





Continuing Medical Education and Continuing Professional Development in the Republic of Armenia: The Evolution of Legislative and Regulatory Frameworks **Post Transition**

Sharon Chekijian 60°, Knarik Yedigaryanb, Alexander Bazarchyanc, Gevorg Yaghjyand and Sona Sargsyane

^aDepartment of Emergency Medicine, Yale University School of Medicine, New Haven, CT; ^bNational Certification Center for Professional Development at the National Institute of Health of Armenia, Ministry of Health, Republic of Armenia, Yerevan, Armenia; 'National Institute of Health, Ministry of Health, Republic of Armenia; dInternational Center for Professional Development, Yerevan, Armenia; Head of National Certification Center for Professional Development at the National Institute of Health of Armenia, Ministry of Health, Republic of Armenia, Associate Professor, Yerevan State Medical University, Yerevan, Armenia

The collapse of the Soviet Union in 1991 left many ex-republics in a financial and administrative crisis for the ensuing two decades. Previously centralised processes like recertification of doctors and healthcare workers and continuing medical education fell by the wayside. Continuing medical education and continuing professional development in Armenia have evolved through multiple phases from Soviet, to immediate, mid and late-transitional post-Soviet periods, to current modernising efforts. This manuscript describes the phases of evolution of continuing medical education chronologically and details the legislative and regulatory framework surrounding each stage of development. Armenia is currently implementing a credit system of continuing medical education with the aim to introduce and adopt new and efficient approaches in this field. Continuing education credits fall into three categories: didactic or theoretical knowledge, practical skills and self-education/self-development. To recertify, professionals must collect credits from all three groups with specified minimum amounts according to their degrees. Armenia's guiding principle is to harmonise the continuing medical education and professional development model with internationally accepted criteria in order to contribute to the international mobility of healthcare workers and to provide for true on-going professional development and knowledge that will benefit our doctors, nurses and above all our patients.

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Background

The collapse of the Soviet Union in 1991 left many exrepublics in a financial and administrative crisis for the ensuing two decades. Previously centralised processes like recertification of doctors and healthcare workers and continuing medical education fell by the wayside. Continuing medical education in Armenia have evolved through multiple phases from Soviet, to immediate, mid and late-transitional post-Soviet, to current modernising efforts. This manuscript describes the phases of evolution of continuing medical education and details the legislative and regulatory framework surrounding each stage of development.

Objectives

This manuscript traces the evolution of continuing medical education/continuing professional

development (CME/CPD) in the Republic of Armenia. Barriers to CME/CPD are described as well as the legislative and regulatory framework of each of these phases in the evolution to the current system, a CME credit system. CME refers to educational activities and CPD is a broader term than includes continuing education in other medical disciplines. As the legislative solutions include non-physician professionals we will use the term CME/CPD.

Armenia and Health Indicators

The Republic of Armenia (RA) is a land-locked country located in the South Caucasus. It is bordered by Georgia to the north, Azerbaijan to the east, Turkey to the west and Iran to the south. The current population of Armenia is 2.965 million. [1] Armenia is divided into eleven administrative regions called marz, one of which is the capital city, Yerevan. (Figure 1)

CONTACT SharonChekijian 🔯 sharon.chekijian@yale.edu 🔁 Department of Emergency Medicine, Yale University School of Medicine, New Haven, US This article has been republished with minor changes. These changes do not impact the academic content of the article.



IRAN

Figure 1. Map of the Republic of Armenia .[2]. Taken from open access CIA worldbook.

