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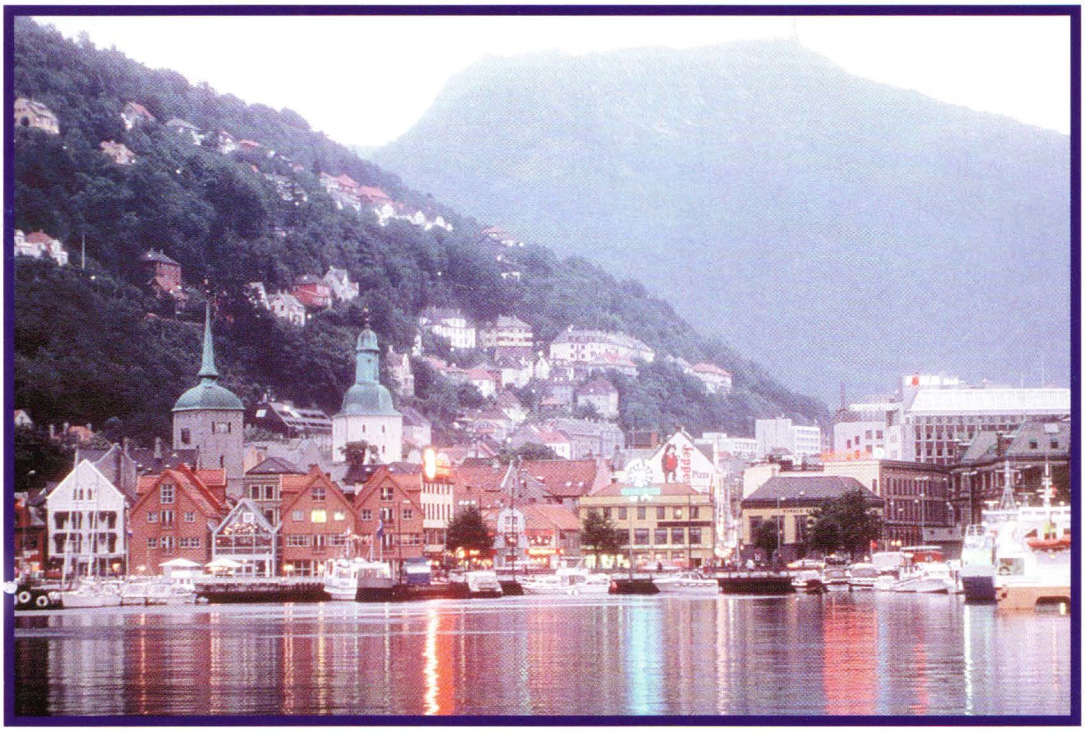
Klinisk Kemi i Norden

Tidskrift för Nordisk Förening för Klinisk Kemi



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INNEHÅLL

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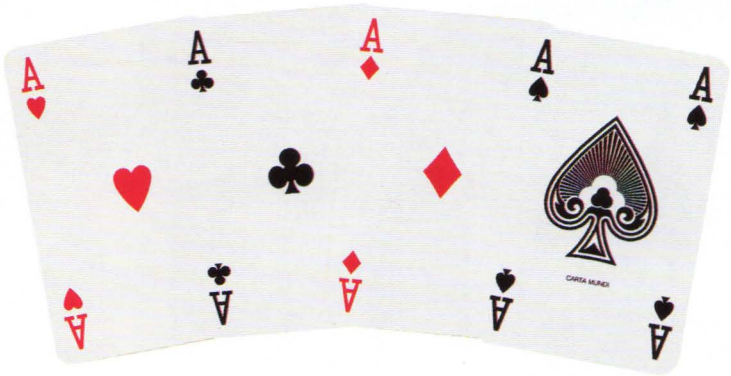

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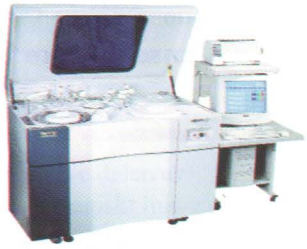

