

Describing osteopaths' scope of practice within the Swiss health system; a practice review study

Research Plan

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Fédération Suisse des Ostéopathes Assistants

Fédération Suisse des Patients

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FONDATION SUISSE EN FAVEUR
DE LA FORMATION ET DE LA RECHERCHE
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This document is not in conflict with applicable transparency rules.

1 Signature Page(s)

Project Title Describing osteopaths' scope of practice within the Swiss health system; a practice review study

The project leader and methodologist Paul Vaucher has approved the research plan version 1.8 dated 23.03.2017 and confirm hereby to conduct the project according to the plan, the current version of the World Medical Association Declaration of Helsinki and the local legally applicable requirements.

Project Leader and methodologist:

Fribourg, le 23.03.2017



Place/Date

Signature

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3 Summaries

3.1 English

Background

In Switzerland, we estimate there are over 1000 working practitioners who have an “inter-cantonal” diploma in osteopathy and are delivering care in all 26 cantons. In 2014, the University of Applied Sciences of Western Switzerland opened a bilingual program in Fribourg to deliver a master’s degree in osteopathy. In June 2016, the Swiss Parliament and the House of States adopted the Law on Allied Health (GesBG/LPSan) that recognised osteopathy as a primary care health profession. Little is known however about how and to what extent osteopaths contribute to public health and the services they offer. Osteopaths have identified that they need to support a study to profile their activity. The Unit of Musculoskeletal Research, Faculty of Health Sciences, University of Applied Sciences and the Arts Western Switzerland (HES-SO) have been commissioned by the Foundation for Promoting Education and Research in Osteopathy to undertake this service evaluation.

Objectives

The aim of this study is to describe osteopathic activity and scope of practice to understand their role within the Swiss health system. This study will provide information and data to describe the profession, to help formulate teaching goals, plan ongoing training, identify research priorities, and provide data for stakeholder negotiation.

Method and Design

We will use a practice review survey to investigate osteopathic practice. We estimate that we will need between 400 and 500 osteopaths to participate in the survey. Both osteopaths and osteopath assistants are to be included. All osteopaths registered to the National Registry of Allied Health Professionals (NAREG) will be approached by E-mail and by mail to participate in the survey. Inclusion criteria is to have an inter-cantonal diploma in osteopathy (GDK-CDS diploma). Assistant osteopaths (those having passed the first inter-cantonal exam) will be approached via the Association of Osteopathic Assistants, via the Conference of Sanitary Directors (GDK-CDS) organizing the exams, and via supervising osteopaths. The study is organised in three phases. The first a pilot phase is designed to develop and validate the questionnaire and to test the feasibility of using patient records to report patient profile. The second phase is the survey for which we will be using a web based online system. It will include a survey designed to describe osteopaths’ profile and working environments in 2016. Each participating osteopath will then be asked to select up to four random health records for encounters that took place in 2016 and extract data from these records rendering all data anonymous. This retrospective descriptive record review is designed to describe osteopaths’ activity with their patients. The final phase of this study is the dissemination of the results and the promotion of the survey instrument.

Significance and impact

We hope this study will help to develop a continuing culture of research within the osteopathic profession in Switzerland as it is a professional initiative supported by academics. The survey questionnaire will be a validated and this instrument will be a resource for future osteopaths to monitor their activity. The data from the survey will enable international comparison and help define national priorities for the profession within the global international strategy. At a national level, the results are expected to help osteopaths better describe themselves to other health professions and the public to enable osteopathy to be recognised as a valued primary care provider in the Swiss healthcare system. Having a better insight in what osteopaths do will also be very valuable for professionals to plan for the future and determine research priorities.

Keywords : Osteopathic Medicine, Delivery of Health Care, Clinical Audit, Switzerland

3.2 French

Contexte

En Suisse, on compte environ 1000 ostéopathes détenteurs d'un diplôme inter-cantonal qui fournissent 1'400'000 consultations par année à la population. En juin 2016, l'ostéopathie a été reconnue comme une profession de santé de première intention au niveau fédéral. La formation requise pour pratiquer est dorénavant un master en science délivré par une haute école. Malgré l'intégration de l'ostéopathie dans la société suisse, nous disposons de peu d'informations sur l'importance de sa contribution dans notre système de santé. Par conséquent, les ostéopathes ont décidé de mieux étudier le profil des services qu'ils offrent. L'Unité de Recherche en Soins Musculo-squelettique de la Haute École de Santé de Fribourg a été mandatée par la Fondation en Faveur de l'Enseignement et de la Recherche en Ostéopathie pour mener cet audit.

Objectifs

Le but de cette étude est de décrire l'activité des ostéopathes en Suisse afin de mieux comprendre le rôle de cette nouvelle profession dans le système de santé. Cette étude devrait fournir des données solides permettant de décrire la profession, de formuler des objectifs d'enseignement, de planifier les formations continues, d'identifier les priorités de recherche et d'aider les autorités à prendre des décisions concernant la profession.

Méthodes

Cette étude est une revue de la pratique. Nous allons réaliser un sondage auprès de 400 – 500 ostéopathes. Pour participer, les ostéopathes doivent soit être détenteur d'un diplôme intercantonal, soit être ostéopathe assistant et avoir passé la première partie de l'examen intercantonal. Afin d'identifier les ostéopathes à inclure, nous utiliserons le Registre National des Profession de Santé (NAREG). Les ostéopathes assistants qui ont passés leur premier examen CDS-GDK seront contactés au travers de la Fédération Suisse des Ostéopathes Assistants (FSOA), par la Conférence des Directeurs Sanitaires qui organisent l'examen, et par les ostéopathes superviseurs. L'étude est organisée en trois phases. La première phase consiste à développer et valider le questionnaire et de tester la faisabilité d'extraire des informations depuis les dossiers médicaux des patients. La deuxième phase est le sondage. Les ostéopathes seront invités à se rendre sur une plateforme web pour s'y inscrire et répondre aux questions. Le sondage comprend une première partie décrivant leurs conditions de travail. Durant 2016, et une deuxième partie qui consiste à décrire leurs activités avec leurs patients. Chaque ostéopathe sélectionnera jusqu'à quatre patients choisis aléatoirement parmi ceux ayant consultés avec un nouvel épisode en 2016. La troisième et dernière phase de cette étude est la dissémination des résultats ainsi que la promotion de l'interface de mesures que nous aurons créée.

