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Educating and training non-MD medical geneticists: development of the system in Lithuania

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Rapid advances in the science of medical genetics have led to an exponentially increasing demand for highly proficient specialists in the field of genetic testing. The **aim** of this study was to present experience in the development of the national system for education and training of non-MD medical geneticists in Lithuania in the European and wider context of the current situation. **The objectives** of this study were (1) to analyse the current situation in the field in Lithuania and other countries on the basis of documents, recent publications, discussions under ESHG, EuroGentest project and other institutions, and the experience of the Department of Human and Medical Genetics of the Faculty of Medicine of Vilnius University and the Centre for Medical Genetics of Vilnius University Hospital Santariškių Klinikos; (2) to suggest a national system for core-competencies-based education and training of non-MD medical geneticists in Lithuania in the context of the EU. **Conclusions**. Analysis of the current situation in the EU, other countries and Lithuania has revealed the necessity to recognise medical genetics both as a clinical and a laboratory speciality both on national and EU levels and to co-ordinate activities in the development of a core-competencies-based system of the training, education and certification of non-MD medical geneticists. A core-competencies-based system for education and training of non-MD medical genetics has been created in Lithuania. It can be proposed as a model for a national system in the context of the EU framework, which is under development.

Key words: education competencies, genetic services, genetic testing, medical geneticist, clinical geneticist

BACKGROUND

It has been known for millennia that heredity affects health. Elucidation of the genetic and molecular basis of inheritance has led to the understanding that every health problem (in fact, every biological condition) has a genetic component and results from the interaction of genetic variation with environmental factors. The genetic component of a disorder ranges from the most straightforward one in the case of monogenic diseases with a high penetrance to a very complicated and not yet resolved interplay of numerous genes and their nucleotide sequence variants and non-genetic factors in common diseases such as atherosclerosis, diabetes or cancer (1–4). The science of medical genetics, which is one of the most rapidly advancing fields of medicine and is expected to play an increasingly important role in medical care over the next decades (5, 6), emerged as a translation of human genetics to medicine with subsequently introducing medical or clinical genetic services (most often referred to as **genetic services**) into the health care system of many countries (7). Genetic services can be defined as health measures implemented to help people with a genetic disadvantage and their families to live and reproduce as normally as possible (8, 9). Genetic laboratory services (or **genetic testing**) are an increasingly important part of genetic services. There are numerous definitions of a genetic test (10–13), but the most widely accepted one specifies it as "the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes" (14). Genetic testing has two general functions of diagnosis and risk assessment, but the context varies widely depending on the clinical purpose (such as the diagnosis of a genetic disease in symptomatic and asymptopmatic newborns, children, and adults; identification of future health risks; assessment of risks to future children; prediction of drug responses; population screening). On the other hand, genetic tests can be classified by the laboratory techniques used. Currently, three major laboratory methodologies are used to categorise clinical genetic tests and laboratories performing them. These are clinical cytogenetics, clinical biochemical genetics, and clinical molecular genetics. These terms are also used to describe the three laboratory areas that geneticists may obtain speciality training (and board certification in some countries).

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The success of the Human Genome Project has led to an increasingly rapid translation of genetic and genomic information into clinical applications, including genetic testing as a medical diagnostic aid, and the latter is apparently the area in which the application of basic genetic research has the greatest impact. Genetic tests for more than 1300 diseases have been developed, with more than 1000 currently (March 2007) available for clinical testing (15) and hundreds more in development. Currently, most out of the constantly expanding number of clinically validated genetic tests are used for the diagnosis of rare genetic diseases, but a growing number have population-based applications, including carrier identification, predictive testing for inherited risk for common diseases, and pharmacogenetic testing for variation in drug response. With advances in technology and additional knowledge concerning the relationship among genetic variations in health, it is expected that genetic testing will soon become a routine part of healthcare. Thus, the **demand** for highly qualified specialists proficiently performing genetic testing, interpreting and communicating testing results is steadily increasing (16).

Unlike other areas of clinical laboratory work, the results of genetic testing often have implications for the entire family. Another aspect specific for genetic testing is that genetic scientists (non-MD) often have a key interpretative role and work together with clinical geneticists to develop clinical services in line with the science base. Hence, there are **unique requirements** for knowledge, skills and attitudes to be acquired by the specialists providing genetic testing services.

Quality assurance of health services in general and genetic testing in particular needs a set of internal and external means, with accreditation considered to be the most effective in this respect (11, 17, 18). Laboratory accreditation standards require that all diagnostic laboratory personnel have an adequate combination of education, training and experience that demonstrates their competence.

As the majority of clinically validated genetic tests are intended for rare disorders, no single genetic laboratory or even a single country can provide recourses for all such tests. Thus, there is a strong need for developing international networking for rare diseases in order to give access to reliable clinical and laboratory resources (11, 17, 19). Accordingly, there is a need to develop the **international consensus and best practice** to assure consistency in the quality of genetic testing services available as well as in specialists' qualification (20).

Thus availability, accessibility, quality and efficiency of genetic testing as part of genetic services and ultimately of health care system as a whole strongly depend on the availability and qualification of the staff that provides such tests. Accordingly, a special system of professional **education and training** (undergraduate and post-graduate) of such specialists, maximally harmonised across countries (European Union in the first place), is necessary to fulfil the exponentially growing demands for genetic testing, to enable an EU-wide coordination of efforts in ensuring the highest quality of genetic testing, and to establish an EU-wide networking for genetic testing of rare disorders.