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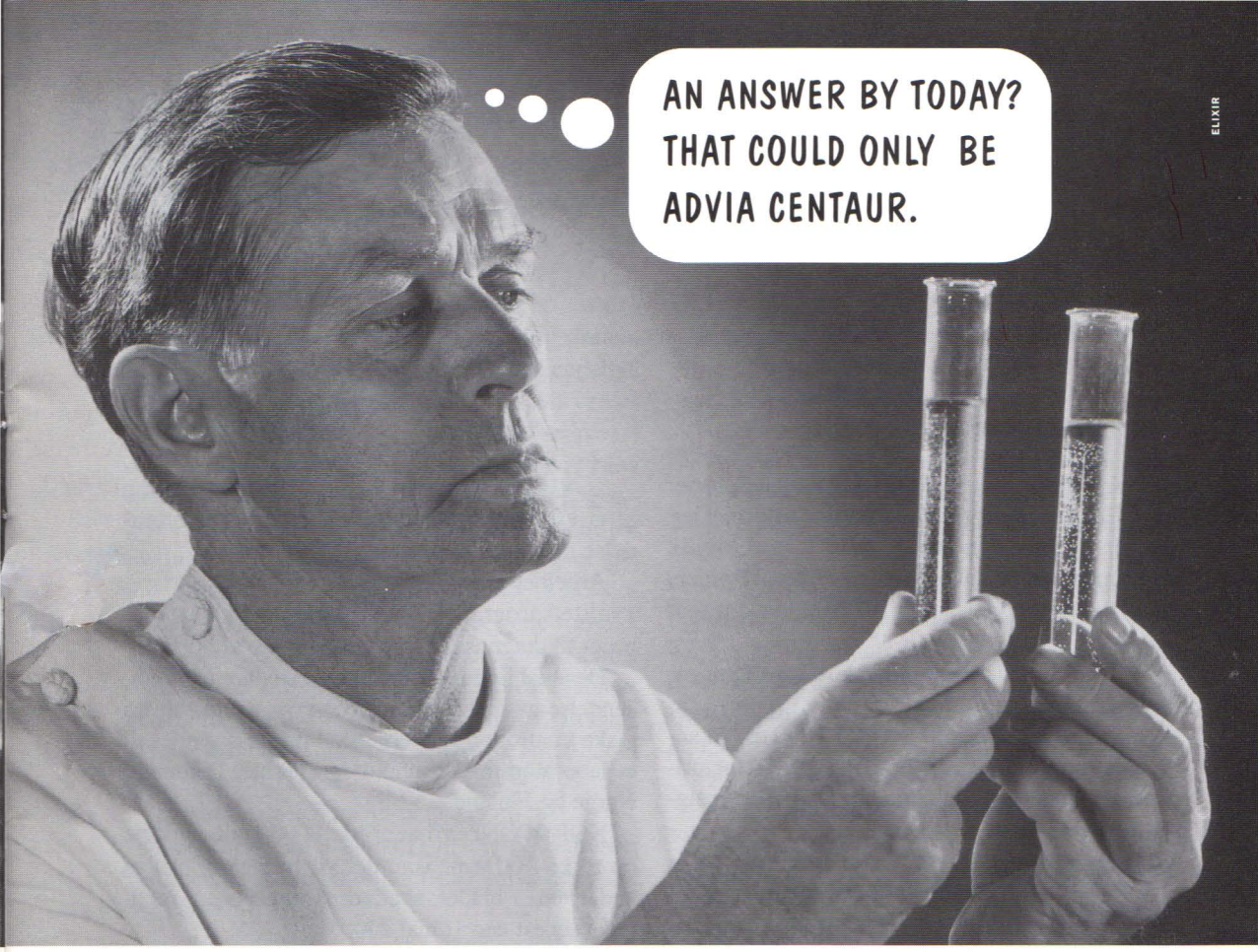

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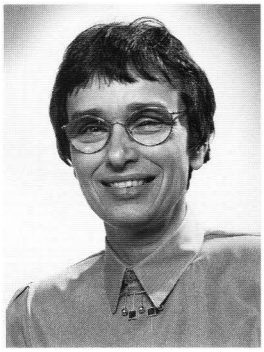
Nyt fra NFKK

EBBA NEXØ



NFKK har takket være NORDFOND muligheder for en gang årligt at uddele midler til projekter, der kan fremme den faglige udvikling af klinisk biokemi og andre laboratoriespecialer i Norden. Der kan årligt uddeles op til 100.000 kr. fra fonden.

Ved sidste uddelingsrunde blev 2 ansøgninger imodekommet:

1. Sverre Sandberg fik NOK 12.000 til "Skandinavisk utprøving av laboratorieutstyr for primærhelsetjenesten. Etablering av SKUP og igangsetting av de forste utprøvingene".

Projektet har tidligere været beskrevet i Klinisk Kemi i Norden (nr. 2/1997). Med den aktuelle ansøgning søges om delvis dækning af udgifter i forbindelse med afholdelse af mode i koordinationsgruppen for SKUP.

2. Ylva Floderus fik SEK 37.700 til etablering af et eksternt kvalitetssikringsprogram i forbindelse med udredning af porhyria.

Arbejdet har til formål at etablere et eksternt kvalitetsprogramskema for erytrocyt enzymer brugt til diagnose af forskellige typer af porfyri.

Der skal findes en standardprocedure for fremsendelse af frisk blod fra porfyripatienter og fra raske kontroller. Prøverne skal primært sendes til et laboratorium i henholdvis Sverige, Danmark, Norge og Finland.

NORDFOND vil atter i år 2000 kunne uddele op til kr. 100.000. Som det vil fremgå af opslag andetsteds i bladet, skal ansøgninger være modtaget senest den 1. maj 2000.

NORDFOND

Ansøgningsfrist 1. maj 2000

Hvad er fondens formål

Fondens formål er at fremme faglig udvikling af klinisk biokemi og andre laboratoriespecialer i Norden.

Resultater opnået via projekter støttet af fonden skal udbredes til laboratorier i Norden gerne via Klinisk Kemi i Norden.

Hvem kan søge

Midler kan søges til projekter, der opfylder fondens formål, og som udføres i samarbejde mellem mindst 2 nordiske lande.

Hvilke udgiftsposter kan drekkes

NORDFOND vil typisk kunne dække udgifter til mødevirksomhed, men vil i et vist omfang også kunne dække driftsudgifter og andre udgifter .

