S5.1

DIDACTIC/PROFESSIONAL ROUTES IN THE POST-GRADUATE SCHOOL IN "CLINICAL BIOCHEMISTRY"

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As recommended by the European Union (EU), the aim of specialist training in Clinical Biochemistry and Clinical Molecular Biology is to provide post-graduate medical and biological students with professional abilities in Laboratory Medicine. During the five years of specialization, students, by participating in didactic and healthcare activities, acquire the knowledge necessary to allow them to evaluate biological parameters related to: physiopathological conditions, hereditary and acquired genetic diseases, disease-predisposing factors, nutrition and motorial activity. Here we describe the didactic model adopted in the Clinical Biochemistry Specialization School of the University of Naples Federico II (Italy), and propose several innovative teaching approaches.

General activities:

Basic and highly automated analytic instrumentations: theory and practice

Advanced technology (HPLC, gas-mass-spectrometry, DNA recombinant methodology, cytofluorimetry, etc.)

Separative clinical biochemistry

Good laboratory practice and safety rules, including quality control procedures

Computer familiarization through practical problem-solving (i.e. reference value calculations; statistical approach to calculate the diagnostic characteristics of laboratory tests; regression curves, comparison tests and multivariate analyses, etc.)

Sample criopreservation procedures (sera, cells, nucleic acid)

Ethical and legal aspects of Laboratory Medicine

Professional training in the following laboratory areas:

Basic Clinical Biochemistry

Clinical Proteinology

Basic and advanced hematology, hemostatis, immunotransfusion

Tumor markers and clinical hormonology

Virology and microbiology

Pharmacology and toxicology

Cellular cultures, cytology and microscopy

Clinical molecular biology (including prenatal genetic diagnosis)

This professional training in diverse laboratory areas involves (according to EU rules) daily full-time participation in laboratory activities under the guidance of university and extra-university tutors (training network). The professional training encourages also interaction between the students and patients; students will attend the Laboratory Medicine Outpatients Clinic and will take part in pre- and post-natal genetic counselling related to genetic diagnoses. Students will also be involved in clinical biochemistry experiments, i.e. methods and instruments comparison, and data analysis and their statistical elaboration.

In addition to traditional frontal lessons, training involves a multidisciplinary approach to specific diagnostic problems. After the topics have been selected (diagnostic approach to: anemias; leukemias; diabetes; dyslipidemias; genito-urinary diseases; genetic acquired and hereditary diseases; gastro-enteric diseases; cardio-circulatory diseases; locomotor apparatus functions, etc), specialists (radiologist, patologist, internist, laboratorist) will spend one-half day dealing with the various aspects of the selected argument. Each meeting is followed by discussions in which the topic is treated in greater detail.

The didactic resources of the school include a weekly Journal Club and clinical case discussions. In a thirty-minute session, the students focus on major current issues of Laboratory Medicine and discuss clinical cases selected by the teachers of the School. Subsequently, the issues raised are discussed by the students, the teacher who selected the case and other teachers of the School. This tool helps students to gain speaking ability and experience in integrated diagnosis arising from a multiple set of laboratory data.

Lastly, the School invites major experts in Laboratory Medicine to seminars entitled "New frontiers in Laboratory Medicine", which are concerned with the most innovative tools and advances in Clinical Biochemistry, thereby ensuring continuous updating in this field.

The formative iter described above exposes post-graduate students to all the main areas of Laboratory Medicine from both a practical and a theoretical viewpoint; it teaches them to contribute to medical diagnosis, also together with specialists in different areas of medicine, and finally, it ensures they are knowledgeable about recent events and advances in the field of Clinical Biochemistry.

References:

Modificazioni all'ordinamento didattico universitario relativamente alle Scuole di Specializzazione del settore medico. D.M. 11/5/95 (GU. n. 167-19/7/95).

Attuazione della direttiva 93/16 CEE in materia di libera circolazione dei medici e di reciproco riconoscimento dei loro diplomi, certificati ed altri titoli. D.L. 17/8/99 n. 368 (GU. n. 250-23/10/99 Suppl.)