The establishment of **core competencies** is currently being used as a basis of undergraduate and postgraduate medical training for health professionals in many countries (21–23). Competencies are defined as a combination of knowledge, skills and attitudes which, when applied to a particular situation, are critical in leading to a given outcome (22). The competencies must be identified, validated, assessed and developed in the context to the essential genetic services in the national / international health care system and in the relation of these services to positive health outcomes. Core competencies are intended to serve as a common foundation for groups involved in designing curricula and presenting educational programs. Recent analysis of the current situation has shown that coherent policies regarding core competencies in genetics in general and genetic testing in particular across Europe have not yet been developed, and in most European countries there are no defined sets of competencies (data for the end of the year 2006) (24). EuroGentest, an EC FP6-supported Network of Excellence for Genetic in Europe, is aimed at harmonising genetic testing services, and one of its objectives is to "define quality criteria for institutional courses and education in genetic testing (e.g. Masters degree) and evaluate such courses" (25–27).

In this context, national / regional problems in providing genetic services, particularly those related to the problems in specialists' education and training, become clearly identifiable and need urgent means to improve the situation. In this paper, we present the Lithuanian experience related to the problems arising from the inadequate current system of training non-MD specialists providing genetic testing services for the population and a project of a new national system developed on the basis of our own experience in education activities and providing genetic services for the population of Lithuania, analysis of the situation in other countries and a close collaboration with EU experts from the European Society of Human Genetics (ESHG) and under the EuroGentest project Unit 6.2.

MATERIALS AND METHODS

This article is based on the analysis of the documents from Lithuania and other countries and recent publications on core competencies and specialists' training in genetics services, discussions under the EuroGentest (25) 6.2 unit and the experience of the Department of Human and Medical Genetics of the Faculty of Medicine of Vilnius University and the Centre for Medical Genetics of Vilnius University Hospital Santariškių Klinikos in educating and training non-MD medical geneticists for genetic services in the health care system of Lithuania, and in providing genetic services for the population of Lithuania.

RESULTS AND DISCUSSION

1. Overview of the current situation with non-MD medical genetics

Although this paper is aimed towards non-MD laboratory specialists in the field of genetic testing, this speciality cannot be considered beyond the context of clinical geneticists and health professionals in general, as the key element of the future genetics policy in the harmonisation of the quality of the services for genetic testing in Europe is a more comprehensive genetic education of all health professionals (20).

1.1. EU and other countries

Clinical genetics services are now established in at least 29 countries of Europe (28). A series of papers resulting from the

Concerted Action on Genetic Services in Europe (1997) (29) have revealed an extreme variability in the level and structure of available genetic services. An additional level of variability is imposed by other countries such as U.S. (30), Australia (31), South Africa (32).

Recognition of medical genetics as medical speciality

Availability of health services strongly depends on the status of the speciality aimed to provide a service. Clinical / medical genetics (in the sense of a MD-based competency to offer specialised genetic services; see also sec. 1.2 for definitions) is officially recognised as medical speciality in several EU countries (e. g., in Czech Republic, France, Ireland, the Netherlands, Norway, Switzerland, Lithuania, etc.) (28, 29), and specialist genetic physicians (MDs) can be trained through a system for post-graduate training (most often residency in clinical / medical genetics). Nevertheless, Medical Genetics is not currently a specialisation listed in Annex C of Directive 93/16/EEC (33), which denotes a medical speciality recognised at the EU level. An urgent need for medical genetics to be recognised as an independent medical speciality in all countries and at the European level has been recognised by ESHG (1, 34). In the U.S., the full legitimization of Medical Genetics as a clinical speciality (the 24th primary speciality of medicine) took place in 1991, although certifying clinical and laboratory-based medical geneticists and genetic counsellors as well as accrediting their training programmes began after 1980 (30).

As regards the recognition of medical genetics as a non-MD laboratory-based speciality with a competency to offer diagnostic genetic testing, the situation is more complicated. There are few known cases of the recognition of the speciality on the national level. Genetic laboratory services in the EU and other countries are largely provided by a mixture of PhD scientists, MD/PhD clinician scientists and technicians with different requirements for their educational background and scientific degree and the necessity for accreditation of laboratories as well as individual accreditation, board certification and state registration of laboratory personnel (28, 29, 35). OECD has recently performed a survey of 18 member countries for quality assurance and proficiency testing for molecular genetic testing (35), but the key conclusions and recommendations from this study and developed draft guidelines (18) appear to be applicable to all laboratory genetics areas. In the first place it is the statement that "Medical Genetics should be recognised as both a clinical and a laboratory speciality". Accreditation is recognised as the most effective way to improve quality assurance in genetic testing, and to achieve it a laboratory must be adequately staffed by personnel with appropriate qualification and training.

Development of core competencies

With the general recognition that genetic and genomic medicine will play an increasing role in all areas of health care in future (5, 6), the challenge to medical education today is to determine the level of knowledge about genetics that graduates ready to provide health services need to acquire to evaluate family history and to recognise clinical findings that indicate increased genetic risk, to collaborate efficiently with clinical geneticists, and to deal with advances in genomic medicine as they arise (36). A number of groups and professional societies around the world have already suggested core competencies in genetics required for health care providers – either most general addressed to all health care professionals or non-genetics healthcare staff (37–40), or tailored to discipline specific needs (as well as national and regional needs) such as core competencies in genetics for all physicians (41), public health professionals (42), optometric students and practicing optometrists (43), family practice residents (44), nurses (45–47). On the other hand, apparently much more efforts were applied to define the core competencies in genetics for non-genetic health care professionals than for non-MD specialists providing genetic testing (48). This is a reflection of the fact that formal training schemes for non-MD medical / laboratory geneticists do not exist in many countries.