Laboratory medicine 2000

XXVII Nordic Congress of Clinical Chemistry

Planleggingen av kongressen nærmer seg slutten. Det vitenskapelige program er under den endelige utforming, hovedtema er bestemt, og det ventes endelig svar fra inviterte ordstyrere (chairpersons) om kort tid. Av programmet kan nevnes "New methods in biology/DNA diagnostic work", "Oxygen radicals and disease", "New analyses in the evaluation of heart failure". Foreløpig er det påmeldt ca. 17-18 utstillere, herav 4 hovedsponsorer. Utstillerne vil få meget gode forhold, god plass, nærhet til møtelokalene, og i de samme områder der kaffepausene er lagt. Travel Planners of Scandinavia,Walckendorffsgate 9, 5012 Bergen, kan også motta påmelding senere så langt det er plass. E-post adresse:

harald.riisnaes@travel-planners.no

Det er sendt invitasjon til i alt ca. 1600 adresser i Norden og til noe ikke-nordiske klinisk-kjemiske selskaper.

Henvendelse til Kongressekretariatet kan også skje ved E-post, adresse:

inger.aarnes@haukeland.no

Bergen er en særdeles velegnet kongressby fordi sentrum er konsentrert, og minst 12 hoteller med over 1000 senger ligger innenfor en spasertur på 10-12 minutter fra Grieghallen. Og vi håper på at de hundretusener rododendroner blomstrer om kapp i overgangen mai-juni. For øvrig gjøres det oppmerksom på at Bergen Internasjonale Festspill har avslutning 4. juni. Deltagerne vil der tor kunne ta med seg de siste konsenene ved Festspillene. Festspillprogrammet vil bli tilgjengelig via Internett. Kongressens Web-side har Internet-adresse:

http://www.uib.no/med/lkb/kongr.html

Velkommen til Bergen og nordisk kongress!

Hvad skal ansøgnjngen indeholde
Ansøgningen skal indeholde:
- Et kort resume
- Projektbeskrivelse (maks. 5 sider)
- Oplysning om deltagere og deres accept for deltagelse
- Budget med oplysninger om eventuel medfinansiering fra anden side

Hvor mange penge er der til rådjghed
i 2000 kan fonden uddele i alt ca. kr. 100.000.

Hvem skal have ansøgningen
Ansøgninger skal sendes til formanden for NFKK:
Professor, dr.med. Ebba Nexø
Klinisk biokemisk afdeling
KH, Århus Universitetshospital
Nørrebrogade 44
DK-8000 Århus C

Ansøgningsfristen er 1. maj 2000.

Hvornår får ansøgeren svar
Ansøgningerne behandles på NFKKs styremøde, og svar udsendes i løbet af juli 2000.

Hvor kan man få yderligere oplysninger
Yderligere oplysninger kan fås hos medlemmer af styret for NFKK. Navne og adresser kan findes i Klinisk Kemi i Norden eller på adressen:
http:/ /e.lio.se/n fkk/index.htm

Fra kaos til centralisering

RUD. KEIDING

Under den 4. Danske Kongres i Klinisk Biokemi i maj 1999 talte de tre æresmedlemmer af Dansk Selskab for Klinisk Kemi om deres oplevelse af klinisk biokemis udvikling og fremtid set i lyset af deres egen indsats for specialet. I de to foregående numre af Klinisk Kemi i Norden har vi bragt professor dr.med. Poul Astrups foredrag: *Fra kaos til videnbaseret adfærd i patientbehandling* og overlæge René Dybkærs indlæg: *Fra kaos til standardisering.* Her følger nu professor, dr.med. Rud Keidings foredrag.

Det har været mødeledelsens intention, at forsamlingen skulle perspektivere sin opfattelse af klinisk biokemi. Til den ende har man så halet de gamle frem, for at de kunne berette om de svundne tider. Jeg skal straks dække mig ind for den efterfølgende beretning ved at citere T.S.Eliot:

Det svundne ændres i samme grad af øjeblikket, som øjeblikket bestemmes af det svundne.

Fremlæggelsen er programsat med en titel, der implicerer, at der i begyndelsen var kaos, det vil sige en tilstand med total mangel på orden. Nu var der i den præcentrallaboratorielle æra jo langtfra uorden. Hver afdeling havde sit eget laboratorium, oftest placeret i et kælderrum eller i et skråvæget loftsrum og bestyret af en ældre dame – oftest en sygeplejerske, der var fundet uegnet til klinisk arbejde. Disciplinen og præcisionen blev opretholdt ved, at guruen – overlægen – lod sit nådes lys skinne over laboratoriet en gang om ugen og hver gang – for en ordens skyld – klagede over resultaternes ringe standard.

Selv mødte jeg første gang den kliniske biokemi som volontør på Rigshospitalets kirurgiske afdeling – det må ha' været ca. 1942. Her stod der i vindueskarmen på sygestuen, hvor der i øvrigt lå 16 patienter, et antal uriner, som det var opgaven at analysere. Efter at have konsulteret en eller anden, som måtte formodes at vide lidt om, hvordan man gjorde, gik man i gang med Hellers prøve, Fehlings prøve, Esbach og Lohnstein, alt under intens opmærksomhed fra patienterne. De lå alle og ventede på, at den nye doktor skulle stødkoge det Fehlingske reagens, så det sprøjtede langt ud i lokalet – og de ventede ikke forgæves! Men det, de med størst forventning så hen til, var, når den skrappe oversygeplejerske efterfølgende kom farende og skældte mig huden fuld.