Importance et impacte

Par ce projet, nous souhaitons stimuler la culture de recherche au sein de la profession ostéopathique en Suisse. C'est un projet initié et financé par les cliniciens et soutenue par les académiciens. Ce sondage pourra facilement être reconduit afin de mesurer l'évolution de la profession. Les informations collectées permettront de définir les priorités de recherche nationales dans une stratégie internationale plus large. L'étude permet de mieux décrire la profession auprès des autres professions de santé et au public. Elle donnera l'opportunité de reconnaître la place de l'ostéopathie en tant que fournisseur de soins en première intention. Cette étude devrait aider à définir l'avenir de la profession et l'orientation de ses recherches.

Mots clefs : médecine ostéopathique, prestations des soins de santé, audit clinique, Suisse

3.3 German

Hintergrund

Rund 1000 Osteopathen praktizieren heute in der Schweiz. Sie besitzen ein inter-kantonales Diplom, und leisten etwas 1'400'000 Sprechstunden pro Jahr in allen 26 Kantonen. Im Juni 2016 wurde die Osteopathie als Gesundheitsberuf auf Bundesebene anerkannt. Um praktizieren zu können, benötigen Osteopathen inskünftig einen Masterabschluss an einer Fachhochschule. Leider verfügen wir derzeit nur über wenige Informationen darüber, welchen Beitrag dieser neue Beruf an unser Gesundheitswesen leistet. Aus diesem Grund haben die Osteopathen sich entschieden, die osteopathischen Dienstleistungen systematisch zu untersuchen.

Zu diesem Zweck hat die « Fondation en Faveur de la Formation et de la Recherche en Ostéopathie » die Forschungsgruppe muskulo-skelettale Pflege der FHG in Freiburg beauftragt, eine entsprechende Umfrage durchzuführen.

Ziel

Ziel der Studie ist es, die Bandbreite der Praxis von Osteopathen zu untersuchen, um so die Rolle dieser neuen Profession im Gesundheitswesen besser zu verstehen. Die Studie soll Grundlagen-Daten liefern, die es erlauben die Profession zu beschreiben, Ziele der Grund- und Weiterbildung zu formulieren, Prioritäten für die Forschung zu bestimmen und die Entscheidungsträger in ihren Entscheidungsprozessen zu unterstützen.

Methode

Diese Studie ist eine Review der Dienstleistungen von 400-500 Osteopathen. Die Studie schliesst diejenigen Osteopathen ein, die die interkantonalen Bedingungen erfüllen, sowie "assistierende Osteopathen". Um die für die Studie in Frage kommenden Osteopathen zu identifizieren, wird das Nationale Register der Gesundheitsberufe benützt (NAREG). Ein weiteres Einschlusskriterium ist der Besitz eines Diploms GDK. Die assistierenden Osteopathen, die ihr erste Prüfung bestanden haben, werden durch die Schweizerische Verband der Osteopathie-Assistenten, durch die GDK kontaktiert, die die Prüfungen organisiert, und durch die Osteopathen-Supervisoren.

Die Studie ist dreiphasig. Die erste Phase besteht darin, den Fragebogen zu entwickeln und zu validieren. Die zweite Phase ist die eigentliche Umfrage. Die Osteopathen werden via Email oder Brief eingeladen, sich auf der Internet-Plattform zu melden und die Fragen zu beantworten. Die Umfrage besteht aus zwei Teilen, der Erfassung der Arbeitsbedingungen der Osteopathen, und der Erfassung der Praxis. Jeder Osteopath soll seiner Praxis nach dem Zufallsprinzip bis 4 Patienten beschreiben, und zwar unter denen, die 2016 zum ersten Mal einen Osteopathen aufgesucht haben. Die dritte und letzte Phase besteht in der Verbreitung der Resultate, sowie der Promotion des Massnahmen-paketes, das wir erarbeitet haben.

Bedeutung und Wirkung

Durch dieses Projekt möchten wir die Kultur des Forschens innerhalb des Osteopathen-Berufs stärken und entwickeln. Das Projekt wurde initiiert und finanziert von Praktikern und unterstützt von Akademikern. Die erhobenen Daten werden internationale Vergleiche möglich machen und dazu beitragen, die nationalen Prioritäten mit einer internationalen Strategie abzugleichen. Auf nationaler Ebene, sollen die Resultate helfen, den Osteopathen-Beruf anderen Gesundheitsberufen und der Öffentlichkeit nahezubringen. Letztlich hoffen wir, dass mit einer solchen Studie die Osteopathen als Dienstleister in der gesundheitlichen Grundversorgung anerkannt werden. Ein besserer Einblick in das, was Osteopathen „machen“, wird entscheidend sein, wenn es darum geht, die Zukunft dieses Berufs sowie die Forschungsprioritäten zu bestimmen.

4 Abbreviations

ASCA	Suisse Foundation for complementary medicines (body that registers osteopaths for them to be refunded by private insurances)
EMR-RME	Registry of empirical medicine (private body that registers osteopaths for them to be refunded by private insurances)
GDK-CDS	Conference of Sanitary Directors (intercantonal body that uniforms and coordinates health policies between cantons)
HRR	Health Record Review
NAREG	National Registry of Allied Health Professionals
SAE	Serious Adverse Events
SAGOM	Swiss Society of Osteopathic Medicine (professional organization grouping physicians with an osteopathic training)
SVO-FSO	Swiss Federation of Osteopaths (Professional organization grouping osteopaths)
SVOA-FSOA	Swiss Federation of Osteopath Assistants (Professional organization grouping osteopath assistants)

5 ADMINISTRATIVE STRUCTURE

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1. ETHICAL AND REGULATORY ASPECTS

1.1 Ethical Conduct of Study

The research project will be carried out in accordance to the research plan and with principles enunciated in the current version of the Declaration of Helsinki (DoH), the Essentials of Good Epidemiological Practice issued by Public Health Schweiz (EGEP), the Swiss Law and Swiss regulatory authority's requirements as applicable.

1.2 Risk categorisation

This study focuses on osteopaths' and their activity as allied health professionals. As such it does not fall under any category. However, the study does require reporting professional management of four cases. Given information from patient record are used, ethical approbation could become necessary.

1.3 Ethics Committee (EC) and Patient representative

The proposed participant information and consent form as well as other project-specific documents has been submitted to the competent Ethics Committee (EC; 2017-00126) who has acknowledged our study does not require ethical approval. A representative of the Swiss Federation of Patients, the Federal Data Protection and Information Commissioner, and the Fribourg Cantonal Data Protection and Information Commissioner were consulted to provide their opinion on the legal aspects of the audit. The sponsor thereby takes legal responsibility for the anonymity of collected data.

