea and vomiting	P6 Acupuncture	Sham	Number of patient suffering of vomiting	Effect
Chemotherapy induced nausea and vomiting	Acupuncture	Sham/placebo/usual care	Incidence of acute vomiting	Effect when compared with usual care but not when compared to sham

3.2 PATIENT POINT OF VIEW

While patients report to be satisfied, they often recognize that the treatment is not effective each time. They appreciate however the relaxation it procures, and they emphasise the role of the quality of the therapeutic relationship in the success of the treatment.

3.3 WHICH RISKS?

The literature does not provide much information. It appears that several minor adverse events could occur, depending on the indication or the technique (including sham therapy): haematomas, irritation, redness, sleepiness, pain, hypertension, bleeding, etc.

Risk of infectious diseases transmission, inherent to the use of needles, is not an issue anymore because practitioners use disposable needles. Besides, two professional associations (BAF and EUFOM) have concluded an agreement with the Belgian Red Cross about the use of sterile, disposable needles in all patients. Before this agreement, patients who had seen an acupuncturist were not allowed to donate blood.

In the interviews, the practitioners mentioned the following risks: pneumothorax, transmission of disease-causing agents, cardiac perforation, haemorrhage, paralysis, septicaemia.

We have no quantitative data on any of these adverse events.

4 TRAINING

From our qualitative interviews, we learned that the motivation to engage in a training in acupuncture often comes from an interest in oriental culture or medicine. A positive personal experience as a patient with this type of treatment could also be a motivation. And otherwise, they just are in search of other, additional ways to help their patients.

Acupuncturists are mainly trained in Belgium; in one third, this includes also courses abroad (33.4%) (in Asia for the most of them, sometimes with an internship), but most of the time, this is not the case (59.6%). It is a postgraduate training and, in more than 80% of our sample, given on a part-time basis, and spread over 2 or 3 years.

There are several schools in Belgium; only one school is reserved exclusively to physicians (ABMA-BVGA).

While the majority of the other schools are accessible to everybody, only medics and paramedics as defined in the Royal Decree 78 can obtain a degree of acupuncturist and claim full membership of a professional association. Nevertheless, the curriculum is focused on the traditional Chinese medicine and its particular symptomatology and diagnosis. The potential shortcomings in the field of the differential diagnosis and medical symptomatology could bear a potential risk for misdiagnosis or of a or of harmful delay in the initiation of an essential conventional treatment.

Only the Europe Shanghai College emphasises the importance of the Chinese culture for the practice of acupuncture. This school trained 18% of the acupuncturists who participated in our survey.

Today, no school is officially recognised. There are some instances of collaboration with a recognised educational institute, but this is restricted to the use of infrastructure and homologation of the certificate delivered.

Internship abroad (in practice in Asia) is necessary for non physicians because, as long as the Colla law is not implemented, they are not legally authorized to practice an alternative medicine, and, as a consequence, it is impossible to organize internship.

5 LEGAL FRAMEWORK

This chapter is common to the three reports on alternative medicines, as most of the issues are common to all non-conventional practices.

5.1 BACKGROUND

During the 1990s, Europe acted as a catalyst in the development of new Belgian legislation concerning non-conventional medicines – at the initiative of a Belgian member of the European Parliament, P. Lannoye. In April 1994, he submitted a proposal to the European parliament ‘Committee on the Environment, Public Health and Consumer Protection’ concerning the status of non-conventional medicines. He called for non-conventional medical acts to be covered by national sickness insurance systems, the integration of complementary systems into the European Pharmacopeia, and a research budget for non-conventional medicines. It was not until three years later, on 29 May 1997, that a first resolution was proposed by the European parliament. The main thrust of this proposal was to encourage the Commission to undertake a recognition procedure for non-conventional medicines and to carry out studies of their safety, advisability, field of application and their complementary/alternative character. On 11 June 1999, it fell to the Council of Europe to adopt a resolution that called for the integration of non-conventional medicines at European level and governed access to these medicines for both practitioners and patients.

In response to this resolution, Belgium decided to amend its legislation. According to Article 2 of Royal Decree no. 78⁵ performing a diagnosis and establishing the treatment of a physical or mental disorder are reserved for the holders of a medical diploma approved by the competent medical commission. Persons that habitually diagnose or organise treatment as described above, who are not doctors, are in principle guilty of the illegal practice of medicine. Osteopaths and chiropractors that perform these acts habitually and are not doctors are working illegally unless they carry out a medical treatment that falls within their specific legal competencies (for example, certain physiotherapy treatments on medical prescription). In this case, patients have no guarantee regulated by the authorities as to the quality of the care and safety.

On 29 April 1999, the Belgian parliament adopted a new law on the regulation of non-conventional medicines, known as the Colla law (after the name of the Minister for Health at the time, Marcel Colla).

5.2 THE COLLA LAW

The purpose of the Colla law is to guarantee that each patient receives quality care. This is ensured mainly by a dual registration system. Not only must non-conventional practices be registered (which is only possible if they satisfy certain conditions), but all practitioners must also be individually registered (for which they must also satisfy certain conditions). A key role is given to a joint commission, which must advise on the general conditions that apply to the exercise of all non-conventional practices and the conditions that practitioners of a non-conventional practice must satisfy to be registered individually.

