PhD Dissertation

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COMPLEMENTARY AND ALTERNATIVE MEDICINE AND THE HEALTHCARE SYSTEM OF GEORGIA

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Contents

Abreviations

AM - Alternative Medicine
CAM – Complementary and Alternative Medicine
CAMbrella – a pan European research network for CAM
CI – Confidence interval
CL – Confidence limit
GP – General Practitioner
CM - Complementary Medicine / Conventional Medicine
EU – European Union
EC – European Commission
EEA – European Economic Area
EFTA – European Free Trade Association
IH - Integrative Healthcare
IM - Integrative Medicine NCCAM – National Center for Complementary and Alternative Medicine
NCCAM – National Center for Complementary and Alternative Medicine
NCCIH – National Center for Complementary and Integrative Health
OR – Odds Ratio
TCM – Traditional Chinese Medicine
T&CM – Traditional and Complementary Medicine
TEM – Traditional European Medicine
TM - Traditional Medicine
OAM – Organization of Alternative Medicine
OTC – Over the counter
UCM - Unconventional Medicine
WHO – World Health Organization

Part I – Literature Review

Chapter 1. Problem Statement

The increasing globalization, climate and environmental changes, resource deficits, poverty, migration, prevalence of non-communicable disease (cardiovascular diseases, mental health disorders, neoplastic diseases and others) and challenges such as antibiotic resistance are some of the health issues expected to become even more relevant in the future. The world is undergoing a period of great environmental, social and demographic transitions (primarily due to globalization, mass migration and population aging). This increase in the global burden of in fact all the healthcare directions challenges the scientific, human and material resource capacities of every healthcare system, and prompts scientific quest for problem solutions.

At the same time a tendency of increase of Complementary Alternative Medicine use has been observed over the last 20 years, forming a problem of epidemiological, economical and politically importance for public health. (Silenzio, 2002) CAM has been mainly used to maintain and improve health, as well as to prevent, diagnose, relieve or treat illnesses outside the conventional healthcare, but in some countries certain treatments are being adapted by conventional healthcare. (Falkenberg et al, 2012) The United States (U.S.) National Center of Complementary and Integrative Health reports the prevalence of CAM use to be over 33% in the adult USA population. (United States Department of Health, 2016, Clarke et al, 2015) More than 100 million EU citizens are 'regular' users of CAM, predominantly for the treatment of chronic conditions. (Eardley et al, 2012) Some authors found that CAM is used for general wellbeing improvement and disease prevention. (Katz, Ali, 2009) It has been suggested population concerns with side-effects of conventional treatments has largely prompted people to resort to CAM, as a consequence of a general dissatisfaction with conventional medicine's abilities to treat chronic diseases. (Barnes et al, 2008), CAM is often regarded closer to patients' views and perceptions of health and illness, its treatment and prevention approaches. (Eisenberg, 1998) Further reasons stated for CAM use are the lack of affordability and unavailability of conventional health services. (Wells et al, 2011) The sale of CAM modalities

and drugs is usually not regulated and therefore simple to access for patients. CAM practitioners tend to dedicate more time to their patients than conventional medicine physicians who have not enough time. CAM thus makes patients feel treated with more attention as they try to avoid the side effects of chemical drugs and surgery complications. (S. Early 2012)

The Association of European CAM organizations "EUROCAM" claims that CAM could contribute to the following healthcare priorities in Europe: patient empowerment, personalised medicine, safety, innovation, cost-effectiveness, healthy ageing, prevention, and other.

The rise of CAM popularity is all the more notable considering the fact that CAM services are often not covered by private or public insurance programmes in a majority of countries. In fact, CAM services accounted for large parts of out-of-pocket expenses for treatment or health maintenance in such nation as the US. (United States Department of Health, 2016)

Medical standards and public health ethics apply to CAM as it applies to any other form of medicine. Informed decision making, autonomy, beneficence, safety, social justice, availability of services and other aspects in the practice of CAM should be studied and applied to CAM as to any discipline of medicine. (Erns, Hung, 2011) For the practice of CAM, the frames of legal responsibility towards the public by a number of key stakeholders applies likewise. (Jacobson et al, 2009, Katz, Ali, 2009)

A number of medical education programmes across the world introduce CAM compenent in their graduate, post-graduate and continuous professional development curricula. At this time, is not clear what is the CAM education status of patients, conventional medicine physicians and if or how such knowledge is delivered to students, physicians and finally patients in Georgia.

Information available to patients and their sources play a crucial role in the patients' decision making regarding their health care. Patients' health literacy and biomedical professionals' attitudes towards CAM influences how do patients obtain information and make health related decisions. Evidence-based patient information is essential to assure safety and appropriate health related decision making process. (Jacobson et al, 2009)

At this time, more and more studies are published scrutinizing efficacy and safety of various CAM modalities from Evidence-Based Medicine point of view. Many of these studies compare CAM to placebo, while others also compare to established "conventional" treatment methods. We should note that until recently good quality studies on these issues were rarely published. Our research doesn't hold an aim to prove or disprove effectivity and/or effectiveness or demonstrate direct evidence-based risks (which, particularly in light of possible CAM-conventional medicine interactions or undertreatment) of any CAM modality, but for general insight into the situation we could use the following comparison given by EUROCAM that: "*A review of 145 Cochrane reviews of RCTs in the field of CAM using the 2004 database revealed that 24.8% concluded with a positive effect or possibly positive effect (12.4%), 4.8% concluded that there was no effect, 0.69% concluded that there was a harmful effect, and 56.6% concluded that there was insufficient evidence. (Institute of Medicine, 2005)* As the safety concerns arise, some institutions raised the issues of not only potential risks but also possibility of use of illegal ingredients and substances in CAM products. (Byard et al, 2017)

Some countries, such as for example the United States, have big, governmental bodies dedicated to CAM research and related activity management. The National Center for Complementary and Integrative Health (NCCIH) (demonstrating gradual shift of focus from providing "alternatives" to integrating health approaches and management). The 124 mil dollar funding was dedicated to: *"Advance fundamental science and methods development; improve care for hard-to-manage symptoms; foster health promotion and disease prevention; enhance the complementary and integrative health research workforce; and disseminate objective evidence-based information on complementary and integrative health interventions".* (NCCIH, 2016)

Such countries as China and India can demonstrate examples of successful medical system integration (particularly in service delivery in China workforce in India). State administration regulating traditional Chinese medicine manages various practices in China, representing 18% of medical visits (900 million visits/year) and 16% of inpatients (13 million patients/year). Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH)

centrally manages CAM in India with over 780,000 registered AYUSH practitioners, and 1 million village-based AYUSH health practitioners. (European Parliament, 2017)

Previous studies showed that CAM users, in general, engage in more positive health behaviors and lifestyle choices than non-users; (Uprurch, 2015, Nahin et al, 2007) CAM users describe their health as positive more often than non users. (Nguyen, 2011) CAM is also seen as an innovative practice contributing to health literacy enhancement. It increases self-awareness about how the individual lives her/his life; helps to (re-) gain greater control and make active choices to support own health and well-being; is a combination of individualized, holistic care and engagement with client; promotes health and contributes to health maintenance, illness prevention. Integration of CAM and conventional care thus adds treatment options for a person with an acute or chronic condition. (Long, 2013)

The World Health Organization (WHO) sets out the course for Traditional and Complementary Medicine for the next decade in the Traditional Medicine Strategy 2014-2023, which mandates all the member states to introduce, improve and develop CAM research projects, as the base for policy development in member states and internationally. (WHO, 2013) Research strategies were developed in various regions, including Europe. (Fischer et al, 2014)

As the international community stimulates research into CAM, research on CAM in Georgia is extremely limited, while anecdotal reports and observations demonstrate high prevalence of use, long lasting traditions and a steady market of services and products. Considering the Association Agreement between Georgian and the European Union which went into force in 2016, more and more liberal trade relations and Georgia's aspirations of EU membership, we considered it timely to initiate a research project addressing the issues of CAM practice, regulations and conventional care integration in the country, both in the national (interests, safety and benefits of our citizens/patients), as well as international (Global Health, European perspective) contexts. We hope that, by producing reliable information, the present research will enable patients, service providers, policy makers and other stakeholders to implement informed decisions.

Chapter 2. Complementary and Alternative Medicine, its Definition, Nomenclature and Classification

Despite the wide range of applications and hundreds of millions of people using it internationally, the exact definition of CAM remains uncertain and difficult to achieve. Different cultures, nations, organizations (international, local, governmental and nongovernmental), unions and persons often define CAM in their own way. In the present chapter, we will try to overview and discuss the present specter of diverse approaches to define CAM, with focus made on the major organization definitions. Research aimed to establish an "operational" definition has been under way for years, with still no agreement, and even doubt such can be developed at all. (Wieland et al, 2011)

There is an overlap between the definitions of CAM and conventional medicine. It is very difficult to unite different methods of treatment, regional and local intervention techniques and medical approaches into one domain, which is called CAM, unless we specify exactly what does CAM mean. There is a real topological difference of practice acceptance into a list of alternative and complementary medical approaches.

The WHO has been using the term "Traditional Medicine". According to the organization, Traditional Medicine is defined as: *"Traditional medicine is the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures that are used to maintain health, as well as to prevent, diagnose, improve or treat physical and mental illnesses".* (WHO, 2008) In another, more simple way, Traditional Medicine can be used to denote any medical tradition with a long history.

Major politico-economic unions such as the EU prefer and tend to use the term "Complementary and Alternative Medicine", although the main structures of the organizations, such as European Parliament, European Public Health Alliance, and others stress, that the definition must be more specified, and a certain selection of treatment disciplines should be available, to differentiate exactly what is CAM and what is not. Some therapies are accepted by majority as CAM while other therapies (such as vitamins or massage) are considered as CAM by some but not others. Explaining what does CAM does literally mean is not difficult, it is obvious, that "complementary" stays for something to complement the widely available and accepted "conventional" approaches to medical services, not rejecting them, and "alternative" mainly means that an alternative method of diagnostic and treatment methods are used by the practitioners to cure a patient. The "alternative" methods are largely considered to be sufficient to provide adequate service to a patient, without a necessity of conventional biomedicine services to be available. According to some sources the term Alternative Medicine should be applied to modalities not proven to be effective scientifically, although such definition leaves a large uncertainty. Others claim that all that lies beyond the limits of conventional medicine, which as well makes us the following question: so what is conventional medicine?

Another commonly used concept is the "Integrative Medicine" or "Integrative Medicine and Health" defined (by the International Consortium for Integrative Medicine and Health) as *"Integrative medicine and health reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic and lifestyle approaches, healthcare professionals and disciplines to achieve optimal health and healing."*

According to the conclusion of the European research network for complementary and alternative medicine, known as CAMbrella, there are terms used in science and "elsewhere". Among those in science are: AM Alternative Medicine, CM Complementary Medicine, UCM Unconventional Medicine, TM Traditional Medicine, IM Integrative Medicine (considering an

integration of conventional and nonconventional approaches and methods of treatment), IH Integrative Healthcare and of course CAM itself - Complementary and Alternative Medicine.

`Traditional Medicine´ used by the WHO is quite imbalanced and not acceptable to be used precisely by Western countries, as the word "traditional" here rises many questions. Another term was proposed: TEM (Traditional European Medicine), which could help to distinguish different aspects of tradition in medicine.

The EU workgroup on CAM developed the following definition:
Complementary and Alternative Medicine (CAM) utilized by European citizens represents a variety of medical systems and therapies, based on the knowledge, skills and practices derived from theories, philosophies and experiences used to maintain and improve health, as well as to prevent, diagnose , relieve or treat physical or mental illnesses. CAM has been mainly used outside the conventional healthcare but in some countries certain treatments are being adopter or adapted by conventional healthcare. (Falkenberg, 2012)

Among other definitions of CAM, the widely-accepted theoretical definition by the Office of Alternative Medicine (OAM, later became the US National Center for CAM (NCCAM)) expert panel presented in 1995. It states that *"Complementary and alternative medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period."* [OAM, 1995]. The Cochrane Collaboration defines CAM as: *"a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health systems of a particular society or culture in a given historical period".* The British Medical Association (BMA) suggests that a more accurate term might be 'non-conventional therapies', defined as: *"those forms of treatment which are not widely used by the conventional healthcare professions, and the skills*

of which are not taught as part of the undergraduate curriculum of conventional medical and paramedical healthcare courses". There are a couple of objections which make this definition not widely acceptable for use. First of all a number of medical schools offer courses and modules on CAM to undergraduate students. At the same time more and more "conventional medicine" doctors of different practices now offer increasing amount of non-conventional treatment methods to their patients.

The head of the CAM department at Exeter University, Great Britain, provided the following definition: *"Complementary medicine is diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine"* (Ernst, 1995). The author gives the definition of the "complementary" but not alternative medicine, making it not functionally acceptable to be a proper CAM definition.

Having reviewed the variety of proposed CAM definitions, we should note that it is difficult even for experts in the topic to choose one which would suit most of the possible situations and audiences. It is hard to apply any of the above mentioned definitions to Georgian reality directly, hence forming one of our research objectives on Georgia adapted definition development or selections of those mentioned above.

CAM classification is a subject of research, is a complex topic influencing research, practice, use and other issues. Classification is directly based on the definition and more precisely, an operation definition, which remains a topic of debate. (Wieland et al, 2011)
Classification of CAM requires a deep knowledge of different disciplines and in its optimal settings can clear much of what should be known by non-specialists and help specialists and practitioners in their work. Some authors suggest that CAM therapies should be simply listed alphabetically, instead of being grouped conceptually. It was found that classification can actually influence the use of CAM by population. (Kristoffersen et al, 2008)

There was a classification provided by the U.S. Department of Health and Human Services, National Center for Complementary and Alternative Medicine (Silenzio, 2002):

- **Whole medical systems** such as homeopathy, naturopathy, TCM, and ayurveda.
- **Mind-body medicine** such as meditation, prayer, mental healing, art or music therapy.
- **Biologically based practices** such as dietary supplements, herbal supplements, and scientifically unproven therapies such as shark cartilage.
- **Manipulative and Body-Based Practices** such as spinal manipulation and massage.
- **Energy therapies** such as qigong, reiki, therapeutic touch, and electromagnetic therapy.

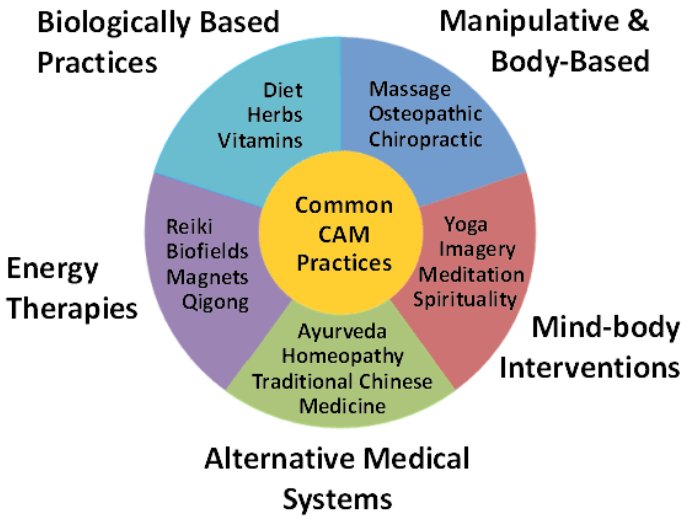

Figure 1. Complementary and Alternative Medicine Classification. Source: National Center for Complementary and Integrative Health (USA)

This classification was later updated, when the center was transformed into a National Center for Complementary and Integrative Health, and now includes Mind-body practices, Natural products, and other medical methods and systems, including traditional healers, Ayurveda, traditional Chinese medicine, homeopathy, and naturopathy.

A special list of non-CAM therapies often considered as CAM can be attached to the classification. Placing therapies in more than one place in the topics list and defining subheadings would be additional goals to achieve.

Chapter 3. Complementary and Alternative Medicine in Georgia

The Republic of Georgia in the South Caucasus is a country of breathtaking natural beauty, with a high culture developed over thousands of years, including an own language and an own alphabet only used in the country. The Georgian population has used different forms of CAM for many centuries. Medical traditions in the region developed under various influences. Traditions from Central Asia, Greece, Byzantine Empire and other areas found an area for influence and development on Georgian soil. First written medical records in Georgia were documented as long ago as in the 10th century (though foreign sources describing Georgian medical traditions date back to antique time). A work titled "Ustsoro Karabadini" provided knowledge on folk remedies, herbs and other health related approaches. (ქანანელი, 1940) Among other well known works are "Tsigni Saakimoi" from 13th century (ხოჯაყოფილი, 1935), "Samkurnalo Tsigni-Karabadini" from 15th century (ფანასკერტელი-ციციშვილი, 1986) and "Iadigar Daudi" first published in the 16th century with subsequent editions published later. (ბაგრატიონი, 1985)

The 20th century and the rise of Soviet Union saw many medical traditions going to background, with fast development of conventional medicine. At the same time complementary and alternative medical methods such as homeopathy or acupuncture reached Georgian population through literature and new-coming practitioners specializing in these modalities. It should be noted that despite general suppression of CAM in the Soviet Union, the knowledge on the methods was not only kept, but also certain research is witnessed to have been underway in the country. With the downfall of the Soviet Union, the use of CAM became more and more

common in the country. On one hand it should be attributed to dissolution of existing medical services, on the other hand lack of finances, as well as change in philosophic and spiritual environment in the country.

Today, use of CAM is expected to be quite prevalent, but no reliable data is available at this time. According to the Analysis and Consulting Team report released in 2014, 18% of the population use CAM services together with conventional medicine, and about 4% use CAM exclusively. In the capital city of Tbilisi, 27% of the population trust alternative treatment methods and 20% had used CAM at least once in their life. The majority (62%) of users were satisfied and report positive outcomes of treatment.

Reliable scientific data through published articles or other peer-reviewed scholarly work on CAM medicine in Georgia is hardly available. Most of it is limited to the description of folk herbal treatment methods and botanic literature (for example as mentioned in the overview of medical plant use in Traditional Medicine of Caucasus (Mamedov, 2015). Descriptive narratives by The Research Department of History of Georgian Medicine and Traditional Medicine (founded in 1956, dissociated and ceasing its functioning in the 1990s) are of particular value. The department, together with the Department of History of Medicine at the Tbilisi State Medical University, has published about a thousand scientific reports on plants used for healing by traditional medicine followers based on more than 40 expeditions to many parts of Georgia. (Shengelia, 1999) Based on the discoveries done by the department, the Georgian Medicine History Museum was founded in 1963. Such authors as M. Shengelia have published dozens of extensive works on medical traditions in Georgia. (მიხლაძე, 2002) Interestingly, specialists in medical history don't percept Georgian Traditional Medicine as "alternative" or "complementary". (Shengelia, 1999) Lately, a study of attitudes towards homeopathy and its possible development in Georgia was published. It concluded that patients preferred homeopathy to conventional medicine, which was attributed to effectiveness, low price, reliability and first of all it was described as

"natural way to cure disease". It was suggested that the method will further develop in the country. This paper also reported skeptical attitudes from conventional physicians. (Verulava et al, 2017)

Certain traditional treatment methods, such as Turmanidze cream, received particular attention from research of medicine history. Basic and experimental research on CAM modalities not originating of Georgian tradition is scarce. An extensive study on anthroposophic medicine application to treat bronchial asthma in children was conducted in Georgia by a team of allergologists. (Andriashvili et al, 2007) Several articles report studies on homeopathy effect on tumor cells and ion homeostasis (Nadareishvili 2006, Mikhvetadze et al, 2006). On the other hand, many websites and periodic publications give unvetted, low quality data without scientific rigor, forming a risky information background to the potential CAM users.

An interesting publication we have obtained was the World Health Organization Global Atlas of Tradition, Complementary and Alternative Medicine. (Bodeker et al, 2005) This publication gives a number of world maps on various aspects of CAM practice, naturally including Georgia. While methodology is not available in the publication, it suggests that there was some kind of CAM related legislation in Georgia in 2005. It also suggests that CAM had public financing at that time. Other maps suggest present regulations, absent education, high level of herbal medicine use.

Systematic research is therefore needed in Georgia to define its standards and foster a dialogue between CAM practitioners and conventional medicine specialists and integrate their efforts to achieve better care for individual patients as well as societies.

Chapter 4. Usage and delivery of Complementary and Alternative Medicine Services

In order to adequately examine and analyze the state and perspectives of CAM in any healthcare system, it is necessary to obtain data for basic descriptive statistics. Most analysis of the statistical data (patient use, effectiveness, cost and spending etc.), will be discussed in the following chapters. Various governmental organizations and NGOs across the globe collect data for statistics in CAM. Before collecting statistics data in our country it would be reasonable to present some data from different regions of the world, and more in details from Europe.

More than 100 million EU citizens are 'regular' users of CAM, and predominantly for the treatment of chronic conditions (CAMbrella reports). According to a recent study of CAM use across Europe some 26% of Europeans had used CAM in the last 12 months, about a third compared to general practitioner visitors (76.3%). *"Among those who had used CAM, 69.4% had used only one kind of CAM modality, and 19.9% had used two. Approximately 8% of CAM users had used CAM exclusively (alternative use), without any visits to biomedical professionals in the last 12 months…"* (Kemppainen et al, 2018) Such countries as Germany or Switzerland have highest prevalence in the EU, while Poland and Hungary have some of the lowest values.

It is also interesting to know what is the number of practitioners of CAM in each modality/category. According to Klaus von Ammon, University of Bern, there were 295100 practitioners of 15 most prevalent CAM therapies in the EU (the total number is over 300 000). There are over 150,000 registered medical doctors (MDs) with additional CAM certification and more than 180,000 registered and certified non-medical CAM practitioners. Among the top three therapies by number of practitioners, there were 96000 practitioners of acupuncture (53% of the total number, 80000 with an MD degree). Homeopathy had 50800 practitioners (27%), among them 45000 MDs, and Herbal Medicine/Phytotherapy had 29000 practitioners, with not specified number of a medical school graduates.

Use of CAM in the USA remains stable at about 1/3 of the population (with varying modality use over the years) (Clarke et al, 2015), while visits to CAM practitioners in Australia have been growing rapidly (over 30% between 1995 and 2005). The number of traditional Chinese medicine (TCM) visits in China was 907 million in 2009 (18% of all medical visits to surveyed institutions); the number of TCM inpatients was 13.6 million, or 16% of the total in all hospitals surveyed. (WHO, 2013) There are almost 50 000 Traditional Chinese Medicine facilities in China. Also 69% of the Korean population has experienced Traditional Korean Medicine, and 60–70% of allopathic doctors in Japan prescribe herbal medicines. (WHO, 2002)

Chapter 5. Financing and Cost-Effectiveness

According to Herman et al, 2012, there were 338 economic evaluations on CAM published (almost all from Western countries). The authors suggest that even though there are quite many CAM cost-effectiveness evaluation studies, more high quality reports are needed.

A primary healthcare study in Netherlands concluded that when GPs have additional CAM training, healthcare costs are up to 30% lower. Though this could have several possible reasons which could not be defined by that study. (Kooreman, Baars, 2011)

Given CAM specificity (treating person and not disease, broad range of outcomes and others points), performing and economic evaluation of treatment was found to be challenging and a number of points were defined as to be considered in such evaluations. (Coulter et al, 2013) Similar idea was previously suggested in another study where additional reasons such as mostly over-the counter realization, chronic disease treatment among those complicated CAM cost-effectiveness studies (Herman et al, 2005)

Financing of CAM by state or insurance companies varies highly not only from country to country but also inside country regions. For example certain CAM modalities are financed in some USA states according to The Patient Protection and Affordable Care (nicknamed Obamacare) as CAM separately or as (through) essential health benefits. The act contains a few mentions of CAM, for example the following directive to health providers can be found in the document: "provide coordination of the appropriate use of complementary and alternative (CAM) services to those who request such services". (PPACA, 2010) Although the Patient Protection and Affordable Care Act promotes wellness, the effect on compensation for integrative medicine services is still unclear. (McClafferty, 2017) Some states include CAM (e.g. acupuncture or chiropractice) as an essential health benefit – something covered by the act, others don't.