S5.2

CLINICAL BIOCHEMISTRY TEACHING IN THE POST-GRADUATE SCHOOL IN "HYGIENE AND PREVENTIVE MEDICINE"°

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One goal in the post-graduate teaching of Clinical Biochemistry, for different specializations in medicine, is to target specific professional requirements. Post-graduate students specialising in Hygiene and Preventive Medicine must learn how to evaluate a work process, the cost/benefit of an activity, and the efficacy of a laboratory service. Therefore, we usually start teaching Clinical Biochemistry by addressing practical problems of specific interest for the specialization. One of the most recent and relevant topics is the identification of "indicators" to evaluate the efficacy of laboratory activities also with a view to their improvement. The project was carried out in four steps: 1) in-depth study of "indicators"; 2) selection of the laboratory areas to investigate and their assignment to different work-groups of post-graduate students; 3) proposals of "indicators" from the work-groups, and examination, and eventual acceptance, of the proposals by all participants in the study; 4) use of the "indicators", data collection and statistical elaboration. Here we present an example of the "indicators" as one of the results of the project and we would suggest this methodology as an adjunctive didactic tool in Clinical Biochemistry teaching in the postgraduate school.

° Study performed in collaboration with: Bucci R., Cerasuolo M.R., Guerrera A., Parascandolo C., Scherillo I., Schiavone D., Schettino A.M., Sibilio F. (Postgraduate students in "Hygiene and Preventive Medicine")

Reference:
Fabio Focarile. "Indicatori di Qualità nell'Assistenza Sanitaria". Centro Scientifico Ed., Torino, Italy, 1998.

S5.3

MOBILE MEDICAL LABORATORY: A NEW PROPOSAL OF "POST LAUREAM" TRAINING

Bamonti F.°, Morace G.*, Rosina M.°, Novembrino C°., Mattina R.*, Ippolito S.°, Lonati S.°, Neri A.M.*

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A caravan motorhome, adequately equipped could prove to be a very useful, efficient and organized instrument for teaching in specialized medical fields, carrying out both routine and research analyses. A mobile unit can, in fact, be fully equipped to perform, in a chosen area, studies involving laboratory research aimed at the prevention of diseases and at preserving people's health. Some epidemiological studies and/or screenings can require immediate treatment and measuring of the samples drawn. This proposal aims at setting up a mobile biomedical laboratory for advanced research on the prevention and diagnosis of nutritional, metabolic, socio-environmental diseases and/or diseases caused by ecological disasters or bioterrorism. Such a service centre can:

1. organize the training "post lauream" of the staff (specialist, technical) which should acquire interests, culture and a practical preparation suitable for experimental scientific research
2. perform diagnostic non invasive qualitative, semi-quantitative and quantitative tests of different levels
3. carry out thorough new screening investigations
4. diagnose nutritional diseases evaluating "in loco" possible aetiological factors and cofactors (dietary, environmental, social, psychological etc) in anyone that may need to be diagnosed "in loco"
5. provide first laboratory aid in areas exposed to ecological disasters, industrial risk, bioterrorist attacks and in areas without adequate diagnostic service and in urgency and emergency conditions: airports, ports, ships, immigration and emigration centres, refugee camps , isolated tourist centres
6. establish links and collaborate with: surgeries (ASL) and health centres; district hospitals; universities and research centres, both public and private, and also extraeuropean; charitable organizations and welfare centres; factories, industries, companies; public institutions
7. perform experimental protocol which can require very strict standards in treating biological samples (sampling, preservation and transport) or in measuring fresh samples as quickly as possible.

Carrying out this project can help to promote research work and experimental clinical-diagnostic studies aimed at resolving socio- medical problems.
Moreover, the University can offer an original, efficient and innovative possibility of "post lauream" teaching and training in laboratory medicine

M Roe et al.J Clin Microbiol, 33 (6): 1551-1553, 1995

S5.4

MASTER IN BIOTECHNOLOGY DISCIPLINES FOR POST-GRADUATE EDUCATION

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Facoltà di Scienze Biotecnologiche, Università degli Studi di Napoli "Federico II", Via Mezzocannone n.16 - 80134 Napoli