However, since in early January 2011 this joint commission had still not been established, it cannot play its key role and consequently the law cannot be fully executed.

The law stipulates that half of the joint commission members should be proposed by the faculties of medicine, and the other half by practitioners of non-conventional medicines proposed by the chambers (art. 5).

One difficulty that arises is that article 5 does not specify whether practitioner-members of the joint commission must be registered individually. In addition, the law does not define what is meant by a ‘practitioner of a non-conventional medicine’. As a result, it is not clear whether the law requires these practitioners to be registered for the composition of the first joint committee.

The law states that no one can exercise a non-conventional practice without being registered (Art. 8 §1). Moreover, the rule is that the professional exercise of a non-conventional practice by a non-doctor is tantamount to the illegal practice of medicine, which is a punishable offence, except for certain treatments that the law allows for certain professionals, such as physiotherapists⁵. If we accept the interpretation that individual registration is necessary to assemble the joint commission for the first time, this raises a problem because it is this very joint commission that must give an opinion on the registration conditions^{6,7}.

At the request of two associations representing osteopaths, the Brussels court of first instance ordered the Belgian state on 22 January 2010 to set up the joint commission. The government appealed but the judgement was for immediate execution. The Belgian state must therefore pay a fine of 5 000 euros a month as from June 2010.

The practitioner members of the joint commission must be appointed by the chambers, which must be established, with one chamber per non-conventional medicine referred to in the Colla law. These chambers are also constituted of representatives of the medical faculties and members appointed by recognised professional organisations. The composition of the joint commission requires prior recognition of the different professional associations by Royal Decree. The Royal Decree of 06 April 2010 recognising the professional organisations for non-conventional practices, or practices that may be considered for qualification as a non-conventional practice⁸, confirmed the recognition of 13 professional associations that satisfy the recognition criteria.

For this decree to be properly executed, under the terms of the Colla law it must be approved by the Parliament within sixth month after its publication in the Belgian Official Journal. However, as the decree was published on 12 April 2010, it should have been confirmed by law at the latest on 12 October 2010; yet, the vote in the Chamber and the Senate to approve the draft law only took place in November⁹. This decision therefore arrived too late. It could be argued that the decree cannot be executed and, consequently, that all subsequent stages, such as the appointment of the members of the chambers, cannot follow. A possible solution would be to republish the Royal Decree and, this time, approve it properly within six months of its publication.

Another interpretation is that the legislator can in principle not compel its successors to follow the former's decisions. As a result, a new legislator should be able to ratify the law after this period of six months. But, wouldn't changing the general rule with an individual legal application, prejudice the fact that each citizen has the same constitutional rights for the same application of the law in similar cases? Effectively, by ratifying the individual recognition of the professional associations beyond the period of six months, the legislator has departed from the general rule. The members of the professional association that will be recognised in the future therefore have no legal guarantee as to the delays in which their 'Royal Decree of recognition' would be confirmed by law.

5.3 CONSEQUENCES OF PARTIAL EXECUTION OF THE COLLA LAW

As long as the Colla law is not fully in effect, the practice of a non-conventional medicine by a non-doctor is tantamount to the illegal practice of medicine. Several non-doctor practitioners of non-conventional practices have already been sentenced for this offence. We note however that jurisprudence tends increasingly towards acquittal, insofar as certain conditions (such as proper training) are satisfied and the Belgian state still fails to execute the Colla law. In addition, certain medical procedures that are also more or less in the realm of alternative therapists can be practiced legally by certain professionals such as physiotherapists.

This failure to execute fully the Colla law has as a consequence that any other law that may have an influence on the therapist-patient relationship does not apply. For example, the provisions of the patients' rights act of 22 August 2002 and the law of 31 March 2010 concerning compensation for damages resulting from healthcare can only be applied to the practitioners of a non-conventional medicine when the Colla law has been fully executed.

Two competing concepts of who can practice healthcare coexist within the European Union. According to the first one, in principle only doctors are authorised to practice medicine. Under the second one, any person who so desires can practice medicine, with the exception of certain acts that can only be performed by doctors.

Belgium falls into the first category because it restricts the practice of medicine to doctors, with the exception of certain treatments such as those provided by non-conventional medicines (once the Colla law will be executed).

6 CONCLUSION

Since its appearance in Belgium in the years 1960-70, the situation of acupuncture in the health system has gradually changed. After a period of marginality and mistrust, it seems today relatively well accepted by a certain number of members of the medical community, as a valid, complementary “medical technique”, albeit only in so far as it is practised by doctors.

Only limited scientific evidence of effectiveness

Overall, evidence of the effectiveness of acupuncture is quite limited and scarce. Only pain and maybe fertility seem to benefit from acupuncture, and the effects are difficult to distinguish from a placebo effect, due to the nature of the conditions for which acupuncture is used and difficulties in blinding the interventions. Applying a good placebo as such in acupuncture is a problem, hence the distinction with real acupuncture is by definition difficult.