In Asian countries such as China, Japan or Korea, CAM has be covered by state for many years (for example since 1951 in China). Mainland China, Taiwan region and Korea had the most reimbursable treatments: acupuncture, moxibustion, cupping, and manual therapies are completely covered, and herbal medicines are partially covered. (Park et al, 2012)

German statutory health insurance (SHI) finances a few CAM modalities with others to be paid out of pocket or by private insurances. (Joos et al, 2008, Joos et al, 2011, OECD, 2017) In the United Kingdom situation of CAM funding by the National Health Service (NHS) remains constantly changing, with debates on what should be funded by the NHS ongoing for quite a long time, but with little conclusions so far. (Wye, et al, 2008, Thompson et al, 2005,

Chapter 6. Legal Status, Regulations and Integration of CAM into National Health Systems

6.1 Baseline for CAM Regulatory Framework Formation

CAM regulation development is a topic discussed at various levels for many years. Despite a series of directives and recommendations issued by the World Health Organization to the Member States, CAM regulatory models are of high variability among countries, with common trends noticeable based on geographic, historic, cultural, economic, religious and other backgrounds. The WHO calls the member states to develop policies and strategies that reflect their specific needs in dealing with the most popular forms of T&CM practiced in their country, as well as to prepare for being introduced from other countries.

The WHO sets out the course for Traditional and Complementary Medicine for the next decade. The standard mandates all the member states to introduce, improve and develop CAM research projects, as the base for policy development in member states and internationally. (WHO, 2013). As a result of the WHO strategies, national and regional policies and regulations have been established to promote the safe use of "Traditional and Complementary Medicine" products and practices in many WHO Member States. It remains a Member States *"responsibility to protect the health of their populations by ensuring the safety of T&CM practice and managing its described risks more effectively".*

In Europe, health policy is a national responsibility of respective countries.

The following EU Directives and Regulations can potentially influence national legislation regarding CAM practices, treatments and patients' rights and safety:

• The "Professional qualifications Directive" 2005/36/EC of 7 September 2005, on the recognition of professional qualifications.

• The “Patient Rights Directive” 2011/24/EU of 9 March 2011, on the application of patients' rights in cross-border healthcare.

Among the topics actively discussed by the European legislators, scientists, public health experts and other stakeholders is formation of common (or more or less common, as the topic is very heterogeneous) frameworks for CAM regulations in EU, EEA, EFTA and EC countries.

Considering the Association Agreement between Georgian and the European Union which went into force in 2016, more and more liberal trade relations and Georgia’s potential EU membership, we consider it necessary to have clear strategy on CAM medical products and practice regulations, both in the context of national interests, safety and benefits of our citizens/patients, and the European perspective context.

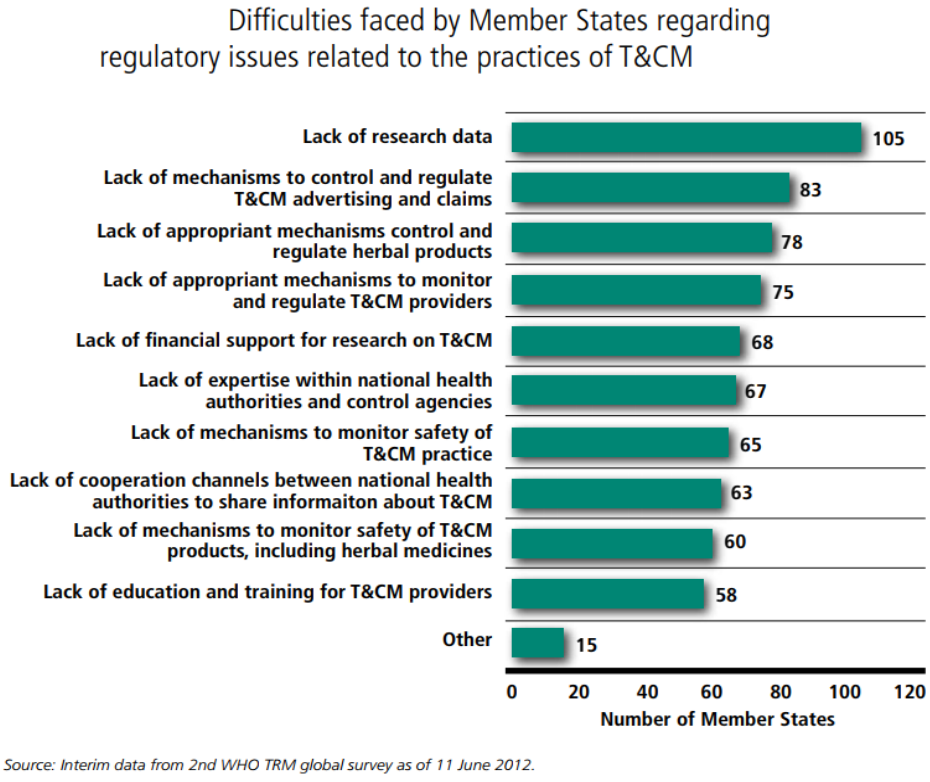

Diagram 1: Difficulties faced by WHO Member States regarding regulatory issues related to the practices of T&CM

Integration of CAM into mainstream medical services is a topic of recent research, with findings demonstrating acknowledgment of broad spectrum of potential benefits of this process to the

health services and patients, while skepticism remaining an important obstacle for the decision makers (hence prompting further studies into effectiveness and safety). (Singer, Adams, 2014, Hilber, Lewis, 2013, Sen, Chakraborty, 2017)

6.2 Regulations of CAM practice

CAM practice regulations diverge to an extraordinary degree not only in various geographical regions, but even within such structures as the EU. This influences education, certification and provision of services. On the other hand, CAM medical product regulations are more or less standard and more widely existent.

According to the WHO report: "Challenges and progress on integration of TM/CAM Into national health system", 2008, number of Member States with Established National Policy on TM/CAM for 2008, was 44, with 51 more WHO members with a pending national policies. At the same time 62 countries had national research institutes for CAM in 2007, an increase from 19 in 1999 and 56 in 2003. (WHO, 2008)

WHO's role in the field of traditional medicine was formulated as: to expand the recognition of TM/CAM; to support its integration into national health systems depending on the circumstance in the use of TM/CAM by countries; to provide technical guidance and information which helps people to use TM/CAM effectively and safely; and to preserve and protect traditional medicine knowledge and resources of medicinal plants for sustainable use of TM.

Two World Health Assembly resolutions are associated with CAM. These are the Resolution on Traditional Medicine (WHA67.18) adopted in May 2014, at the 67th World Health Assembly. Some of the key messages of the resolution are: importance and value of traditional medicine grows nationally and globally, such medicines are no longer limited to any particular region or community; interest in related practices is increased, governments should consider integration

of these elements into health service delivery, supporting healthy living; knowledge-based management, policy and appropriate regulations of practices and practitioners are of deficit; monitoring and implementation or regulation on products and integration into health care service delivery and self-health care are also deficient.

It urges Member States (MS) *"to adapt, adopt and implement the WHO strategy as a basis for national T&CM programmes and/or work plans; develop and implement working plans to integrate traditional medicine into health services, particularly at the primary healthcare level, as well as report to the WHO on progress in implementing the strategy.*

In return, the Resolution requests the WHO Director General *"to facilitate MS implementation of the WHO strategy, as well as provide policy and technical guidance on how to integrate T&CM into healthcare systems, and help ensure the safety, quality and effectiveness of T&CM services."* Finally the resolution requests the Director-General:

"(1) to facilitate, upon request, Member States' implementation of the WHO traditional medicine strategy: 2014–2023, supporting their formulation of related knowledge-based national policies, standards and regulations, and strengthening national capacity-building accordingly through information sharing, networks and training workshops;

(2) to continue to provide policy guidance to Member States on how to integrate T&CM services within their national and/or subnational health care system(s), as well as the technical guidance that would ensure the safety, quality and effectiveness of such traditional and complementary medicine services with emphasis on quality assurance;

(3) to continue to promote international cooperation and collaboration in the area of traditional and complementary medicine in order to share evidence-based information, taking into account the traditions and customs of indigenous peoples and communities;

(4) to monitor and allocate appropriate funds in accordance with the WHO programme budget towards the implementation of the WHO traditional medicine strategy: 2014–2023;

(5) to report to the World Health Assembly periodically, as appropriate, on progress made in implementing this resolution."

The other resolution is the World Health Assembly Resolution on Strengthening Integrated, People-Centered Health Services (WHA69.24) adopted in May 2016. It urges WHO MS *"to integrate T&CM into modern health services, based on knowledgebased policies, while assuring the safety, quality and effectiveness of health services and taking into account a holistic approach to health."*

According to the European Parliament Resolution on non-conventional medicine from 1997, the first step of CAM regulatory framework formation is accepting a definition, formation of classification and later formation of unique regulations and not just adapting the existing conventional medicine ones.

A publication by the European Parliament titled "Complementary and Alternative Therapies for Patients Today and Tomorrow" was distributed in 2017. In this publication, the authors state that *"the growing use of CAM among European citizens and practitioners creates a regulatory challenge for the European Union; Regulation of CAM professions, inhibit the development of cross-border research, and ultimately reduce accessibility of CAM to patients".*

While Georgia is an EU partner country, with the association agreement ratified in 2016, and has recognized EU membership perspectives, it is not EU member. On the other hand, Georgia has been a Council of Europe member since 1999. Resolution 1206(1999) adopted by the organization supports the European Parliament Resolution A4-0075/9732 on the status of "non-conventional medicine", which stresses the importance of professional training for doctors and for other practitioners of non-conventional medicines. University courses and official recognition are pointed out as important efforts to strengthen this field. Importance of research is pointed out, particularly on effectiveness of CAM methods. Both resolutions advise a stronger harmonization of "non-conventional medicine" in Europe.

CAM treatments and practices are regulated through different levels, directly or indirectly. Regulations on supervision, reimbursement, professional authorization, licensing and others usually need to pass through a number of legislative bodies before taking into force.

(Wiesener et al. 2012) In such countries as Germany, Hungary and France, only authorized/licensed specialists can treat patients. On the other hand in Norway practice is allowed without any professional qualification. This situation brings common ethical principles such as autonomy or non-maleficence into high risk, as well as complicates investigation and quality assurance process when safety issues arise.

So far, no clear criteria for the integration of TM into national health systems have been established by WHO. It could be explained that the integration of TM and CAM means that the national health system includes two parallel systems, i.e. conventional medicine and TM/CAM.

According to WHO, to be considered as having an integrative system a country must: have comprehensive and coherent national policies and national regulation and legislation including both the practice and products of TM/CAM; have remedies and practices at all health care levels, including private and public services; have health insurance coverage for TM/CAM (either national or private); have fully established official national curricula for TM/CAM at university level and national qualification schemes; have TM/CAM research institutions and ensure appropriate research grants to support research institutions and research projects on the same basis as those for conventional medicine (WHO working group meeting on integration of TM/CAM in to health system 2006).

Nineteen of 39 countries participating in the European project CAMbrella had a general CAM legislation, 11 of these had a specific CAM law and 6 countries had sections on CAM included in their health laws. In addition to the general CAM legislation some countries have regulations on specific CAM treatments, with the following consequences (among others):

When **patients** cross borders they may face completely different services and conditions, while not suspecting this. This situation raises patient safety, autonomy and treatment access concerns.

In case of **practitioners**, as professional backgrounds are regulated differently, it is hard to have collegial cooperation or ensure quality control.

When **researchers** cross borders they will face different laws and principles of research. *"Any observational or experimental study will therefore be generalizable only within a narrow national or cultural context"*. (Wiesener et al, 2012)

While the EU tends to leave the regulatory framework development to individual countries, a potential way out could be "voluntary harmonization". Selfregulation statutory or voluntary is another option, while in those situations where there are no dedicated regulations, different treatment approaches can be indirectly regulated via such laws as the criminal code, laws on education, and health financing.

Practitioners of CAM

In its Traditional Medicine Strategy, the WHO suggests that in *"many developing countries, TM knowledge and skills have been transferred from generation to generation orally, making it difficult to identify qualified practitioners"*. WHO advises that the Member States perform situational analyzes and identify their specific needs. (WHO, 2013)

Regulated professions who practise CAM are often divided into:

1. Health professionals:

A. Medical Doctors (MDs),

B. Other health professionals (e.g. nurses, midwives) This category can also include: osteopath, physiotherapist, chiropractor, manual therapist, and some other specialties.

2. Other CAM practitioners:

This category includes CAM practitioners with a short or no medical education or training.

If we talk about not European countries we can look at Asian experience. There are three different CAM specialties in mainland China: Traditional Chinese Medicine, integrative medicine, and other folk medicine doctors. A Traditional Korean Medicine (TKM) specialist

training resembles the model of the Conventional Medicine specialist system, and considers care provided through various departments. It takes 4 additional (after licensing) hospital training years to become a TKM specialist. In Japan, Conventional Medicine doctors can practice any CAM modality including acupuncture and Kampo, but not every doctor practices it. They can choose CAM modalities for further specialization. (Park et al, 2012)

6.3 Regulations on CAM products

According to the WHO, Traditional and Complementary Medicine products include *"herbs, herbal materials, herbal preparations and finished herbal products that contain parts of plants, other plant materials or combinations thereof as active ingredients. In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials)"*. As regulations of CAM products vary a lot across the globe, in this chapter we will focus on those regulations active in Europe and the US.

As was previously discussed, CAM practice has no united regulatory framework, not only worldwide but also in such blocks as the European Union. But the medicinal products practitioners prescribe or recommend are regulated uniformly in the EU.

The EU/EEA states can't break the following three EU directives:

1. Directive 2001/83/EC of the European Parliament and of the Council, of 6 November 2001 (on the Community code relating to medicinal products for human use).
2. Directive 2004/24/EC of the European Parliament and of the Council, of 31 March 2004 (amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use 2001/83/EC).
3. Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (amending the Directive 2001/83/EC).

These directives state that *"No medicinal product may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities of that Member State in accordance with this Directive or an authorization has been granted in accordance with Regulation (EEC) No 2309/93."* Herbal medicinal products must have a registration or marketing authorization according to directive 2001/83/EC - and amended by Directives 2004/27/EC and 2004/24/EC - before they can be marketed in the EU/EEA states.

In the EU, herbal products are defined as: *"any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations".* A homeopathic medicinal product is defined as *"Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles".* Manufacturing and technical standards for homeopathy and herbal products are same as for all medical products, while documentation of efficacy can be not required. (Fonnebo, et al, 2012) Specifically, homeopathic medicinal products are allowed to present an alternative documentation of efficacy, while herbal products can be registered via a number of ways, while a "well-established use authorization" is specific for herbal product registration and marketing.

Homeopathy products registered or authorized by states on or before 31 December 1993 and herbal medicine products authorized according to Regulation (EEC) No 2309/93 or supplied in response to a bona fide unsolicited order can be marketed irrespective of the two directives. This allows professionals to provide products necessary for patient care in response to a necessity of a particular medical case and formulated in accordance with the specifications of and for use by an individual patient under his direct personal responsibility. This is a necessary provision which give health-care professionals access to products currently without a registration or marketing authorization. This rule of exception applies to herbal and homeopathic products

irrespective of the provisions set out in Directive 2001/83/EC and its 2004 amendments. There is an additional directive from 1992 on homeopathic medicinal products (Directive 92/73/EC), which defines a homeopathic product as one made using homeopathic manufacturing procedures according to the European Pharmacopoeia. It allows homeopathic products simplified registration, provided they are administered orally or externally, have no specific indication on the labelling, and are enough diluted to guarantee the safety of the patient. (The Council of European Communities, 1992) As homeopathic medications are related to extremely low safety concerns, the exception doesn't put citizens at high risk. It ensures that previously authorized homeopathic products are still available to patients and practitioners. Research shows vast variety of CAM product regulations indeed vary a lot which influences range of products available to consumers (e.g. Chinese Herbal Medicine). (Fleischer et al, 2017)

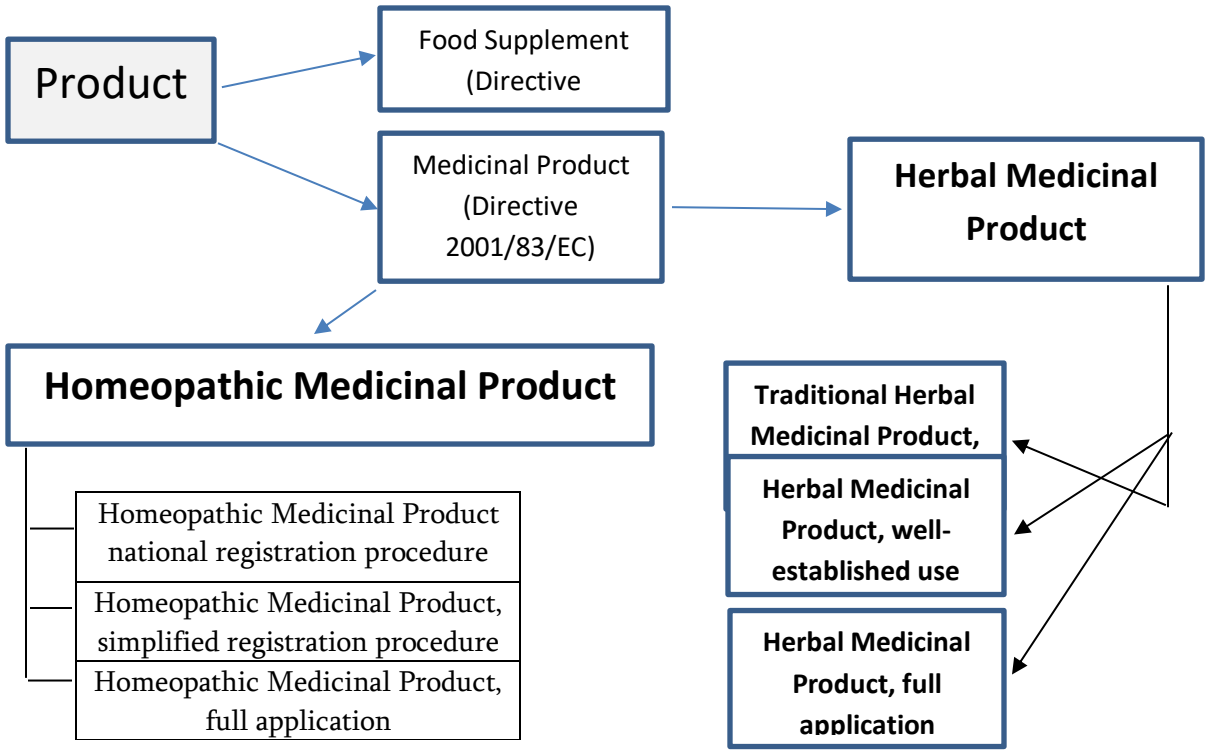

Figure 2: Procedures for registration of herbal and homeopathic products in the EU. Source: CAMbrella project

In the United States, a U.S Dietary Supplements Health and Education Act (DSHEA, 1994) changed the reality of herbal and biologic product markets, rising sales across the country. An important step brought up by DSHEA was a definition of dietary supplements. The definition goes as follows: *"A dietary supplement is a product other than tobacco that is intended to supplement the diet and contains one of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients"* (US Congress, 1994). *A dietary supplement is also ingested by mouth in pill, capsule, tablet, or liquid form. It is not intended or represented for use as a conventional food or as the sole item of a meal or diet and must be labeled as a "dietary supplement".* According to the Act, it is allowed to state a nutrient deficiency disease which could be managed with the supplement, stating also prevalence of that specific disease in the U.S. Any claim of therapeutic effect for various diseases is not allowed unless approved by the Food and Drug Administration (FDA). The labeling may contain claims regarding supporting "structure and function" or general "well-being" as long as they are truthful and contain the following: *"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."*

We should note that the Act regulates not only labeling of the supplements but also such marketing points as distribution of information printed specifically for advertising reasons or articles which can influence consumers' decisions. The "adds" should be displayed separately from the product, must contain only true and proofed information, can't promote a specific brand of supplement. It should be noted that Internet was just in early stages of development in 1994 and enforcing the rules is even more difficult today than it was upon original publication of the regulations. The label must also identify the product as a dietary supplement and contain nutritional labeling, as required in food products. (Cassileth et al, 2009)

Chapter 7. Complementary and Alternative Medicine and Medical Education

As CAM becomes increasingly popular among patients across the world, the appropriate education of future providers in this field has gained attention among medical educators and related expert circles to ensure safe practice of quality CAM. (Institute of Medicine, 2005, Onal et al, 2016, WHO, 2013)

The prevalence of CAM teaching varies in European Union, USA and other high-income countries, but in general most medical schools welcome further development of CAM in their curricula. While only few universities provide specialized degrees dedicated specifically to CAM knowledge and skills, CAM curricula are implemented in over half of all medical schools in the United States through at least one course or clerkship. The majority of the CAM teaching courses (70.9%) were didactic electives. Only six schools required a CAM course or clerkship. (Institute of Medicine, 2005) Other sources previously reported prevalence of CAM course teaching to be up to 98% among American medical schools. (Cowen and Vicki, 2015) European countries such as Germany, Austria, the Netherlands or Switzerland less commonly have comprehensive CAM curricula, but often teach specific CAM modalities, primarily homeopathy. (Berman, 2001) In summary, CAM teaching is becoming increasingly common in many high-income countries around the world. (Quartey, 2012) In the US, core competencies for Integrative Medicine fellowships were developed and test-implemented (there were 13 fellowships active in Integrative Medicine across the US in 2014) by The Consortium of Academic Health Centers for Integrative Medicine. In fact the competencies were found to be shared with most other medical specialties and needed only modification and adaptation for Integrative Medicine practice. One of the latest developments on CAM teaching for physicians was addition of Integrative Medicine course to 5 pediatric residency training programmes in the United States. (McClafferty et al, 2015) The programme had over 500 physicians trained in CAM through a 100 hour long course by 2016. There are also residency programmes in family medicine providing Integrative Medicine course (200 hours) at over 40 residency programmes in the US. The online “Pediatric

Integrative Medicine in Residency (PIMR)" course was created. Another US study defined 16 programmes providing education in CAM/IM to pediatrics residents and even suggests that IM could be a subspecialty of pediatrics. (Vohra, 2012) In Australia, the Royal Australian College of General Practitioners developed proposals for a curriculum on Integrative Medicine. The College suggests that general practitioners are the best level for health professionals' interaction in patient management through Integrative Medicine as general practitioners have constant contact with the community and a broad spectrum training. The special training for general practitioners should start from MD student level and continue into specialist fellowships. The training goes repeatedly through the following 5 domains, while changing content: *"1. Communication skills and the patient-doctor relationship; 2. Applied professional knowledge and skills; 3. Population health and the context of general practice; 4. Professional and ethical role; 5. Organisational and legal dimensions"*.

In contrast, medical schools in low and middle income countries have been ignoring CAM (for example within African countries, notably the South African Republic (Chitindingu, 2014)).
Using CAM is quite common among medical students, and they generally hold positive attitudes towards CAM. (Akan et al, 2012, Ameade et al, 2016, Abbott et al, 2011, April and Gaboury, 2013, Jocham et al, 2017, Joyce et al, 2016) The majority of medical students favored the creation of CAM as a major subject. Professionalism improvement was also suggested to be one of the outcomes of CAM teaching to medical students. CAM teaching is more classically provided in Asian countries such as China, India, Korea or Japan, where it is taught by many universities, providing bachelor, masters and other degrees to the graduates after completing educational programmes of various duration. (Park et al, 2012)

Comprehensive integrative medicine training will enable the general practitioners to *"provide a greater range of therapeutic options to patients, help patients make safe and balanced decisions regarding complementary medicine use and avoid potentially harmful interactions between complementary and conventional therapies"*. (The Royal Australian College of General

Practitioners, 2011) We should note that CAM introduction was suggested to be beneficial not only for MD curricula but also for pharmacy ones. This could potentially reduce neglect of CAM in pharmaceutical research among other benefits. (Lam Ung et al, 2017)

Chapter 8. Sources of Information for the Public

There is a need of easily accessible and reliable information on CAM. There are two general problems concerning CAMs information sources: lack of high quality information and complicated and inadequate access to the information. Social networks represent main source of information in some states while in other biomedical professionals are able to provide reliable information and are the main source of it. People also get information from printed or broadcast media. (CAMbrella WP3 report, 2012) Disease or place specific studies on source of information show that CAM information mostly comes from friends or other patients, and to the very less extent from medical professionals. (Bahall, 2017)

It is known, that most of the patient decisions to use certain treatments or not for their conditions is based on the information about the effectiveness and safety of CAM (considering specific conditions or for general well-being) and about the CAM practitioner. Conventional medicine professional's lack of knowledge and negative attitude to patients' use of CAM often lead to non-disclosure of CAM use during patient visits to their physicians and thus constitutes a significant barrier to accessing information about CAM or referrals to CAM provision via biomedical professionals. (Nissen et al, 2012) It is known that CAM use increases when the citizens have more information regarding it. The lack of trustworthy information and an opportunity to make an informed decision about the patient's own health is opposing the public health ethics, and state policies on patient rights.