1.4 Participant Information and Informed Consent

Osteopaths are informed about the research project (what, how, by whom) within the survey (see Part A of questionnaire, Annexe A). To collect information, they provide their explicit written consent at the end of Part A of the questionnaire. They are attributed 4h of continuous training for their participation. All participating osteopaths will be asked attest they have read the information provided to them in either French, German or English in Part A of the survey (Registration). They are asked to provide their consent by accepting to participate in the first part of the survey (see Annexe A).

Osteopaths are requested to describe their activity with four patients. The Data Protection and Information Commissioners have confirmed there are no legal obligation to obtain consent if the collected data is made anonymous. It has nevertheless been agreed with the Swiss Patient Foundation that patients' interest will be protected and the entire process made transparent to patients. All future analysis on the collected data that are not planned in this protocol will only be done with the consent from the Foundation, the academics (i.e. HES-SO(FR) or investigators), and the Swiss Patient Foundation.

1.5 Participant privacy and safety

The Project Leader affirms and upholds the principle of the participants' right to dignity, privacy and health and that the project team shall comply with applicable privacy laws. Especially, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals.

Names of the participating osteopath is used to verify the eligibility of responders. If requested by participants, it will also be used to provide a certificate for their contribution to be counted as continuous training. The survey system (RedCap) registers data from the questionnaires separately from the file monitoring data entry making it impossible for researchers to link back responses to osteopaths. To assure an additional level of security, data extracted from patient records are registered separately and are therefore not linked to the osteopath who entered them. Once entered, it is therefore impossible to trace anonymised patient data back to the osteopath who entered the data.

Individual participant medical information obtained as a result of this research project is considered confidential and disclosure to third parties is prohibited. Participant confidentiality will be further ensured by utilising identification code numbers to correspond to medical information in the computer files.

For data verification purposes, authorised representatives of the Sponsor, a competent authority, or an ethics committee may require direct access to parts of the resulting dataset.

All data will be encrypted. The data is sent via the Internet and recorded on a certified secured data centre at the Institute of Information Systems, HES-SO. Data protection is guaranteed at the level of data handling and data hosting. Data can be made entirely anonymous and IP addresses are not made available. The full dataset is only made accessible to the study staff. It will be archived at the University on a secured site for at least 10 years.

All data will be handled in accordance to the EU Data Protection laws and guidance set therein. All research data will be anonymized and used in accordance with the guidance set out in EU Directive 2005 on Good Clinical Practice in research.^a

1.6 Early termination of project

There are no apparent reasons to terminate the audit early and none have been planned.

1.7 Amendments, Changes

All changes to the protocol are communicated to the Funder, the Sponsor, the overseeing committee, the ethical committee, and staff. The Project Leader shall submit to the EC any application documents, which are affected by the change. At the same time, the project leader shall provide information on the reasons for the change. Substantial amendments are only implemented after approval of the EC.

1.8 Liability

The study is covered by the liability insurance (Annexe B) with Baloise Assurance, police no 30/4.076.039 for an amount up to 10'000'000.- CHF. This assurance has been tacitly renewed for the period 2017-2020.

^a http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000072.jsp (accessed 23.6.16)

1.9 Dissemination

The audit protocol will be made publicly available on the study web page prior to the start of data collection. The same will be applicable for the study report.

6 Introduction

On the 7th of June 2016, osteopathy was voted, at a federal level, as a recognised health profession^a within the Swiss health care system. This new status will mean that statutory regulation and registration for osteopaths in Switzerland will need to be implemented. Therefore, describing osteopathy, defining practice standards and ensuring patient safety will need to be more formalised.

This political recognition has foresight, as there are increasing demands in primary healthcare that cannot be met solely by primary health care physicians, therefore integrating osteopathy and other allied health professions as usual primary care is based on sound rationale.¹

Due to the ageing population, the Federal Office of Statistics estimate that by 2030, 39% of the needs for consultations in primary care by primary care physicians will not be met, this represents between 3.5 and 9 million encounters.² Osteopaths are in a position to help manage this shortfall. The profile of osteopathic practice in other countries (Australia³, UK⁴, and Canada⁵) reveals that osteopaths provide health care for conditions that are mostly musculoskeletal in nature, but patient profiles indicate that more than a third of patients have other coexisting conditions, therefore osteopaths are also in a position to act as a screening and triage point for onward referrals and to provide general health care advice and support.

In Switzerland,⁶ Belgium,⁷ the United States,⁸ and the United Kingdom⁹ osteopathy has been shown to be widely accepted and appreciated as a health service by the population. Studies have shown that nearly all patients seek care from their osteopaths without seeking prior care.³ They expect professional expertise from their osteopathic care providers.¹⁰ They also accord importance to their practitioner's capacity to listen, inform and respect them.⁹ Osteopaths are generally appreciated for their use of multiple manual therapies, for the time spent by the osteopath to investigate and assess the problem, for the quality of the provided education on health conditions, for lifestyle advice, for the person-centered approach, and for the quality of the therapeutic relationship.¹¹ As such, patients seem to expect osteopaths to play an important role in the management of their health.

In Switzerland, osteopathy has gained in popularity since the 90s.⁶ Osteopathy is perceived as safe given serious adverse events (SAE) following osteopathic care are extremely rare (19.7 SAE per year per 1000 osteopaths).¹² The profession is generally well accepted in the healthcare system even if other healthcare providers lack information on clear indications for osteopathic care.^{13,14}

There are now over 1000 practitioners in Switzerland. Over 99% of osteopaths work independently and provide care in private practices. From Herzig's survey,¹⁵ we estimate osteopaths in Switzerland deliver around 1,400,000 encounters annually. Furthermore, we estimate 280,000 new patients seek osteopathic care every year. Osteopaths are highly

^a GesBG/LPSan 15.077 adopted by the House of States on the 2nd March 2016 (unanimously adopted by 44 votes) and by the National Parliament on the 7th June 2016 (181 votes for, 4 against).

trained primary care practitioners. Switzerland is among the three first European countries to have set the osteopathic education standards at a university master degree level. This is in line with the European Standards for Osteopathy Services^a that recommends European countries provide educational at a level 7 standard in the European Qualification framework (i.e. Equivalent to a Masters degree). All but two cantons, Basel Land and Ticino, have specifically regulated osteopathy as a health profession.

However, little is known about the true role osteopathy plays within the Swiss healthcare system. There are existing indicators for demographics and healthcare service provision from other health providers¹⁶⁻¹⁸ but not for osteopaths. Now that the profession is integrated within the Swiss health system, there is a need to describe osteopaths' scope of practice to better understand their role. This study aims to provide a clear picture of osteopathic activity in Switzerland thereby making it easier to describe the profession, formulate teaching goals, plan ongoing training, identify national research priorities,¹⁹ and provide data for stakeholder negotiation.