Senere, da jeg blev turnuskandidat, forventedes det, at man i vagten, foruden at skrive journal på 20 nyindlagte patienter, analyserede for blodprocent, blodsukker, blod-type og forlig og – som det store dyr i åbenbaringen – blodets totalkuldioxyd ved hjælp af et van-Slyke apparat. Jo, der var nok alligevel en vis form for kaos!

Specialist i klinisk kemi og laboratorieteknik blev jeg efter ét års ansættelse på Finsens-laboratoriet. På dette laboratorium forudsattes det, at man ikke involverede sig i laboratoriets daglige drift. Det eneste pligtarbejde var at undersøge knoglemarvsprøver. Laboratoriet blev i øvrigt på bedste måde passet af to pharmaceuter. Og så havde laboratoriet i øvrigt en raffineret facet på kontrolsystemet, idet alle laboratorieskemaer fra hospitalet blev indsamlet hver dag, og en særlig betroet sekretær indskrev dagens resultater, men frasorterede dog alle resultater, som hun ikke fandt i harmoni med de tidligere udførte.

Med denne klinisk biokemiske ballast suppleret med en måneds kursus i dyrkning og resistensbestemmelse af urin, fik jeg til opgave at centralisere laboratorievirksomheden i Viborg Amt.

Det skal her indskydes, at den daværende medicinaldirektør havde foreslået, at man ansatte folk til at markere disse stillinger, indtil man kunne skaffe personer med relevant uddannelse.

Tre år senere fik jeg opgaven at centralisere laboratorievirksomheden på Århus Kommunehospital.

Generelt var der i begyndelsen modstand mod at indføre centrallaboratorier. Den for hospitalsvæsenet så karakteristiske åndelige inerti markerede sig også her. Der var mange medicinere, der ikke kunne forstå, hvorfor der skulle oprettes et speciale i noget, som de syntes, de vidste alt om i forvejen. Nogle var bange for at miste magt, andre bekymrede for, at der nu var flere om at dele bevillingerne. Endelig mistede man muligheden for – i ly af laboratoriet – at krige sig forskningslaboranter.

Så den egentlige grund til, at centrallaboratorierne blev oprettet, var administrationernes forfængelige håb om rationaliseringer og besparelser.

Set fra laboratoriespecialets side var det åbenbart, at der trivedes vildtvoksende aktiviteter på mange afdelingslaboratorier: irrationalitet, ukorrekte analyser, store konti for prøver sendt ud af laboratoriet og alt for stor overlapning af analyseprocedurer laboratorierne imellem.

Det var under disse vilkår, vi begyndte vor virksomhed. Der er næppe grund til at detaljere karakteren af vore problemer i opstartsfasen for dette forum al den stund, de såmænd stadig er aktuelle. Det var pladsmangel, udstyrsmangel, repertoireudvidelse, for mange hasteprøver, ambulantorganisationen, undervisning, oplæring og integration i hospitalshelheden. Hvis nogen tror, de har løst disse problemer, ja så er de enten naive eller grundtvigianere.

Det viste sig snart efter starten, at der var et stort latent, ja næsten umætteligt behov for analyser. Stakåndede arbejdede vi for at følge med i det eksplosivt stigende arbejde, og vi offentliggjorde i de første ti år de rapidt stigende produktionstal, måske nok mest fordi vi derigennem troede at kunne dokumentere vor uundværlighed.

Nå, i virkeligheden var det jo både udfordrende og spændende at udvikle centrallaboratoriet. Man fik en masse kemi på fingrene, man udviklede nyt udstyr, man lærte glaspustning, fik oplæring i elektronik, og mest af alt fik man udviklet og slebet sine diplomatiske evner.

Hos den meget inspirerende professor Lehmann i Gøteborg lærte vi at bygge flammefotometer i en sæbekasse, og hos Svendsen i Randers – denne hugaf af en overlæge med den store hjælpsomhed – lærte vi at bygge filterfotometre med noget så raffineret som en gennemløbscuvette.

De analyseprocedurer, som var tilgængelige, var ikke just nemme og hurtige. Et eksempel er blodsukkeranalysen:

Blodsukker a.m.Hagedorn-Norman-Jensen (1921)

0,100 ml øreblod (stangpipette) fældes i

6 ml Zn.sulfat-NaOH.

Koges på vandbad 4 min. Filtreres og vaskes 2 gange.

Hele filtratet tilsættes 2 ml Ka.ferricyanid.

Kogende vandbad i nøjagtig 4 min. Afkøling.

Tilsættes 5 dråber K.jodid.Omhyggelig omrystning.

Tilsættes 1 ml Citronsyre-Zn.sulfatopl.

Titreres med 0,005 N Na.thiosulfatopl.

Undervejs tilsættes 2 dråber stivelsesopløsning.

—-

Kontrol af K.ferricyanid og Na.thiosulfat én gang ugtl.

Blindværdier-kontroller.

Denne "lille og simple" analyse skulle tre gange daglig udføres på ca. 50 prøver og to gange om ugen på 100-120 ambulante patienter mellem kl. 8 og kl. 10.

Da man efter års puklen kunne trække vejret lidt, begyndte diskussionen om, hvad endemålet med disse laboratorieafdelinger skulle være. To typer holdninger udviklede sig.