Chapter 9. Stakeholder Needs and Attitudes

The World Health Organization (WHO) Traditional and Complementary Medicine Strategy 2014-2024 states that "policymakers and consumers should consider how [CAM] may improve patient experience and population health", emphasizing global demand for individualized and person-centered care (WHO, 2013). The Strategy outlines actions to be taken by relevant stakeholders, with healthcare integration being one of the core objectives. The same document suggests that though "there are common themes underlying the reasons which motivate people to use [CAM], there are also many differences between individual countries and regions". Patients and their needs hold the central position in CAM healthcare integration studies (Nissen, 2012, Institute of Medicine, 2005, Truant et al, 2015, Robotin, 2005, Frenkel, 2003). The European public's urgent need for more reliable and accessible information about CAM was taken into consideration and reflected in the roadmap for future CAM research and integration in Europe (Fischer et al, 2014).

Why and how patients consider complementary therapy as holistic is unclear. (Van den Bulck and Custers, 2009, Bahall and Edwards, 2015), Understanding this could inform the future integration of both medical fields. (Richardson, 2004) Studies on CAM patient-practitioner relationship are scarce, particularly qualitative ones. (Adler, 2003)

The paper by Fischer and co-authors from 2014 suggests that in-depth understanding of patients' insights on CAM, health and medicine is useful to develop safe and effective CAM treatment options and ultimately improve public health. By understanding the attitudes of patients towards CAM and associated qualities, it could be possible to "predict" potential CAM users which could potentially contribute to reduce such unfavorable scenarios as conventional medicine treatment – CAM interaction or adverse reactions. (Islahudin et al, 2017)

An Australian report indicates that CAM users find themselves better acknowledged and stronger empowered by relationship with CAM practitioners that with their physicians.

Additionally patients believe that health professionals don't respect their choice to use CAM. Patient-doctor relationship dissatisfaction was also reported earlier. (Emmerton et al, 2012) Additionally, CAM workers were named an underutilized workforce in Australia. (Grace, 2012)

A qualitative study by White et al, 2008, suggests that CAM using cancer patients have a feeling of "more control" over their health. They also had beliefs of body healing, and were tending to be managing their condition through lifestyle modification, diet and other approaches. Though they valued conventional physicians' expertise they were concerned about possible unwanted effects of conventional treatment.

The CAMbrella project showed that many Euroeapen citizens wish to have increased access to CAM provision. For example: UK studies show that a majority (up to 66%) of healthcare users support the provision of CAM in the National Health Service. In Norway, between 43% and 63% of citizens feel that CAM should be an option for cancer patients in hospitals; and in Germany and Switzerland, where CAM is often provided by general practitioners (GP), close to 70% of primary care patients would like to be treated more frequently with CAM. (Nissen, 2012) It was demonstrated that CAM is primarily used by educated citizens of working age and with an above average income (which can be explained by mostly out-of-pocket payment for the services). Social justice is one of the obligatory themes of public healthcare and whether CAM should be considered to be part of this public obligation is a topic of debate. A lack of documented effectiveness and various research findings are often used to ground and justify the not inclusion of CAM in public healthcare.

Physicians are supposed to play a major role in their patients' informed decision regarding their own health. To support patients' informed decision making process regarding CAM, physicians would need substantial knowledge regarding this topic. A Mayo Clinic cased study from the United States showed that 76% of physicians had never referred a patient to a CAM practitioner, though 44% would like to do so, if CAM practice was available at their hospitals. Incorporating CAM therapies were expected to improve patient satisfaction and attract

patients. (Wahner-Roedler et al, 2006) Another study demonstrated positive attitude but low prevalence of use about primary care providers in USA. (George et al, 2012)

We should note that not only physicians but also other health specialists such as for example pharmacists share responsibility on patient safety and best benefits. It was though found that most of them don't find themselves able or motivated to take such a responsibility. Among factors influencing this situation education holds the central position. (Lam Ung et al, 2017) Certain pharmacist professional associations such as the Pharmaceutical Society of Australia. Recognized the responsibility and adopted special position statements (Complementary Medicines Position Statement, 2015)

Part II - Study Objectives

Chapter 10 - Study Objectives

We aimed to understand full complexity of the complementary and alternative medicine in Georgia and it implication to the healthcare system in the country, contribution to patients and community health, as well as possible risk CAM can represent for the patients, addressing the WHO and EU calls to form knowledge base for informed decision making among key stakeholders through enhancement of research in CAM

10.1 General Objective

To explore the perspectives of Complementary and Alternative Medicine and Conventional Medicine practice and service delivery integration in Georgia

10.2 Specific Objectives

A) To estimate the scale of CAM use in Georgia, obtain comparable data on prevalence.

B) To analyze the factors forming a patients' need of alternatives or complement existing conventional medicine already available. Describe a typical CAM user.

C) To explore specific CAM modality delivery and use in 5 Georgian regions.

D) To explore patient needs and perspectives on CAM and conventional care integration

E) To explore CAM practitioners, Conventional Medicine leaders and Medical Educators perspectives on existing reality of CAM practice, collaboration with conventional care providers and obstacles, perspectives and ways to achieve integration/optimize the existing situation

F) To identify active and previous CAM practice and product marketing regulations in Georgia, analyze their strengths and weaknesses, and propose general framework for policy makers, based on the own findings and best international experience

G) To explore CAM practice related education issues in Georgia

H) To form a research based ground for informed decision making among patients, their physicians and other stakeholders, provide basis for further academic research

Part III- Methodology

Chapter 11 - Methodology

The methodology of the present research included three phases and involved a variety of qualitative and quantitative techniques, built around the health policy and systems research methodology approaches (WHO, 2012) as well as process tracing methodology (Institute of Development Studies, 2015) Data collection of the present research was step wise. Each of the seven steps (see diagram) interconnected (they do not follow systematically the order represented in the graph below). In each study group an individual approach was used. The total duration of the study was 48 months.

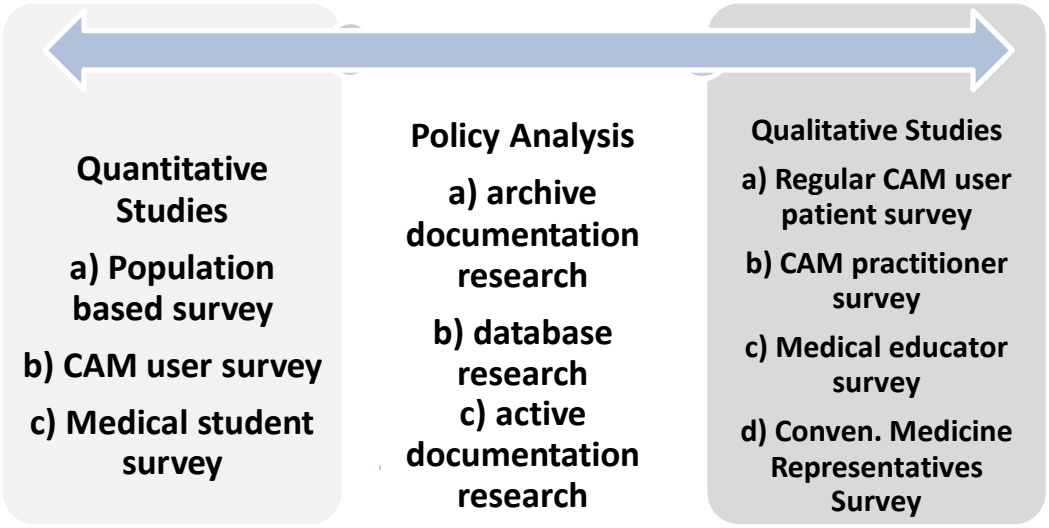

Figure 3: Research methodology components

11.1. Policy Analysis

• The first phase of our study utilized policy analysis methodology (Collins, 2004). It focused on documentation review and preparatory missions to review statistical sources and existing research with a view of mapping the main CAM stakeholders the country. The targeted populations were selected for the second phase of the research. We searched for any CAM

specialty in the Ministry of Labour, Health and Social Affairs of Georgia list of regulated medical specialties. We used the Medical Subject Heading list of CAM modalities/specialties and optimal definitions/classifications available. (Wieland 2011; MeSH)

We then submitted a request for information on current regulatory frameworks on CAM to the Ministry of Labour, Health and Social Affairs of Georgia State Regulation Agency for Medical Activities. We also conducted online search of legislation in Georgia, to have retrospective image on the development of regulations in the country.

We also did a search of online archives of the Georgian Parliament and such websites as the governmental publication "Matsne" (www.matsne.gov.ge) for any mention of CAM related keywords in the documents stored in their databases, getting opportunity to get an isight into past regulatory frameworks.

We made a search at the National Registry website (www.napr.gov.ge) for Non-Governmental Organizations and private commercial companies (e.g. limited liability companies) using the following keywords: traditional medicine, homeopathy, homeopathic, homeopathist, herbal medicine, phytotherapy, anthroposophical, folk medicine, complementary medicine, hirudotherapy, accupunture and several other related keywords. This way we conducted identification of various legal bodies related to CAM in Georgia, obtained and studied their organizational statues and bylaws, structure and got impression on the organization background. It also gave us an opportunity to obtain contacts for further inquire in related activities.

In order to identify CAM providers we conducted an internet search through Google.com advertisement websites, hospital and various medical center websites, searching for CAM services using similar keywords search as in search through the National Registry website. We also contacted relevant physicians via the Georgian Association of Medical Specialties in order to receive information on certain modalities use in conventional medicine, and whether they are used as CAM or not.

11.2. Quantitative Methodology

•The second phase consisted of quantitative field surveys among a) general population, b) CAM users, c) medical students.

With an aim to build a general impression on CAM use scales we conducted a population based survey using a combination of non-probability sampling approaches such as accidental, quota and judgment sampling. The survey was conducted in a mixed-mode approach to avoid frame-coverage bias. With a total of 700 persons invited into the survey (with expected response rate of 50-60% for a confidence interval of about 95% and an approximate 20% expected prevalence of use) half were quoted to men and half to women. A preliminary ethnographic observation was conducted which gave valuable input to design detailed in-depth schedule and selection of survey locations, in order to ensure diversity in socio-demographic (education, occupation, economic status, ethnic, geographic, etc.) backgrounds of the respondents. The method of sampling in the selected locations was an accidental sampling. The simple- random sample is a probability sampling technique in which each subject in the population has an equal chance of being chosen for the study. This procedure makes the result more likely to be generalized to the entire population. The respondents' age varied between 18 and 79 years. The respondents had to answer 9 questions with the investigator filling down the questionnaire forms. No informed consent forms were required for this survey.

In the quantitative survey among CAM user patients, we conducted a cross-sectional study recruiting respondents at 20 CAM service offices in which had been referred to us by professional unions and societies. The sample included 300 CAM user patients (aged 18-75 years) systematically selected from waiting or appointment lists or sequentially selected when such lists didn't exist. The survey took place in five Georgian cities (east part of Georgia, capital Tbilisi (biggest city in the country), cities of Rustavi (fourth biggest city in the country) and Telavi; center-west part of the country, second capital Kutaisi (third biggest city in the country), and west part sea side city Batumi (second biggest city in the country). We arranged for an

appropriate environment at the CAM service provision offices to conduct the survey. The following CAM modalities were included into the study: homeopathy, phytotherapy, folk medicine, biologically active supplements, acupuncture, anthroposophic medicine and chiropractic/manual therapy.

We developed an electronic questionnaire comprised of 63 items for the study. Please note that while the questionnaire was surveymonkey based, we had them printed out for most cases and filled in together with the patients during the interview sessions. The quationnaire aimed to elicit answers to the following aspects:

1) Characteristics of CAM users (origin, education, employment etc.)

02) Common health conditions prompting CAM use.

4) Patient determinants in deciding to seek CAM treatment.

5) Patient expectations regarding CAM services.

6) Pattern of CAM use as exclusive or in combination with conventional medicine.

7) Patients perspectives on the future of CAM.

8) Patient satisfaction with treatment results, and money spent by patients.

We pilot test the questionnaires and all items in winter 2015-2016 ahead of the 6 months data collection period from December to May, 2016-2017. The questionnaire consisted of both multiple-choice questions, open, and closed ended questions Items included contact information, demographic data, health status, disease description, previous and current treatment, and financial questions. Finally, we asked those who reported using CAM at least once per months questions on perceived satisfaction, treatment results, expenses and future plans. A trained interviewer verbally administered all questionnaires and clarified further where necessary, without leading to any answer or additional information, hence avoiding bias.

Patients were not paid for their participation in the study, were informed on study details and could decline participation or particular question answering.

Medical students' needs and attitudes were assessed using the Georgian Medical Students' Association network. A specially designed questionnaire was distributed to 100 local and foreign medical students studying in Georgia to assess their attitudes to CAM and related education.

We used both descriptive and analytic statistics in our study. In the general population survey, dependent variable was set as "CAM user", or those who answered YES to the question if they had ever used any form of CAM, and if they did so over the last 12 months. Independent variables were demographic, health status and socio-economic status indicators.

Frequencies and percentages were used to assess the prevalence. Chi-square test was used to chart comparisons of the variables between users and non-users of CAM. A p-value of < 0.05 was used to determine statistical significance. In our study the null hypothesis H0 suggested that the two groups of people (CAM users and non-users) were actually similar as for the independent variables. Statistical analysis was performed using IBM SPSS version 22 software.

To address the question of sources of information for the public, we also conducted a systematic search of internet resources on CAM in Georgia, to estimate the impact of health related websites, social networks, video sharing sites, radio and television media sites and others on population information.

11.3. Qualitative Methodology

In the qualitative component of the study we used a grounded theory analysis approach (Charmaz, 2006), collecting data in individual, face-to-face, semi structured contextual interviews as an in-depth explorations of local experiences and practice, as proposed in the "Research Roadmap for Complementary and Alternative Medicine", addressing European

nations. (Fischer et al, 2014) The qualitative study engaged CAM users, practitioners, conventional medicine physicians, public health specialists and medical education experts.

- The thirst stage of the project was a sequence of qualitative studies

11.3.1 Qualitative study with CAM patients

Participants:

We recruited and interviewed 20 regular, long-term CAM users (defined as having seen a CAM practitioner at least twice per months for at least a years) into the study using a purposive sampling method, ensuring respondents' ability to speak reflexively about their Complementary and Alternative medicine experience. Age range was 30-75 years old. The patients were asked to take part in the interviews after completing a questionnaire designed for a related descriptive, quantitative study component. While administering that questionnaire, the interviewer got a general impression of the patient's insight into and experience with CAM, and would invite those who were communicative and willing to share their perspectives for further contextual interview. Of 25 patients invited until we received saturation of data (and the data obtained was sufficient for explore the study question adequately) 20 agreed to give the interviews, while 5 declined mostly for time reasons.

Data collection:

We interviewed 14 patients at the CAM facilities and all others at other places convenient for the respondents. We stopped interviewing the patients as the data started repeating and didn't give us new information about our research subject. In all cases, the interviews took place in calm, relaxed atmosphere. The interview protocol and guide were designed in winter 2016-2017 and pilot-tested on additional five volunteering CAM users prior to study inception. The conversation was conducted in a "semi-structured" way, and the patients were given freedom to express their ideas and talk about their experience with CAM. The interviews were conducted

by an epidemiology and a sociology specialists. The following domains were discussed among others: disease and health conceptualization; CAM experience; perceived benefits; knowledge and information sources; traditions and backgrounds; attitudes and impressions; comparison of CAM and conventional services. The interviews were conducted in the Georgian or Russian languages per the participant's preference. All interviews were digitally audio recorded.

Data analysis:

After collecting all the interviews we started creating transcripts of audio recordings (all of them clear for transcription). Holding the transcripts together with 2 other professionals we conducted a thematic analysis with line by line primary open coding, and then axial coding (of themes that seemed related to our research questions). Two researchers started the first round of data analysis after the transcription of first 5 interviews and continued until the last interview was analyzed, applying codes and concepts to the following interviews. The remaining authors then analyzed the codes and selective coding was performed resulting in a number themes. As the research team leader is not fluent in Georgia, all the materials were thoroughly translated into English for his input. The authors built links between the codes and themes, developing a concept on the studied topic.

We distributed related quotes to relative themes, to build a clear picture on patients' perspectives of CAM experiences and potential integration with conventional medicine.

11.3.2. CAM practitioners

The qualitative study then continued to study CAM practitioner perspectives on their job, relationships with conventional medicine and regulating bodies, legal base, education and other aspects of their practice. The study had same methodology as with the CAM users, where used semi-structured interviews for qualitative data collection and further contextual analysis. Semi-

structure interviews were held with some of the leading CAM practitioners (including heads of professional unions) of 6 CAM modalities. A total of 12 interviews with CAM representatives were held as we achieved the saturation of data. Interviews consisted of open-ended questions. We also interviewed conventional medicine physician union leaders, hospital managers and medical academicians for their point of view.

11.3.3. Medical Educators

The study then moved to the medical education institutions for the analysis of related educational issues in MD, postgraduate or Continuous Professional Development levels, as well as CAM practitioner education. We identified sixteen (16) medical schools and faculties accredited in Georgia using the World Directory of Medical Schools website. Each medical school's websites were thoroughly reviewed, primary to analyze the existing programme curricula leading to the degree of medical doctor (MD).

Of all the semi-structured interviews conducted in our study, 11 discussed the medical education issues. We specifically interviewed 5 medical education experts in the country, 3 of them heads of medical faculties and two representatives of Continuous Professional Development and Continuous Medical Education (CME) programme and credit providing organization were interviewed, one of them the organization's president. We also interviewed 3 conventional medicine representatives for insight on CAM practice and collaboration, related problem and opportunities. We should note, that interviews with CAM practitioners (representing Homeopathy, Traditional Georgian Medicine, Acupuncture and Anthroposophical Medicine) also included medical education related problem discussion.

Two different definitions were suggested to define CAM and Traditional Medicine, respectively. The following topics were primarily discussed: Opportunities and need of CAM educational component introduction into MD and CME educational curricula; problems which stakeholders are facing in regards to this topic; possible strategies addressing the existing situation.

Expert interviews. We conducted all the interviews in the Georgian or Russian language at places convenient for the interviewees in a calm, comfortable atmosphere. The interview protocol was designed and pilot-tested on 3 volunteering medical education PhD students. The conversation was conducted in a "semi-flexible" way, and the respondents had freedom to express their ideas and talk about their CAM experience.

Each participant was introduced to the study and signed an informed consent form after reading an information paper and getting further verbal information about our study. Line by line, focused and theoretical coding approaches were used to build theories and conclusions.

Chapter 12 - Ethical Considerations

We obtained Approval to conduct the study from David Tvildiani Medical University Biomedical Ethical Committee. Research followed ethical guidelines of the DTMU biomedical ethical committee and the Council for International Organisations of Medical Sciences based on Helsinki Declaration. Ethical and technical aspects were be discussed with the appropriate authorities, and field research started after due approval. Participation in any stage of the project is solely voluntary. All participants received written and/or verbal details on study background, aims, funding sources, etc. We obtained informed consents from patients participating in qualitative study and assured each participant of the confidentiality and anonymity of their data. All the recorded data will be destroyed after two years all the project findings are published. The team of researchers considered the possibility and did maximum effort not to influence patient decisions against or in favor of CAM.

Part IV - Results

Chapter 13 - CAM Practices and Market, and their Regulatory Environment in Georgia

13.1. Identification of CAM practices

CAM Key Actors

We identified a vast variety of CAM practices and products available in Georgian market. Herbal and non-herbal dietary supplement are not only provided/prescribed by CAM practitioners or conventional medicine physicians, but also marketed online and even available in some of the biggest pharmacy networks such as Pharmadepot, PSP or AVERSI pharma (mostly marketed in Vitamin and dietary supplements subheading), as well as smaller pharmacy companies, including a few specialized ones. Excluding traditional healers and dietary supplements and massage, some of the most prevalent CAM services were: homeopathy, ultrasonic therapy, arts therapy, (additionally many conventional medicine specialists use it in their practice not as CAM); acupuncture; chiropractic spinal manipulation; craniosacral manipulation; reflexology. Less prevalent but available are: Anthroposophical medicine, lectric stimulation therapy, hydrotherapy, magnetic field therapy (as CAM), aromatherapy, Meditation (as CAM), Naturopathy, Osteopathic manipulation, Ozone therapy (as CAM), Qi gong (as CAM) and Yoga (as CAM). Balneotherapy is not included in the list not only because it is not seen as CAM by most specialists, but also due to the fact that Georgia is home to over 130 defined balneologic or spa spots. Their potential though is not utilized equally. (საკაშვილი, 2011). Such CAM modalities as “Distant healing”, “Massage”, or even “Bee products” or “Diet Therapy” (both of them though can be seen as “medical tradition”) are also hardly applicable to Georgian reality as CAM. Prayer for health is also hard to be considered as CAM in Georgia as praying for health is done by a great part of Georgian population on regular basis. We could not identify some CAM modalities such as Hyperbaric oxygenation (as CAM) or Hypnosis (as CAM).

We identified professional unions in Naturopathy (Georgian Association of Biologic Medicine, registered in 2013), Acupuncture (“Georgian Association of Acupuncturists”, founded in 1997),

Anthroposophical Medicine ("International Anthroposophic Society in Georgia", founded in 1998), Traditional Chinese Medicine, five professional unions of Homeopathists (such as "Liga of Homeopathy and Georgian Traditional Medicine" (founded in 2006), "Independent Homeopathist Association of Georgia" (Founded in 2000), "Homeopathy Development Foundation" (founded in 2000), "Association of Classical Homeopathists of Georgia" (founded in 2003) and "Union of Georgian Homeopathists" (founded in 1999), formed by representatives on conventional medicine, biology, toxicology and associated specialties), an association of Hirudotherapy practitioners, an association of "Integrative (classical, eastern, traditional) medicine" (founded in 2010, by a group of conventional medicine physicians, with the main aims of research, database formation and integration with conventional medicine, evidence-based information delivery to wider population and cooperation with relevant international bodies), a few massage organizations such as a "Georgian Massage National Federation", "Association of Georgian Massage Practitioners", "International Association of Massage Practitioners" and others; a Taichi and Qigong Federation of Georgia, and a "National Federation of Yoga". It might be that there are more organizations active, which could not be identified through our search through the national public registry of Georgia. The professional associations' activities are mostly limited to internal information and experience exchange and small group case discussions. Some of the local organizations were members of their specialty international federations respectively (for example Liga Medicorum Homoeopathica Internationalis or International Federation of Anthroposophic Medical Associations). Activity in the international organization frameworks was rare and declined significantly during the last few years.

Among the educational or academic organization with the main focus on Complementary and Alternative Medicine we would like to mention the Classical and Traditional Medicine Academy, which was founded by conventional medicine physicians and was accredited as a higher education institution delivering medical education programme with a focus on traditional and Chinese medicine.

The following table shows the identified practices and specific number of service provision spots identified.