Armenia became an independent republic after the fall of the Soviet Union in 1991. Initially dire conditions immediately post transition have been followed by impressive growth, and economic and developmental progress in most sectors. Armenia is now classified by the World Bank as an upper middle-income country. [3] The average life expectancy at birth in the RA has been increasing over the last two decades and was estimated at 75.9 years in 2018 reaching 79.0 years for women and 72.4 years for men. [1] This improvement in life-expectancy places Armenia in first place among the ex-Soviet republics. However, despite this progress, Armenia faces continued challenges in the health sector which is plagued by a lack of prioritisation in both strategy and financing. This neglect has taken its toll on the state of the hospitals and the CME of Armenian doctors, nurses and other healthcare workers. The lack of participation in CME should theoretically decrease the quality of knowledge and thus the quality of healthcare provided. We postulate that a non-functioning CME system would negatively affect health outcomes in the long run thereby making this an important topic to address [4].

Workforce

40 km

40 mi

20

According to 2017 data, the overall number of doctors and nurses employed at public, private, academic, research, higher and secondary vocational educational institutions was 29,760. The total number of doctors of all specialities including dentists, was 12,964 or 43.6 per 10,000 population. The total number of nurses was 16,796 in 2017 or 56.5 per 10,000 population. This relatively high physician to patient ratio can be misleading. The ratio of active physicians to patients differs greatly across the capital city and the regions. In 2017 the number was 57.8 per 10 000 population in Yerevan and as low as 12.7 per 10,000 inhabitants Gegharkunik. The concentration of active nurses, both outpatient and inpatient, is also uneven. Again, with nurses and other healthcare professionals the situation looks better in Yerevan and much worse in the marzes. [5] In addition to unfavourable ratios of doctors to patients, regional doctors face many challenges including low salaries, lack of equipment and medications and difficulties obtaining CME. This puts their patients at increased disadvantage and highlights

Table 1. Doctors per 10,000 people by marz [5].

Marz	Doctors per 10,000 population
Armenia Overall	43.6
Yerevan	57.8
Lori	21.4
Shirak	20.4
Kotayk	17.7
Syunik	17.5
Tavoush	16.8
Vayots Dzor	16.6
Aragatsotn	16.0
Ararat	15.7
Aramvir	13.6
Gegharkunik	12.7

major disparities between Yerevan and the other

Table 1. Ratios of doctors to 10,000 people by marz [5]

A Chronologic History of the Legal and **Regulatory Basis of the CME System in Armenia**

Soviet Period

During the Soviet period, certification for physicians was mandatory every 5 years with at least 2-6 months (estimated to be 144-488 educational hours) over the five-year period. Each republic had a Governmental Institute for Doctors' Professional Development under the Ministry of Health. Each institute had its own faculty exclusively devoted to formulating and teaching CME coursework. [6] Physicians were encouraged to fulfill their hours at the Institutes in other republics, the philosophy being that to truly expand knowledge one should leave the home republic to benefit from specialists and faculty not already known to the learner. An oral examination at the conclusion of the course was required and a certificate was awarded to the physician for presentation to their home institution and Ministry of Health for recertification. Attendance at outside conferences could not be counted as CME.

Immediate post-Soviet Period (1991-1994)

In the transition period after Soviet collapse there was a void of directives. In general, physicians continued to accumulate their educational hours according to previous requirements but there was an absence of a certifying authority. Without centralised enforcement and organisation, systems of CME fell by the wayside in the former Soviet republics including Armenia. Continuing education hours were called into question mainly during lawsuits or court cases.

Post-Soviet Early Transitional Period (1994-1996)

In 1994 a new CME system was instituted in Armenia requiring 2-6 months (approximately 175 hours) of CME over 5 years. According to the decree No. 330 dated the 19th of July, 1994 of the Government of the Republic of Armenia "On Improving the Postgraduate Professional Education System of Physicians and Providers of the Republic of Armenia" the hours had to be completed at the National Institute of Health of Armenia, or the Yerevan State Medical University[7]. This was done to ensure quality of the course offerings but from the point of view of current healthcare needs, didactic teaching alone is not enough. It does not provide an opportunity for the healthcare workers to familiarise themselves with innovations in the field, nor to acquire and apply the necessary knowledge and skills. We know now that continuing professional development (CPD) is a multi-component process that involves the acquisition of both theoretical and practical knowledge in various ways, e.g. participation in conferences, seminars, workshops by visiting physicians, on-the-job professional training courses, conducting scientific work, etc. However, the state did not recognise these methods as a form of continuous development. This decree also marked the first time that non-physician healthcare workers were included in CME legislation and regulation.