6.1 Identified objectives

The study's objectives are to:

- Profile osteopaths' working conditions, their workload and working environment including interdisciplinary collaborations.
- Profile the type of patients seen by osteopaths including their insurance coverage.
- Describe and quantify the primary reasons for consultation osteopaths are facing.
- Profile osteopaths' scope and type of practice
 - Describe average length and frequency of encounters.
 - Describe what type of care is delivered during encounters.
 - Profiling referrals (ei. frequency, conditions or reasons for referral, concerned health professionals).
 - Describing mechanisms for recording adverse events.
 - Describing mechanisms in place to record obtained consent.

6.2 Significance and Impact

This study will provide high quality information for stakeholder decision making. The results will be of interest for those planning continuous training, those preparing students for their clinical activities, for professional associations to promote the activity of their members, for public health policy makers to help decide on the role osteopathy could play to face emerging problems, and for research funders to define their priorities.

Results from this study are expected to help osteopathy manage and promote its position in the Swiss healthcare system. This study will also illustrate that Swiss osteopaths are capable

^a Osteopathic healthcare provision EN 16686:2015

of embracing their own future in a responsible, transparent, and documented way that is focused on the interest of patients.

7 Method and Design

7.1 Design

This study is an audit, or more precisely a practice review, which is a subtype of service evaluation^{20,21}.

There are three work packages (**Figure 1**): the developing phase, the execution phase, and the dissemination of results. Data will be collected by osteopathic clinicians who will be asked to complete an online survey about their practice in 2016. The main part of the survey includes two sections. The first section is to describe the osteopaths' professional profile, the second is to describe what type of service they offer to their patients. To prevent osteopaths changing their behaviour because they are observed, we plan a retrospective health record review (HRR)²² that will have them report their activity during 2016. Figure 1 shows the stages of the survey and estimates for identifying the participants.

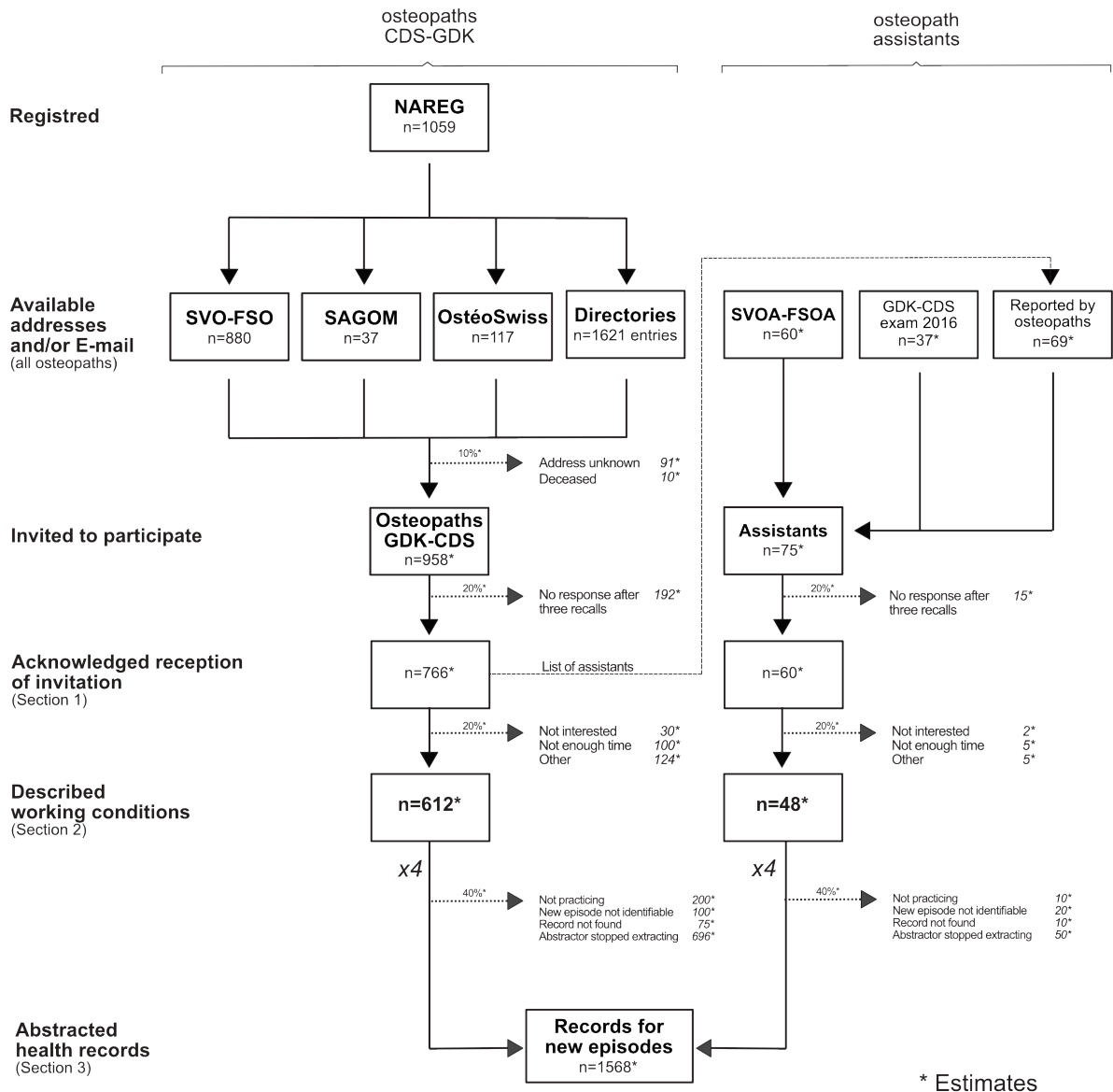


Figure 1 Flow chart for the OsteoSurvey study

7.2 Target practitioners

There are important regional discrepancies in the way osteopaths are registered and regulated as health professionals. The Conference of Sanitary Directors (CDS-GDK) set unified standards for osteopath regulation in 2007. Between 2008 and 2012, over 900 osteopaths, with prior professional experience, passed a simplified procedure with an inter-cantonal exam to be registered as “osteopath CDS-GDK”. Since 2012 all the Swiss Cantons but three (e.i. Basel Land, Ticino, Zurich) now require osteopaths to successfully pass three exams, set and organised by the CDS-GDK. Practicing officially as an independent osteopath without a CDS-GDK equivalence has become an exception in Switzerland.