Table 6. Identified CAM service providers

#	Practice	Spots Num.	Professional Organizations/Unions (number of members)/remarks	Some provider website
1	Acupuncture	3	საქართველოს აკუპუნქტურის ასოციაცია NV	sujoktherapy.ge, ostheopath.ge
2	Anthroposophical Medicine	1	"საქ. ანთროპოსოფიურად ორგანიზებულ ექიმთა კავშირი"	
3	Aromatherapy	1		Auraplus.ge
4	Arts therapy	4 + CM	Many conventional medicine centers and specialists use arts therapy	therapiehaus.ge mhc.ge ndc.ge venusgeorgia.ge
5	Ayurveda	0	Might be provided through distance healing and/or home services	
8	Biofeedback	0	Might be provided through distance healing and/or home services	
9	Chelation therapy (as CAM)	0		
10	Chinese traditional medicine (TCM)		ჩინური ტრადიციული მედიცინის ცენტრი - ბოაი, ჩინური მედიცინის ცენტრი,	
11	Chiropractic spinal manipulations	3		Auraplus.ge Healthcarecenter.ge sanni.ge
12	Color therapy (chromotherapy)	0		
13	Craniosacral manipulation	2		simmetria.ge osteopathyc.blogspot.com/
14	Dietary supplements (non-herbal)			herbalmedicine.ge
17	Electric stimulation therapy	1		medicalgroup.ge
18	Electromagnetic therapy (as CAM)	0		
19	Herbal supplements			
20	Homeopathy	>20	ჰომეოპათიის და ქართული ტრადიციული მედიცინის ლიგა", "საქართველოს დამოუკიდებელ ჰომეოპატთა ასოციაცია", "საქართველოს ჰომეოპატთა კავშირი", "ჰომეოპათიის განვითარების ფონდი", საქართველოს კლასიკური ჰომეოპატიის ასოციაცია".	
21	Hydrotherapy	1		gudushauri.ge
22	Hyperbaric oxygenation (as CAM)			
23	Hypnosis	0		
24	Hirudotherapy		„საქართველოს ჰირუდოლოგთა ასოციაცია"	auraplus.ge hirudologi.ge hirudamedi dema medical გამაჯანსაღებელი კაბინეტი

				venusgeorgia
25	Imagery (visualization techniques)	0		
26	Integrative Medicine		"ინტეგრალური (კლასიკური, აღმოსავლური, ტრადიციული-ხალხური) მედიცინის ასოციაცია"	
27	Light therapy (as CAM)	0	Used by conventional medicine physicians	
28	Magnetic field therapy (as CAM)	1		borjomipalace.ge
29	Massage	Numerous	„საქართველოს მასაჟისტთა ეროვნული ფედერაცია", „საქართველოს მასაჟისტთა ასოციაცია", „მასაჟისტთა საერთაშორისო ასოციაცია"	
30	Meditation	1		sujoktherapy.ge
31	Naturopathy	1		naturopath.ge
32	Osteopathic manipulation	1		Ostheopat.ge
33	Ozone therapy (as CAM)	1		gvaramia.com/
34	Qi gong	1	Taichi & Qigong Federation of Georgia	Wushu.ge
35	Reflexology	3		auraplus.ge, ostheopat.ge venusgeorgia.ge
36	Reiki therapy	1		Venusgeorgia.ge
37	Relaxation techniques	0		
38	Speleotherapy	0	Planned by tskaltuboresort.ge	
40	Tai chi	1		taichi.ge
41	Traditional healers (not TCM)			
42	Georgian Traditional Medicine			
43	Ultrasonic therapy (as CAM)	>13		medicalgroup.ge medimedi.ge higeorgia.jimdo.com unimedi.ge juventa.ge reabilitacia.ge ent.com.ge tsmuclinic.ge bazi.ge enmedic.ge tatishvili.connect.ge ivermedi.com gudushauri.ge
44	Yoga (as CAM)	1	საქართველოს იოგას ეროვნული ფედერაცია	Yoga.ge

13.2 Existing CAM Regulations review

According to the list of medical specialties recognized by the Ministry of Health of Georgia, no CAM specialty is currently regulated as medical specialty.

The Ministry of Health official reply to our inquiry regarding CAM regulations is as follows:

"… Complementary and Alternative Medicine methods/approaches use is not regulated by the acting legislation. Certain Complementary Medicine concrete method knowledge can be defined by physician-specialist professional competency (for example, "acupuncture" method and application/contraindications are included in competencies of physical medicine, rehabilitation and spa treatment physician general knowledge), but this doesn't mean that the acting legislation regulates use of this method by physicians.

Regarding our vision on Complementary and Alternative Medicine regulations, we inform you that the Ministry of Labour, Health and Social Affairs of Georgia currently doesn't work in this direction." (MOH, Official Letter, 2018)

Through the documentation and archive search we could identify a few historical regulatory documents. Homeopathy was officially regulated until 2013, as a sub-specialty of Internal Medicine and Pediatry (MOH 2011), but it was removed from the list since Jan.1, 2013. (MOH 2012) Those who had received certificates of Homeopathy practice (or we might say "license") before that date, are mentioned to have rights to continue practice as specialists of Internal Medicine. But in fact, the specialty became unregulated. According to the medical practice regulatory agency at the Ministry of Health, the decision to take homeopathy out of the regulatory frameworks was made due to the fact that it is not an evidence-based medical system. According to the agency, a total of 67 practitioners are registered.

According to the ministry of Economy, Department of Statistic, the following specialties can be found in the classification of specialties: Homeopathy (under code 3229 – "Supporting Specialties of Medicine") as well as a "small group" titled "Folk and Non-traditional Medical Specialties" under the code 324. (სტატისტიკის დეპარტამენტი 2006)

The specialties under code 324 are described as: "traditional medicine practitioners consult patients on health protection and improvement as well treat psychological and physical illnesses using folk medical methods, which have an idea of stimulation and support of organism functions using natural means. They consult on healthy diet aimed to protect physical and psychologic strengths. The same document gives further details on sub specialties coded under 3241 and 3242. Folk medicine is defined as a treatment of a persons physical and psychologic

disorders using herbs, medical herbs and other folk methods, with an idea of stimulation and support of the body functions using natural means; provide consulting in health protection and improvement issues".

Their responsibility is:

- Treatment of ill and injured using herbs, medical herbs and other folk means, which are traditionally used by public, and provide natural approaches to organism function stimulation and support.
- Consulting public and separate persons on rational diet and healthy lifestyle, to protect and improve health.
- Executing similar tasks.
- Overview other workers.

The following professionals are attributed to this group: healers not using medications, healers using herbs, rural healers, naturopathists.

The Non-traditional medicine practitioners united under code 3242 are defined as those treating diseases using such approaches as hypnosis, spiritual impact or prayer. They have responsibilities almost identical to those of "Folk Medicine" specialists.

We can find regulations on Acupuncture practice in a regulatory document titled "Technical rule – on the approval of infection prevention and control sanitary norms for the public esthetic and cosmetic procedures", issued by the government of Georgia and signed by Prime Minister. (საქართველოს მთავრობა, 2015) Acupuncture is defined as "use of long, narrow needles with a medical purpose, which are inserted into the skin, in the so called "energetic zones" of the body". The document gives a detailed instruction on acupuncture practice safety and other procedures.

We also identified mentioning of biofeedback in 2 separate guidelines approved by the Ministry of Health. One suggesting biofeedback for headache management and the other for back pain management. (MOH 2016, MOH 2010)

We were unable to identify any other state regulatory (or more or less regulatory) frameworks for CAM practices, leaving all the other related specialties in fact not regulated. Self-regulation could not be identified either, while professional organizations obviously lack resources (both professional and material) to establish and implement self-regulation.

13.3 CAM Practitioners' and Physicians' Perspective on CAM regulations

There is no central registry of CAM practitioners, or in many cases same persons can practice different CAM modalities as well as work from time to time or part-time. This makes CAM workforce estimation difficult. The practitioners agree that there should be some regulations, probably in a form of self-regulation, and that a CAM practitioner should hold an MD degree. Tough many of CAM practitioners in the country are MD degree holders and hold state certificate of physician, there is no specific certification in CAM specialties. According to the representative of regulatory agency on medical activities, medical ethics and malpractice responsibility cannot be applied to those who are not certified as physicians in the country.

According to the president of one of the CAM professional organizations educational courses are no longer provided as: "there is no law for [CAM modality] and as a result anybody can sit in an office, pay money, and start work. The other reason is that there are now some 200-300 people only in Tbilisi practicing who have no education at all and they are still working". He agrees that there should be regulations "of some kind", and concludes "the education [of practitioners] must be medical, there is no second opinion on this".

A head of another professional organization tells his story "I was and still am an expert in [CAM modality] at the Ministry of Health. For 7 years our method was in the list of medical specialties. Later it was again taken out, but for 7 years it was in, and over 100 people got certified in this specialty. At this time we don't cooperate with the ministry of health, as the interest and capacity there is low. In 1998 a department was established aimed to study Georgian Traditional Medicine, with a laboratory and supporting facilities. Now nothing is done there. The whole ministry works in a police regime. Only looking whom and for what to blame. Regarding regulations they delivered all the responsibilities to professional organizations. Of course it is preferable that the person has an MD degree and complete a course by a professional organization. Probably a person without such can face more problems. So the regulations are in hands of non-governmental organizations." When asked what are the mechanisms for regulations he states that "it is first of all being a member of specific professional union. Certificates can't be received now by new generations."

One of the long experience practitioners recalls that a working group was established at the Ministry of Health which had an aim to "spread, popularize and develop this area [CAM] in Georgia". He though didn't see much progress and left the group, and currently could only conclude that "as we see there are no results at all". He confirms the worries that anybody can practice CAM (in this case another modality) and there is no mechanism to control it. He adds that even though "various professional associations were established but none was following any particular aim and were dissolving soon".

A head of another modality professional union tells a little bit different story: "our organization exists for 27 years... and over all these years many governments changed, many ministers changed, and we tried to cooperate with each of them, we wanted to form a management body in the ministry for CAM, including naturopathy, homeopathy, traditional medicine, but until now we didn't achieve not only this, but neither a united association of practitioners from different modalities. Patients approach various specialists at the same time […] This is why we see such a "integrative medicine" center is necessary. The ministry recognizes only those sciences, generally, which are taught in higher education programmes. A kind of "higher educational" institution was once providing education in [CAM modality], and even licensing people. We don't know how it [education process/licensing] was done and with what quality." "The ministry says that they neither prohibit neither recognize, because there is no education institution providing related programmes. In our case we are licensed "classical" physicians and we are free to prescribe [CAM] or for example amoxicillin. There are some methodologies which are not financed by state programmes, hence leaving patients with a choice either to pay out of pocket or to remain without opportunity to get that service for [disease example]."

Another practitioner seems to be unsure about existing situation: "[CAM modality] is officially recognized. People get certified." When the interviewer informed that it is not so, he expressed idea that it is not right to leave the modality unregulated as it is recognized in many developed countries of the world and suggests that a professional board should be formed to address this issue, uniting "only certified specialists" of the modality. He adds that medical education is necessary as a base to become a good practitioner, even though there are world leading practitioners without any medical degree.

Yet another one goes as far as stating: "I myself am an expert at the ministry and I issue the state certificates to those who pass special examination and complete a residency course."

Conventional medicine specialists talk about same problems. A manager of a private hospital which provides CAM services side by side to conventional medicine says: "Very often CAM services are provided by people without medical education or even without any education at all. This of course puts patient safety at risk. Yes, knowledge is often transferred through generations in families or from teacher to teacher, and this way it works for ages, but it needs a lot of experience and knowledge. In our hospital we have qualified practitioners of several modalities."

According to the Georgian Association of Medical Specialties, the way out would be management by an "independent board with cooperation with the Ministry of Health, but this board must be self-governing. There are many examples of this in various countries such as

Poland, German, Austria, France, etc.", he adds that "those who are interested in this area should show initiative to deliver educational courses and modules, if such educational components won't be formed, how knowledge can be evaluated? And of course the basis of this must be MD degree.". "There is no structural approach to treatment, no regulations. Eventually patients depend on their luck, if they come to a qualified specialist or risk to be harmed".

Additionally all CAM practitioners we interviewed confirmed that patients are often forwarded from conventional medicine physicians to CAM and vice versa.

13.4 CAM Product Regulations in Georgia

According to the law on drugs and pharmaceutic activities of Georgia, the regulations in the law are including complementary medical means, biologically active supplements, and "paramedical" means only in case an interested body initiates registration process voluntarily. The registration then goes in accordance to the national standard. The law defines pharmaceutical products (medical means) as drugs or physiologically active, natural or synthetic substance or a combination of them, which is allowed to be used in medical practice, including the complementary medical means, biologically active supplements, and "paramedical" means which can be registered on voluntary basis (since 2009).

Complementary medical means is defined as – natural (mineral, herbal or animal origin) substance (or substances) based preparation, which's effect and standardization is not proven by objective evidence. Biologically active supplement – a mean to preserve physiological condition. Paramedical means – mineral, herbal, or animal source preparation which has certain therapeutic effect, and contains such concentration of active substance that could be classified as a drug. Voluntary registration – not obligatory registration, which allowed only for the CAM methods stated previously, and is initiated by the interested body.

Not registered CAM preparations can't be labeled as a treatment for a specified disease treatment or marketed as a pharmaceutical product.

In order to register a biologically active supplement the following documents need to be submitted:

a) Content/composition
b) Analysis methods
c) 2 standard packages and preparation enough for 2 tests, with according quality certificate, a certificate of free trade (if existing).

In order to register a complementary medical mean:

a) Content/composition
b) Analysis method
c) 2 standard packages and preparation enough for 2 tests, with according quality certificate
d) Monographies on use of the preparation in clinical practice, their safety and effectivity with respective bibliographic resources.
e) Explanation of the action and presribtion of the preparation.

A total of 139 “Paramedical means”; 37 Biologically Active Supplements and 99 Complementary Means have been voluntarily registered as of Oct. 2014.

The agency stated that voluntary registration is requested mostly for marketing purposes and to increase trust to the medical product. For example insurance companies finance only those medical products which are registered.

The agency has no data on how many medical products are marketed and are not registered. This accordingly puts quality, composition and effect in doubt.

Making preparation importing process easier, and relative safety of the products is stated to be the reason of limited regulatory demands.

According to the data we could obtain, a total of 22 Biologically Active Supplements, 14 Complementary treatment remedies and 135 “paramedical” treatment means were registered for the first time in the period from 2010 to 2013. Much more were among those “re-registered”, though we could not define the exact numbers. This might be not that much compared to the total number of medical products registered at the same period (over 19 000). But this might also mean that much more preparations are imported/produced and used by the patients which are not registered.

According to the Ministry of Health pharmaceutical regulatory agency, such medications as Homeopathic remedies have not evidence-based background, and it is not reasonable to perform expertise to register the remedies on the market.

The order from 2015 titled: “ტექნიკური რეგლამენტის - საქართველოს ბაზარზე ფარმაცევტული პროდუქტის სახელმწიფო რეგისტრაციის ეროვნული რეჟიმით დაშვებული ფარმაცევტული პროდუქტის მარკირების წესის დამტკიცების შესახებ” (On the approval of the Technical guideline – regarding the state registration process of pharmaceutical products on Georgian market, according to the national regulations) signed by then Prime Minister of Georgia, states that homeopathic preparation must be labeled: “homeopathic”, biologically active supplements as: “biologically active supplement” or “BAS” or “Not a Drug”.

Additionally the law on Advertising states that stating a disease to be treated by a CAM product is prohibited.

We would like to mention two interesting cases of CAM products mentioned in official state regulations.

First, in the regulations on Bioproduction (საქართველოს მთავრობის დადგენილება #198 ბიოწარმოების შესახებ), according to the government of Georgia decision, from July 30, 2013, signed by the Prime Minister of Georgia we can find the following information: from the paragraph 3 we get the information that Homeopathic preparations are not regarded as food

products; paragraph 7 contains the following directive: “in order to prevent animal suffering, diseases must be treated immediately. In case phytotherapy or homeopathy appears to be ineffective, it is allowed to use allopathic drugs synthesized chemically, including antibiotics, in accordance to the determined principles.”; paragraph 8 states that: “in order to protect from and treat diseases (such as varroa destructor invasion and others) it is allowed to use acids, sulphur, natural ethers, vapor and fire, in case veterinary treatment was not successful, with priority given to phytotherapeutic and homeopathic medication.

Additionally, we can find a call to regulated biologically active supplements approved by the Ministry of Sports and Youth of Georgia in the antidoping strategy.

Chapter 14 - CAM Use Prevalence and Correlates

Of 700 persons invited to take part in the survey, 476 agreed to participate (68% response rate (RR)). Response rate among women was 90% (314/350) and among men the RR was about 46% (162/350). About half of the respondents were born in Tbilisi, while another half was born elsewhere in Georgia. Lifetime prevalence of CAM use among our respondents was 31%, while 12 month period prevalence of use was 18% (CL 95%). Furthermore about 35% of respondents didn't exclude using CAM in the future, while about a third excluded such a possibility.

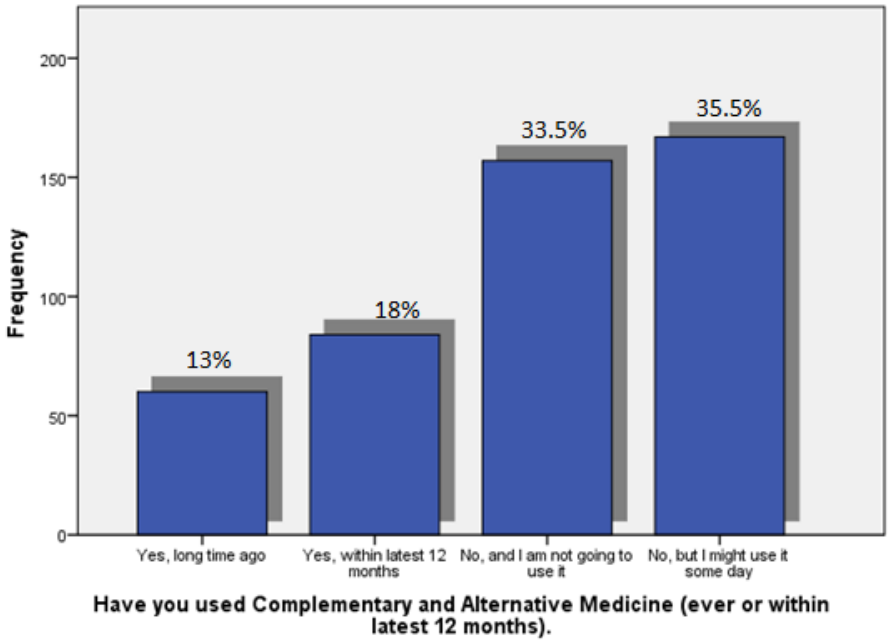

Diagram 1. Prevalence of CAM use.

The use of CAM was not significantly correlated with any of the independent variable except of sex (p=0.036) and education (p=0.033) as found using the Pearson Chi-Square test (the rest were: age, place of origin, frequency of visits to physicians, insurance status, etc).

	CAM users	CAM non users	*Row Totals*
Women	107 (96.97) [1.04]	207 (217.03) [0.46]	314
Men	40 (50.03) [2.01]	122 (111.97) [0.90]	162
Column Totals	147	329	**476 (Grand Total)**

Table 1. CAM use distribution by sex.

Chapter 15 - Patient Survey Results

Of 300 persons approached during the survey period, 217 agreed to participate, yielding a response rate of 72%. The median respondents age was 45 years. Almost half of respondents (43%, n=94) were born in Tbilisi, while 17 were born in other larger cities of Georgia, 3 were born abroad and the rest were born in other towns and rural areas of Georgia. Most of the respondents currently resided in Tbilisi, and about 1/5 of respondents in rural areas and or other cities, respectively.

Of all who agreed to participate in the survey 76%were females, while 24% were males, which was representative of the gender breakdown of all visitors to CAM service centers taken from the patient registry records.

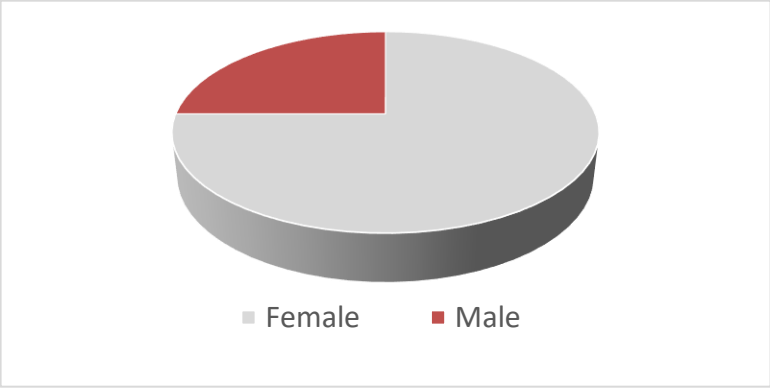

Chart 1. Distribution of CAM users by sex

Most CAM patients have higher education (bachelors', masters' or doctoral degree) 74.04%; while 25.48% had secondary education and only 0.48% had only elementary education. Most of the patients were employed and working (47.89%), 26.29% were unemployed, 12.21% were on pension, 10.80% were studying, and 2.82% didn't answer the employment status question.

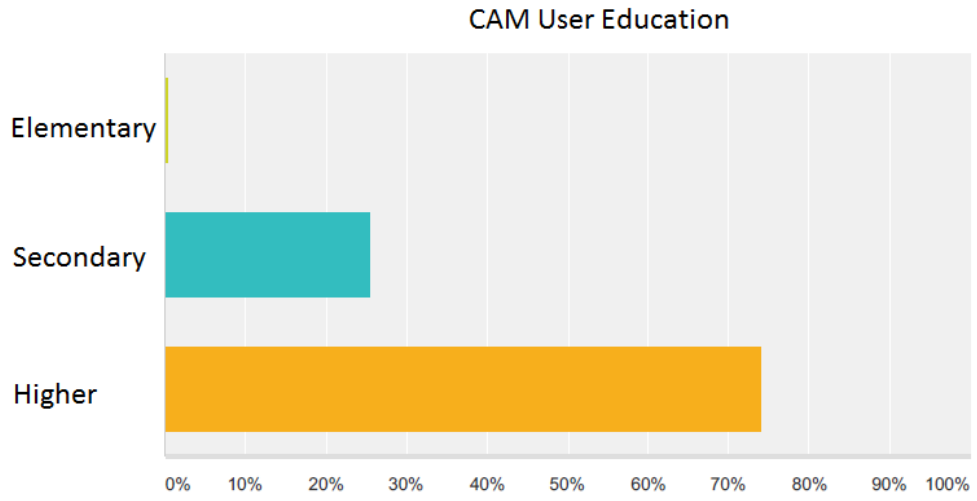

Diagram 2. Distribution of CAM use by Education

The following table demonstrates how did the patient self-reported their health status:

Answer Choices	Percent
Ideal (no health problems)	1.40%
Good (some health problems)	21.50%
Moderate	55.61%
Satisfactory (I am very often getting sick)	12.62%
Bad (I am almost always ill)	8.88%

Table 2, Chart 2. Perception of own health by CAM users

Distribution of top 10 health conditions types due to which the surveyed patients seeked CAM treatment (Table 3):

Rank	Diagnosis group	N=
1	Gastrointestinal Conditions, including liver diseases	47
2	Endocrinology Conditions	21
3	Psychiatric Disorders	20
4	Cardiovascular Conditions	17
5	Rheumatologic Conditions	15
6	Immune System Diseases	15
7	Neurologic Conditions including chronic pain	13
8	Genitourinary diseases	11
9	Gynecologic, Sexual and Reproductive Health Cond.	10
10	ENT and Respiratory Cond.	7

Most of the patients had their diagnoses done by conventional medicine physicians (80.48%) while 15.24% were diagnosed by CAM specialists while the rest of the patients did not have specified diagnosis. About half had a chronic condition (whether as primary reason of visit or as an additional background condition). Over 40% of the interviewed patients (94) had more than 1 health condition currently altering with their wellbeing.

For 70% of respondents, it was not a first CAM experience, while 27% were receiving their first CAM treatment. 57% had received CAM within the previous 12 months.

Most of the patients were using CAM to either treat their chronic medical condition (36%) or improve general health (33%), while 20% of those answering the question for main reason of use stated acute disease treatment. Over half of them expected complete cure of the disease (55%); 30% expected strengthening of their organism; 23% used CAM to manage their symptoms; 18% wanted to get their organism "clear"; 15% were using CAM as they wished to "try everything to fight the condition" and 12% wanted to improve their emotional/psychological condition.

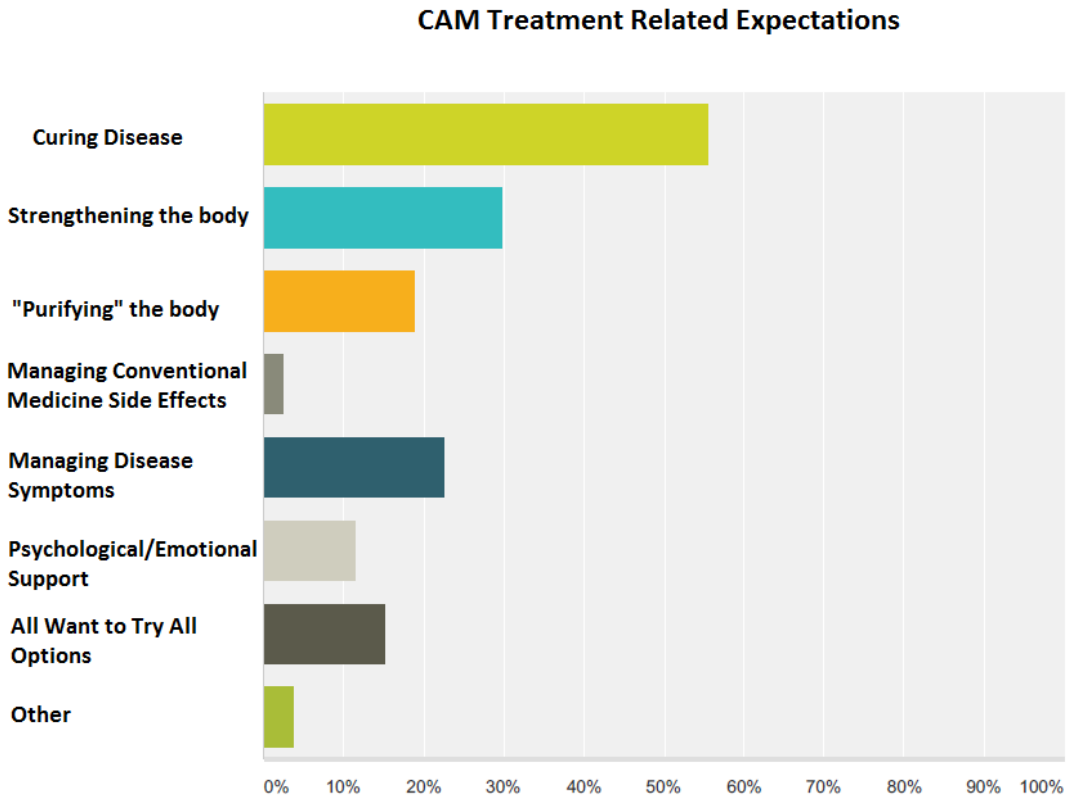

Diagram 3. Treatment related expectations among CAM users.