The organisation for Economic Co-operation and Development (OECD) has recently suggested Education and Training Standards for laboratory personnel. They were developed for quality assurance in molecular genetic testing (see sec. E of Part I of the "Draft Guidelines for Quality Assurance in Molecular Genetic Testing" (18)), but actually are applicable for all main areas of genetic testing and should be taken into account when considering the education and training of specialists for genetic testing services.

In summary, analysis of the current situation in the EU by the EuroGentest 6.2 Unit experts (20) has shown that there are no coherent policies regarding core competencies in genetics across Europe and in most European countries there are no defined sets of competencies. This is particularly relevant for laboratory geneticists. While setting curricula for the EU was not viewed due to the differences in systems, it was agreed by the EuroGentest Unit 6.2 experts to develop a set of core competencies that could apply to health professionals in Europe as an appropriate framework to develop curricula tailored for national / regional conditions and help countries to adjust their education and genetic service delivery systems for the future, according to a coherent set of standards. Groups of health processionals that require different level of education and training in genetics – including geneticists responsible for laboratory services – were categorised, and the development of core competencies was initiated (in 2006).

Non-MD medical geneticists' certification

Alongside with the accreditation of diagnostic laboratories which provide genetic testing, individual accreditation, board certification, state and international registration of laboratory personnel are being acknowledged as an important instrument relevant to regulation of quality assurance in genetic services. Currently there are significant differences in the field across the EU as well as in other countries (35).

As no single genetic laboratory or even a single country can provide recourses for all genetic tests, particularly those for rare diseases, there is a strong need for developing a national and the international (particularly important for relatively small countries such as Lithuania) networking for rare diseases in order to give access to reliable clinical and laboratory resources (11, 17, 19). Accordingly, an EU-level performance in genetic testing should be ensured in different countries by establishing equivalence between jurisdictions in specialists' qualification. On the other hand, mobility of non-MD medical geneticists

from Member States across the EU is essential. Thus, it is evident that an EU system for non-MD medical geneticists' certification (e. g., similar to that applied in the U.S. for laboratory specialties of Clinical Biochemical Genetics, Clinical Cytogenetics and Clinical Molecular Genetics (49) and / or that already in action in the EU for specialists in clinical chemistry and laboratory medicine (50)) is necessary. Such certification would allow entry to an EU specialist register of clinical / laboratory geneticists (more exactly, a special section corresponding to the specialisation). A registered specialist would be able to work in any clinical / medical genetics laboratory across the EU. At the same time, the EU-level certification would be an official document confirming specialist's qualification in his / her native country.

1.2. Lithuania

The terminology used in the sections related to Lithuania referring to the specialists providing genetic services should be defined because of the range of terms used in different countries. Thus, physician (medical doctor, MD) trained in genetics and competent to offer specialised genetic services is referred to as **clinical geneticist**. Laboratory non-MD specialist (with MS degree or higher) trained in human and medical genetics and competent to offer diagnostic genetic testing in a laboratory environment is referred to as **medical geneticist.**

The current public health care system of the Republic of Lithuania is based on compulsory health insurance, which is executed by the State Patient's Fund. Diagnostic testing can be performed only in accredited laboratories according to certified protocols (accreditation of medical laboratories is performed by the State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania (51)). Genetic services are an important, although at present rather limited, part of the Lithuanian health care system. They are available for the population of Lithuania since the establishment of the first Genetic Counselling Office in Vilnius in 1971.

Clinical genetic testing is part of genetic services in Lithuania and is mostly coupled to genetic counselling in state health care institutions. Currently it is largely being provided by the Centre for Medical Genetics of Vilnius University Hospital Santariškių Klinikos, which has accumulated the greatest experience and potential for most complex genetic testing. Some types of genetic testing are also being introduced in other medical centres of Lithuania.

Genetic services at the state health care institutions of Lithuania are being provided by the specialists of two recognised specialities: clinical geneticists (MD) (recognised in 1991 (Act No. 199/1991 of the Ministry of Health)) and medical geneticists (non-MD) (recognised in 1999 (Act No. 61/1999 of the Ministry of Health)).

The system for clinical geneticists' (MD) education and training has been in action in Lithuania since 1992 and consists of three stages: 1) integrated studies in medicine (6 years), 2) internship (1 year), and 3) residency in genetics (4 years). National Standards for Genetic Counselling and Professional Responsibilities of Clinical Geneticists have been adopted in 1997 (Act No. 706/1997 of the Ministry of Health) and updated in 2003 (Act No. V-220/2003 of the Ministry of Health). According to the National Standards, the licence of a clinical geneticist is provided after the specialist's graduating residency and passing exams.