Since 2012, osteopaths need to work under the supervision of an osteopath with a CDS-GDK diploma for at least two years before obtaining their title of “osteopathe CDS-GDK”. These dependant professionals are called “osteopath assistants”. They represent an important part

of the osteopathic workforce. In most cantons they are required to have passed the first of three of the exams set by the CDS-GDK or be registered for their international statutory recognition.

Osteopathic assistants are not registered on the National Registry of Allied Health Professionals (NAREG) or any other osteopathic registers and do not require an authorisation to practice in most cantons.

This study intends to include only those osteopaths who have an inter-cantonal diploma in osteopathy (CDS-GDK diploma) and a representative sample of osteopath assistants.

There are some non-CDS-GDK accredited osteopaths working either with or without authorisation to practice. Sometimes these osteopaths work in hospitals, others are practicing illegally, some are in cantons that have accorded authorisation for osteopaths without a GDK-CDS diploma (eg. Geneva, Vaud, Ticino, Zurich), and some work in Basel Land, a canton where there is either no requirement to have a specific authorisation to practice. We estimate that there are about 400-600 of these osteopaths. We are not including these osteopaths within this survey as we have no access to the registers of these practitioners. The other reason for exclusion is that we suspect in the future all osteopaths will require the CDS-GDK certificate to be in the national registry, and insurances will not cover 'health care providers' that do not meet the minimum standards to be registered. Finally, the consolidation of unified standards across Switzerland will help protect patients and push cantons to prevent 'health care providers' that do not meet these standards to be able to practice or call themselves osteopaths.

7.2.1 Identifying eligible osteopaths

To recruit independent osteopaths, we will use the National Registry of Allied Health Professionals (NAREG) held by the Red Cross. This registry includes all osteopaths that have had their diploma recognised by the GDK-CDS since 2000. It therefore includes all osteopaths who have passed the inter-cantonal exam organised since 2008 and have received the title "osteopath GDK-CDS". In June 2016, there were 1059 osteopaths with a GDK-CDS diploma.

In June 2016, there were also 230 GDK-CDS osteopaths registered at the Swiss Foundation for Complementary Medicines ASCA, an alternative body working to register osteopaths for complementary insurance companies. The total number of osteopaths with a GDK-CDS diploma reported on MEindex, the official public list of osteopaths registered at the EMR-RME (a private body working for the main private complementary insurances and making refunds for patients possible) was of 84. Both these lists are believed to largely underestimate the total number of working CDS-GDK osteopaths given there are 1621 entries under "osteopathy" in the Swiss phone directory and 1368 refundable practitioners for osteopathic care registered on the lists provided to insurances by the EMR-RME.

For osteopath assistants, there are no existing registries, therefore we will approach all assistant osteopaths affiliated to the Swiss Federation of Osteopath Assistants and ask independent osteopaths participating in the study to report non-affiliated assistants working under their supervision.

7.2.2 Recruitment procedure

All independent osteopaths with a CDS-GDK diploma, and all osteopath assistants supervised by an osteopath with CDS-GDK accreditation will be invited to participate in this online-survey. They will be contacted initially by E-mail and non-responders will then be invited by post or by phone.

The invitation letter will provide each osteopath GDK-CDS with links to their questionnaire and to the study's web site. The survey system will ask them to set their password to access to the questionnaire. We will ask those osteopaths who do not want to participate their reasons for non-participation where relevant. After one month, all those that have not accessed to the invitation will be sent a reminder. Non-responders will then be reminded a third time one month later.

7.2.3 Inclusion criteria for osteopaths

All osteopaths with a GDK-CDS diploma listed on the NAREG registry are eligible. Criteria for been registered are^a:

- Have an Intercantonal diploma in osteopathy (GDK-CDS diploma).
- Be under 70 years of age.

Osteopath assistants are eligible if they are working under the supervision of a GDK-CDS osteopath and that they have passed the first of three of the exams set by the CDS-GDK or be registered for their international statutory recognition.

Those willing to participate are to attest they have read and understood the information letter, that they agree to participate voluntarily to the study (for further details see section **Error! Reference source not found.**).

7.2.4 Expected response rate

A prior survey on the same topic¹⁵ on a random sample of 200 osteopaths had a response rate of 60%. We expect about 600 osteopaths to be included (Number registered = 1059). Each osteopath will be asked to provide information on their activity with four patients to give a sample size of approximately 1,500 records.

Measures we will take to increase recruitment rates are:

- Receive the approval of professional organisations,
- Have professional organisations promote the study among their members,
- Have osteopaths own the study as theirs,
- Value the importance of having high response rates for the image of the profession,
- Send two reminders in case of a non response to the initial invitation,
- Accord an attestation of four hours of continuous professional development training for those participating.

^a Art. 12^{ter}, al. 8 from the "Accord intercantonal sur la reconnaissance des diplômes de fin d'études"

7.2.5 Health record sample selection

To ensure that we have a representative sample of patients, osteopaths are to report profiles from new patients or returning patients with a new complaint or a new episode. Selecting patients from encounters only might lead to an over-representation of those consulting for conditions that require more visits. To achieve the set statistical power, we have estimated that we need 1,500 patient records.

We will use a quota sampling method to have each osteopath select a fixed number of pseudo-random health records of new patients who visited them in 2016. For them to select records, we will provide a random list of appointments time frames. The patient health record to be selected is the one belonging to the first new or returning patient with a new episode that was seen within the 24h period after the given appointment time. If no new patients were seen during that period, the clinician has a second level choice, and so on until the osteopaths locates a patient record belonging to a new patient from 12 possible choices. The same procedure is repeated for each of the four health records to be included.

List of random appointment days have been generated for 1,200 potential participating osteopaths using an Mersenne Twister algorithm that randomly assigned 12 possible dates for each of the four new patients to be selected. We stratified randomisation by half quarterly. Therefore, each osteopath selects patients throughout the year. Time for each appointment was randomly selected between 8:00 AM and 17:00 PM.

Within the survey, each osteopath will receive instructions to look at a specific time frame. These random time frames are provided automatically by the RedCap survey platform. The advantage of this approach is that it makes it possible for osteopaths to select the record using their agenda. They will have selected a patient within a 24h timeframe from 12 possible dates. Patient level data is anonymised and does not hold any information making it possible to link back to the patients. Furthermore, patient data is recorded separately from osteopaths' data making it impossible to link patient data back to each osteopath. Finally, we will not retain the exact time of the consultation making it impossible to link back to the patient's identity even if osteopaths' agendas were accessed to.

This sampling method is not totally at random given that periods that follows a day or time during which encounters are less frequent will be over-represented (e.g. Mondays, time slots following lunch breaks, early morning consultations for those that do not begin at 8:00 AM).