University of Naples "Federico II" is proposing for the year 2003-2004 a MASTER program in Combined Genomics and Proteomics addressed to post-graduate students with degrees in different biological areas (Medicine, Biology, Biotechnology, Chemistry and Chemistry and Pharmaceutical Technology). The MASTER program is divided in 60 credits that are further subdivided into two parts, an introductory part (12 credits) a bioinformatic part (6 credits) and a laboratory training part (42 credits). The introductory part is aimed at deepening the knowledge of the students in the basics of advanced Genomics and Proteomics. The students will also improve their knowledge regarding the application of integrated bioinformatic instruments to these disciplines. The students will be tested and evaluated after each part of the MASTER program.
After the introductory part the students will choose either a Genomics or a Proteomics curriculum to further focus the practical application of the aquired basic knowledge and receive extremely specialized laboratory training. This part is definitively less theoretical and it is aimed to involve the students in a research project in the chosen area. As final test, the student will have to defend a thesis focused on methodological aspects of the chosen area.
The aims of the MASTER program are therefore to: a) give to the students knowledge of the basic instruments available in the fields of genomics and proteomics for the solution of biological problems, b) bioinformatic tools applied to these disciplines and c) specific knowledge in several techniques of the area chosen for the laboratory training part. We expect that the MASTER program will contribute to the aquisition by the student of specific knowledge in the field of Genomics and Proteomics providing integrated instruments that will be beneficial for professional figures both in the academic aea and in the biotechnology industry field.

MEDLAB 15
AVANZAMENTI DELLE CONOSCENZE NEL DIABETE MELLITO
Sala C
Venerdì 20 settembre, ore 10.00-12.00

S6.1

GENETICS OF TYPE 2 DIABETES MELLITUS

Ferrari M.

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Type 2 diabetes mellitus is a heterogeneous disorder that develops in response to both genetic and environmental factors. It is a complex group of disorders characterized by two apparently distinct pathophysiologic defects: insulin resistance and a failure of the pancreatic β-cells to compensate for this resistance by appropriately increasing insulin secretion. There is strong evidence for an important role of genetics in both of these components.
Attempts to identify the type 2 diabetes genes responsible for the most common forms, that probably will disaggregate into a large number of disorders, none of which will constitute more than a small percentage of the total disease burden, have depended on genome-wide linkage studies or studies of candidate genes. The results of the first generation of the genome scan studies caused concern because of a perceived lack of reproducibility. More recently, however, a number of replications have emerged, specifically on chromosomes 1q, 2q, 3q, 9p, 10q, 11q, 12q and 20q. Moreover more than 60 potential candidate genes involved in insulin action, insulin secretion and adipose metabolism have also been examined. Although variants have been identified in many of these, only a few have been shown to associate with diabetes.
At present, most of the success in defining type 2 diabetes genes has been achieved by studying relatively rare forms of the disease.
Maturity-onset diabetes of the young (MODY) is an autosomal dominant disease that only accounts for about 2% of all diabetic patients. Up to now six forms of MODY have been defined, each involving a gene important for the β-cell function.
Although insulin resistance seems to be the earliest defect in most patients, insulin receptor mutations are very rare. Moreover 0.1-1% mutations are maternally inherited and caused by defects in the mitochondrial genome.
In conclusion this is exciting time in the field of genetics but much needs to be done if we wish to find the major type II diabetes genes.

Reference: Permutt M.A., Hattersley A.T. Searching for type II diabetes genes in the post-genome era. Trends Endocrinol. Metab. 2000; 11:383-393.

S6.2

DIABETES AND AUTOIMMUNE DISEASES

Songini M

Diabetes Unit - Dept. of Internal Medicine – Azienda Ospedaliera Brotzu – Cagliari

Type 1 diabetes (T1D) is the result of autoimmune destruction of the pancreatic beta-cells. The development of T1D requires a genetic predisposition to the disease and enviromental triggers. Several genes provide the genetic susceptibility to T1D even if the genes located in the HLA region are the most important. The influence of enviromental on the etiopathogenesis of T1D is also evident. Epidemiological research identified a number of putative etiological factors, none of which resulted crucial in the disease development. T1D has a long pre-clinical stage characterised by presence of autoantibodies against beta-cells: ICA, GADA, IA-2, IAA.
Genetic and enviromental factors are also involved in causing a variety of autoimmune disorders such as autoimmune thyroid disease, Addison's disease, coeliac disease and putative autoimmune disorders as multiple sclerosis and many others. It is also well established that autoimmune diseases occur together more frequently than expected by chance. This association is particularly well established in the Poliglandular autoimmune syndrome 1 (PGA-1) characterised by a recessive autosomal inheritance and by the association of candidiasis with a variety of autoimmune disorders. No clear inheritance pattern has been identified for the PGA-2 characterised by a various association of autoimmune disorders.