Den ene

at oprette store klinisk-biokemiske borge, godt bemandet og godt bevæbnet, inden for hvis mure man kunne søge dækning for og beskyttelse imod fjenderne fra de andre afdelinger for i fred at kunne dyrke klinisk-biokemisk introspektion og videnskab.

Den anden

at oprette store åbne bazarer, hvorfra man kunne falbyde de renvaskede, lægekontrollerede kliniskbiokemiske varer,og hvor kunderne til ingen pris kunne tage sig til gode med udvalget i ubegrænset mængde, selvom de forspiste sig.

Så vi os om dengang, kunne vi – specielt i udlandet – finde dobbeltholdninger, d.v.s. opdeling i to separate afdelinger, en for rutinen og en for den højere rideskole, men med samme ledelse (eksempelvis i Belgien, Schweiz, Norge). Den mest ren-

dyrkede "bazarholdning" så vi hos Lehmann i Gøteborg.

Ihvorvel man her i landet ret hurtigt så tendenser til at koncentrere sig omkring fagets formale aspekter, blev centrallboratorierne almindeligvis blandingsmodeller mellem de to tendenser, ikke på grund af en planlagt strategi, men mere som en konsekvens af omstændighedernes lov.

Fraset de store laboratorier i København iagttog man snart en øget influx af folk, der ønskede at dyrke systematisk analytisk arbejde (kald det forskning eller research), og som fandt det formålstjenligt at udøve denne aktivitet på centrallaboratoriet. Dette var overordentlig befordrende for laboratoriet, bl.a. fordi det stimulerede det faglige miljø, og så skabte det en bedre kontakt med det øvrige hospital og derigennem en større integration af laboratoriet i hospitalsenheden.

Hvad det gik småt med, var at udbrede kendskabet med de klinisk-biokemiske varer. Det var Eldjarn i Oslo, der sagde, at det bekymrede ham mindre, at folk brugte for mange analyser, men mere at de ikke forstod at udnytte den informationsværdi, der var indeholdt i dem.

Hvad der så senere skete er kendt af alle her. De automatiserede analyseudstyr holdt deres indtog, og håndkemien forsvandt efterhånden næsten helt. Edb blev et altdominerende redskab på godt og ondt.

Man kunne nu – her fra sidelinjen – spørge: Har I nu videreudviklet laboratoriet i pagt med den tekniske og den hospitalsmæssige udvikling, eller sidder I og ruger over, om nogen skal tage noget af jeres arbejde fra jer? Er jeres forskning og udvikling styret af hospitalets behov, eller sidder I og forsker i venstredrejet oxalsyre i kammervandet eller for den sags skyld i esoteriske knopper på det tredvte kromosom? Kan I styre jer fri af de spændetrøjer, som for øjeblikket truer jeres laboratoriums frihed?

Da jeg – i anledning af dette foredrag – for nylig aflagde visit på et par centrallaboratorier, måtte jeg efter at have set dem erkende, at det om min snart gennem 50 år indsamlede erfaring i kliniskbiokemi gælder (som Mogens Fog har sagt)

Erfaring er som at være i besiddelse af en billet til et tog, der er kørt.

Role of EC4 in the Harmonisation of Clinical Chemistry in the European Union

GTB SANDERS, RTP JANSEN and MT PARVIAINEN

Authors:

Professor Gerard TB Sanders

Past President of EC4; Academic Medical Center (AMC), Department of Clinical Chemistry, P.O. Box 22660, 1100 DD Amsterdam, the Netherlands.

Dr. Rob TP Jansen, PhD

President of EC4; Chairman EC4 Working Group on Harmonisation of Quality Systems and Accreditation; St Anna Hospital, Department of Clinical Chemistry, P.O. Box 90, 5600 AB Geldrop, the Netherlands.

Dr. Markku T Parviainen, PhD

Member of EC4 Board; Technology Centre Teknia Ltd, P.O. Box 1750, FIN-70211 Kuopio, Finland.

Introduction

In this article the position and activities of EC4, the European Communities Confederation of Clinical Chemistry will be explained.

The confederation was formally instituted April 27, 1993 in Nice (France). Before that date informal contacts between the clinical chemistry societies in the EU existed since the seventies. Already then visions about the practice of clinical chemistry in the different EU countries were exchanged. Common aspects concerning the national contents of our profession, professional post-graduate training, quality assurance systems and other issues were addressed. It was hoped to obtain a specific directive for clinical chemistry at the European Commission in Brussels, but this exertion failed and finally was stopped.

What did not end, and even was strongly reinforced, was the work on harmonisation of our profession, especially after the official foundation of EC4.[1]

EC4 is the organisation of societies of clinical chemistry in the European Union (EU). Thus the EC4-board consists of representatives of the national European Union societies of clinical chemistry. All these societies are members of the International Federation of Clinical Chemistry (IFCC) and its European regional branch, the Federation of European Societies of Clinical Chemistry (FESCC).

Within FESCC the clinical chemistry societies within the EU have realised themselves that due to the different treaties a special situation exists for professionals and the way they perform their services. For our discipline it means the clinical chemists are subject to the different directives and other regulations which may influence the practice of clinical chemistry.

The structure of EC4 based on membership of EC4 by societies, means that individual professionals cannot be members. Only via their national IFCC-related societies the contact with EC4 exists.