As regards non-MD medical geneticist's education and training, the situation in Lithuania is still problematic. Up to now, there are two stages of the education system to acquire a MS degree level speciality enabling to be engaged in diagnostic genetic laboratories of the Centre for Medical Genetics of Vilnius University Hospital Santariškių Klinikos. The first stage is the First Cycle studies resulting in the Bachelor degree (see Table 1 for a speciality) necessary to comply with admission requirements for the second stage studies in Medical Biology or Genetics (Table 1). As evident from the description of the aims and learning outcomes of both programmes, competencies developed and the professional status of the graduate, none of these two specialities provides competencies adequate for a qualified non-MD medical geneticist: geneticists have no background knowledge in laboratory medicine and are not familiar with specific requirements for diagnostic genetic testing, while medical biologists have inadequate knowledge and skills in human genetics. As a consequence, a number of problems emerge.

1. The system for the accreditation of health services in Lithuania requires the presence of national standards for a

Table 1. **Description of the Master studies programmes in Vilnius University (52) allowing to be engaged in diagnostic genetic laboratories of the Centre for Medical Genetics of Vilnius University Hospital Santariškių Klinikos**

Criterion	Description	
	MS studies programme in Medical Biology	MS studies programme in Genetics
Faculty of Vilnius University	Faculty of Medicine	Faculty of Natural Sciences
Title of the degree programme	Medical Biology	Genetics
National code	62101B106	62101B105
Study area	Biomedical Sciences	Biomedical Sciences
Study field	Biology	Biology
Study level	Second Cycle studies	Second Cycle studies
Level of Qualification	Master studies	Master studies
Official length of programme (years)	2	2
Credits	80 (LT); 120 (ECTS)	80 (LT); 120 (ECTS)
Degree awarded	Master in Biology	Master in Biology

Criterion	Description	
	MS studies programme in Medical Biology	MS studies programme in Genetics
Admission requirements	BS degree in biology, biochemistry, public health or nursing, recognized in the Republic of Lithuania	Bachelor work of biomedical sciences, B – Biochemistry, Genetics, Microbiology, Human and Animal Physiology C – Immunology, Molecular Biology, Gene Engineering
Learning outcomes and aims of the programme	Educating medical biology professionals following the qualification requirements of the EU and WHO. The competence should cover: -background laboratory medicine knowledge -knowledge of causes, development mechanisms and modern research methods of human diseases, factors influencing the laboratory tests and quality assessment principles -knowledge of the laboratory test principles as well as practical skills in laboratory testing and assessment. Medical biology programme is aimed to give a solid theoretical and practical knowledge in laboratory medicine as well as provide analytic research skills	To develop experience of the experimental work in Genetics, which can be realised by original experimental work in various fields of genetics (molecular, plant, human genetics or genetics of microorganisms, gene engineering, cytogenetics, genotoxicology).
Competencies developed	Graduate of Medical Biology programme is able to select, implement and apply analytical methods and equipment, independently interpret test results, control the test applicability and relevancy (including economical reasons), use IT applications and conduct scientific research	A holder of a Master's degree in Genetics has good working knowledge in molecular, human, plant genetics, cytogenetics, genotoxicology, gene informatics and is competent to carry out original investigations in field of theoretical and applied genetics, molecular biology, genotoxicology. He/she also has acquired IT, teamwork, critical and analytical thinking skills, has abilities of extending his knowledge without guidance and is ready to hold personal responsibility for his/her professional development.
Professional status	Graduate of MS in Medical Biology (possessing also relevant laboratory work experience) is qualified to be employed at the governmental and private laboratory facilities of the Laboratories of Health Care Institutions and Research institutes	A graduate is able to work in the field of biotechnological and biomedical industry, at research institutions of biomedical profile as well as at educational institutions.

health service defining professional core competencies and responsibilities of the specialists. Such standards cannot be developed for the speciality "Medical Geneticist" (corresponding to laboratory geneticist or scientist in some other countries) in the absence of the established system for specialists' education and training. As a consequence, a system of medical geneticists' certification in Lithuania is also absent.

2. Graduate non-MD medical geneticists must be further trained at their working place, but there are no system and budget for such training.

3. In the absence of standards for the speciality "Medical Geneticist", an adequate system for certification (analogous to time-limited licensing in the case of clinical geneticists) and continued education has not yet been developed in Lithuania for non-MD medical geneticists.

4. Lithuania is an EU member, but there are persisting problems in specialists' mobility within the EU without a certificate of EU-level qualification in medical genetics. Contrary to the problems Nos. 1 and 2, this problem is not limited to Lithuania but is characteristic of the whole EU.

One more problematic aspect of genetic services in Lithuania is the relatively low number of specialists providing genetic services for the population in comparison to the leading West European countries. The constantly expanding number of clinically applicable diagnostic genetic tests increases the demand for qualified specialists able to perform such tests, interpret and communicate their results.

Thus, there is an urgent need in Lithuania – as well as in other EU countries – to develop an adequate EU-level system for training non-MD specialists in medical genetics. We suggest the outline of such system, prepared on the basis of the analysis of the experience of other countries, discussions and collaboration under the EC FP6 Network of Excellence – the European Network of Excellence aimed at harmonizing genetic testing services (EuroGentest) Unit 6.2 "Professional Perspective" (25–27) as well as Lithuanian experience in medical geneticists' training (since 1991) and providing genetics services for the population of the country (since 1971).