S6.3

GESTATIONAL DIABETES MELLITUS

Lapolla A., Dalfrà M.G., Masin M., Fedele D.

Dipartimento di Scienze Mediche e Chirurgiche, Università di Padova

Background: Gestational Diabetes Mellitus (GDM) is a carbohydrate intolerance of variable severity with onset or first recognition during pregnancy. As this condition is characterised by high maternal and fetal morbidity, screening and diagnostic procedures must be utilised to achieve early identification of this disease. In the past years there has been a lot of controversies regarding the risk to pregnancy outcome associated with GDM because of a lack of uniformity in diagnostic procedures utilised.
Approach: The recommendations of the Fourth International Workshop Conference on GDM, held in Chicago in 1997, and the recommendations of the Study Groups on Pregnancy of SID (Italian Society of Diabetology) and SIGO (Italian Society of Gynaecology), regarding screening, diagnostic procedures and management of GDM will be discussed. These recommendations serve as temporary guidelines, until finding of the international Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study will be available. HAPO study is being conducted under the aegis of the National Institute of Health in order to define uniform international criteria for diagnosis of GDM.
Summary: This presentation, together with those of the same session will be elaborated into a unique document to be developed as an approved Italian guideline with specific recommendation for the laboratorists, within the continuous educational program promoted by the Italian Society of Clinical Biochemistry and of Clinical Molecular Biology(S.I.Bio.C)

Reference: Metger BE, Coustan DR Summary and Recommendations of the Fourth International Conference on Gestational Diabetes Mellitus. Diabetes Care 1998,21:161-167.

S6.4

RECCOMENDATIONS FOR LABORATORY ANALYIS IN THE DIAGNOSIS AND MONITORING OF DIABETIC PATIENTS

Mosca A., for the SIBioC Working Group "Diabetes Mellitus"

Dipartimento di Scienze e Tecnologie Biomediche, Università degli Studi di Milano

Background: Multiple tests are available for the diagnosis and management of patients with diabetes mellitus. At present, there are no Italian official guidelines concerning this aspect, although some documents elaborated by experts or working groups of Laboratory Societies have been elaborated in the past. An approved guideline has been recently developed by the US National Academy of Clinical Biochemistry.
Approach: The topic of the laboratory tasks in the diagnosis and management of diabetic patients will be dealt with on the basis of the following criteria: a) clinical needs and evidence based medicine; b) biological variation; c) present analytical quality. The presentation will deal with tests for blood glucose (fasting and OGTT), ketone bodies, microalbumin, glycated hemoglobin and serum insulin. Particular emphasis will be given to the themes of the harmonization of glycohemoglobin measurements, POCT devices for glucose, and to the International Federation of Clinical Chemistry (IFCC) global campaign effort for improving the diagnosis and management of diabetes.
Summary: This presentation, together with those of the same session, will be elaborated into a unique document to be developed as an approved Italian guideline with specific recommendations for the laboratorists, within the continuous educational program promoted by the Italian Society of Clinical Biochemistry and of Clinical Molecular Biology (S.I.Bio.C.).

Reference: Sacks D.B., Bruns D.B., Goldstein D.E., Maclaren N.K., McDonald J.M., Parrott M. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin. Chem. 2002;48:436-72.

MEDLAB 13

TECNOLOGIE DELL'INFORMAZIONE: FIRMA DIGITALE E PRIVACY

Sala A

Venerdì 20 settembre, ore 11.30-13.00

S7.1

LA FIRMA DIGITALE: NUOVA NORMATIVA E PIANI DI E-GOVERNMENT

Benzi R.

In questo intervento verranno brevemente discusse le caratteristiche della nuova normativa sulla firma digitale e del recepimento della direttiva europea. La nuova normativa cerca di semplificare alcune delle procedure per la firma digitale introducendo nel contempo una nuova disciplina per quanto concerne i certificatori. Per quanto riguarda la pubblica amministrazioni sono confermate le regole di interoperabilità e le caratteristiche del formato di firma. I piani di e-government ampliano la possibilità di utilizzare la firma digitale in quanto sia la carta di identità elettronica, sia la carta nazionale dei servizi possono essere utilizzate come strumenti di firma sicuri. Questa innovazione consente di estendere progetti attualmente in corso dotando cittadini e impiegati delle pubbliche amministrazioni di un unico strumento che consente l'accesso ai servizi in rete e la possibilità di sottoscrivere, con pieno valore legale, documenti elettronici.