Goals

The main goal of EC4 is harmonisation of clinical chemistry in the European Union in particular and Europe in general. It is the aim of EC4 to improve the quality of all aspects that comprise clinical chemistry in the EU, and this of course can be accomplished best and foremost by raising the level of the quality of the individual professionals. By doing so we wish to influence clinical chemistry in a positive way and to bring the practice of clinical chemistry more on one line. For that the EU has chosen the mechanism of harmonisation. This we consider not to be the same as unification, since EC4 wishes to respect the way clinical chemistry is performed and has developed itself within the national health care systems. By doing

so we try to learn from each other's national systems, and we hope to be able to recognise the best elements of clinical chemistry in the separate countries to bring them into practice in the whole European Union.

Under the umbrella of harmonisation EC4 set itself two main tasks: quality of the laboratory and quality of the professional. These two main goals are of course inter linked and in itself consist of a number of minor aspects.

For the quality of the professional the initiative for the European register of Clinical Chemistry was taken. For the quality of the clinical chemistry laboratory, as for other disciplines in health care, accreditation is the recognition of the status of the overall diagnostic process. One of the conditions for recognition of excellence of a laboratory is that the professional contribution is of the highest possible, proven, level. So, accreditation cannot be complete without relevant training of professional staff and technicians. There the European registration and accreditation meet at the interest of the patients for whom we perform our activities.

European register

The institution of the EU Register for Clinical Chemists is one of the best ways to regulate the profession of clinical chemistry, since it is based on a common EU training program. That is where harmonisation should start. The activities EC4 has undertaken to reach this goal in the past years, are (1) publication of European Syllabus for Postgraduate Training, (2) make a proposal for a sectorial directive for clinical chemists in the EU, and (3) the institution of a European Register for Clinical Chemists.

Before the European Register itself is dealt with, a short explanation of the content and position of clinical chemistry in the EU is given.

Clinical Chemistry in the EU is practised by some 25,000 professionals and the estimated total annual turnover is 15 * 10^9 Euro. The background of the professionals can be

Medical, Pharmaceutical, Science-oriented, Veterinary, and Microbiological. For all, a university education is the basis for postgraduate training in clinical chemistry. The average number of training years is 11 (8-13), average years of university education 5-6, average years of postgraduate training 5 (4-6), the minimum standard is 8 years of study after entering university ('BAC + 8' or 'Abitur + 8 Jahre').

The most appropriate way to regulate a profession in the EU would have been to create a Specific Directive dedicated to that profession. For Clinical Chemistry that was not feasible and thus the profession became subject to the so called General Directive 89/48/EEC (and 92/51/EEC).

This Directive regulates the recognition of all higher education diplomas awarded on completion of professional education and training of at least three years' duration (instead of the 8 years vocational training necessary to obtain sufficient knowledge in clinical chemistry). It assures recognition of certain diplomas, but not the admission of all clinical chemists to health-related activities of the national healthcare systems.

Therefore, EC4 has taken the initiative to regulate Clinical Chemistry in the EU based on the harmonisation of vocational training in Clinical Chemistry in the European Union.

That initiative has led to the European Register for Clinical Chemists. The initiative of the European Federation of National Engineering Associations (FEANI) has served as an model for EC4. According to the European Commission this is an excellent example of self-regulation by a profession at the European level.[2]

The EC4 European Syllabus for Postgraduate Training forms the basis for the European Register. It is not a training guide as such, but must be seen as an indication of the level of requirements in post-graduate training and the content of national programs needed to obtain appropriate knowledge and experience. It is a common minimal program approved by all EU societies of clinical chemistry and leaves undisturbed the different structures of medical laboratories as developed in their national environments. Some of the core elements are: Knowledge in clinical chemistry, hematology, blood banking, immunology, etc.; Pre-analytical conditions; Analysis and methodological evaluation of analytical findings; Medical interpretation of analytical findings; Clinical training; Research and develop-ment; Laboratory management and quality assur-ance.

Such a syllabus is the reflection of a profession

of which the contents are changing continuously. Therefore, it should never be made to last for ever and it needs regularly updating. The next syllabus update will be published in due course.

A guide to the EC4 Register has been published, leading to the title of European Clinical Chemist (EurClinChem).[3, 4]

A European Register has advantages for the individual professional, the profession, and the patient. The individual professional can prove to be a qualified clinical chemist, may use the title EurClinChem, is recognized at least by all clinical chemistry societies, allover the European Union even where under local law no protection exists, and free movement within the EU is facilitated.

For the profession of clinical chemistry the advantages of a European Register are: the profile of clinical chemistry is raised within the EU, and common high standards of education, training, experience, and compliance with continuing professional development are instituted. Moreover, comparability of professional training, and of content and practice of clinical chemistry is facilitated, and mobility is improved.

The Register is beneficial to the patient (and employer) since it guarantees adequate professional training, and assures adherence to the Code of Conduct added to the Register.

The European Register is kept by EC4 Register Commission (EC4RC), advised by the National Clinical Chemistry Register Committees (NCCRC). Another important task for the NCCRC is to guarantee the equality of the vocational training at a national level.

A clinical chemist wishing to register, sends an application with personal details and a curriculum vitae to the NCCRC. This committee keeps the national register and assesses the suitability of the candidate. After recommendation the final decision is at the EC4RC. The Registration in the EC4 Register thus assures professional training according to the standards and the connected competencies, grants the title EurClinChem, and guarantees that the registered professional adheres to the Code of Conduct.