Close person's advice was the most common reason of application of CAM (40%), while 14% decided to visit CAM center after hearing a patient treatment success story and 7% said they had no other option. About 17% of patients said that their either don't trust or are unsatisfied with conventional medicine or don't take chemical drugs. Some 6% used CAM for prevention or due to their philosophical insight on health and illness.

Subjective satisfaction with the treatment (n=113): about 29% of respondents said that the treatment was "very effective"; about 36% said that it was quite effective; about 25% evaluated treatment as partially effective, 5% said it was not effective and the rest 5 were still not sure or decided not to answer the question. Half of those who said that the treatment was effective added that the first benefits of treatment were felt several weeks after the treatment began. While 40% said that they needed several days.

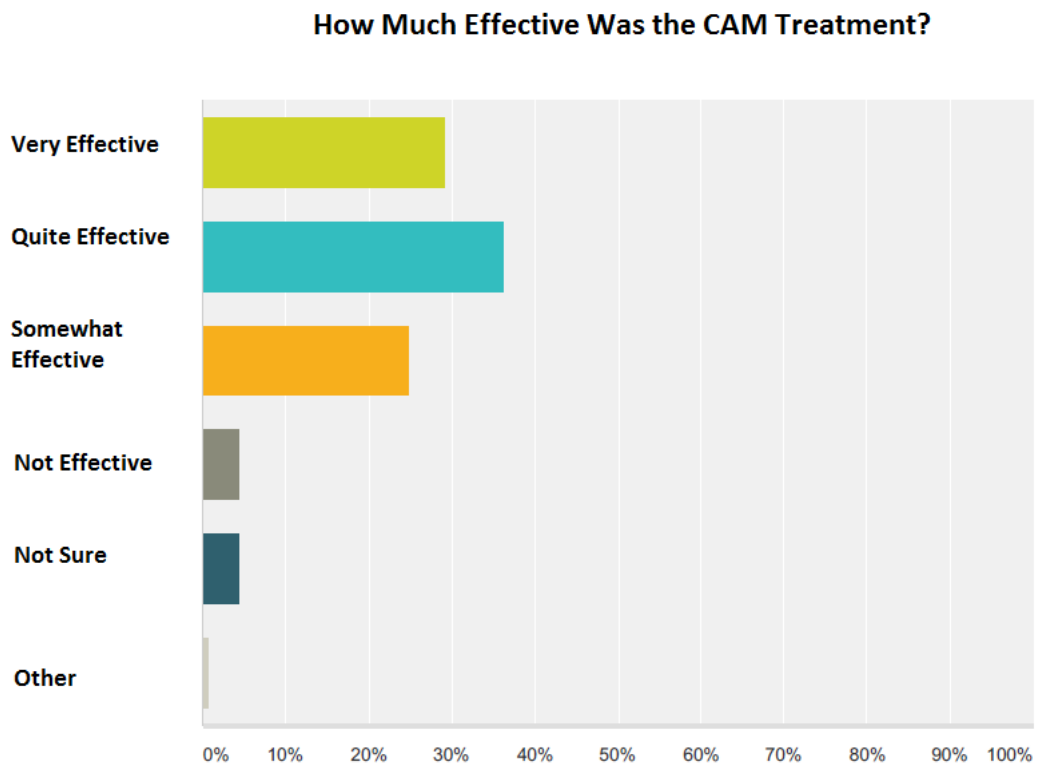

Diagram 4. CAM treatment satisfaction.

Absolute majority (85%) considered treatment to be worth the time and money spent, while 5% said it was not worth it, while the rest weren't sure.

Analyzing the data from patients using CAM for at least 1 month, there was no statistically significantly difference between subjective satisfaction with CAM treatment and such factors as gender, age or education and CAM exclusive use vs. CAM in combination with conventional medicine use groups (analyzed by X2 statistics). (Tables 3,4,5,6)

Table 3. Satisfaction and gender correlation.

Groups	Very of Quite Effective	Partially or Not effective
male	17 (15.63) [0.12]	5 (6.37) [0.30]
female	59 (60.37) [0.03]	26 (24.63) [0.08]
Column Totals	76	31

The chi-square statistic is 0.5248. The p-value is .468797.

Table 3. Satisfaction and age groups correlation.

Age Cat.	Very of Quite Effective	Partially or Not effective
18-34	22 (20.36) [0.13]	7 (8.64) [0.31]
35-50	26 (26.67) [0.02]	12 (11.33) [0.04]
51-69	21 (21.76) [0.03]	10 (9.24) [0.06]
70+	4 (4.21) [0.01]	2 (1.79) [0.03]
Column Totals	73	31

The chi-square statistic is 0.6272. The p-value is .890189.

Table 4. Satisfaction and education correlation.

	Very of Quite Effective	Partially or Not effective
Higher	50 (52.25) [0.10]	28 (25.75) [0.20]
Second	19 (16.75) [0.30]	6 (8.25) [0.61]
Column Totals	69	34

The chi-square statistic is 1.2119. The p-value is .270965.

Table 5. Satisfaction and CAM monotherapy or combined with conventional therapies.

	Effective	Not effective	***Row Totals***
CAM only users	42 (40.61) [0.05]	18 (19.39) [0.10]	60
CAM and Conventional Med. Users	25 (26.39) [0.07]	14 (12.61) [0.15]	39
Column Totals	67	32	**99 (Grand Total)**

The chi-square statistic is 0.3758. The p-value is .539862.

About half of those responding to the question said that they had stopped conventional treatment since the CAM one brought benefits. The other half decided to continue with both. About 35% of respondents informed their physicians regarding CAM use while about half did not, and 15% did not have a managing physician.

Of all the patients who were applying CAM treatment, about half used it in parallel with the conventional medical approaches (48.33%) to manage their health conditions.
In 27% of cases, the applied treatment was prescribed by conventional medicine physicians, about 44% by CAM specialists exclusively, and about 27% were taking medications prescribed by both fields in medicine. Additionally, about one third of the interviewed patients had prescribed some kind of CAM treatment for themselves, while the rest 2/3 were only utilizing treatment prescribed by specialists.

About 35% of respondents informed their physicians regarding CAM use while about half didn't. Such reasons as: "considered not necessary" (the most frequent reason); "their treatment was not effective"; "pharmaceuticals are not effective"; "their treatment was not effective anyway"; "I didn't visit my physician any more"; "they are not interested" were stated among others when asked why conventional physicians weren't informed. It was also mentioned that the news on CAM use was met both positively and negatively by the physicians. In a few cases physicians recommended keeping away from CAM use, but there were also examples of very positive attitude.

Most of the patients followed the guidelines correctly and took their medications as prescribed, though a troubling 34.76% did not always follow the doctors' instructions on medication application. Those not following the prescribed regimens stated the following reasons for their actions: don't want to take chemical drugs – 39.33%, don't want to take any kind of drugs – 11.24%, am afraid of side effects 25.84%, can't afford buying prescribed drugs – 7.87%, 8.99%

said that drug taking was interfering with daily lifestyle and regimen, while 37.08% couldn't state the reason.

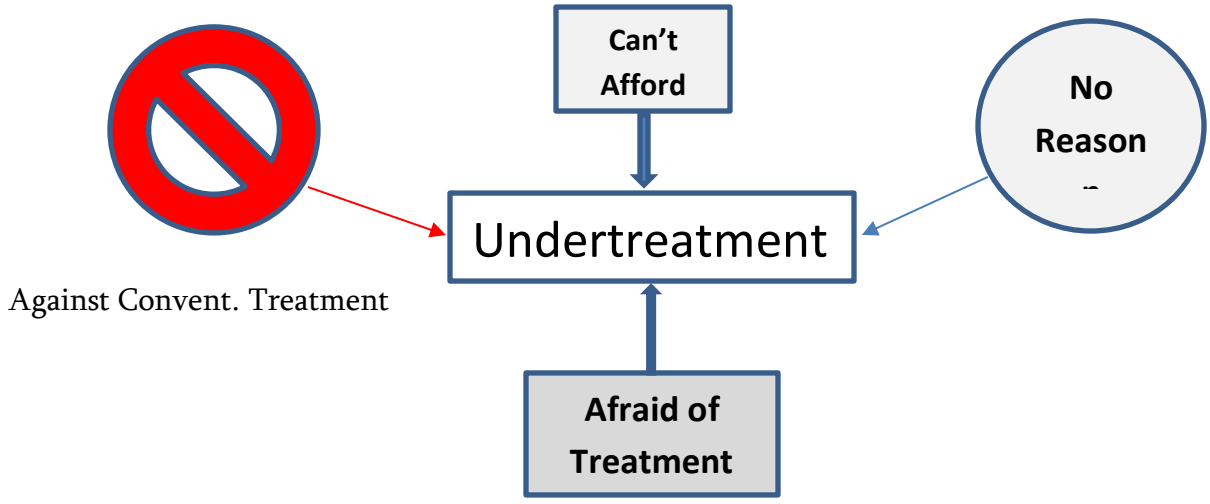

Figure 4. Reasons of not following conventional medicine physician prescribed treatment

Healthy lifestyle – CAM users consider CAM visits and utilization to be beneficial for their ability to follow healthy lifestyle. Most of the patient associate this perception of benefit with feeling stronger for physical activity, improving eating habits, and feeling less or no pain from their medical condition which was restricting them from following healthier lifestyle before starting CAM treatment. It was also seen that most of the patients do not smoke (71%) or drink alcoholic beverage at all (52%).

Average CAM related expenses per month was – 63 GEL. As it expected, absolute majority of CAM users (90%) were financing their treatment at CAM facilities either themselves or by their families. Most of the surveyed users were aware of being a part of the Universal Health Coverage governmental health financing programme in Georgia. About 1/5th had private insurance.

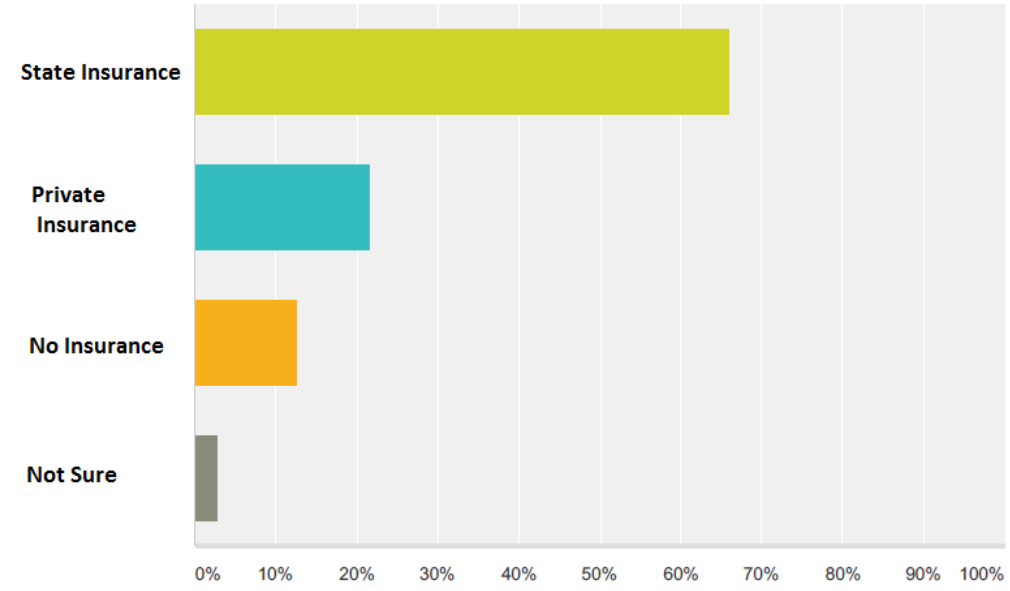

Diagram 5. Insurance status among CAM users.

Most of the Georgian citizens get most of the knowledge about CAM from their family, friends or other people they know (76.56%), while books, printed press or media is contributing knowledge to a cumulative 43.54% of users. Only 11% of patients had received information from conventional medicine specialists/physicians.

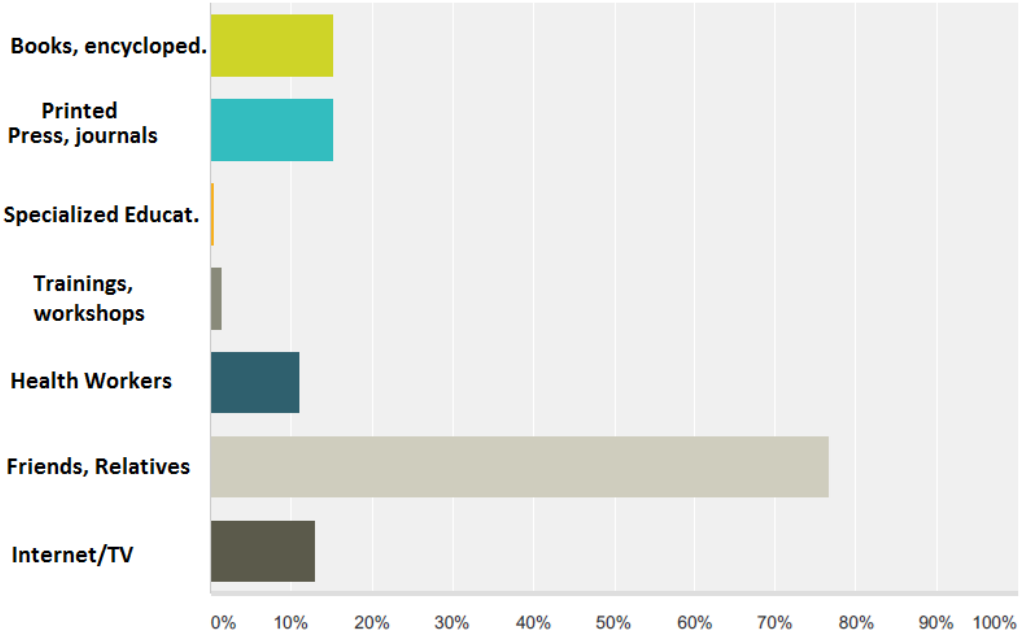

Diagram 6. Sources of information on CAM among the users.

Almost all of the interviewed patients expect CAM to achieve wider spread than today, primary due to the increase in interest and demand from the patients, and to a lesser extent due to the expected scientific progress and wider academic and professional recognition. A large portion of them would also suggest using CAM to those around them in need for health services.

We estimated the patients' awareness on various treatment methods and found that most of the interviewed patients reported to be familiar with homeopathy, phytotherapy, folk medicine, prayer for health, chiropractice and massage, vitamins as a treatment method and some other examples of CAM approaches is. While such methods as bio regulatory medicine, hyrudotherapy, acupuncture were less commonly known or understandable names for the interviewed patients. It was also shown that though most people were familiar with Traditional Chinese Medicine, meditation, relaxation technics, art therapy and some other modalities mean, utilization of these methods was not common among CAM users.

Chapter 16 - CAM Patients' Needs and Attitudes

The key themes defining the factors driving CAM use in Georgia and needs for integration are given below.

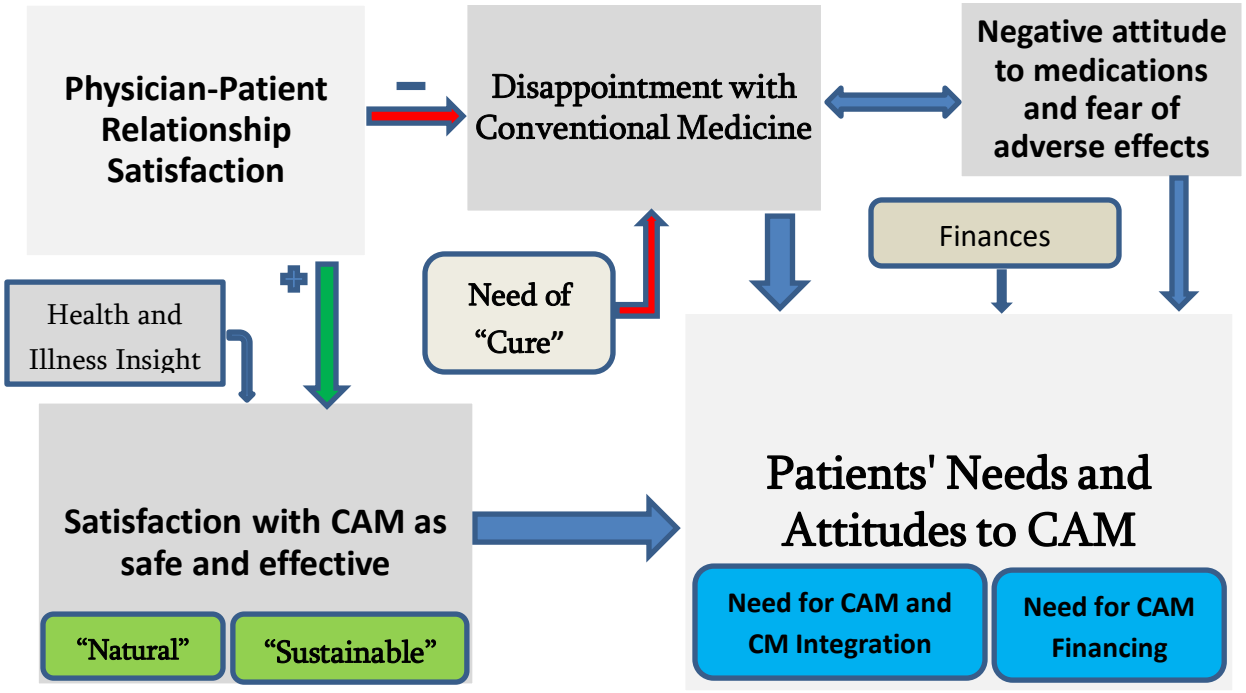

Figure 5: Factors forming patients' needs and attitudes to CAM as per qualitative study results.

16.1 Disappointment with Conventional Medicine: Patients seek cure, not symptom relief

Patients tended to feel uncertain about their health and expressed a general dissatisfaction with conventional medicine treatment. All respondents had tried conventional medicine before consulting CAM practitioners. They had found conventional methods not efficient or too costly as prices of medications have been increasing, spurring their interest in CAM as an alternative option. It seems that these experiences prompted participants to seek alternatives, as the core need of the patients was to address the cause of their complaints and re-establish their health.

Conventional medicine was perceived as too superficial to providing relief only for disease-related complaints, able only to address symptoms but not disease causes. Some patients found that their holistic point of view on organism and health, for example related to the integrity of body and mind, was not accommodated in conventional health facilities.

A young man complaining of phobias and anxiety suggests: *"People expect to be cured. I know a girl who went to many other physicians. Nobody could help her. She was advised to come here, but had no hope. She just came because she wanted everything possible. Within six months, she felt healthy again. That means that one disorder in one organ can cause problems for the whole organism. That's is why the whole organism should be cured together."*

· *I am not sure if I feel safe from a health point of view. Physicians as I understand tend to address manifestations of diseases. But they are not dealing with the causes of diseases.*

· A young lawyer describes her experience: *Previously, I spent really a lot of money on conventional treatments, but problems only went worse. I met several Physicians, even professors, and I would never have thought that after all these efforts, it would be herbs that would cure me.*

· *I had surgery done three times before. Some people there had surgery done tens of times. So that means that surgery doesn't cure you. I heard later about CAM, so I came here with hope.*

· *Our family started using CAM when conventional medicine appeared too weak.*

16.2 Negative attitude to medications and fear of adverse effects: patients want natural approaches as a sustained approach to their health

Fear of side-effects from conventional treatment was a main reason to seek CAM as an alternative, as supported by almost all the respondents. Patients referred to medications as "chemical drugs", reflecting a preference for "natural" compounds as a more sustained approach:

· *Everyone is treating with pills. Drugs are not alive. They are chemical. Herbs or homeopathy are fine with me, but chemical drugs don't cure. Maybe they delay a disease for a bit, but eventually they will cause a lot of side-effects. We should be careful. People are taking them [drugs] because there is no other way out.*

· *Originally, I visited a physician. When I was told to increase the dosage of my drug, I came here immediately. As I know chemical drugs kill both healthy and sick cells. They damage the organism. Maybe young people can cope with it, but weaker people die.*

· *Chemical drugs are so damaging, I have never seen them to be fully curative. They are more poisonous.*

16.3 Satisfaction with CAM as safe and effective

Opposite to general disappointment with conventional medicine, we found high satisfaction with CAM among our respondents. Indeed some patients credited CAM to be life-changing, framing themselves as "believers" in CAM.

• A young man with long lasting depression tells his story with the CAM clinic*: I was about to kill myself, but nobody would believe me that I was feeling bad. I can say only good things about it (CAM). I visited very many physicians in Tbilisi, Marneuli and many other districts. But nowhere did I get so much help as I did here.*

• *People wait to see their practitioner for hours. If it was not effective, I would never believe that people will do this for many years. Once you see how grateful people are here, you will get more faith.*

Additionally, CAM was perceived as a safe treatment option.

· *There is no risk, for example me, I don't take any drugs, and I am getting better.*

16.4 Physician-Patient Relationship: Patients seek empathetic therapeutic and preventive settings

Patients valued the good practitioner-patient relationship often found in CAM. Relationships are often friendly and warm (with some CAM users building friendly relationship with the practitioners). It seems that patients seek empathetic relationships with physicians more commonly found with CAM practitioners.

· *When you go to a physician, you should meet a human, who also sees a human in you and not somebody who talks to you roughly, gives you orders etc. It is something to be taught in universities. And this skill must be developed [in conventional medicine].*

· *Here I get more attention and am treated in a more appropriate way, what I don't get from physicians. Physicians don't do that.*

Good patient attitude and trust was considered an essential part of treatment: *"The main ideology of CAM is to treat a patient as your close ones. And later you can give some remedy and the patient will be cured."*

· An elderly lady tells about her experience: *"There is a lot of trust. When you go to a physician, [trust] is half of it all. If you trust it will help you, you are half-treated."*

A middle aged long time CAM user says: "*Everyone needs individual treatment. And here people are listened to with attention, and get individual prescription. This gives hope to being cured."*

In contrast communication with physicians can be a reason for doubts for their patients*: "Physicians want to treat as radical as possible because it brings money. They don't talk to you."*

Conventional medicine physicians' expertise and effectiveness was also put into doubt.

· *Patients use it [CAM] because the official medicine is weak, not effective and is low quality. Physicians' education and expertise is unfortunately very low. People expect CAM to help them.*

16.5 Integration with conventional health services through government support and regulation

Although CAM users tend to be disappointed from and lack trust in conventional medicine, patients still acknowledge the role of conventional medicine as potentially mutually beneficial.

· *Conventional medicine has many side-effects, which can result in damaging health generally. Pain killers can help you for some time, but pain will come back again later. But in this case, I think that with time, people will realize that conventional medicine is sometimes necessary, like emergency medicine, surgery etc. But still, in everyday life, I would always prefer homeopathy.*

· *It is better to treat with both CAM and conventional medicine. It is of course much better to come here, and the [CAM] specialist will tell himself if additional support from conventional medicine is needed.*

· *Of course conventional medicine also has its place. It would be stupid to refuse it overall. There should be a collaboration.*

· *"Physicians should have knowledge about both… there are some things which can't be cured without surgery for example, but many things can be cured by it [CAM]… my mother didn't avoid physician treatment, but it is thanks to the various herbal treatments that she lives to this day".*

Regarding the integration of CAM into Georgia's health care systems, some suggested that patients would benefit if there was stronger support and involvement of governmental structures in CAM regulations and practice. This process might start with government endorsement:

· Governments should support it. They should say that this is helping and can cure. Why take drugs which can harm you. If there is a possibility to get cured this way, with herbs or homeopathy, it is better to use this method. Most of the people are satisfied. It is curing you, it works.

· CAM treatment is necessary and we need to find ways for CAM methods in regulatory frameworks in order to deliver best care to patients in need. CAM needs some attention.