This early transitional period correlated with a time of deep economic uncertainty in the country. In many cases, the costs associated with obtaining these required hours, which frequently involves transportation and lodging costs for those from the regions of Armenia, were not affordable for physicians. Consequently, many physicians in the regions of Armenia were not able to participate in CME training for a considerable time. [8]

This was a perfect storm of lapsed CME and a concomitant decrease in enforcement of CME requirements for relicensing by the certifying authorities. In addition, further exacerbating the problem, individuals who graduated from respective educational institutions were also free to function, even if they had a long break in their professional career. This legislative and enforcement gap created great risk due to the loss of skills and abilities and or lack of experience at the outset.

Post-Soviet Mid Transitional Period (1996-2002)

In 1996 the recertification procedure in the Republic of Armenia changed again with the addition of a computer-based test of professional knowledge and ability in accordance with the Government Decree N188 from the 24th of June, 1996[9]. Physicians, dentists, and nurses, as well as pharmacists and pharmacist assistants were granted a 5-year licence for professional activity based on the test and fulfilment of the CME hours. The tests were speciality based and degree specific and were administered by the Ministry of Health. The decree remained in effect from 1996-2002. In 2002, relicensing of medical personnel was suspended entirely due to concerns over inconsistencies in test administration.

Disbanding of CME (2002-2004)

During the intervening period from 2002–2004 relicensing at the Ministry of Health or any other governmental entity was completely suspended. In the void of directives, most physicians continued to amass CME using previous guidelines. On-going credentialing within the hospital system remained the only safeguard on CME. Hospitals were required to report CME to the Ministry of Health in order to continue to provide clinical services. Hospital credentialing is generally carried out once every four years.

Post-Soviet Late Transitional Period (2004-2016)

For the first time in 2004, the Ministry of Health of RA introduced elements of a credit system in the Republic of Armenia in lieu of hour requirements by order N 417-A from 23 April 2004[10]. The order also introduced flexibility and granted credits for certain types of activities, such as publishing scientific papers and defending dissertations. Early in this period of time, Yerevan State Medical University (YSMU) and the National Institute of Health (NIH) of Armenia both independently developed credit systems[11]. Although seemingly trivial, the conversion from hours to credits was important as it led the way to being able to accumulate experience and skills from multiple sources domestically and internationally in lieu of previous set certificate programmes. However, without being enshrined in law, this system of granting and accumulating credits did not work in practice instead remaining as a recommendation for best practices in continuing education.

Period of Modernisation and Harmonisation of CME/CPD (2016-present)

Formalised CME/CPD programs in Europe appeared in 1999 under the auspices of the European Union of Medical Specialists (UEMS). UEMS is comprised of all the National Medical Associations member organisations. Under their umbrella the European Accreditation Council for CME (EACCME) was established to transition from voluntary to mandatory CME. [12]. The EACCME aims to harmonise CME/ CPD programs in Europe. Currently, nearly all the European Union member states and UEMS countries have a CME/CPD system in place with cohesive standards[13]. The UEMS also includes countries outside the true European area such as Turkey, Azerbaijan, Georgia and Israel. Armenia became an associate member in 2009 and started to develop a modern national CME/CMD model in harmonisation with European and US models of CME/CPD.