2. The system for education and training of non-MD medical geneticists in Lithuania: a project

The suggested system for the education and training of non-MD medical geneticists in Lithuania is being developed by the specialists of the Department of Human and Medical Genetics

of the Faculty of Medicine of Vilnius University on the basis of the experience acquired during 17 years of education activities at the Faculty of Medicine of Vilnius University and 26 years of providing genetic services for the population of Lithuania alongside and in close collaboration with EU experts from the ESHG Education Committee (53), GenEd Project (54), under the EuroGentest project (24) Unit 6.2, as well as some other national and international institutions. It is based on a three-level (bachelor–master–PhD) university education system which is in action in Lithuania as well as in the majority of the EU countries. As it was agreed under EuroGentest Unit 6.2 that a workable solution would be to describe and agree, by consensus, a set of core competencies that could apply to health professionals in Europe, the development of the above-stated system in Lithuania is also based on core competencies. We propose three subsequent levels of core competencies alongside with the stages of education to acquire them (Fig. 1).

The central stage, and the scope of this paper, is a new Master studies programme in Medical Genetics to be introduced at the Faculty of Medicine of Vilnius University as a subspeciality of the already existing Master studies programme in Medical Biology (namely, "Medical Biology (Medical Genetics)"). Admission requirements for this programme are graduating from an accredited bachelor studies programme of a university with life sciences orientation.

1st stage: Bachelor Studies. Bachelor studies (four years in Lithuania) should result in acquiring knowledge base of fundamental principles and approaches (i. e. basic competencies) to serve as a foundation for the subsequent Master studies programme in Medical Genetics:

- fundamentals of general, inorganic, organic, physical chemistry;
- fundamentals of biochemistry;
- fundamentals of microbiology;
- fundamentals of cytology: morphology and physiology of the cell, organelles and their properties, cell cycle, cell proliferation and its regulation, apoptosis;
- fundamentals of the biologic and molecular basis of inheritance: essentials of general genetics, chromosomal theory of inheritance, essentials of molecular genetics including concepts of gene, genome, transcriptome, proteome, metabolome;
- principles of instrumental and laboratory testing;
- principles of biomedical statistics;
- principles of metrology.

Bachelor examinations essential to enter the Master studies programme should be in genetics, cytology, molecular biology, biochemistry. If one or more relevant courses are not included in the applicant's Bachelor studies curriculum (e. g., after graduating from Bachelor studies programme in chemistry), passing relevant examination(s) after completing (or without) bridge course(s) can compensate the difference.

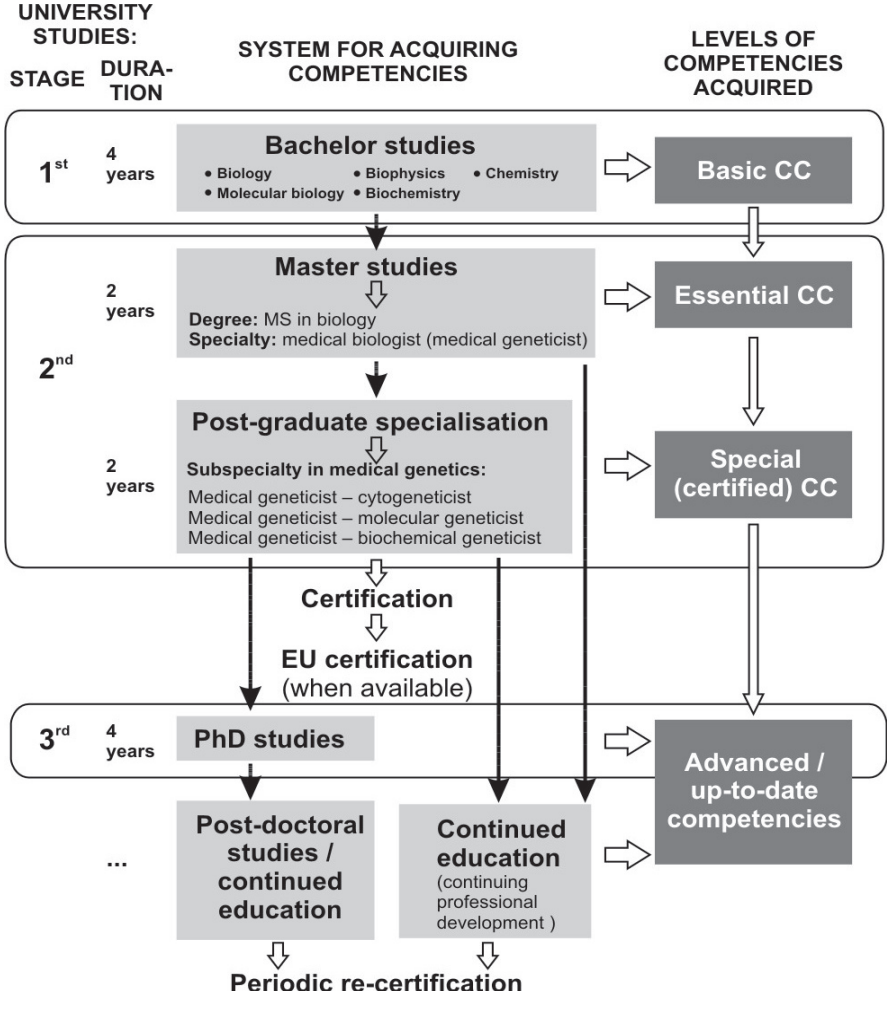

Fig. 1. A scheme of different level core competencies (CC) of non-MD medical geneticists and the system of university-based education to acquire them

The 2nd stage comprises two steps:

Step 1: Master studies programme resulting in the MS degree in biology and acquiring the speciality "Medical Biologist (Medical Geneticist)" which ensures a set of essential core competencies of a medical geneticist.