Interestingly some patients didn't perceive CAM as "alternative" treatment. Instead they saw this as their primary and sole source of medical care.

· It is a safe and even not alternative, but an approach which has no alternatives.

· It is not alternative medicine. It has no alternatives. It is the only chance of cure.

16.6 Patients have reservations about Conventional Medicine

Participants repeatedly made suggestions as to the connection of conventional medicine with CAM. Some of the respondents would prefer physicians having basic insight on CAM. For some patients, conventional physicians supported their CAM use, while others faced negative attitudes from physicians.

· CAM should be integrated into healthcare system, and I believe such time will come. Because now both physicians and CAM specialists don't respect or trust each other… it will be better if we fix these problems as soon as possible.

· I understand that they (physicians) are not obliged to know everything, but they should have at least a bit of knowledge. I have met physicians who admit great results by CAM, but there are also other ones.

· Some physicians have a negative attitude. I know of a case of a person who is doing well with renal failure using homeopathy. But a nephrologist is very angry with him, And would prefer his condition to get worse and then put him on dialysis. So the physician is always arguing with him not to use homeopathy. But it is a fact that after starting using, the person is doing much better and his creatinine went down.

16.7 Coverage of payments for CAM visits and treatments

All patients expressed that it was important for health insurances to cover CAM. Several participants cited that CAM is covered by insurance in several European Union countries. Patients were however dissatisfied with what insurance could provide to them even for conventional medicine services.

· *It would be good if insurance would cover [CAM visits]. Georgia is a poor country [economically], and if people would be able to come here* [to the CAM facility], *there would be a line day and night.*

· A young regular patient states: *Drugs which are healthy and are natural are not financed by insurance, and those which ruin your organism are. You need to really fight to get anything financed. Still for example neither my remedies nor the consultation* [with CAM practitioner] *are financed. So why do I need insurance if I don't go to any physicians anymore?*

· A middle aged woman previously involved in politics states: *Even though over 3 billion lari is spent in healthcare in Georgia every year, it is managed very commercially and not patient oriented. This is one of the reasons that healthcare management and ministry should pay attention to CAM.*

Chapter 17 - CAM and Medical Education

The programme search did not identify any CAM dedicated courses in MD curricula. Some (probably little) content is delivered through history of medicine classes in one of the universities (with such keywords as "homeopathy"; "folk medicine" and others identifiable in the syllabi). Some amount of CAM knowledge is delivered through rehabilitation and/or wellness medicine, body manipulations teaching, etc.

17.1 Qualitative interviews.

This is how a medical education expert commented the situation: *"The knowledge on CAM among physicians or students is unfortunately often based on certain [financial] interests, or on personal experience, but unfortunately it is not available in the form of structured modules in medical education"*.

The attitude of medical education experts was partly positive related to some CAM modalities, while skeptical to others. The frequency (and high rate) of success stories they have heard and the demand from patients make the experts reconsider their skeptical attitude towards CAM. the same can be attributed to physicians, who reported that many patients are referred to CAM specialists by conventional health specialists and vice versa.

A general consensus observed among the participating stakeholders was that future doctors should have at least some basic knowledge on CAM. A CAM expert practicing acupuncture (with a previous long career as a physician) stated: *"The question if CAM should be introduced into medical curricula is not a question to discuss. It needs to be implemented definitely."* A PCD expert stated that: *"it is elementary that some basic knowledge on some historical modalities such as homeopathy or Tibetan medicine is a must for a modern doctor, despite the limited evidence."* An interviewed dean said: *"We raise future doctors. Doctors have contact with patients, while the patients have various experiences with treatment approaches and products available in our country. These products are easily available. When a patient tells that*

he is using these methods, doctors must have some knowledge regarding these methods. Such questions, what is the effect of CAM on our patients' health; if it can be utilized together with the conventional medicine and others topics are very important. Another dean stated: *"If such a practice represents risks for patients, we are obliged to address it in some form in our curricula".*

Regarding the importance to introduce CAM as a CME course for physicians, a long time practitioner of homeopathy and head of professional union expressed the idea that many physicians prescribe homeopathic and other CAM preparations, not knowing what they are prescribing. *"If you ask them what you think about homeopathy, they will say it is a wrong direction. But in fact many of them prescribe the remedies themselves, and they should at least know what they are prescribing. They really don't know. This is risky".* An idea suggesting necessary integration of knowledge was supported. For example, one of interviewed CAM experts said: "*Physicians should not be limited by frames. They should know their options. If a drug didn't help or a homeopathic remedy didn't help, maybe there is something else which can benefit the patient. A strong team uniting the sides and sharing the experience should be established. This way physicians will be aware that in such cases where they can't help a patient they should know what other options exists for a patient who needs relief."*

When asked if a course can be provided to medical schools to teach medical students, one of the CAM society leaders stated: *"Though there is no course ready at the moment, we can develop one according to the medical school requirements, using various available educational resources… Of course, it is possible to form such a programme."* An academic dean stated: *"A separate course can be created, not only covering the pharmacology aspects, but also discussing various approaches (maybe inviting various specialists to give lectures). I see this course like this, this should be taught in a complex way, with two or three days dedicated to each course".* But some of the practitioners said that it is not enough to teach only theory, and students need to have some practical classes, in fact introducing certain CAM modalities as a separate subject.

Others said that quite a lot could be taught regarding certain CAM system in as little time as a couple of days. The rest is a matter of self-education for those who get interested.

There was a conflicting position regarding the question of why such courses are not yet implemented? CAM practitioners suggested that academic staff in universities have a generally negative attitude. For example, a physician and professor of internal medicine we interviewed mentioned that medical curricula tend to be built according to the qualification requirements for MDs, which doesn't consider CAM skills or knowledge.

It was also recognized that medical curricula are often overloaded, and time restrictions are crucial in this case. A medical educator says: "*I myself am teaching pharmacology, and in our textbook there is a chapter which is dedicated to CAM approaches. Unfortunately we don't teach this chapter, due to the limits of time. I think it is necessary…"* Others prioritized such complicating reasons as no clarity on who should be teaching (as CAM is largely unregulated, while practitioners are not professionally certified) and what should be taught (with an idea that it should depend on prevalence of use, while such data is not available). *"In the existing reality, where CAM is not regulated, whom can we trust to teach future and practicing physicians?"* It was agreed that teaching must be objective, guaranteeing that physicians don't obtain more problems than benefit out of the content. Ideas on how much content should be taught ranged. The medical education experts were conservative and suggested that an elective subject is a good option. *"Unfortunately today we don't teach CAM in our university. But I personally as a dean have a great wish to introduce it in some form, at least as an elective subject, I think this knowledge is necessary. For the beginning it can be elective and in future might be transferred to general courses".* An MD programme dean suggested that it would be good to introduce the subject to medical residents. A CAM practitioner suggested that a foreign model can be introduced – blending face-to-face sessions with online work and independent work. A medical education expert: "*It should be delivered in an interactive format, in a form of discussion. Probably a problem based learning is preferred rather than didactic."* Sides agreed that a lot of work needs to be done, and currently there is no initiative or project working on

this. One of the practitioners said: *"I think this should be led by youth. It needs a young health professional full of energy, knowledge and objectives good to patients".* A medical school dean noted: *"Today we can safely introduce CAM content for MD students through studies of public health (covering such topics as epidemiology, patient safety, medical ethics, expenses and others) while deeper integration of CAM into MD and CME curricula should be a step by step process based on an international collaboration."*

17.2 Learner survey results.

Response rate in the medical student network survey was 55%. About half of the surveyed students were familiar with CAM (mostly stating they were "somewhat familiar), predominantly through literature. Most of them would like to receive further knowledge on CAM. The absolute majority (95%) would like the universities to develop a CAM course (if even only a few days long). About half said they would enroll in such a course if it was obligatory, another half would join in any case. Many of those who were familiar with CAM didn't exclude practice in one of the disciplines. It appears that a majority of students had used CAM previously, primarily herbs, homeopathy, dietary supplements, vitamins/minerals and manual therapy/massage.

Part V – Discussion

Chapter 18 - Discussion

18.1 Discussion of General Population and Patient Quantitative Surveys

At an estimate 31% prevalence of CAM use, our findings of Georgian population survey are comparable to that in western countries. (NIH, 2016, Fischer et al, 2014, Eardley et al, 2012)

We observed a steady number of users vising CAM service facilities, sometimes waiting for several hours in queues for a short encounter with a CAM practitioner. Patients use CAM for a wide range of diseases from various medical disciplines, which can be seen as similar tendency as in other European countries, where skin conditions, chronic pain, allergies, stomach or digestive system-related problems are the main reasons of CAM use. (Kemppainen et al, 2018) We can also see that many Georgian patients prefer CAM for chronic conditions, something which can also be seen in other countries. (Chung et al, 2013) Often bypassing a specialized physician and instead seeking help from CAM practitioners, who on their half tend to treat wide variety of nosologies. According to the data we obtained we can conclude that CAM users are mostly people with higher education who care about their own health a lot, and try not only to treat their serious chronic conditions or acute disease, but many of them seek help in improving their general wellbeing and state of health. This supports the results of the studies done in the United States in surveys lead by Barnes, Astin, Eisenberg and Nahin (Barnes et al, 2008, Astin 1998, Eisenberg 1998, Nahin et al, 2007),

Given that in the General Population Census males constitute 47.7% of the population of Georgia and females 52.3% (in urban settlements male constitute 46.2%, while female - 3.8%; in rural settlements the shares of male and female in the total population equaled 49.8% –and 50.2%, respectively) suggests that CAM is generally more popular among female. (National Statistics Office of Georgia, 2016) In comparison of CAM user education status to nationwide statistics, according to the 2014 census conducted in Georgia, the population who completed higher education stands at 26% across the whole country and at 35% in cities. As the majority of our respondents currently resides in major cities, we conclude that chances persons with

higher education are overrepresented in CAM service provision facilities by a factor of 2 compared to the general population. In these two variables: sex and education, our findings are similar to those reported previously. (Barnes, 2010, Institute of Medicine, 2005, Egger, 2018)

CAM users have high expectations from CAM treatment (hence adding knowledge regarding this issue, as in response to the call by Ernst in a literature analysis on patient expectations (Ernst, Hung, 2011), while their trust to conventional medicine is generally low, supported by fear of side-effects, philosophic and belief backgrounds and other factors. Being afraid of conventional medicine side-effects was also shown to predispose to CAM use by some other authors before. (Lakatos et al, 2010) Patients expect cure, expect strengthening of their bodies and feel positive about taking CAM. We also see that most of their expectations are met, at least subjectively, from the patient's own point of view, almost equally for various categories of patients. This combined with conventional medicine dissatisfaction, mistrust, disbelief, low cost of CAM services and remedies/preparations, as well as other factors forms an opinion that CAM use will have a stable, notable (if not constantly increasing) part in health service delivery in Georgia. Indeed, even such major healthcare reform as Universal Health Coverage programme, which made health services much more affordable and available to millions of Georgians, CAM probably didn't lose its positions, as we saw no large dependency on health insurance (whether state or private) among the interviewed.

It must be mentioned that the belief/assumption that "natural equals safe" or "long-term use equals effective" was stated to be false. (Cassileth et al, 2009) In fact, certain CAM product safety should be seen in about the same light as most of the conventional medicine drugs. Drug specific and clinical use factors such as storage, drug interaction, incorrect drug preparation, contamination, manufacturing, nomenclature and others must be considered in CAM practice. And of course the most important factor is probably the lack of safety studies. (Zhang et al, 2012)

We can note, that while almost all of the patients came to CAM facilities with previously diagnosed condition (primarily by conventional medicine specialists), many of them aimed on improving general health, with a holistic approach, hence fighting their condition by strengthening the body, than trying to manage symptoms. We can suggest that the WHO objective "to promote universal health coverage by integrating T&CM services appropriately into health service delivery and self-health care" (WHO, 2013) is logical considering the existing practice discussed above.

Most of the patients get knowledge and respective advise on CAM use from other citizens who have had previous experience with CAM, with additional source of information for the Georgian citizens such as social networks, newspapers and internet. On the other side health specialists are providing a limited amount of information. As the result most of the citizens don't have the reliable information and accordingly are not prevented from the possible damage to their health as well don't have a proper access to CAM services. Lack of knowledge among conventional medicine specialists and their frequent negative attitude often leads to non-disclosure of CAM use, as well as prevents patients from obtaining information on CAM from biomedical professionals. There have been calls to stimulate conventional physician education on CAM (though many physicians prescribe CAM or forward their patients to practitioners themselves) as well as motivate them to get CAM related information from the patients before (Wahner-Roedler et al, 2006, Furlow et al, 2008). We would like to note the importance of this issue, and plan to continue research in this direction, including studies in physician attitudes. It is known that CAM use increases when the citizens have more information regarding it. (Wilkinson, 2004, Nissen, 2012) The lack of trustworthy information and an opportunity to make an informed decision about the patient's own health is opposing the general patients' rights, ethics, and health policy objectives of most of the states.

18.2 Discussion of Qualitative Study on Patients Perspectives

The qualitative study we did can be seen as a base for further research, giving the impression on what is the current reality about CAM practice in Georgia; generating ideas and hypotheses for future studies. Qualitative and quantitative research combination gives broader perspective on the problem and research strategies including clinical trial planning, quality monitoring and treatment assessment, as quantitative results are supported by qualitative findings.

In this study, participants voiced that because they seek cure, not symptom relief, they were disappointed with conventional medicine, the "chemical" medication with potential adverse effects involved. Since they wanted natural approaches as a sustained approach to maintaining and reestablishing their health, they perceived CAM as safe and effective treatment system typically with a positive physician-patient relationship in an empathetic therapeutic and preventive setting.

As concept of health and illness changes for the patients, demands of medicine evolve likewise, and while the demand for holistic approach and cure increases according to our study or other ones, demand for CAM is projected to increase, too. (Hildreth et al, 2007) Terms such as "Chemical Drug"s or "Chemical treatment" were mentioned by half of the respondents over 25 times. This language might express people's quest for natural interventions; it is also used by many CAM practitioners.

Our study found that the often superficial relationship with care providers in conventional medicine was a strong factor prompting patients to avoid conventional medical service, at least among the CAM users we explored. Studies on patient avoidance of medical care, particularly qualitative ones, are scarce. Non-compliance to treatment, resistance to cooperation and other related complications of care is a topic of extensive research, while poor physician-patient communication was found to be one of the leading reasons of the problem. (Taber et al, 2015, Ha et al, 2010)

This study supports our previous quantitative survey findings of high satisfaction rate (75%) among CAM users, which was used mostly to treat chronic diseases or improve general health. Our prior study showed relative affordability, high patient to patient recommendation rate, and prognosis of further growth in CAM prevalence. We found that half of those trying CAM treatment continue to also use conventional medicine, while the other half discontinues seeing their conventional medical provider. Many patients in Georgia didn't see any reason to disclose their CAM use to their regular physicians, preventing an effective collaboration of both sectors. (Nadareishvili et al, 2017) A study from Australia concludes that the paradigms of positive CAM experience among consumers could be applied by all health practitioners, including conventional provider, with the main objective to develop a concordant relationships between patients and care givers. (Emmerton et al, 2012) These findings make a strong argument conventional care and CAM integration in Georgia, considering our study on Medical Education in context of CAM, where medical education experts and leaders endorsed the importance of introduction of CAM education component in graduate and Continuous Professional Development/Continuous Medical Education (Nadareishvili et al, 2017) we propose to stimulate this process, and allow exchange of best practices regarding effective, patient-centered practitioner-patient relationships starting with graduate or post-graduate medical education programmes and courses. This could enhance treatment compliance and trust.

Previous findings are thus consistent with this study's result that patients strongly favor integration of CAM into conventional health services through government support and regulation. A survey published in 2016 by Transparency International Georgia reported that almost half of Georgians either trust physicians only partially or don't trust them at all. Integration, training and education of conventional providers in CAM methods, and the close collaboration between modalities could help reestablish patient trust of providers in Georgia.
Patients' endorsement of CAM integration with conventional medicine is consistent with the World Health Organization Traditional Medicine Strategy, (WHO, 2013) which calls the

members state to integrate CAM into healthcare, however this remain largely not implemented. Study participants found it important for the health system to cover payments for CAM visits and treatments. Financing of CAM by state or public insurance companies varies highly from country to country and within regions, and changes in same regions over time, with a not homogenous coverage across Europe. (Wiesener et al, 2012)

Finally, considering the high contrast of satisfaction with care in conventional medicine and patients' experience with CAM (mainly based on physician/practitioner-patient relationship and fear of side-effects, as well as hope and desire for cure by CAM), the best CAM practice principles need to be studied and shared by conventional medicine to boost its attractiveness for patients, thus potentially increasing the number of physician visits, improving quality and treatment outcomes of services provided by conventional medicine centers. The typically positive attitude and satisfaction with CAM practitioner-patient relationship, might be a sign that relationship-centered care (Beach and Inui, 2006) should obtain more attention in graduate and postgraduate medical education in Georgia. Interview and practice style of physicians have much influence on patient satisfaction with and outcomes of the treatment. (Bertakis et al, 1991, Stewart 1995, Williams et al, 1998, Flocke et al, 2002) We would like to second an earlier study suggesting, that expecting physicians to have in-depth knowledge on certain CAM modalities is unreasonable, though they should have basic knowledge on CAM and should raise the topic of CAM use during the patient interview. (Wainapel et al, 2015) To add to the topic, research showed that physician express will to enhance their CAM knowledge and find it beneficial for their practice, while this need remained unmet. (Winslow, 2002)

18.3 CAM and Medical Education in Georgia, Discussion

Our findings, though limited by small sample size, support the findings abroad (Akan et al, 2012, Ameade et al, 2016, Abbott et al, 2011, April and Gaboury, 2013, Jocham et al, 2017, Joyce et al, 2016) that medical students' attitude is generally positive rather than negative, and they would generally welcome introduction of a CAM course. On the other hand, unlike in studies from

abroad, medical students in Georgia have very limited academic knowledge on CAM. We see, that medical education experts in general support the idea expressed earlier (Witt et al, 2010) that future medical doctors need to be informed about CAM to ensure safe and competent patient care. The high interest could be explained by high rate of personal experience of CAM treatments by students.

The fact that most medical schools curricula are overloaded leaves very little or no time for CAM component (often as an elective subject) was earlier mentioned by Berman in 2001. The author also expressed the idea that unless qualification requirements are changed, will to change curricula will not be strong enough. The idea of using PBL classes to give students necessary knowledge was mentioned.

Qualification requirements for future doctors are in a developmental stage in this country. This doesn't allow the priorities to be defined firmly, resulting in great variations among the medical school programmes. In spite of time deficits as described by academic deans, doubts remain whether it is indeed impossible to introduce a short course on CAM.

In consideration of the possible risks of CAM therapies, high prevalence of CAM among their own patients must be known by physicians, and they must be ready to discuss this issue with those patients. There is a wide variety of approaches to content and amount of studies on CAM to MD students. Curriculum developers should consider the importance of evaluating the impact of CAM inclusion in medial curricula (including perspective of producing dual trained clinicians). (Berman, 2001, Owen et al, 2001) Additionally, many institutions globally, provide CME credits for CAM teaching (Wentz, 2011)

Our findings that there is no common agreement among Georgian physicians on benefits or risk represented by CAM resemble those of a study by Wahner-Roedler et al, which showed that approximately the same proportion of physicians think CAM has certain benefits and/or thinks that CAM represents a risk for patients (67 and 70% respectively). (Wahner-Roedler et al, 2006)

Educating physicians on some aspects of CAM could be of additional benefit, as it was shown that physicians trained in integrative medicine or collaborating with CAM providers guide patients (particularly with chronic conditions) more effectively. (Ventola 2010, Cassileth 2009)

18.4 CAM integration into Georgian Healthcare

18.4.1 CAM Practice Regulations

We see, that CAM professional regulations are in fact non-existent in Georgia.

We should note that while such specialty as homeopathy is not regulated today, some official orders issued by the Ministry of Health of Georgia mention homeopathy and homeopathists in their texts (such as the rule for the hospitals on reporting data to the National Center for Disease Control and Prevention of Georgia). (MOH2016) This means that hospitals can employ homeopathists while no rule or simple definition exists on who are these homeopathists.

Professional organizations while currently inactive could play a more active role, as in a few EU countries. (Wiesener et al, CAMbrella WP2 report) But this looks unlikely in the situation of no cooperation among these organizations, lack of management and leadership transparency, will to invest time and material resources and other reasons. Weak professional organizations in part can be attributed to decades of neglecting and avoiding the discussed problem. The structures are not supported by strong academic background of most of the members, and those who have educatory experience, are mostly not actively involved in education for many years. Various stakeholders don't recognize each other's authority to initiate educatory and certificatory processes. None of the identified CAM professional unions is listed at a registry of medical associations of the Ministry of Health (MOH, List of medical associations, 2018) On the other hand, governmental structures lack resources, both human and material in order to pay more attention on the issue and initiate a step by step policy development, based on a parallel research process, as advised for the European countries following the Pan-European CAMbrella project. (Fischer et al, 2014) Additionally, we observe that some practitioners (all of them members of professional unions) are not informed on the actual state of the related regulatory frameworks, some of them claiming existence of such regulations and even active certification process and holding other false (according to documents we obtained) information on the topic. There are three points which closely resemble the findings from Canada: that self-regulation

can be a way out (supported in some way by all our respondents); that it is currently not clear who has the capacity and "expertise" to implement the self-regulations and take leadership and that there is no clear research strategy or will to implement systematic research. The Canadian study suggests that lack of motivation for research can be one of the main obstacles for systematization and regulation, as "the generation of peer-reviewed research assumes critical importance for the distribution of power in healthcare". (Welsh et al, 2004) Georgian CAM practitioners in each discipline could work on setting own standards and competence, similarly to the model suggested in the United Kingdom (Mills, 2001). There is no vision or prospects for "statutory regulations" while this approach seems to gain momentum internationally, (Ijaz, 2018). The tendency to agree on MD degree as a base for any further CAM career is coherent to the existing regulations in a number of European countries, as evident by the CAMbrella report, though some respondents suggested that such specialties as biology or biophysics could also be adequate prerequisites for CAM practice.

In light of stable if not increasing CAM use in by patients and high rate of non-disclosure to their physicans (Nadareishvili, 2017) only increases urgency of the problem.

The fact that many CAM users had diagnosis done by the practitioners or didn't have specific diagnosis suggests that it could be reasonable to propose a rule that CAM practitioners not holding medical practice license would need a diagnosis proving document from a licensed physician (e.g. health certificate) in order to prescribe treatment or to oblige practitioners to obtain informed consent from the patients, informing them on the treatment they obtain (providing evidence-based information) and possible risk/complication it could bring.

18.4.2 Financial Aspects of CAM Healthcare Integration in Georgia

Study participants found it important for the health system to cover payments for CAM visits and treatments. Many think that CAM is financed by state in such countries as Germany or the United Kingdom. But as presented in Chapter 5 on CAM Financing, the actual reality is different from what patients think or know about it.

Our findings demonstrate the right conclusions of the EU report "Citizens' Needs and Attitudes Towards CAM", which suggests that high variety of CAM funding among European regions highly influences patients' choice of treatment. (CAMbrella WP3 report, 2012)

Today absolute majority of healthcare expenses in Georgia are covered by the state budget via the Universal Health Coverage programme, (Verulava, Maglakelidze, 2017). The UHC covers basic outpatient elective services, most emergency care services, and elective inpatient services, subject to certain limits. The programme itself was largely reviewed and adjusted to optimize spendings in 2017. It was suggested that patients were more motivated to seek care in areas with perceived higher quality of services (Gotsadze et a, 2015). Middle aged men, suffering chronic diseases and with lower education level were less likely to seek outpatient care compared to other Georgia population groups. (Gotsadze et al, 2017) Access to medical products remains problematic for large portion of Georgian population. (Verulava, 2015) Even though the number of visits to various physicians increased after the introduction of the Universal Health Coverage, it still remains quite low. (Verulava, et al, 2017) In the light of this reality, we see that there are a lot of various kind problems in conventional healthcare service delivery and medication accessibility, and it is unlikely that much attention and/or efforts will be turned to CAM by key policy makers in the nearest years.

18.4.3 CAM Product Regulations

The fact that CAM medical products are effectively not regulated as drugs in Georgia resembles the situation in the United States, or certain European countries. For example upon approval of the DHSEA herbal products are available over the counter and are not controlled by FDA. FDA though has rights to remove a product if it is found to be dangerous for human health. We should note that certain CAM products can fall under either food or pharmaceutical legislation, hence in many cases registered through an easier pathway – as food products. In general, the exposed problem is a problem of international community, as it is demonstrated by international research (Ajazuddin, & Saraf, 2012) while there is still no common agreement or strategy.