The 6 October 2015 Law of the Republic of Armenia "On making amendments and changes in the Law of the Republic of Armenia on medical aid and service to the population" was adopted (which came into force on 4 May 2016)[14]. Introduction of this law was based on the need to address enforcement and regulation of recertification, and to introduce and adopt more comprehensive approaches to CME. The comprehensive approach recognises the need for skills and knowledge in the practical field. An amendment to this law went into effect on 30 May 2020 which is discussed below. [15]

The law requires that working physicians and dentists earn 220 credits every 5 years in order to recertify. There are no speciality-based CME requirements. The CME/CPD requirements vary by professional degree. Pharmacists need 160 credits, nurses 140 credits and pharmacists' assistants 100 CPD credits. CME for international physician conferences held in Armenia is sometimes certified by the EACCME or the AMA in order to attract international participation. AMA and EACCME credits are both accepted in Armenia at face value, however, the certificate must presented and validated at the National Certification Centre for Professional Development which is described below.

For the first time, the law stipulated the need to formally recertify those satisfying the CME/CPD activity requirements for a five-year term in order to continue clinical practice. The programme applies to physicians, dentists. nurses, pharmacists and pharmacist assistants. Healthcare workers need to obtain a "certificate of professional activity" renewable every

5-years. The certificate is awarded if the healthcare worker obtains the required CPD credits and has been in active clinical practice at least three years out of the last five years.

In the original draft of the law, in the case of not meeting clinical practice requirements or of not obtaining adequate CPD credits, a certificate with reservation was to be issued. The certificate with reservation would serve as a permission for the healthcare worker to resume professional activity under supervision, until the deficit is corrected. Those who were just starting their clinical practice activity for the first time during the first five-year round, could receive a certificate, which allows an independent clinical practice, if they started their practice not later than two years after the graduation from the respective medical or professional educational institution.

The original law stipulates that CME/CPD activities may be carried out by the following local, foreign and/ or international organisations;

- 1) educational institutions implementing medical education programs as prescribed by law,
- 2) medical professional non-governmental organisations;
 - 3) medical or allied health organisations;
 - 4) other organisations active in the health sector.

Certain types of CPD within the state targeted health programs may be carried out in accordance with the procedure established by the Government of the Republic of Armenia.

In the RA, CME/CPD credits are divided into three groups granted for the development of didactic, or so called "theorectical" knowledge, development of practical skills, and self-education or self-development. Healthcare workers may obtain CME didactic credits if they participate in, or organise, professional courses, seminars, symposiums, conferences, etc. in Armenia or abroad. CME practical credits are granted for organising or participating in events containing practical activities such as on-the -job professional development or master-classes. Selfeducation credits are granted for participation or conducting distant or on-line courses, as well as for publication of scientific work. For certification purposes, the healthcare professionals must collect credits from all three groups in line with a specified minimum amounts of five credits in each category. The new model allows for more flexibility and enables the healthcare workers to collect credits in wider circles, choosing from diverse range of CME activities, based on their own needs. The first round of certification is envisaged to be complete in January of 2023 and will encompass the time period from 2016-2023 instead of the initial 5 year period from 2016-2021.

Recent Amendment

A previously mentioned amendment was made to the Law of the Republic of Armenia "On making amendments and changes in the Law of the Republic of Armenia on medical aid and service to the population". The amendment negates the granting of a certificate with reservation and instead states: "In the case of not satisfying the minimal clinical requirement or not obtaining at least 70% of required CME/CPD credits, in order to receive CPD certificate and continue clinical practice healthcare workers must pass a test. In failing to obtain the minimum of 70% of required credits, the healthcare worker will have to correct the deficit according to general regulations[14]..

Regulation and the Establishment of the **National Certification Centre for Professional Development**

To enforce the law the National Certification Centre for Professional Development (NCCPD) was established as a subdivision of the National Institute of Health of Armenia under the Ministry of Health of RA. The centre operates as an organisation independent of medical and professional associations. The main functions of the NCCPD are; certification of medical professionals, quality assurance and monitoring in continuing medical education, accreditation of CME/CPD events, e-learning materials, and selflearning activities and maintaining a registry and database of all healthcare workers.

Efforts at Harmonisation with European CME/CPD

The philosophy of the current CME/CPD system is based on the idea of harmonising the current CME/ CPD model with internationally accepted criteria of the EACCME. This will contribute to the international mobility of healthcare workers and allow Armenian healthcare workers to take advantage of learning opportunities abroad. The Ministry of Health and the NCCPD are constantly looking for best practices and the most efficient ways to ensure high quality of CME/CPD.