Step 2: post-graduate specialisation studies programme (comparable to the residency studies programme for clinical specialities) ensuring high-level knowledge and expertise in one of the basic specialisations (subspecialities in medical genetics): molecular genetics, cytogenetics, or biochemical genetics.

Principal courses of master studies should be 1) molecular genetics and DNA diagnostics in medicine, 2) clinical cytogenetics, 3) biochemical genetics, 4) bioinformatics, 5) essentials of genetic counselling. Additional courses should be basic disciplines in laboratory diagnostics. Master studies curriculum in Medical Biology (Medical Genetics) prepared for Vilnius University is shown in Table 2.

Table 2. **Master studies curriculum in Medical Biology (Medical Genetics) prepared for Vilnius University**

Semester	Course	Number of credits	
1st	Clinical biochemistry	4	20 cred.
	Laboratory haematology	4	
	Cytology and urinalysis	4	
	Immunoanalysis, immunohaematology and cancer biology	4	
	Molecular biology, human biology and genetics	3	
	Scientific research	1	
2nd	Biotechnology, human physics and bioinformatics in medicine	4	20 cred.
	Clinical cytogenetics. Laboratory diagnostics of chromosomal disorders	4	
	Genetic counselling and application of bioinformatics in genetic diagnostics	4	
	Clinical genetics, cancer genetics, immunogenetics, pharmacogenetics, genotoxicology	4	
	Scientific research	4	
3rd	Biochemistry of hormones and vitamins. Genetics in endocrinology and reproductive medicine	4	20 cred.
	Molecular medicine. DNA testing based disease diagnostics	4	
	Inherited metabolic disorders, their biochemical and molecular diagnostics	4	
	Physical methods of human genome analysis	4	
	Scientific research	4	
4th	Laboratory investigative practice	4	20 cred.
	Master degree work	16	
	TOTAL	**80**	

Master students' exchange between EU universities (other developed countries may also be involved) should be encouraged, if not being a compulsory part of a master studies programme.

A graduate of the Master studies programme in the speciality of Medical Genetics or Medical Biology (Medical Genetics) will be qualified to be employed at the governmental and private laboratory facilities of health care institutions providing genetic services and biomedical research and educational institutions.

Each medical geneticist, being a specialist who provides a specific set of health care services (namely, genetic testing), at the same time, at a more general level, belongs to the diagnostic laboratory testing system and, ultimately, is a health service professional. Therefore, his / her essential competencies comprising knowledge, skills and attitudes must include both specific and general aspects and can be grouped accordingly to:

1) **basic** competencies **extended** with respect to human biology, human genetics and genomics, human molecular pathology;

2) competencies **specific to clinical genetics**;

3) competencies **specific to diagnostic laboratory testing**;

3) competencies **specific to health service professionals**.

Genetics in general and medical genetics in particular represent both the basic and the clinical science bordering with and / or influenced by other biomedical and physical sciences. Thus, **basic knowledge** acquired in the Bachelor studies programme should be extended with respect to human biology, human genetics and genomics, and human molecular pathology to acquire specialised factual knowledge. As a result, this part of knowledge competencies should comprise the essentials (factual awareness level) of:

- biochemistry with respect to human biochemistry and metabolism;
- molecular pathology;
- microbiology, methods of classification, structure and general properties of pathogens, infectious diseases, epidemiology;
- haematology; stem cell biology;
- human general genetics;
- human molecular genetics and genomics;
- human medical genetics;
- human cytogenetics, molecular cytogenetics;
- human immunogenetics;
- pharmacogenetics and pharmacogenomics, genotoxicology;
- human genome analysis;
- human transcriptome, proteome;
- postgenomic developments;
- cancer biology, cancer genetics, oncocytogenetics;
- cellular and gene therapy.

As regards the second group of core competencies related to **knowledge specific of medical geneticists**, they should include essentials of clinical genetics: monogenic (including inherited metabolic disorders), chromosomal, complex diseases and congenital pathology / conditions, mode of their inheritance;

• genetic counselling: estimation the recurrent risk of genetic / congenital pathology for individuals, families, risk groups;

• prenatal and postnatal genetic diagnostics: principles, indications;

• variety, principles, possibilities, clinical value, validity and limitations of diagnostic, prognostic, selective and investigative genetic laboratory testing: cytogenetic, molecular cytogenetic, molecular genetic, biochemical genetic; modern trends in their development and introduction into clinical practice;

• principles of diagnostic genetic laboratory organisation and management (including quality assurance);

• national and EU / international legislative and bioethical standards in performing diagnostic and non-diagnostic genetic testing, obtaining, storing and using human biobanks and personal genetic information.

The 3rd group or core competencies related to **knowledge specific of diagnostic laboratory services specialists** should include:

• general principles of diagnostic laboratory organisation and management (including safety and quality assurance);

• general, national and institutional requirements for diagnostic testing, recording and reporting, storing biomaterials and testing results;

• national and EU / international legislative and bioethical standards in performing diagnostic testing, obtaining, storing and using personal health information.