We should note that further research (in this case in depth study of safety, quality, effectiveness, etc.) in CAM, and specifically Georgian Traditional Medicine, could allow Georgian practitioners and/or producers of herbal products to register, in some case get patent for composition (this practice is documented abroad) and potentially export the products, which could be an important contributor to economy (for example in China this is a part of national strategy and resulted in 2 billion USD income for the country in 2010, which is probably much higher now). (Mossialos et al, 2016)

18.5 Present Research in Broader Context of CAM Research

What we see from our research does follow the observation across Europe, that there are no regulatory or financial “gatekeeper” controlling their CAM therapies and "agents" before they are marketed. This means that treatments can be widespread and researchers, educators or policy makers don’t even know about their existence. In case of Western countries, a 5 stage research strategy was proposed: (Fønnebø et al, 2007)

1. Context, paradigms, philosophical understanding and utilization
2. Safety status
3. Comparative effectiveness.
4. Component efficacy
5. Biological mechanisms.

Our research addresses the first of the proposed stages, technically questing an answer to the “what’s going on?” question. This study addresses the calls by the World Health Organization or European community to enhance research in CAM across the international community (WHO, 2013, Fischer et al, 2014).

Chapter 19 - Study Limitations

There are a few limitations in our study. First of all, prevalence of CAM use in Georgia can only be estimated, and we can't claim an exact nationwide prevalence finding. Additionally response rate among men (particularly over 40 years of age) was much lower than among women. Therefore the actual prevalence and CAM usage attributable factors can be different if a country-wide random selection was applied, which at this point is technically impossible. Another limitation is related to the patient survey, which was conducted in 5 cities which though are attracting people from many corners of the country, but still folk medicine practices of rural areas could be missed and could add to the picture on CAM use in the country. Additionally, CAM use among self-treatment cases would not be possible to evaluate. Responses were dependent on participants' recall of such facts as e.g. use of CAM approaches in the last 12 months, as well as their willingness to report their use accurately.

In the qualitative component of our study, an important limitation of the study is our purposive sampling focus on experiences, needs and attitudes of CAM users in Georgia. This could introduce a bias into our findings, as they are limited to perspectives of those with insight into CAM practice. Further research is necessary to include those less familiar with CAM, who might have reservations of even resistance against CAM which would be relevant to its integration into the current health care system. Same can be applied to other qualitative quests we did in the frameworks of this study.

Finally, documentation research doesn't include resources not available in electronic databases, leaving a chance of certain documents remaining out of our reach and analysis.

Part VI - Conclusion

Chapter 20 – Study Conclusions

- CAM practice and integration into healthcare system in Georgia is seen as a field of opportunities by the stakeholders, but lack of dialog platforms, coordinating bodies and resources prevents the progress in the problem solution. Communication and collaboration of CAM and conventional medicine can be described as neglected.
- Regulations on CAM practice are currently effectively non-existent and Georgia as a whole is currently not in line with the World Health Assembly Resolutions on Traditional Medicine (WHA67.18) and Strengthening Integrated, People-Centered Health Services (WHA9.24), other WHO and EU directives and recommendations. Regulations on CAM product production and marketing are present but not obligatory.
- Prevalence of CAM use in Georgia is high (about 30%), primarily used by middle-aged, educated, employed people. Use among women is higher than men. Users are satisfied with services/outcomes. Information on CAM is spread verbally, while research based information availability, access, health professionals' guidance on CAM remains low.
- People in Georgia value the positive physician-patient relationship often found in CAM as they commonly use these settings, contrasting with usual disappointment with the service and low trust to treatment provided by conventional medicine.
- Healthcare workers have low understanding and research based knowledge on CAM. Medical education frameworks for CAM component integration into graduate, post-graduate and continuous professional development curricula are under consideration and could be considered as a first step on integration process.

- Poorly informed decision making among patients, questionable safety and not conclusive evidence on benefits forms an urgent necessity for further research and initiation of interdisciplinary process of regulatory, education and other framework development.
- The way CAM is regulated, financed and offered, as well as how information on CAM reaches patients is influencing the core biomedical ethics values, such as autonomy, justice, beneficence and non-maleficence.

Part VII - Recommendations

Chapter 21 – Study Recommendations

- Efforts must be done to follow relevant WHO calls to member states, strategic objectives, recommendations and World Health Assembly resolutions.
- Stronger involvement of academic institutions, medical faculties and professional organizations is required for effective and optimal development of regulatory frameworks on CAM practices.
- As a first step of CAM integration into the medical curricula in Georgia, we recommend to develop and offer an elective subject and/or public health based content teaching for MD students and CPD/CME courses for physicians. These educatory frameworks should also pay more attention on physician-patient relationship and communication skills.
- We advise initiation of interdisciplinary and international collaborations to foster best care and outcome, and ensure safe practice of CAM in Georgia, forming a base for physician – CAM practitioner collaborations for quality care for patients in Georgia.
- We advise establishment of a national working group (representing academia, physicians and practitioners and other actors) to map, define, classify CAM practices, form a practitioner/service provider database and propose a core document as a principle for regulatory frameworks and accreditation of CAM practice in Georgia. The work should proceed with mapping services available in the country.
- Interdisciplinary cooperate is required for the effective development of a normative document and policy (at least general guidelines on safety and quality). Involvement of academic educational institutions is suggested to install (at first) basic educatory and certificatory frameworks for no medical specialist CAM practitioners.

Part VIII – Research Novelty

Any research should serve society needs. Preferable research should find out, explore and express these needs. The research design was specifically aimed to bring out real life picture and understand the problem from its depth, which is important to develope certain procedures and standards to ensure safe and effective medical practice. Our study formed first research-based knowledge on CAM practice and utilization in Georgia, patient needs, and practitioner-physician relationships, explored and proposed steps to develop regulatory frameworks and perspectives of integration with conventional medicine practice, medical education issues and other aspects of study problem.

As it is seen from the research thesis, every country and state and every nation is unique in its rules and traditions, while globalization moves hundreds of treatment methods across the world, ignoring borders and laws of the states. Therefore, citizens of any country get exposed to new treatments, or get old treatments in absolutely different way, with no consensus on service and product reimbursement, regulation and integration. People's needs and attitudes vary, as do the interests of providers or other stakeholders. In this light, conducting a study like ours in various populations and countries contributes to not only local but also global understanding of the Complementary and Alternative Medicine, and gives base for research based informed decision making among the stakeholders.

Bringing reliable quantitative and qualitative findings (and also data), our research contributes to the international knowledge base on CAM, forms a base for following interdisciplinary research. This should enhance quality and increase productivity of those studies.

In short term we expect related educational frameworks development, increase in stakeholder awareness (for which we plan to disseminate our findings, using various modes of media and communication platforms) and development of follow-up interdisciplinary research processes. In medium term we expect it to contribute to market standardization, marketing and industry planning, collaboration among the stakeholders and other processes. And in long-term we expect our research to improve patient safety, quality of life and health as well as improvement of cost-effectiveness of care.

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ANNEXES

ANNEX 1

QUEALITATIVE INTERVIEW QUESTIONNAIRE

კომპლემენტარული და ალტერნატიული მედიცინის არსებული პრაქტიკის შესწავლა საზოგადოებრივი ჯანდაცვის პოლიტიკის მეცნიერულად დასაბუთებული საფუძვლის შემუშავებისთვის

კითხვარი

ანკეტის ნომერი _____ **თარიღი**_____

I. საბაზისო მონაცემები [სოციო–დემოგრაფიული ბლოკი]

1. დაბადების წელი		
	2. დაბადების ადგილი	3. ამჟამინდელი საცხოვრებელი ადგილი?
თბილისი		
საქართველოს სხვა ქალაქი		
სოფელი		
4. ქალაქის/დაბის/სოფლის სახელი		
5. რეგიონის დასახელება		

6. სქესი	1. მდედრობითი	2. მამრობითი

7. როგორია თქვენი ამჟამინდელი ოჯახური მდგომარეობა?

დასაოჯახებელი, არასდროს ვყოფილვარ ქორწინებაში.	1
დაოჯახებული	2
ცხოვრობს პარტნიორთან ერთად სამოქალაქო და რელიგიური ქორწინების გარეშე.	3
განქორწინებული/დაშორებული	4
ქვრივი	5

8. როგორია თქვენს მიერ მიღებული განათლების ყველაზე მაღალი დონე?

დაწყებითი განათლების გარეშე.	1
დაწყებითი განათლება (დასრულებული ან დაუსრულებელი).	2
არასრული საშუალო განათლება.	3
სრული საშუალო განათლება.	4
საშუალო ტექნიკური / საშუალო სპეციალური განათლება.	5
არასრული უმაღლესი განათლება.	6

უმაღლესი განათლება (ბაკალავრის, მაგისტრის ან სპეციალისტის დიპლომი).	7
სამეცნიერო ხარისხი.	8

9. ამ ჩამონათვალიდან, რა უფრო შეესაბამება თქვენს მდგომარეობას? გთხოვთ, შეარჩიეთ ის საქმიანობა, რომელიც თქვენთვის ძირითადია.

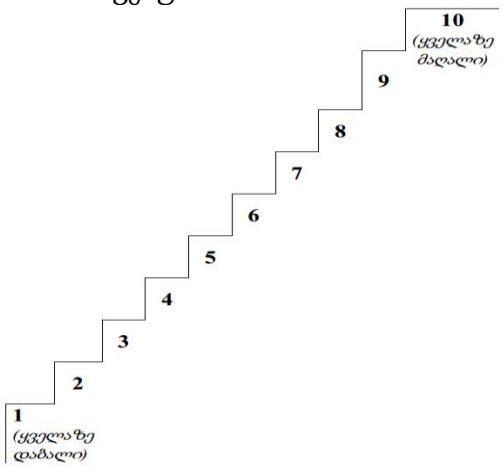
[ინტერვიუერის საყურადღებოდ! მხოლოდ ერთი პასუხი, რომელიც შეესაბამება რესპონდენტის ძირითად საქმიანობას.]

ვარ პენსიონერი და არ ვმუშაობ	1
ვარ სტუდენტი და არ ვმუშაობ	2
ვარ დიასახლისი	3
ვარ უმუშევარი	4
ვმუშაობ სრულ ან ნახევარ განაკვეთზე (მაშინაც კი, როდესაც რესპონდენტი პენსიაზეა / სტუდენტია), სეზონური სამუშაოს ჩათვლით	5
ვარ თვითდასაქმებული (მაშინაც კი, როდესაც რესპონდენტი პენსიაზეა / სტუდენტია), სეზონური სამუშაოს ჩათვლით	6
ვარ ინვალიდი / უნარშეზღუდული და მუშაობა არ შემიძლია	7
სხვა	8
(არ ვიცი)	-1
(უარი პასუხზე)	-2

10. ოჯახების ეკონომიკური მდგომარეობის ამსახველი 10-საფეხურიანი კიბე.

[ინტერვიუერის საყურადღებოდ! ჩაწერეთ რესპონდენტის მიერ დასახელებული საფეხური.]

---------- საფეხური



11. რამდენად ხშირად დადიხართ ეკლესიაში?

კვირაში რამდენჯერმე	1.
კვირაში ერთხელ	2.
თვეში რამდენჯერმე	3.
თვეში ერთხელ	4.
წელიწადში რამდენჯერმე	5.

მხოლოდ ქორწილის დროს	6.
არასოდეს	7.
უარი პასუხზე	–2

IIa. საბოლოო კითხვების ბლოკი *[დამოუკიდებელი ცვლადები]*

1. რამდენად ენდობით... (გთხოვთ, მონიშნოთ მხოლოდ ერთი პასუხი თითოეულ ხაზზე)

	ძალიან ახლოს	ახლოს	არც ისე ახლოს	საერთოდ არ ვგრძნობ სიახლოვეს	მიჭირს პასუხის გაცემა
ა) ექიმებს	1	2	3	4	5
ბ) ტრადიციული მედიცინის სპეციალისტებს	1	2	3	4	5

2. რამდენად ეთანხმებით ან არ ეთანხმებით ქვემოთ მოცემულ დებულებებს? (გთხოვთ, მონიშნოთ მხოლოდ ერთი უჯრა თითოეულ ხაზზე)

	სრულიად ვეთანხმები	ვეთანხმები	არც ვეთანხმები, არც არ ვეთანხმები	არ ვეთანხმები	სრულიად არ ვეთანხმები	მიჭირს პასუხის გაცემა
ა. ტრადიციული მკურნალობა მირჩევნია ნებისმიერი სხვა მეთოდს (მათ შორის საყოველთაოდ მიღებული სამედიცინო სერვისებს).	1	2	3	4	5	1
ბ. დღესდღეობით საქართველოს რეალობაში არსებობს რიგი საკითხები, რომელთა გამოც ვერიდები ექიმთან მისვლას.	1	2	3	4	5	1
გ. უკეთესი იქნებოდა ტრადიციული მედიცინის შესახებ ცოდნა რომ გაღრმავდეს და გარცელდეს.	1	2	3	4	5	1
დ. საქართველოში ვიცავთ ჩვენ ხალხურ მედიცინას.	1	2	3	4	5	1
ე. ტრადიციული მედიცინის სპეციალისტი მეტ დროს მეტად ყურადღებიანია პაციენტის აზრების და განცდების მიმართ.	1	2	3	4	5	1

ზ. ხშირად ისე არ ვარ ქკმაყოფილი მკურნალობით როგორც ვისურვებდი.	1	2	3	4	5	1
თ. მსოფლიო უკეთესი იქნებოდა, ექიმები მედიცინის ნაკლოვანებებს რომ აღიარებდნენ.	1	2	3	4	5	1

3. რას ნიშნავს თქვენთვის ჯანმრთელობა?

4. გსურთ თუ არა, იცხოვროთ და იმუშაოთ ისეთ ქვეყანაში, რომელშიც ტრადიციული და დამატებითი მედიცინის სერვისებს ფარავს საყოველთაო ჯანდაცვა/დაზღვევა?

ნამდვილად მინდა	1
ურფო მინდა, ვიდრე არ მინდა	2
ურფო არ მინდა, ვიდრე მინდა	3
ნამდვილად არ მინდა	4
(არ ვიცი)	-1
(უარი პასუხზე)	-2

რამდენად ეთანხმებით ან არ ეთანხმებით შემდეგ მოსაზრებებს:

5. „სამედიცინო ტრადიციები - ის სიბერძნეა, რომელმაც სიმძლავრე და კეთილდღეობას მოუტანს საქართველოს ჯანდაცვის სისტემას და პაციენტებს“.

საერთოდ არ ვეთანხმები	ძირითადად არ ვეთანხმები	ძირითადად ვეთანხმები	სრულად ვეთანხმები	(არ ვიცი)	(უარი პასუხზე)
1	2	3	4	-1	-2

6. “ტრადიციული მედიცინით სარგებლობის გამო ბევრი პაციენტი არ ღებულობს საჭირო მკურნალობას რაც რისკში აყენებს პაციენტის ჯანმრთელობას და სიცოცხლეს“

საერთოდ არ ვეთანხმები	ძირითადად არ ვეთანხმები	ძირითადად ვეთანხმები	სრულად ვეთანხმები	(არ ვიცი)	(უარი პასუხზე)
1	2	3	4	-1	-2

7. ტრადიციული მედიცინის რეპრესიების შესახებ თუ ვისაუბრებთ, რომელ მოსაზრებას ეთანხმებით?
[ინტერვიუერის საყურადღებოდ! შემოხაზეთ შესაბამისი ვარიანტი]

ეს არის პაციენტის მიმართ დანაშაული, ამ მიდგომებისგამართლება შეუძლებელია.	1
ეს მეთოდების აუცილებლობას წარმოადგენენ, ისინი გამართლებულია, თუ გავითვალისწინებთ მედიცინის და ჯანდაცვის მდგომარეობას.	2

(არაფერი ვიცი ამ მეთოდების შესახებ)	-5
(არ ვიცი)	-1
(უარი პასუხზე)	-2

IIIა. ზოგადი აზრის შემაფასებელი კითხვები

1. სად იღებთ პრევენციულ მომსახურებას?
2. სამკურნალო მომსახურებას?

3. იღებთ თუ არა ამ მომსახურებას პოლიკლინიკების და საავადმყოფოების გარეტ? მაგალითად თქვენ ან სხვის ბინაზე?

4. მოგვიყევით ცოტა მეტი ამ სამკურნალო მეთოდზე და თქვენს გამოცდილებაზე.

5. მოგვიყევით ალტერნატიული ანდ ადგილობრივი სამკურნალო მეთოდზე. გვითხარით რას ფიქრობტ „ტრადიციულ, კომპლემენტარულ და ალტერნატიულ მედიცინაზე“.

6. რა დაავადებების პრევენციის ან მკურნალობის ტრადიციულ მოთოდებს იხსენებთ? სადაური მეთოდებია? რა როლი აქვს ტრადიციულ მედიცინას ჩვენს ისტორიაში/კულტურაში? რამდენად მნიშნელოვანია ტრადიციული მედიცინა ჩვენი ხალხისთვის?

7. იქნებ გაიხსენოთ ცხოვრების ასეთი მოვლენები, რომლებმაც ყველაზე მნიშვნელოვანი გავლენა მოახდინეს თქვენს ჯანმრთელობაზე? რატომ ფიქრობთ ასე?

8. რას ფიქრობთ საქართველოს ჯანდაცვის სისტემაზე? გრძნობთ თუ არა თავს სოციალურად დაცულად?

IIIბ. კითხვები ტრადიციული, დამატებითი და ალტერნატიული მედიცინაზე

Q 6. გვითხარით როგორ გამოიყენებთ ტკმ-ს.

Q 7. რა არის თქვენთვის „შედეგიანი“? რა არ არის? სხვებისთვის?

Q 8. ხომ ვერ გაიხსენებდით, რა იყო თქვენს მიერ ამ სამკურნალო მეთოდებისკენ მიმართვის მთავარი მიზეზი (როგორ და რატომ მიიღეთ გადაწყვეტილება?) და რატომ მიანიჭეთ უპირატესობა საყოველთაოდ მიღებულ მედიცინასთან შედარებით?

Q 9. თუ შეგიძლიათ გვითხარით მეტი იმაზე თუ რატომ სარგებლობთ ტკმ-ით? (ოჯახის ისტორია, რჩევები და ა.შ.).

Q 10. რა იყო თქვენთვის მკურნალობის დროს ყველაზე მნიშვნელოვანი?

Q 11. ხომ ვერ გაიხსენებდით, რა შედეგები იქონია მკურნალობამ თქვენს ჯანმრთელობაზე? გაქვთ თუ არა ეს გადამოცმებული დიაგნოსტიკური მეთოდებით?
Q 12. გვითხარით როგორ მუშაობს ის სამკურნალო მეთოდი რომლითაც სარგებლობთ.

Q 13. თქვენი აზრით, რაში მდგომარეობს ალტერნატიული მედიცინის უმთავრესი იდეოლოგია?

როგორ შეაფასებდით ამ იდეოლოგიას? რატომ ფიქრობთ ასე?
Q 14. როგორ ფიქრობთ რისთვისა სასარგებლო ტკმ? რისთვის არ არის სასარგებლო? როგორ ფიქრობთ, არის თუ არა ტკმ-ის გამოყენება მიზანშეწონილი მხოლოდ მცირე ჯანმრთელობის პრობლემების დროს თუ ასევე სერიოზული დაავადებების დროსაც?

Q 15. სად ღებულობთ მკურნალობას ყველაზე ხშირად? თვლით თუ არა რომ სასყრვეკუა ტკმ-ს ცდა სანამ მიხვალთ საყოველთაოდ მიღებული მედიცინის ექიმთან?

Q 16. გვითხარით რა როლი შეიძლება დაიკავოს ტრადიციულ, დამატებით და ტრადიციულ მედიცინამ საქართველოს ჯანდაცვის სისტემაში?

Q 17. გვითხარით რას ფიქრობს ხალხი ტკმ-ზე? თქვენი აზრით, რას ფიქრობს დღეს ქართული საზოგადოება ამ სამკურნალო მეთოდების შესახებ? თქვენ როგორ აფასებთ ამ მეთოდებს? რატომ?

Q 18. მოგვიყევით ჰომეოპათიის; ხალხური მედიცინის; აკუპუნკტურის და/ან რომელიმე ზ/ა სამკურნალო მეტოდის შესახებ.

Q 19. რა როლი უკავია ამ მეთოდებს თქვენს ოჯახში?

Q 20. ხომ ვერ დაგვისახელებთ რაიმე „ხალხურ თქმულებას“ ან კონკრეტულ რჩევას რომელიც დაკავშირებული ტრადიციულ, დამ გამოყენებასთან? ვისგან/როგორ შეიტვეთ ამის შესახებ?

Q 21. თუ გადააფასეთ თქვენი ჯანმრთელობა ტრადიციული, დამ გამოყენებისას? თუ კი, რამ განსაზღვრა ეს პროცესი? **(დღეს როგორ აფასებთ?)**

IIIc. კოლექტიური მეხსიერება

Q 22. როდესაც იზრდებოდით, თქვენს ოჯახში რა გესმოდათ ტრადოცოული მედიცინის შესახებ?

Q 23. თქვენი აზრით, როგორ უნდა ისწვლებოდეს ტკმ?

Q 24. როგორ ფიქრობთ, რატომ მიმართავენ პაციენტები ტრადიციულ მედიცინას? რა მოლოდინები აქვთ?

Q 25. რას ფიქრობთ ტრადიციული მედიცინის სამკურნალო ცენტრების შესახებ?

Q 26. თუ გსმენიათ ტრადიციული მედიცინის მიმართ უარყოფითი დამოკიდებულების ან საუბრის შესახებ? *(თუ არ სმენიათ ამ მოვლენაზე, აუხსენით თავად და გაარკვიეთ როგორ აფასებენ თავად ყოველივე ამას)*

ANNEX 2.

ტრადიციული, დამატებითი და ალტერნატიული მედიცინის შესახებ კითხვარი საქართველოს მოსახლეობისთვის

1) ასაკი

a) 18-27
b) 28-35
c) 36 – 50
d) 51-65
e) 66 - 80

2) სქესი

a) მამბრ.
b) მდედრ.

3) დაბადების რეგიონი

a) თბილისი
b) ქვემო ქართვლი
c) შიდა ქართვლი
d) მცხეთა - მთიანეთი
e) კახეთი
f) სამცხე-ჯავახეთი
g) იმერეთი
h) რაჭა-ლეჩხუმი
I) სამეგრელო-ზემო სვანეთი
j) გურია
k) აჯარა
l) აფხაზეთი

4) თქვენი განათლება

a) უმაღლესი
b) საშუალო
c) დამწყები

5) ამჟამინდელი საქმიანობა

a) ვსწავლობ
b) ვმუშაობ
c) უმუშევარი ვარ
d) პენსიონერი ვარ
e) სხვა _____

6) როგორ აღწერდით თქვენს ჯანმრთელობას?

a) იდეალური (არასოდეს არ ვარ ავად)
b) ძალიან კარგი (იშვიათად ვარ ავად)
c) კარგი (ხანდახან ვარ ავად)
d) დამაკმაყობილებელი (ხშირად ვარ ავად)
e) ცუდი (მუდმივად ვარ ავად)

7) ვინ აფინანსებს თქვენს სამედიცინო ხარჯებს, როცა საჭიროა?
a) მე თვითონ ვიხდი ყველაფერში
b) მე მაქვს კერძო დაზღვევა
c) საყოველთაო ჯანდაცვას/სახელმწიფო დაზღვევას ვიყენებ
d) სხვადასხვა დროს სხვადასხვა წყაროებიდან ფინანსდება

8) რამდენად ხშირად დადიხართ ექიმთან?
a) ყოველ კვირას
b) ყოველ თვე
c) ყოველ რამდენიმე თვე
d) იშვიათად
e) არასოდეს
f) სხვა

9) გისარგებლიათ თუ არა ტრადიციულ, კომპლემენტარულ და ალტერნატიულ მედიცინით, ბოლო 12 თვის მანძილზე ან ზოგადად (მაგ. ხალხური მედიცინა, ჰომეოპათია, ფიტოთერაპია)?

a) კი, დიდი ხნის წინ
b) კი, მათ შორის ბოლო 12 თვის მანძილზე
c) არა, და არც გამოვიყენებ მომავალში
d) არა, მაგრამ შესაძლოა მომავალში გამოვიყენო

1) თუ კი, კონკრეტულად რომელ მკურნალობის მეთოდს იყენებთ?