To this end, we have translated UEMS guidelines on EACCME criteria for the accreditation of live educational events (LEE), e-learning materials (ELM) and recognition of CPD/CME activities and adopted those by the order of the Minister of Health of RA (order 1491-A, from the 6th of May, 2017 which was later amended and adopted as a normative act by the of Health's order N 20-N, from Minister

26 April 2019) [16-19]. The order N 20-N of the Minister of Health of RA on "Requirements for organization, conducting and participation in CME/CPD events, number of CME credits awarded for each type of CPD and procedure of their granting" came into force on 25 May 2019. This legally binding act has made the process of granting credit to CPD activities more manageable and controllable, but also in line with international standards, principles and requirements.

This decree stipulates that:

- Educational materials provided within the context of CPDs should have a substantive basis, contain a scientific-medical innovation, reflect on current approaches to medicine, introduce new methods, data, recommendations, analysis and include links to relevant scientific research.
- All educational materials must be free of any form of advertising and any form of bias. Events organised by companies producing and importing pharmaceutical and/or medical equipment and medical products will not qualify as CPD events for credits. Activities which are provided entirely by a pharmaceutical or medical equipment industry will not be considered for accreditation.
- Sponsorship should not affect the objectivity of the information provided within the frame of the events, including the selection of topics and/or lecturers.
- No sponsor or staff member may be included in the Organising/Scientific Committee
- The names of sponsors or their trade names incorporated into event names are unacceptable.
- Along with the applicable restrictions, sponsors may be mentioned in a separate section of the program or within the last page of the e-learning materials, with a thank you note for support and a clear indication of sponsorship. If there is sponsorship of a masterclass, the program should include information on other similar products available to participants. In the case of evidencebased efficacy of a particular drug or a treatment method, the information may be presented in a form acceptable for scientific publications.

Internationalisation and Mobility of Healthcare **Professionals**

As noted by this legislative act N 20-N, the procedure for incorporating CME credits granted abroad is regulated in Armenia. Moreover, if the relevant documents are submitted, credits can be also be obtained for participation/completion of professional development programs at university hospitals or research centres abroad, even if the programs have not been accredited by the relevant national authorities. Given the economic challenges facing the nation and our doctors and healthcare workers, we have lost many to work opportunities abroad in a ferocious "brain drain". This new system is an important step towards internationalisation and promotion of mobility of healthcare providers so that they can easily return to practice in Armenia without hindrance.

Pending Legislation

It is important to operationalise the NCCPD. There are three key draft laws currently in play; one decree and two ministerial orders. These documents are intended to regulate the organisation and implementation of the certification of medical practitioners including first time professional practitioners, delineate the process of recertification via implementation of testing for those healthcare professionals without adequate CPD, as well as support registry and database formation at the NCCPD. These drafts are; the decree of the Government of RA "On the Procedure Organization and Implementaion of Testing for Obtaining CPD Certificate" the Order of the Minister of Health of RA "On the Requirements for the Healthcare Registry, the Forms and the Procedure for Designing and Maintaining a Database" and the Order of the Minister of Health of RA "On the Procedure for Organization and Implementation of Certification, Types of Certificates and the Procedure for their Issuing".

Discussion

According to World Health Organisation, CME/CPD is a process of continuing learning to retain, upgrade and maintain professional competence[20]. A comprehensive approach to CME/CPD is desirable and should go beyond clinical updates, to include wide-ranging competencies like clinical skills, research and scientific writing, multidisciplinary care of patients, professionalism and ethical practice, communication, leadership, management and behavioural skills, team building, information technology. [20] CME/CPD is an important link in filling the gap between the medical education and practice of the health care provider. Cooperation between healthcare professionals, the government, NGOs and international organisations is essential[21]. CME/CPD is an activity that involves many stakeholders and most importantly benefits the patient[22].