Application is open for EU citizens trained within EU, EU citizens trained outside EU, and non-EU citizens trained within the EU. Non-EU citizens not trained in an EU country are not eligible for registration.

The present status of the Register is that it was launched after the publication of the documents mentioned in references 3 and 4. Also, an information leaflet has become available.

The first certificates to European Clinical Chemists were granted in Helsinki on October 3rd 1998. A few days later three Italian colleagues followed and increasing amounts of applications are coming in now. By now 104 certificates have been awarded.

For more in formation the EC4 website may be consulted.[5]

Accreditation of laboratories

There is increasing awareness in medical laboratories for the need of total quality management. After a long history of the use of internal quality control and external quality assessment schemes, there is now the requirement for control of the complete laboratory process. An important tool to achieve such control is a total quality management system.

But as far as accreditation of laboratories is concerned, the situation is different from that concerning vocational training. No EC4 accrediting body exists, and EC4 does not wish to fulfill that role. It only has tried to describe the guidelines (Essential Criteria) which it judges appropriate for establishing the quality of laboratory service. Thereby EC4 focuses on medical laboratories in general because in most EU countries clinical chemistry is a polyvalent discipline. With the Essential Criteria EC4 tries to influence international standardisation organisations like CEN and ISO in the development of documents concerning quality of medical laboratories. It is hoped that accrediting bodies in the EU will proceed along these lines when judging quality systems present in a laboratory. In these the whole process from pre-analysis to interpretation has to be included. That means that EC4 is strongly of the opinion that medical laboratory accreditation must be service rather than test based.

A quality system requires a quality manual to be compiled describing the organization of the laboratory including functionality and the responsibilities of staff. Operating procedures would describe pre-analytical, analytical and post-

analytical activities.

Pre-analytical aspects include consultation on appropriate investigations, patient preparation for sampling, and sample collection techniques. Analytical aspects include procedures for calibration, analysis, internal quality control and external quality assessment. Post-analytical aspects include procedures for authorisation, timely and accurately reporting, and consultation on the interpretation of results in relation to diagnosis, treatment, prognosis and further investigations.

There exist international standards for certification (ISO 9001) and for accreditation (EN 4500 and ISO Guide 25). However these standards are either very general (ISO 9001), or are developed for testing and calibration laboratories (EN 45001, ISO Guide 25), and therefore do not address specific aspects of the work of medical laboratories. The scope of medical and clinical laboratories is different from these laboratories and needs additional criteria.

The Working Group on Harmonisation of Quality and Accreditation Systems of EC4 has prepared a set of documents describing essential criteria for quality systems in medical laboratories to clarify the specific needs. [6, 7, 8, 9, 10] Clinical laboratories that have implemented quality systems based on the Essential Criteria fulfill all criteria for accreditation. EC4 considers this as a European Union harmonised accreditation system. EC4 provides guidelines for implementation of total quality systems in medical laboratories. It is easily applicable for multi disciplinary and other types of medical laboratories. The quality systems of medical laboratories would reflect the special tasks of such laboratories. Therefore, the emphasis is on all previously described phases. Not only on analytical and observational aspects, but also on the pre-analytical and post-analytical phases, on consultation and on efficacy and efficiency of requested investigations.

A medical laboratory that has implemented a quality system according to the criteria described in the EC4 document, fulfills ISO 9001, EN 45001 and ISO Guide 25 standards that are relevant to medical laboratories, and is prepared for accreditation or certification by all relevant schemes. Particularly schemes originating, though independently operating, from the professions, like the Belgian system, CCKLtest in the Netherlands, CPA in the United Kingdom, the French GBEA system, are suited for such accreditation. Guidelines published by these organisations are in agreement with the present international document and the Handbooks and Model Quality Manuals based on the guidelines and issued in these countries are of use for laboratories wishing to implement a quality system based on the present document.

The new ISO/DIS 15189 recognises the special position of medical laboratories much better than the ISO 25 Guide. The EC4 Essential Criteria have strongly influenced the contents of this draft document. From it the following text is derived: "Medical laboratory services, including appropriate consultation services, are essential to patient care and therefore should be available to meet the needs of all patients, their physicians, and other clinical personnel responsible for patient care. Specific functions include requisition, patient preparation, collection (where applicable), proper identification, transportation, storage, processing, and examination of clinical samples with subsequent reporting of results. When necessary medical laboratory services should include the examination of patients in consultation cases and active participation in prevention, diagnosis, and management of patients. Each service should also provide suitable educational and scientific opportunities for the academic and technical staff. Governmental bodies may provide license to a medical laboratory to do certain examinations (tests) on specified conditions."

The Executive Board of EC4 therefore recommends that ISO/DIS 15189 "Quality Management in the Medical Laboratory" be supported as a reference document for laboratory accreditation. Its final version should be considered together with the EC4 Essential Criteria when defining a national scheme for laboratory accreditation.

As an extension of its activities in the field of accreditation EC4 has recently also taken the initiative to create a European Co-operation for Accreditation of Medical Laboratories (ECAML), as a commission to harmonize the work of national accreditation bodies.

Activities of CEN and ISO

EC4 considers it also one of its tasks to monitor the activities of the different standardizing bodies that might influence the practice of clinical chemistry.

The main ones are: ISO/TC 212 Working group 1 and CEN TC 140. The former is concerned with accreditation and the latter with In Vitro Diagnostics.