S7.2

GESTIONE DEL REFERTO DIGITALE: ASPETTI TECNICI

Bettiol G., *coordinatore del progetto ESCAPE*

Il progetto ESCAPE prevede la gestione interamente digitale dei referti: dalla produzione-firma-trasmissione-memorizzazione, alla estrazione-integrazione. Il sistema è uno standard aziendale, riguarda tutti i referti prodotti dai vari sistemi dipartimentali, radiologie, laboratori (Chimica Clinica, Microbiologia, Anatomia Patologica, etc.), trasmessi sia ai vari reparti interni ospedalieri, sia all'esterno sul territorio, ai distretti, medici di medicina generale e cittadini stessi; applica la firma digitale "forte", con riferimento quindi ad una certificazione qualificata: garanzie di identificazione ed autenticazione del sottoscrittore; sono applicate le regole tecniche di cui alle più recenti leggi e normative nazionali ed europee. Il progetto è in fase di avanzata applicazione nella Azienda ULSS N.9 di Treviso, riguarda un volume di circa 5000 referti giornalieri, è in fase di diffusione nelle aziende sanitarie di Venezia, Belluno e Città di Castello. Nel seguito sono descritti i vari moduli funzionali.

certificazione

il sottoscrittore è dotato di smart card personale: tipo RSA, autogenerante le chiavi di sottoscrizione, con capacità di firma all'interno dello stesso dispositivo; il sistema di certificazione inserisce nella smart card la coppia di chiavi di sottoscrizione, gestisce il certificato standard di sottoscrizione e le relative liste di revoca o sospensione dello stesso (accesso LDAP);

firma

il referto prodotto dal sistema dipartimentale viene validato e presentato a video al sottosrittore per la firma; il modulo ESCAPE: verifica la presenza di smart card e di validità del certificato di sottoscrizione, genera, tramite funzione di hash, l'impronta del documento, la invia alla smart card, che cifra l'impronta con la chiave privata del sottoscrittore; la smart card restituisce l'impronta cifrata (firma digitale del referto) ed il certificato del sottoscrittore;

trasmissione

il modulo ESCAPE cifra il referto con una chiave che fa riferimento al destinatario, es. reparto interno, medico o cittadino esterno; viene "imbustato" con modalità standard ed inviato al data base di memorizzazione dei referti firmati;

memorizzazione

il modulo ESCAPE provvede alla memorizzazione dei referti firmati digitalmente in un data base (oracle) di transito; da questo sono prelevati per la distribuzione sia interna che esterna;

estrazione

il modulo ESCAPE provvede, attraverso un sistema di "servizi web", all'estrazione dei referti firmati dal data base di transito ed alla loro distribuzione, per gli interni attraverso la rete intranet aziendale, per gli esterni attraverso la rete standard internet; il sistema di estrazione decifra il referto,

effettua i controlli di validità del certificato, tramite accesso alle liste crl/csl del sistema di certificazione, quindi di autenticità della firma; visualizza, eventualmente stampa, copia del referto;

integrazione

il modulo ESCAPE, attualmente in fase di sviluppo e test applicativo, prevede la strutturazione del referto in formato standard XML, accompagnato da "foglio di stile" contenente le indicazione per la restituzione in visualizzazione (e stampa) attraverso comuni strumenti (browser) in collegamenti internet; la strutturazione XML rende individuabili i singoli componenti del referto, es. risultati di esami, quindi consente l'inserimento automatico degli stessi in un data base base, es. cartella clinica;

archiviazione

il modulo ESCAPE provvede alla conservazione (archivio legale) dei referti firmati digitalmete, tramite il riversamento periodico degli stessi in un sistema a dischi ottici non riscrivibili, prelevandoli dal data base di transito; effettua le operazioni di controllo di autenticità, elabora e firma il registro di controllo, mette a disposizioni gli strumenti informatici per la ricerca dei referti archiviati, la visualizzazione e la stampa.