The main objective of CME/CPD accreditation is to promote and guarantee the quality of CME programs [23-25]. Many countries around the world have begun to apply different models of CPD. Although the international systems vary in detail, there are many common features of content and process that allow international mutual recognition professional of activities in development[26]. However, most systems are based on an hour-based credit system. Where revalidation or recertification of practitioners is required, demonstration of CPD is an integral part of the process[26]. In general, all models of CME conform to the following principles: improving professional knowledge, improving the abilities and skills of the healthcare provider; providing quality medical care to the patient and in turn improving the country's health system.

Because of the major changes that CME has undergone in recent years in terms of the underlying theories, teaching methods, expectations for results, as well as in the learning objectives, continuing education has received increasing attention [25,27]. Although there is harmonisation, at present, there is no standardised system across Europe for accrediting CME/CPD activities nor for granting credits. Some European countries have established CME/CPD systems with a legal obligation to collect a certain number of credits in order to practise medicine. In other countries no such system exists, and CME is considered to be an ethical and moral responsibility of each individual practitioner.

Our progress is not without impediment. When deploying legally regulated CME/CPD systems, both developed and developing countries face difficulties associated with both quality improvement data and analysis, development of legislation, scarcity of funds, and other more human factors. Confronted with the reality of work and family, professional doctors need an exogenous motivation to commit to continuing education when compared with students in undergraduate training. Professional physicians typically experience more barriers to learning for varied reasons. [28-34] Doctors need time to study, for reflection and to attend learning courses. Lack of time due to pressure of work and lack of funded study leave have been identified as major barriers to CME/CPD activities. Administrators consider allotting professional work hours to CME/CPD as a luxury[21]. Another barrier is finances. Most doctors have to pay for their participation in external CME/CPD activities. In developing countries, salaries often just enough to meet basic family needs. Many doctors work extra hours in private practice to supplement

salaries. Funds are not generally made available to satisfy these requirements. CME/CPD can become an unfunded mandate. In many countries there are no budget lines for CME/CPD[21]. Our country is not free from the above-mentioned obstacles[35]. The introduction of the new system in Armenia creates an opportunity to perform a comprehensive temporal, analytical, legal, and financial study to assess existing risks and find ways to overcome them.

Conclusion

The hard work to establish CME/CPD has already been undertaken in the Republic of Armenia. The next steps are to maximise the CME/CPD system in Armenia to international standards, establish parity of CME credits with developed countries, ensure access to CME/CPD through the use of modern technologies, and to digitalise the CME/CPD process and professional registry. The objective is to lay a solid foundation for CPD. These next steps are related to the creation, improvement or development of legal, financial, practical and technical means. Already having modern CME/CPD systems in place, makes it easier to realise pan-European CME harmonisation. Most importantly, it allows our professional to excel, to fulfill professional dreams and to provide excellent care for patients. CME/CPD has been shown to have a clear effect on patient outcomes[20]. CME/CPD of health care providers is a key component of improving health care. Armenia is the first country in the region to introduce the CME system as a mandatory requirement for a health care provider's professional activity. International recognition of CME national credits will also promote the recruitment of highly qualified medical professionals to pursue their continuing education in the Republic of Armenia and receive internationally recognised credits. It is our hope that we will see its impact on professional development and patient care in the years to come.

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SS, KY and AB are current employee of the NIH of Armenia, GY is a former Vice Dean for CME at the Yerevan State Medical University. The authors have no additional conflicts of interest to declare.

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Author Contributions

SS and GY conceived the study. KY and SS collected and analysed the initial data and co-drafted the initial manuscript under the supervision of SS. SC conceived the final manuscript structure and wrote and prepared the final manuscript, SS and AB critically reviewed and revised the manuscript. All authors read and approved the final version of the manuscript.

Declarations Of Interest

The authors report no declarations of interest.

ORCID

Sharon Chekijian http://orcid.org/0000-0001-5514-3349

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