In general, non-conventional therapist judge the effectiveness of their treatment on the basis based of their patients' satisfaction. Our findings from the population survey and from the interviews of convinced users indicate that patient satisfaction is quite high, even if it seems more related to the quality of the therapeutic relationship and to the sensation of wellness that acupuncture procures, and not necessarily to the actual therapeutic outcome.

Execution of the Colla law

Even if their scientific basis is appallingly poor, these therapies encounter a considerable success, and they are not likely to disappear soon, nor is their prohibition realistic from a political point of view. This only adds to the urge to regulate their position in the health care system.

Generally speaking, the main issue for all four alternative medicines recognised by the Colla law, is the actual execution of the law.

The current situation is problematic for almost 70% of acupuncturists who are not trained as a medical doctor, and are therefore practicing illegally, even though the recent jurisprudence takes an attitude of tolerance.

Guaranteeing the safety of patients

Today, patients have no means to ascertain whether they are going to consult a health professional who can legally certify his competence or not. Moreover, they have no official guarantee of quality before undertaking a treatment. Likewise, the various provisions of the law on patient's rights and the law on compensation for damages resulting from healthcare cannot be applied to the patients of non-physician practitioners as long as the Colla law has not been executed.

Hence, without official recognition of therapists or protection of the title of acupuncturist, patients have no objective guidance in their choice of a therapy or a particular therapist. Furthermore, since the surgeries of non-doctor therapists are mainly private, they are not backed by the confidence of an institution (medical centre, polyclinic, hospital, etc.) into which such practices would be integrated.

Supervising the training

To ensure patient safety, alternative practitioners must have a sound knowledge of semiology. This can be dispensed in different training courses leading to an acupuncturist qualification. Currently there is no external validation of the quality of the different training curricula offered in Belgium.

In order to remain coherent with the rest of the health system, the guarantees potentially offered by a better control of the training should go further than the mere aspects of safety and demonstrable effectiveness. A good number of the other practices currently used would still not be covered. This poses a problem for the Public Health authorities, which is still far from being resolved.

The question of (the recognition of) the training for established acupuncturists also remains unresolved.

Physician or non-physician ?

The practitioners having a medical training insist that access to the practice of acupuncture should be limited and they contest practice by non-physicians. They try to preserve their prerogatives in the domain, arguing that safety is at risk when non-physicians treat patients. In the absence of standards for training and access to practice, physicians provide more guarantees. Under the Colla law it could be possible to offer some guarantee on safety for patients by regulating access to the profession.

Increase financial accessibility ?

The financial accessibility of non-conventional medicines is linked to the price of the consultations. There is no control on the fees charged; for non-physician practitioners, there is no reimbursement by the compulsory health insurance, unless they fraudulently invoice services that are included in those they have access to on behalf on their INAMI/RIZIV recognition number (if any).

Given the limited evidence of a relative efficacy for some conditions, we cannot expect to devise meaningful information on cost effectiveness.

Many patients use relatively expensive medicines whereas the scientific evidence of their effectiveness lacks or is not very convincing. Even if these patients show a high level of satisfaction with these therapies, this is by no means a proof of effectiveness. Despite its valuation by users, acupuncture does not pass the test that is usually applied to judge the appropriateness of a reimbursement by the health insurance.

Allow reimbursement of acupuncture sessions by physicians ?

Currently, patients might have a financial advantage when they consult an acupuncturist who is also a physician because they could benefit from a double reimbursement of the session: once by the compulsory health insurance and once by their complementary insurance. One could ask whether the reimbursement of a consultation devoted to a non-conventional therapy, even when practiced by a physician, is not a misappropriation or an abusive use of public funds. It seems hard to justify the difference with, e.g. acupuncturists who are physiotherapist and who are obviously not allowed to use their INAMI/RIZIV registration number to give their patients a care attestation for reimbursement by health insurance, for essentially the same treatment. The different policies of the different sickness fund reinforce this inequality. Furthermore, we have no evidence that acupuncture would be more effective or efficient when practiced by a physician rather than by another therapist.

Work under prescription or not ?

The professional associations for kinesi therapists or paramedically trained acupuncturists see acupuncture as a complementary therapy, in combination with the conventional medicine. However, they reject the obligation to work under prescription of a physician, and they fear that their workload would decrease if a medical prescription is required.

The Royal Decree 78 states that a diagnosis can only be established by a therapist with a medical degree. All other therapists need the medical diagnosis, established by a physician, to initiate a treatment. Consequently, seen from this stance, it seems obvious that non-physician acupuncturist should work under prescription.

Solutions proposed by the acupuncturists themselves to avoid the need of a medical prescription are: to treat only after referral (letter) by a physician, rather than under prescription; to have a systematic informed consent by the patient (as foreseen in the Colla law) and/or to require systematic reporting to the referring practitioner or GP. Still, in view of the limited evidence, there is no justification whatsoever to be less restrictive towards non-physician acupuncturists than towards others (kinistherapist or paramedical professions).

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COLOPHON

Synthesis of report I53C

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- **The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content.**
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