ANNEX 3
INFORMATION SHEET

საინფორმაციო ფურცელი მონაწილესათვის

თქვენ დაპატიჟებული ბრძანდებით მიიღოთ მონაწილეობა სამეცნიერო კვლევაში. გთხოვთ ყურადღებით წაიკითხოთ მოცემული საინფორმაციო ფურცელი და ამის შემდეგ მიიღეთ გადაწყვეტილება მონაწილეობის შესახებ.
რა არის ამ კვლევის მიზანი?
ჩვენ ვსწავლობთ სხვადასხვა სამკურნალო მეთოდთა გამოყენებას საქართველოს მოსახლეობის მიერ.
რატომ ვარ ამორჩეული?
იმიტომ რომ ჩვენ გვჭირდება გავიგოთ ბევრი სხვადასხვა ადამიანის აზრი საკითხის შესახებ.
რა მოხდება თუ დავთანხმდი მონაწილეობაზე?
თუ თქვენ მზად ხართ მიიღოთ მონაწილეობა, გთხოვთ შეავსოთ მოცემული კითხვარი. ვფიქრობთ, რომ ამაზე 10 წუთზე მეტი დრო არ დაგეხარჯებათ.
რა მოხდება თუ თქვენ არ გინდათ მონაწილეობის მიღება, და აპირებთ ამაზე უარის თქმა?
გთხოვთ არ იგრძნოთ არანაირი ზეწოლა მონაწილეობის მიღებასთან დაკავშირებით. ეს სრულიად თქვენი არჩევანია. თქვენ შეგიძლიათ უარის თქმა ნებისმიერ დროს და არ არის საჭირო უარის მიზეზის ახსნა.
არის თუ არა დაცული ინფორმაციის კონფიდენციალობა?
ჩვენ გთხოვთ კითხვარის შევსების დროს არ დაწეროთ თქვენი სახელი. ამით თქვენ შეგიძლიათ დარწმუნდეთ რომ თქვენი პასუხი კითხვარზე არის ანონიმური.
რა მოხდება იმის მერე, რაც ჩავაბარებ შევსებულ კითხვარს?
მონაცემები შეიკრიბება, დამუშავდება სტატისტიკურად. მიღებული დასკვნების გამოყენება მოხდება მოსახლეობის ჯანმრთელობის, საზოგადოებრივი ჯანდაცვის და მეცნიერების ინტერესებში.
ვინ აფინანსებს კვლევას?
ამ ეტაპზე კვლევა არ ფინანსირდება, ყველა ხარჯის დაფარვა ხდება სამეცნიერო ჯგუფის პირადი ფინანსური რესურსებით.
ნებისმიერი სახის დამატებითი ინფორმაციის მისაღებად დაგვიკავშირდით:
ილია ნადარეიშვილი, დოქტორანტი
დავით ტვილდიანის სახელობის სამედიცინო უნივერსიტეტი
ტელეფონი: 995593939725. Email: ilianadareishvili@yahoo.com

ANNEX 4
Informed Consent Form

ინფორმირებული თანხმობა კვლევაში მონაწილეობის მიღების შესახებ
კვლევის მიზანი: საქართველოს ჯანდაცვის სისტემაში დამატებითი და ალტერნატიული მედიცინის საკითხში პოლიტიკის შემუშავებისთვის მეცნიერულად დასაბუთებული საფუძვლის შექმნა.

გთხოვთ ყურადღებით წაიკითხოთ შემდეგი განცხადება.
წაკითხვის მერე, გთხოვთ დაწეროთ თქვენი სახელი, ხელი მოაწეროთ ამ დოკუმენტს და მიუთითოთ თარიღი.

1) ვადასტურებ, რომ წაკითხული მაქვს საინფორმაციო ფურცელი.
2) მქონდა ფიქრის და გადაწყვეტილების მიღების თავისუფლება და საკმარისი დრო, შეკითხვის დასმის შესაძლებლობა და პროცესის დეტალური ახსნა.
3) ვიცი რომ ჩემი მონაწილეობა სრულიად თავისუფალია და ვოლონტორულია და ნებისმიერ დროს შემიძლია უარის თქმა მონაწილეობაზე, რაიმე ახსნის გარეშე.
4) მე ვიცი რომ ინტერვიუ ჩაიწერება და რომ ჩანაწერის გამოყენება მოხდება მხოლოდ მეცნიერული მიზნებისთვის და კვლევის დასრულების შემდეგ განადგურდება.

მე თანახმა ვარ მივიღო მონაწილეობა კვლევაში

სახელი, გვარი _____
თარიღი _____
ხელმოწერა _____

ANNEX 5
Medical Student Survey Questionnaire

1. Definition of Complementary and Alternative Medicine: CAM is the phrase used to define medical treatments and techniques that are not part of conventional care. Complementary and alternative medicine includes treatments that are used instead of or along with conventional therapies, such as synthetic/pharmaceutical drugs and surgery. The range of CAM treatments include but are not limited to acupuncture, yoga, tai chi, herbal medicine, massage, chiropractic, Ayurveda, homeopathy, and vitamins/minerals.Did you read the definition of Complementary and Alternative Medicine above?

Yes
No

2. Your Country of Origin

3. Your Age

4. Your gender

Male
Female
Other

5. Your current college standing (year)

6. Are you planning on pursuing a healthcare-related career (i.e., medicine, nursing, pharmacy, hospital administration)?

Yes
No

7. Have you had any of the following forms of education on Complementary/Alternative Medicine?

College Course __
Certification Course __
Elective Course
Online Course __
Reading a book for your personal knowledge __
Seminar
__ N/A __
Other __

8. if yes, did your education help spark an interest in undertaking further education on CAM?

Yes
No
9. If not, would you like your university to develop at least some basic course on CAM, lets say a few days long?

Yes
No

10. Did your education of CAM help spark an interest in incorporating any amount of CAM into your future career?

Yes
No

11. If offered at your university, would you consider majoring/minoring in CAM?

Yes
No

12. Would you enroll in a college course which incorporates CAM if the class: (Please check all that apply)

Fulfilled a requirement for graduation
Was offered within your major
Was not offered within your major
Not interested in taking a college course on CAM

13. How would you rate your familiarity with CAM?

Very familiar
Familiar
Somewhat familiar
Not familiar

14. Did your education on CAM help increase your use of CAM?

Yes
No

15. Have you ever been personally treated with or used CAM?

Yes
No

16. If yes what types of CAM have you been treated with or used for yourself? (Check all that apply)

Acupuncture
Ayurveda
Biofeedback
Body Movement, Tai Chi, Yoga
Chinese/ Oriental Medicine
Chiropractic
Dietary Supplement
Diet-Based Therapies
Energy Healing, Energy Medicine, Reiki, Therapeutic Touch
Herbal Medicine
Homeopathy
Hypnosis
Massage
Meditation
Naturopathy
Prayer for Health Reasons
Vitamins/Minerals
Other (please specify)

17. If not, why?

ANNEX 6, CAM User Survey (visually modified)

დამატებითი და ალტერნატიული მედიცინის შესახებ კვლევის კითხვარი

- დამატებითი და ალტერნატიული მედიცინის მეთოდი

1) სახელი

2. გვარი

3. ტელეფონის ნომერი (მობილურის)

4. თქვენი ასაკი

5. სქესი

მამრ./მდედრ.

6. თქვენი დაბადების ადგილისი (ქალაქი, რაიონი)

7. თქვენი ამჟამინდელი საცხოვრებელი ადგილი (ქალაქი, რაიონი)

8. თქვენი განათლება

დამწყები განათლება (4 კლასი)/საშუალო განათლება (10-11-12 კლასი)/უმაღლესი განათლება (ბაკალავრი, მაგისტრი, დოქტორი)

9. თქვენი ამჟამინდელი საქმიანობა

ვსწავლობ/ვმუშაობ/უმუშევარი ვარ/პენსიონერი ვარ/სხვა

10. გაქვთ თუ არა მხედველობის გაუარესება, სათვალეებით ან მის გარეშე

არა - არანაირი გაუარესება/კი - გარკვეული გაუარესება/კი - დიდი გაუარესება/საერთოდ ვერ ვხედავ

11. გაქვთ თუ არა რაიმე სირთულე სმენაში, სმენის აპარატის გამოყენების დროსაც

არა - არანაირი სირთულე/კი - გრაკვეული სირთულე/კი - დიდი სირთულე/საერთოდ არ მესმის

12. გაქვთ თუ არა რაიმე სირთულე კიბეზე ასვლისას?

არა - არანაირი სირთულე/კი - გარკვეული სირთულე/კი - დიდი სირთულე/ვერ ავდივარ საერთოდ

13. გაქვთ თუ არა რაიმე მეხსიერების ან კონცენტრაციის სირთულე?

არა - არანაირი სირთულე/კი - გარკვეული სირთულე/კი - დიდი სირთულე/საერთოდ ვერ ვიმახსოვრებ და ვერ ვკონცენტრირდები

14. გაქვთ თუ არა სირთულე (თვით მოვლაში როგორიცაა) ბანაობის ან ჩაცმის

არა - არანაირი სირთულე/კი - გარკვეული სირთულე/კი - დიდი სირთულე/საერთოდ ვერ ვაკეთებ

15. გაქვთ თუ არა სირთულე ურთიერთობისას, თქვენი მშობლიური ენის გამოყენებით, მაგალითად, სხვების გაგებაში ან სხვების მიერ თქვენი ნათქვამის გაგებაში?

არა - არანაირი სირთულე/კი - გარკვეული სირთულე/კი - დიდი სირთულე/საერთოდ ვერ ვაკეთებ

16. ზოგადად, როგორ აღწერდით თქვენ ჯანმრთელობას:

იდეალურია (არაფერი არ მაწუხებს)/ძალიან კარგი (ძალიან იშვიათად ვარ ავად)/საშუალო/ დამაკმაყოფილებელი (ძალიან ხშირად ვარ ავად)/ცუდი (მუდმივად ავად ვარ)

17. ჯანმრთელობის რა ძირითადი პრობლემა (დაავადება) გაქვთ (რის გამოც მომართეთ ამ სამკურნალო დაწესებულებას)?

18. ვის მიერ იყო დასმული დიაგნოზი/დაადგინა თქვენი პრობლემის არსებობა?

ექიმის მიერ (მაგალითად თერაპევტის ან კარდიოლოგის მიერ საავადმყოფოში ან პოლიკლინიკაში და ა.შ.)/ექთნის მიერ/ტრადიციული, დამატებითი და ალტერნატიული მედიცინის პრაქტიკოსის მიერ (მაგალითად ჰომეოპათის, ფიტოთერაპევტის და ა.შ.)/აფთიაქში მომუშავე პერსონალის მიერ/მედიცინასთან არა დაკავშირებული პირის მიერ (მაგალითად მეზობლის, ნაცნობის ან ოჯახის წევრის მიერ)/თვითონ დავისვი დიაგნოზი/სხვა ვარიანტი

19. თუ არ იცით თქვენი დიაგნოზი, რა ჩივილებით მიმართეთ ტრადიციულ, დამატებით და ალტერნატიული მედიცინის სერვისებს?

20. რა ტიპის სამკურნალო საშუალებებს იღებთ თქვენი ჯანმრთელობის ძირითადი პრობლემების სამკურნალოდ?/საყოველთაოდ მიღებული მედიცინის წამლებს

ტრადიციული, დამატებითი და ალტერნატიული მედიცინის სამკურნალო საშუალებებს/არ ვიღებ/ორივეს ვიღებ
21. თუ იღებთ სამკურნალო საშუალებებს, წამლებს, ვის მიერ იყო დანიშნული მკურნალობა?
ექიმის მიერ (მაგალითად თერაპევტის ან ენდოკრინოლოგის მიერ საავადმყოფოში, პოლიკლინიკაში და ა.შ.)/ექთნის მიერ/ტრადიციული, დამატებითი და ალტერნატიული პრაქტიკოსის მიერ (მაგალითად ჰომეოპათის მიერ, ფიტოთერაპევტის მიერ და ა.შ.)/აფთიაქში მომუშავე პერსონალის მიერ/მედიცინასთან არადაკავშირებული პერსონალის მიერ (მაგალითად მეზობლის მიერ, ოჯახის წევრის მიერ და ა.შ.)/თვითონ დავნიშნე/სხვა
22. გაქვთ თუ არა რაიმე ისეთი მკურნალობა დანიშნული რომელსაც არ ასრულებთ (არ ღებულობთ დანიშნულ წამლებს), ან ოდესმე თუ ყოფილა ასე?
კი - არასოდეს არ ვღებულობ დანიშნულ წამლებს/კი - ზოგჯერ არ ვღებულობ დანიშნულ წამლებს არა - სულ ვასრულებ ექიმის დანიშნულებას/არ მაქვს პასუხი
23. თუ არ იღებთ, რატომ?
არ მინდა ქიმიური წამლების მიღება/არ მინდა არანაირი წამლების მიღება/გვერდითი ეფექტების მეშინია/საშუალება არ მაქვს წამალი ვიყიდო/წამლის მიღება მიშლის ჩემი ჩვეულებრივი ცხოვრების რეჟიმით ვიცხოვრო/სხვა
24. გაქვთ თუ არა რაიმე მავნე ჩვევა ქვემოთ ჩამოთვლილებისგან (ან წარსულში დიდი ხნის განმავლობაში თუ გქონდათ)?
სიგარეტის მოწევა/ალკოჰოლური სასმელის ჭარბი ოდენობით მოხმარება/ადრე ვიყავი მწეველი არ ვეწევი სიგარეტს/ალკოჰოლური სასმელს საერთოდ არ ვსვამ
25. ვინ აფინანსებს ამჯამად თქვენს მკურნალობას ამ დაწესებულებაში?
მე (პირადი სახსრებით)/ოჯახის წევრები (ნათესავები)/სახელმწიფო/კერძო დაზღვევა/არ ვიცი/უფასოდ მემსახურებიან
26. ხართ თუ არა დაზღვეული?
კი, სახელმწიფოს მიერ/კი, კერძო სადაზღვეო კომპანიის მიერ/არა/არ ვარ დარწმუნებული
27. რამდენჯერ ისარგებლეთ სარგებლობთ თქვენი დაზღვევით (1 წელიწადში)?
0-5 ჯერ/6-15 ჯერ/16 და მეტ ჯერ
არ ვარ დარწმუნებული
28. ჩამოთვლილიდან, რა ხარჯები იყო დაფარული თქვენი დაზღვევის მიერ, არსებული მდგომარეობის მართვისას?
ექიმის კონსულტაციის/დიაგნოსტიკის (ნაწილობრივ)/დიაგნოსტიკის (სრულად, მათ შორის ძვირადღირებულ ტესტებს და მეთოდებს)/მკურნალობის (ნაწილობრივ)/მკურნალობის (ნებისმიერ წამალს, ოპერაციას, სამკურნალო მეთოდს)
29. გაქვთ თუ არა რაიმე ქრონიკული (დროშიგახანგრძლივებული) დაავადება, ან უნარშეზღუდულობა? (დროშიგახანგრძლივებული - ანუ რაც გაწუხებთ გარკვეული (საკმაოდ ხანგრძლივ) პერიოდის
განმავლობაში)
კი/არა
1)
2)
3)
30. სხვა რა ჯანმრთელობის პრობლემა (ან პრობლემები/დაავადებები) გაქვთ?
31. გისარგებლიათ თუ არა აქამდე ტრადიციული, დამატებითი და ალტერნატიული მედიცინით ბოლო 12 თვის გამავლობაში?
კი/არა/არ ვარ დარწმუნებული
32. გისარგებლიათ თუ არა ტრადიციული. დამატებითი და ალტერნატიული მედიცინით როდესმე ცხოვრებაში?
კი/არა/არ ვარ დარწმუნებული
33. ტრადიციულ, დამატებით და ალტერნატიულ მედიცინაზე ცოდნა და ინფორმაცია მიღებული მაქვს ძირითადად:

წიგნები, ენციკლოპედიები, სახელმძღვანელოები/პრესა, ჟურნალები, გაზეთები/მაქვს მიღებული სპეციალიზირებული განათლება/ტრენინგი/სემინარები/ ჯანდაცვის/ სპეციალისტებისგან/ექიმებისგან/ნაცნობებისგან/ნათესავებისგან/ტელევიზორი/ინტერნეტი
34. გამოიყენებდით ან ურჩევდით სხვას ტრადიციულ, დამატებითი და ალტერნატიული მედიცინით სარგებლობას რადგან:
საყოველთაოდ მიღებული მედიცინა ძვირია/სხვა მკურნალობა არ არის ეფექტური/არ ვარ კმყოფილი საყოველთაოდ გავრცელებული (აღიარებული) მკურნალობის მეთოდებით/საყოველთაოდ გავრცელებული მკურნალობა არ არის ხელმისაწვდომი/ჩემი ფილოსოფიური მსოფლხედველობა უფრო ახლოა დამატებით და ალტერნატიულ მედიცინასთან არ ვურჩევ არავის მიუხედავად იმის რომ მე ვიყენებ/ სხვა (გთხოვთ მიუთითოთ)
35. ჩემი აზრით, შემდეგი 5 წლის განმავლობაში ტრადიციული, დამატებითი და ალტერნატიული მედიცინა:
უფრო გავრცელებული გახდება საყოველთაოდ მიღებული მედიცინის ექიმების მხრიდან რჩევების და დანიშვნების გამო/უფრო გავრცელებული გახდება სამეცნიერო პროგრესის და კვლევების გამო/უფრო გავრცელებული გახდება მომხმარებლის (პაციენტების) მხრიდან მოთხოვნის გაზრდის გამო/გავრცელება დაიკლებს ექიმებისგან უარყოფითი შეხედულებების გამო/გავრცელება დაიკლებს ეფექტურობისა და უსაფრთხოების მტკიცების ნაკლებობის გამო
გავრცელება დაიკლებს მომხმარებლის (პაციენტების) მხრიდან ინტერესის სიმცირეს გამო
სხვა (გთხოვთ მიუთითოთ)
36. გისარგებლიათ თუ არა ჩამოთვლილი სამკურნალო საშუალებებით/მეთოდებით ან მომსახურებით?
37. თუ წინა კითხვაზე დადებითად უპასუხეთ: რა მიზნით გამოიყენეთ აღნიშნული სამკურნალო მეთოდი?
ქრონიკული დაავადების მკურნალობის მიზნით/მწვავე დაავადების მკურნალობის მიზნით
ჯანმრთელობის ზოგადი მდგომარეობის გასაუმჯობესებლად/სხვა (გთხოვთ მიუთითოთ)
38. რამ განაპირობა თქვენს მიერ ტრადიციული, დამატებითი და ალტერნატიული მედიცინით სარგებლობა?
ახლობლის ან ოჯახის წევრის რჩევამ/კმაყოფილი პაციენტის ისტორია გავიგე/რეკლამამ
სხვა გამოსავალი არ მქონდა, ბოლო იმედი იყო (ან არის)/არ მჯერა საყოველთაოდ მიღებული მედიცინის/ქიმიურ წამლებს არ ვიღებ/ჯანმრთელობის ზოგადად გაუმჯობესება მინდა
ფილოსოფიურად და/ან რელიგიურად ახლოს არის/არ ვარ კმაყოფილი საყოველთაოდ მიღებული მედიცინის სერვისებით/ეკლესიაში/რელიგიურ დაწესებულებაში მირჩიეს (მაგალითად მოძღვარმა)/სხვა/თუ კი, რომელი (რომლები)?
39. გაქვთ თუ არა საკუთარი თავისთვის დანიშნული ან თქვენი ინიციატივით მიღებული რომელიმე ზემოთ აღნიშნული სამკურნალო საშუალება ან მეთოდი?
კი/არა
40. თვლით თუ არა რომ ტრადიციული, დამატებითი და ალტერნატიული მედიცინა გეხმარებათ ჯანსაღი ცხოვრების წესებით ცხოვრებაში?
კი/არა
არ ვარ დარწმუნებული
41. თუ წინა კითხვაზე პასუხია "კი", რა გზით ახდენს გავლენას დამ თქვენი ცხოვრების წესებზე?
42. რა მოლოდინები/იმედები გაქვთ აღნიშნული მეთოდით მკურნალობის პროცესიგან?
დაავადებისგან განკურნება/ორგანიზმის გაძლიერება (მაგალითად იმუნური სისტემის) ორგანიზმის გაწმენდა/საყოველთაოდ მიღებული სამკურნალო მეთოდის გვერდითი ეფექტების მართვა/დაავადების სიმპტომების მართვა/პსიქოლოგიური/ემოციური მდგომარეობის გაუმჯობესება/ყველაფერი მინდა ვცადო დაავადებასთან ბრძოლისთვის
სხვა

1 თვის შემდგომი საკონტროლო გამოკითხვა

43. აგრძელებთ თუ არა მკურნალობას?
კი/არა
44. რამდენად ეფექტური იყო მკურნალობა? (1 თვის შემდეგ)
ძალიან ეფექტური/საკმაოდ ეფექტური/ნაწილობრივ ეფექტური/არ იყო ეფექტური
არ ვიცი/სხვა (მიუთითეთ)
45. რამდენ ხანში იგრძენით ეფექტი? (1 თვის შემდეგ)
იმავე დღეს/რამდენიმე დღეში
რამდენიმე კვირაში/არ ვარ დარწმუნებული/არანაირი შედეგი
46. თვლით თუ არა რომ მკურნალობაზე დროის და ფინანსების ხარჯი იყო გამართლებული (1 თვის შემდეგ)
კი/არა/მიჭირს პასუხის გაცემა
47. თვლით თუ არა რომ მკურნალობის პროცესში მეტი ზიანი მიიღეთ ვიდრე სარგებელი? (1 თვის შემდეგ)
კი/არა/მიჭირს პასუხის გაცემა
48. რა თანხა დახარჯეთ ამ მკურნალობაში (დამ მეთოდებში/სამკურნალო საშუალებებში/კონსულტაციებში)? (ლარებში) (1 თვის შემდეგ)
49. შეაჩერეთ თუ არა საყოველთაოდ მიღებული მედიცინის მკურნალობა იმის მერე რაც მკურნალობთ ტრადიციული და კომპლემენტარული სამკურანლო მეთოდით?
კი/არა
50. შეატყობინეთ თუ არა თქვენს მკურნალ ექიმს ამის შესახებ ან იმის შესახებ რომ სარგებლობთ ტრადიციული და კომპლემენტარული მედიცინით?
კი/არა/მკურნალი ექიმი არ მყავს/თვითონ იმ ექიმმა მირჩია/დანიშნა ტრადიციული და კომპლემენტარული მკურნალობა/ვერ გიპასუხებთ
51. თუ არ შეატყობინეთ, რატომ?
52. თუ შეატყობინეთ, რა რეაქცია ქონდა ექიმს?

2 თვის შემდგომი საკონტროლო გამოკითხვა
53. რამდენად ეფექტური იყო მკურნალობა?
ძალიან ეფექტური/საკმაოდ ეფექტური/ნაწილობრივ ეფექტური/არ იყო ეფექტური/არ ვიცი/სხვა
54. რამდენ ხანში იგრძენით ეფექტი?
რამდენიმე დღეში/რამდენიმე კვირაში/რამდენიმე თვეში/არ ვარ დარწმუნებული/არანაირი შედეგი
55. თვლით თუ არა რომ მკურნალობაზე დროის და ფინანსების ხარჯი იყო გამართლებული?
კი/არა/მიჭირს პასუხის გაცემა
56. თვლით თუ არა რომ მკურნალობის პროცესში მეტი ზიანი მიიღეთ ვიდრე სარგებელი?
კი/არა/მიჭირს პასუხის გაცემა
57. რა თანხა დახარჯეთ მკურნალობაში (2 თვის განმავლობაში, ლარებში)?

3 თვის შემდგომი საკონტროლო გამოკითხვა
58. რამდენად ეფექტური იყო მკურნალობა?
ძალიან ეფექტური/საკმაოდ ეფექტური/ნაწილობრივ ეფექტური/არ იყო ეფექტური/არ ვიცი/სხვა
59. რამდენად სტაბილური და მდგრადი იყო ეფექტი?
ძალიან სტაბილური, დღემდე კარგად ვარ/ნაწილობრივ სტაბილური, ისევ გაუარესდა მდგომარეობა/ძალიან ხანმოკლე ეფექტი მქონდა/არანაირი ეფექტი
60. თვლით თუ არა რომ მკურნალობაზე დროის და ფინანსების ხარჯი იყო გამართლებული?
კი/არა/მიჭირს პასუხის გაცემა
61. თვლით თუ არა რომ მკურნალობის პროცესში მეტი ზიანი მიიღეთ ვიდრე სარგებელი?
კი/არა
62. რა თანხა დახარჯეთ მკურნალობაში (3 თვის განმავლობაში, ლარებში)?