7.2.6 Inclusion criteria for patient records

Inclusion criteria for health records are:

- The record belongs to a patient who was seen by the osteopath within 24h of the provided date and time given at random by the system.
- The record belongs to a new patient or to a returning patient with a new complaint or a new episode. A new episode is defined as a recurrent complaint that has been symptom free for at least six weeks since the last visit.
- This encounter took place in Switzerland.
- The patient provided their oral consent for information from their record to be transmitted anonymously.

7.3 Survey tool

The study will collect data using a user-friendly web interface compatible with smartphones. A dedicated website will be opened specifically for the study.

7.3.1 Web pages

For this study we will put up a Web site dedicated to monitoring scope of practice. It will be organised in eight sections:

- Language choice
- Patient / osteopath interface (three languages)
- Welcome page (three languages)
- Start Survey (link not page)
- About this study
- Instructions
- Newsletter
- Contact information
- FAQ

Language will be chosen by default depending of the user's computer's browser display language.

7.3.2 Survey system

The registration – Part A, the Survey – Part B, and the Survey – Part C, will be constructed using a user friendly web based online study data management system called RedCap making it possible for osteopaths to enter data using their computer or smartphone. Using their login, participating osteopaths will be able to re-enter and complete their survey at any time.

7.3.3 Languages

The invitation letter, the information form, also included in the Registration – Part A, web pages and their content will be provided in French, German and English. The default language will be chosen by the user on the entry page. Survey questions will be translated by professional interpreters from English to French and German and back-translated to English by a second translator to verify consistency. Discrepancies are to be discussed between translators before coming to a final resolution.

7.4 Survey framework

For comparability, we will be using similar questions to those used in validated questionnaires used in prior surveys.^{12,23} These might however need adaptation to fit to the Swiss setting. The first draft (see Annex 2) of the future survey questions will therefore be seen, critical appraised and discussed by a validation group.

The survey is organised in three parts. The first part is to record if the contacted osteopath is willing to participate and collects informed consent from those that are. The second part collects demographic information on their working condition. The third and last part collects extracted data from the anonymised patient health records.

All contacted osteopaths and osteopath assistants are expected to provide a response to the first part. Those who wish to participate to the survey will need to provide their online informed consent. They will be asked to attest they have read and understand the information related to the study, that they were able to receive any information they needed from the research staff to help make their decision, and that their decision to participate is revocable at any time. Once Part A is completed, the system automatically registers them as participants and opens Part B of the survey. Using a link, all GDK-CDS osteopaths are invited to send an E-mail reporting contact information for an assistant working for them that would not be a member of the SVOA-FSOA.

Questions for Part B (working conditions) and Part C (patient profiling) are constructed from validated questions extracted from the KPMG Report,²⁴ the Snapshot Survey,²⁵ The CRAn Project,¹² and from the Standardised Data Collection Project.²³ Questions on information and consent are to be included given patients seem to have high expectations.²⁶

Details of the developed questionnaire are made available in the Annexe A.

7.5 Optimizing the quality of the responses from the survey

Particular attention will be taken to ensure that the nature of the collected data corresponds to future needs (external validity) and that the provided responses reflect at best what the osteopaths have experienced (internal validity).

To assure the external validity we will convene a focus group of osteopaths, stakeholders and researchers (up to 6 people) to test the questionnaire's face and content validity. This is organised in three steps.

First, six osteopaths will be asked to read the English version of the questionnaire and provide their feedback during a 1-2h structured interview. At each step, the questionnaire is improved and tested onwards.

Second, we are to use a think aloud approach with five osteopaths to test the English version of the questionnaire.

Finally, 10 French speaking and 10 German speaking osteopaths are to provide their feedback on the translated versions.

For internal validity, we will pre-test (pilot) the survey to test the reliability of health record selection, the data extraction, and data entry using the online system. We will have 20 osteopaths extract and enter data from one of their patients record and from a second anonymised record from another unknown osteopath. The research team will also extract data from the 20 records. We will therefore have 20 patient records entered three times

making it possible to study the consistency of the data extracted by and between the osteopaths.

7.5.1 Study governance - Oversight committee

We will appoint an oversight committee. To oversee the conduct, progress and the integrity of the study. The oversight committee will check that the study is conducted in accordance with: the Principles of Good Practices and relevant regulations. They will review adherence to protocol, any participant safety and or ethical issues. It will include members who represent the Swiss Federation of Osteopaths (FSO), and the Swiss Federation of Osteopath Assistants (FSOA), and the Swiss Federation of Patients. The main concern been the use of the data and the respect of confidentiality for extracted data from patient records.

7.6 Quality assurance and surveillance

7.6.1 Monitoring data entry

Survey status can be monitored from the survey software and targeted reminders will be sent updates and reminders automatically. This is particularly important for patient health record entry given we expect participant abstractors to enter their data on more than one occasion. Patient information is entered anonymously from the start. For data entered by osteopaths, only their status within the survey is linked to their identity.

During the first month, all entries will be screened to detect difficulties in answering questions from the survey. Open fields and reasons for leaving unanswered questions will be explored.

7.7 Statistical analysis

7.7.1 Sample size calculation

In Switzerland, we estimate that there are 280,000 new patients per year attending one of the 1033 osteopaths. From previous surveys, we expect a 28.1% response rate. To have a 5% margin of error with confidence intervals of 95% for conditions that have at least a 5% prevalence, we therefore need to include at least 1365 health records. Expecting 10% of missing data, the total number of records to include is rounded to 1500.

7.7.2 Managing missing data

Data is collected anonymously. It is therefore impossible to contact osteopaths to complete data. For data extraction from the health records, abstractors will always be given the opportunity to answer “unknown”. For other questions, osteopaths are always invited to answer “not applicable” and provide a text for explanation. Missing data should therefore only occur if participant cease answering the survey prematurely. In the analysis, unknown or non-applicable answers will be analysed alongside other possible answers.

7.7.3 Accounting for sampling error

There are two levels of sampling errors; at an osteopath level, and at a patient health record level. To infer results to the general population, we will therefore be using multilevel modelling to account for disparities in characteristics between those included in the study and those having refused or having dropped out. We will be using a maximum likelihood

strategy after searching for dropout patterns. All estimates will be provided with confidence intervals of 95%. For comparing sub-groups, statistical significance is set at $p < 0.05$ without adjustment for multiple testing.

8 Timeframe

The study is designed to start in September 2016 and lasts one year. Details on the schedule of each planned task is provided in **Table 2**.