Finally, core competencies related to **knowledge and skills necessary for all health services professionals** should include:

• essentials of national and EU / international public health care and medical legislation, social and health insurance;

• knowledge and skills in urgent first aid;

• requirements for managing relevant medical and office documentation;

• knowledge of and complying with the requirements of bioethics, medical ethics and deontology.

After graduating the 1st step of the 2nd stage of training (Master studies) non-MD medical geneticist should have **skills** enabling him / her to:

• manage workload effectively;

• appropriately prioritise ordered tests;

• independently perform routine testing in diagnostic cytogenetics, molecular genetics and biochemical genetics laboratories (Table 3) as well as research laboratories;

• record testing results, interpret and report testing results under the supervision of a certified medical geneticist / senior specialist (laboratory supervisor);

• derive a clinically useful opinion from raw data of genetic tests;

• perform complex genetic tests under the supervision of a certified medical geneticist in diagnostic cytogenetics, molecular genetics and biochemical genetics laboratories or senior specialists in research laboratories;

• execute measures for internal quality assurance of genetic testing in a diagnostic or research laboratory; participate in EQA schemes for routine diagnostic genetic tests;

• effectively use information technologies (particularly specialised genetics services) to obtain current information about scientific and clinical applications of genetics and genomics; critically assess appropriate literature and other genetic information resources;

• participate in professional and public education programs about genetics to maintain currency of his / her knowledge and to transmit information to others (colleagues, students, society);

• safeguard privacy and confidentiality of client's genetic, health and other personal information to the greatest extent possible.

As regards **attitudes** as part of essential core competencies to be obtained in the course of Master studies programme in Medical Genetics, they have much in common with those specified for all health professionals with respect to the role, applications and bioethical background of genetics in health care and are general for all subsequent stages in post-graduate training in the field. Non-MD medical geneticists of all professional levels ought to:

• be prepared to recognise and address the complex personal, cultural, theological, ethical, legal, and social issues associated with genetic testing and the use of genetic information and other genetic issues commonly encountered in clinical practice;

• appreciate the sensitivity of genetic information and the need for privacy and confidentiality;

• recognise the importance of performing genetic testing and delivering its results fairly, accurately, and without coercion or personal bias;

• seek coordination and collaboration with interdisciplinary team of medical geneticists, clinical geneticists and other health professionals;

• recognise the limitations of the current state of knowledge in the field of human and medical genetics and the possibilities of its application in clinical practice;

• recognise the limitations of performance and clinical value of investigative and diagnostic genetic tests;

• recognise the limitations of his / her personal knowledge and genetics expertise and act within these limits;

• expect changes and advances to occur in the course of his / her professional career and demonstrate willingness to update his / her genetic knowledge and laboratory skills as well as knowledge in the related fields.

The 2nd step of the 2nd stage studies, namely **post-graduate specialisation** comparable to a residency studies programme for medical specialities, is aimed to ensure a high-level knowledge and expertise on the basic specialisations (molecular genetics, cytogenetics, or biochemical genetics) by extending core competencies to a special level, which enables **certification**. Thus extended core competences in specific fields of medical genetics should enable the specialist:

• to acquire knowledge and skills in the latest developments in diagnostic and investigative genetic testing;

• to select independently an optimal testing method;

• to perform, interpret and report independently complex diagnostic tests in the field of specialisation and keep records of performed analyses (special skills are summarised in Table 3);

• to participate, together with the clinical geneticist, in clinical evaluation of genetic test results;

• to select and introduce new diagnostic genetic testing methods (in the field of specialisation) into clinical practice of a diagnostic genetic laboratory;

- to supervise and train laboratory technicians and not yet certified non-MD medical geneticists;
- to direct diagnostic laboratories performing routine genetic testing or diagnostic laboratories performing complex genetic testing in the specific field;
- to organise internal quality assurance and quality control in the diagnostic genetic laboratory performing routine genetic testing or diagnostic laboratories performing complex genetic testing in a specific field;
- to participate in available external quality assurance schemes for diagnostic genetic testing.

Specialists graduating from the 2nd step of the 2nd stage University studies programme and passing qualification examination will be able to apply for certification by a recognised national certification body or national testing agency. Current certification (possibly time-limited certification) should be maintained on regular intervals (five years) by continuing education units.

On the other hand, a system for non-MD medical geneticists' certification on the basis of a EU-level examination (still to be developed) would enable unrestricted mobility of non-MD medical geneticists from Lithuania or other countries and at the same time would ensure the EU-level genetic testing services in Lithuania.

Table 3. **Essential core competencies (skills) of non-MD medical geneticist in Lithuania (to be introduced)**

Depth criteria:		Specialisation in medical genetics:	
	Knowledgeable (performance under supervision of a medical geneticist certified in the specific field)	**CG,**	medical geneticist – cytogeneticist
		MG,	medical geneticist – molecular geneticist
	Proficient (independent performance)	**BG,**	medical geneticist – biochemical geneticist