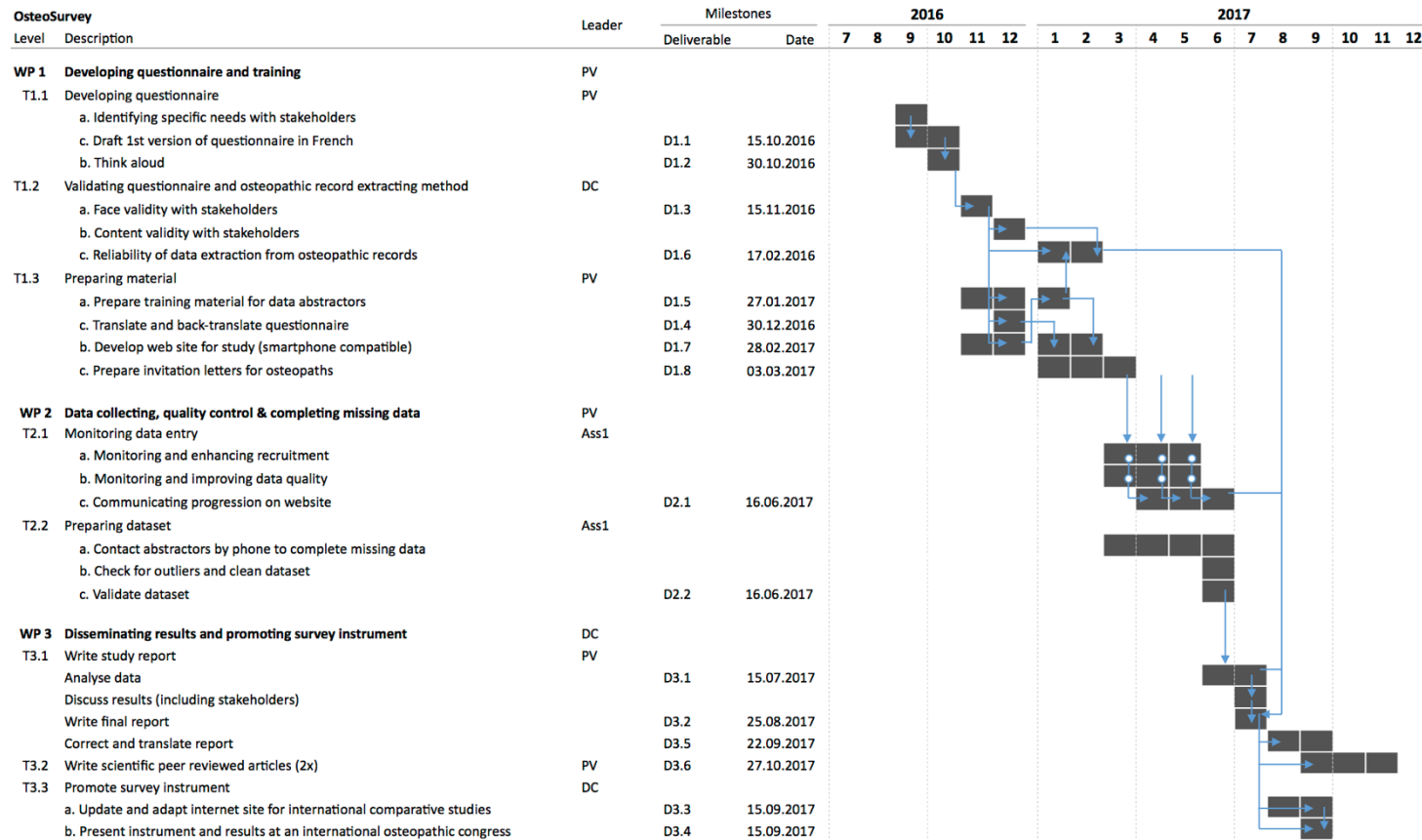


Figure 2

Gantt chart for the OsteoSurvey study

9 Deliverables

Among the 16 planned deliverables (see the **Table 1** below and the blue triangles in the Gantt chart on **Figure 2**), three are of major importance for stakeholders. These are:

- The short report written in three languages to communicate and promote the importance of osteopathic care in the Swiss healthcare system (D3.5).
- A video of the oral presentation planned for the Osteopathic International Alliance Congress (D3.4).
- Two scientific articles in indexed scientific journals (D3.6) written in accordance to the GATHER statement.²⁷

Code	Description	Delivery date
D1.1	1 st version of questionnaire	15.12.2016
D1.2	2 nd version of questionnaire in English	25.12.2016
D1.3	3 rd and final version of questionnaire before translation	03.02.2017
D1.4	Electronic questionnaires in four languages	20.02.2017
D1.5	Training material for practitioners (abstractors)	27.02.2017
D1.6	Report on feasibility of using health records	27.02.2017
D1.7	Web platform tested and ready for use	28.02.2017
D1.8	Post material to osteopaths	03.03.2017
D2.1	Final report on recruitment and data quality	16.06.2017
D2.2	Cleaned and sealed dataset	16.06.2017
D3.1	Statistical report and statistical output file	15.07.2017
D3.2	1 st draft of full report & short report in English	25.08.2017
D3.3	Internet page including report and ready to run new surveys	15.09.2017
D3.4	Oral presentation for OIA congress	15.09.2017
D3.5	Short report in French, German, and English, full final report	22.09.2017
D3.6	Submit two articles to indexed peer reviewed journals	27.10.2017

Table 1 *Planned deliverables for the OsteoSurvey study*

10 Budget

The total budget for this study is of 152'680 CHF.- The study is funded by the HES-SO and by the Foundation Promoting education and Research in Osteopathy. Details for every work package is made available in the following table.