Core competencies: skills	**Front line staff (MS)**	**Certified* senior level staff (MS + 2 years specialisation course and passing exam)**		
		CG	**MG**	**BG**
Molecular genetic testing				
Isolation of nucleic acids from human tissues				
Standard PCR amplification of DNA fragments				
Special PCR: QT-PCR, RT- PCR				
Restriction enzymes digestion analysis				
Nucleic acids electrophoresis on agarose and polyacrylamide gels				
Testing for known mutations using commercial kits / standard PCR-based protocols				
Testing for any nucleotide sequence change (mutation)				
Alien genome detection				
Capillary DNA electrophoresis				
DNA hybridisation				
Microarray based genotyping				
Microarray based expression analysis				
Cytogenetic testing				
Differential banding of metaphase chromosomes preparations				
Differential banding-based karyotyping: chromosome number analysis				
Differential banding-based karyotyping: chromosome structure analysis				
Molecular cytogenetic testing: FISH, chromosome painting, SKY,				
CGH, array-CGH				
Biochemical genetic testing (testing biochemical phenotype for inherited metabolic disorders				
Simple urine tests				
Thin layer chromatography (urine amino acids & carbohydrates)				
Urine glycosaminoglycans estimation: spectrophotometry, isolation and electrophoresis				
Isoelectrofocussing (IEF)				
High performance liquid chromatography (HPLC): quantitative estimation of aminoacids, purines, pyrimidines, phenolic compounds, etc.				
Gas chromatography coupled to mass spectrometry (GC/MS): quantitative estimation of organic acids, very long chain fatty acids, monosaccharides and sugar alcohols, sterols				
Tandem mass spectrometry (MS/MS):				
Enzyme activity estimation				

* Certified by a recognised national certification body or national testing agency.

The proposed system for non-MD medical geneticists' education and training is expected to be implemented at Vilnius University in 2008.

CONCLUDING REMARKS

Analysis of the current situation in the EU, other countries and Lithuania has revealed the necessity to recognise medical genetics both as a clinical and a laboratory speciality on both the national and the EU levels and to co-ordinate activities in the development of a core-competencies-based system of the training, education and certification of non-MD medical geneticists. While EuroGentest and ESHG experts are evaluating the situation in the EU and over the world and developing the framework of core competencies in genetics for the EU, experts in Member States (particularly those participating in the activities of the EuroGentest Unit 6.2) consider the development of national systems of the education and training of undergraduate and graduate health care system specialists. Lithuania is an example of a country ready to introduce (at the Faculty of Medicine of Vilnius University) a contemporary education and training system for non-MD medical geneticists based on the Master studies programme in Medical Genetics as a subspeciality of the Medical Biology Master studies programme followed by post-graduate specialisation in one of the major laboratory genetic testing areas. The proposed system is an example of a balance achieved between the EU level regulatory framework and guidelines under development by the EuroGentest project Unit 6.2 and the national background, demands and possibilities. Such system is expected to be flexible enough to be revised and modified in the light of the developments of the ESHG and EuroGentest project, changes related to new achievements in human genetics and genomics and related fields, changes in the national and EU policy and legislation related to health care and education.

Lithuanian specialists share the view that genetic testing represents progress in health care and an opportunity with the potential to lead to developments in preventive medicine. It should also be recognised that progress in the field is impossible without cost and investment, in the first place in the infrastructure and personnel – both on the level of specialists' education and training, and clinical practice in the national health care system.

Lithuanian experience supports the notion that genetic and genomic education (and efforts to increase its quality) is necessary at all levels including health professionals, policy makers, opinion leaders, the media and the general public. Education of the public and the mass media is the most important factor if progress is to be made in the clinical application of human genome research and to avoid "genohype".

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SISTEMOS, RENGIANČIOS MEDICINOS GENETIKUS, KŪRIMAS LIETUVOJE

S a n t r a u k a

Sparčiai plėtojantis medicinos genetikos mokslui nuolat didėja labai kvalifikuotų specialistų, atliekančių genetinius tyrimus, poreikis. Šio straipsnio **tikslas** yra pristatyti Lietuvos patirtį kuriant nacionalinę medicinos genetikų rengimo sistemą dabartinės būklės Europoje ir kitose šalyse, kylančių problemų ir ES ekspertų veiklos šioje srityje kontekste. **Uždaviniai:** 1. Atlikti šios srities būklės Lietuvoje ir kitose šalyse analizę apžvelgiant Lietuvos ir kitų šalių dokumentus bei naujausias publikacijas, Europos žmogaus genetikos draugijos, EuroGentest ir kitų projektų bei institucijų ekspertų teikiamus šios srities būklės vertinimus ir siūlomus problemų sprendimus, taip pat įvertinant Vilniaus universiteto Medicinos fakulteto Žmogaus ir medicininės genetikos katedros bei Vilniaus universiteto ligoninės Santariškių klinikų Medicininės genetikos centro patirtį. 2. Pagrindinių kompetencijų pagrindu pasiūlyti nacionalinę medicininės genetikos specialistų rengimo Lietuvoje sistemą, derančią prie Europos Sąjungos sistemos. **Išvados**. Dabartinės būklės Europoje, kitose šalyse ir Lietuvoje analizė rodo, kad medicininę genetiką būtina pripažinti klinikine ir laboratorijos specialybe tiek nacionaliniu, tiek ir ES lygmeniu ir kad, kuriant medicinos genetikų rengimo ir sertifikavimo sistemą, būtina koordinuoti veiklą pagrindinių kompetencijų pagrindu. Lietuvoje pagrindinių kompetencijų pagrindu parengta medicinos genetikų rengimo sistema gali būti teikiama kaip nacionalinės sistemos modelis kuriamos Europos Sąjungos sistemos kontekste.

Raktažodžiai: studijose įgyjamos kvalifikacinės kompetencijos, genetinės paslaugos, genetiniai tyrimai, medicinos genetikas, klinikinis genetikas