	WP1 (Sep 2016 – March 2017)		WP2 (March 2017 – June 2017)		WP3 (June 2017 – Nov 2017)		TOTAL	
	Foundation	HES-SO	Foundation	HES-SO	Foundation	HES-SO	Foundation	HES-SO
Direct personnel costs								
Key personnel								
Paul Vaucher, Project leader (110.-/h)		CHF 31'020		CHF 3'520	CHF 1'760	CHF 33'440	CHF 1'760	CHF 67'980
Dawn Carns, Scientific advisor and supervision (110.-/h)		CHF 2'200		CHF 660		CHF 10'560	CHF 0	CHF 13'420
PhD graduate student								
Research assistant (35.-/h)	CHF 11'460		CHF 11'460				CHF 22'920	CHF 0
Other Personnel								
Olivier Desmeules, informatics & technologies (70.-/h)	CHF 1'120		CHF 840		CHF 280	CHF 280	CHF 2'240	CHF 0
François Moser, administration (70.-/h)		CHF 560		CHF 280		CHF 280	CHF 0	CHF 1'120
Nicole Demierre Rossier, communication (70.-/h)	CHF 1'120				CHF 420		CHF 1'540	CHF 0
TOTAL Personnel	CHF 13'700	CHF 33'780	CHF 12'300	CHF 4'460	CHF 2'460	CHF 44'280	CHF 28'460	CHF 82'520
Subcontracting costs								
Translations Transit TXT								
Questionnaire (F + D)	CHF 5'280						CHF 5'280	CHF 0
Instructions / invitation letter	CHF 1'000						CHF 1'000	CHF 0
Web page	CHF 1'200						CHF 1'200	CHF 0
Short report					CHF 3'520		CHF 3'520	CHF 0
Counselling (overview committee)								
Swiss Federation of Osteopaths	CHF 500		CHF 100		CHF 200		CHF 800	CHF 0
Swiss Federation of Assistant Osteopaths	CHF 500		CHF 100		CHF 200		CHF 800	CHF 0
Swiss Federation of Patients	CHF 500		CHF 100		CHF 200		CHF 800	CHF 0
TOTAL Subcontracting costs	CHF 8'980	CHF 0	CHF 300	CHF 0	CHF 4'120	CHF 0	CHF 13'400	CHF 0
Other direct costs								
Materials and supplies								
Postal (paper, envelopes, stamps 2'600x)	CHF 5'200						CHF 5'200	CHF 0
Travel costs								
Members of the pilote steering committee	CHF 600				CHF 400		CHF 1'000	CHF 0
IOA congress						CHF 1'500	CHF 0	CHF 1'500
Ethical commission								
	CHF 800							
Publication Costs								
Editing English					CHF 1'600		CHF 1'600	CHF 0
Open source publications					CHF 3'000		CHF 3'000	CHF 0
TOTAL Other direct costs	CHF 6'600	CHF 0	CHF 0	CHF 0	CHF 5'000	CHF 1'500	CHF 10'800	CHF 1'500
TOTAL Direct costs	CHF 29'280	CHF 33'780	CHF 12'600	CHF 4'460	CHF 11'580	CHF 45'780	CHF 52'660	CHF 84'020
Indirect costs (max 25% direct costs)								
Building (incl. electricity and heating)		CHF 2'400		CHF 1'600		CHF 1'600	CHF 0	CHF 5'600
Informatics (licenses, hardware, web hosting)		CHF 300		CHF 200		CHF 200	CHF 0	CHF 700
Secretary work / telephone		CHF 1'000		CHF 750		CHF 750	CHF 0	CHF 2'500
TOTAL Indirect costs	CHF 0	CHF 3'700	CHF 0	CHF 2'550	CHF 0	CHF 2'550	CHF 0	CHF 8'800
TOTAL	CHF 29'280	CHF 37'480	CHF 12'600	CHF 7'010	CHF 11'580	CHF 48'330	CHF 52'660	CHF 92'820

Table 2 *Planned budget for the OsteoSurvey study*

11 Terms of reference^a

11.1.1 Guiding principles

- This project will engage a set of principles that will foster osteopaths' ownership. This includes empowerment among team members of the oversight committee.
- This project will engage in an open and transparent process where a collective vision of research goals and objectives is shared, and where the roles and expectations of team members are clearly understood;
- This project will provide opportunities for capacity building through “learning exchanges” where team members can learn about research skills, public health principles, and informed decision making;
- This project will employ dissemination strategies leading toward education, advocacy, community benefit, and social change;
- This project will foster a supportive team environment through critical reflection of our work and group process.

11.1.2 Access and dissemination of data

The principle investigator and the co-investigator share ownership and have full access to the research data. Usage of the data will be in accordance with the project goals.

Data will be used for:

- advancement of knowledge;
- identification of future research questions;
- making recommendations for policy and service provision.

The data should not be for:

- individual interests that are not related to the goals of the research.

We are proposing a model of dissemination that encourages the active involvement of all research team members while taking into account their varying responsibilities and capacities. Research findings will be disseminated in various ways including community forums, conference presentations, agency workshops, newsletters, and journal articles. The Principle Investigator, the Co-investigators, and the Funder are all encouraged to engage in dissemination of the research findings, and are encouraged to share information about potential dissemination activities.

The Principle Investigator will take the initiative in identifying potential journal articles and discussing them with the team. Articles may be written by individuals or by writing groups formed to develop particular manuscripts. All members of a writing group will share authorship on a manuscript. Order of authorship and mechanisms for feedback on manuscript drafts will be decided up front by writing group members. Groups may also be formed for the development of conference presentations, community forums, and other dissemination activities.

^a Adapted from https://depts.washington.edu/ccph/pdf_files/MOU6.pdf

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11.1.3 Role and responsibilities

This project recognises that roles and responsibilities differ among Principal Investigators, Co- Investigator, staff, oversight committee, sponsor, and funder.

- **Principal Investigator's (PI) responsibilities:** The PI will provide leadership in every aspect of the project with support from the Co-Investigator. This includes overseeing the entire project, coordinating research team activities, managing the budget, reporting to funders, supervising staff, and ensuring the dissemination of research findings.
- **Co-Investigator's responsibilities:** The co-Investigator will participate in all aspects of the research project, taking into account individual and organizational capacities, (skills, available human and other resources). The co-Investigator will participate in team meetings, learning exchanges, the formulation of research questions, provide suggestions and feedback on the methodology, and provide input on recruitment, data collection, data analysis and interpretation, and dissemination. The co-investigator will lead the writing of at least one scientific article as first author.
- **Staff responsibilities:** Staff responsibilities will include team building (e.g., facilitating meetings and learning exchanges, liaising with individual team members), coordinating project administrative activities (e.g. minutes, meeting agendas), service providers, and key informants, and setting up and monitoring data collection. Staff will also check data and contact participating osteopaths to complete missing data when possible.
- **Oversight committee responsibilities:** The committee ensures the protocol is adhered to and take action, as necessary, to remedy any difficulties. It ratifies any protocol amendments or deviations as required. It considers ethical issues and determine necessary actions. It coordinating outreach to practitioners for recruitment, it ensures the funders interests are accounted for (adherence to the protocol as the contract and budget expenditure), and it determines a schedule of meetings as seen as appropriate for the study.

- **Funders' responsibility:** The study funders, the Foundation Promoting Education and Research in Osteopathy and the School of Health Science–Fribourg are responsible for accepting the project, providing financial resources to meet expectations, verifying expectations are met, and for promoting the implementation of results from the research.
- **Sponsor's responsibility:** The sponsor, the School of Health Sciences – Fribourg, is liable for the entire study. It is responsible for covering damages occurring during the study, to manage juridical aspects of eventual legal actions, and to administer the budget for the study.

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