It is advised to every national clinical chemistry society to follow these activities and to find out which committees are involved in these matters on a national level.

Future strategy

EC4 is actively busy performing all the tasks it has set for itself, but future goals are also a matter of discussion. The strategy document has been prepared.

The key words for future activities of EC4 will remain clinical chemistry in its broadest sense, European Union and harmonisation.

Within these boundaries the work on the register and the accreditation will continue, and EC4 will follow the activities of CEN and ISO to see what the consequences for our profession they might have.

In relation to these key items four aspects may be discerned: profession (contents of clinical chemistry), performance of the profession, performance of laboratories, profiling of clinical chemistry.

The profession now has an established register and re-registration will be an issue for the future. Also the European Syllabus which will always form the basis of the register should be updated regularly, which is essential in a dynamic profession as ours.

The performance of the profession will profit most from strategies for interpretation of test results, diagnostic strategies, and clinical decision making and evidence based laboratory medicine.

The performance of laboratories can be based on the essential criteria that the EC4 Working Group on accreditation has published. Harmonisation of national systems for accreditation of medical laboratories will lead to general EU qualifications for heads of clinical chemistry laboratories, advised requirements for their organisation and quality assessment schemes, and the level on which they perform their services.

Profiling of clinical chemistry in the EU will be necessary once EC4 has results of its activities to show.

And last, but not least, the extension of the European Union will force EC4 to orient itself to the practice of clinical chemistry outside the EU. EC4 realizes that its activities may influence the position of professionals in other, non-EU, countries. Therefore, a good cooperation with FESCC will remain essential.

References

1. Sanders GTB, Kelly AM, Breuer J, Mocarelli P. The role of European Communities Confederation of Clinical Chemistry (EC4) in the harmonisation of Clinical Chemistry in the European Union (Letter to the Editor). Eur J Clin Chem Clin Biochem 1995; 33:947-948.

2. Document 94/C 268/72 of the European Commission, March 1994.

3. Sanders GT, Kelly AM, Breuer J, Kohse KP, Mocarelli P, Sachs C. The European Register for Clinical Chemists. Eur J Clin Chem Clin Biochem 1997;35:795-796.

4. Sanders GT, Kelly AM, Breuer J, Kohse KP, Mocarelli P, Sachs C. European Communities Confederation of Clinical Chemistry Guide to the EC4 Register: European Clinical Chemist. Eur J Clin Chem Clin Biochem 1997;35:797-803.

5. EC4 website: http://www.uni-oldenburg.de/ec4.

6. Jansen RTP, Blaton V, Burnett D, Queraltó, Huisman W. Quality and accreditation systems in clinical biochemistry in the European Union. Eur J Clin Chem Clin Biochem 1995; 33:393-398.

7. EC4 Working Group on Harmonisation of Quality Systems and Accreditation: Jansen RTP(chairman), Blaton V, Burnett D, Huisman W, Queralto JM, Zérah S, Allmann B. Essential Criteria for Quality Systems of Clinical Biochemistry Laboratories in the EU. Published in: Burnett D. Understanding Accreditation in Laboratory Medicine. London: ACB Venture Publications, 1996: Appendix 5.

8. Jansen RTP, Blaton V, Burnett D, Huisman W, Queraltó JM, Zérah S, Allmann B. Essential criteria for quality systems in medical laboratories. Eur J Clin Chem Clin Biochem 1997; 35:121-122.

9. Jansen RTP, Blaton V, Burnett D, Huisman W, Queraltó JM, Zérah S, Allmann B. European Confe-deration of Clinical Chemistry: Essential criteria for quality systems of medical laboratories. Eur J Clin Chem Clin Biochem 1997;35:123-132.

10. Jansen RTP, Blaton V, Burnett D, Huisman W, Queraltó J, Zérah S, Allman B.Additional essential criteria for quality systems of medical laboratories.Clin Chem Lab Med 1998;36:249-252.

Population-based genomics and the Icelandic Health Database

Two steps in the same direction

KRISTJAN ERLENDSSON MD,
VP of clinical collaboration Decode Genetics

Decode Genetics is a population-based genomics company that was founded in 1995 in Reykjavik, Iceland. The company has set out to conduct research into the inherited causes of common diseases and aims, together with pharmaceutical companies and other healthcare institutions, to utilize its research to develop new methods for identifying, treating and preventing diseases. In doing so, Decode has created numerous opportunities for highly educated young scientists, thus generating new possibilities for them to return to Iceland with their scientific experience and know-how. The company has generated 290 jobs in this new industry in Iceland.

The emphasis on population-based genomics and later the expansion of information technology for the progress of healthcare and research as well as its linking to genetic research and genealogy, has generated a new era in the Icelandic health science sector. It has opened up new research possibilities and putting Icelandic scientist on the forefront in the discussion about ethics of scientific research and numerous aspects of data protection in the increasing use of computers in medicine and science in general.

Genomics and the Icelandic Population

Most common diseases have a genetic component, often combined with certain environmental influence. Iceland has a relatively homogeneous population and has preserved detailed genealogical records dating back to the ninth century. It has proven very difficult to find causative genes for common diseases in heterogeneous populations, but an isolated population, one containing minimal diversity, with extensive genealogical and medical information is an ideal system to discover new disease genes. Geographically isolated until the 1900's, the entire Icelandic population has descended from a small number of individuals.

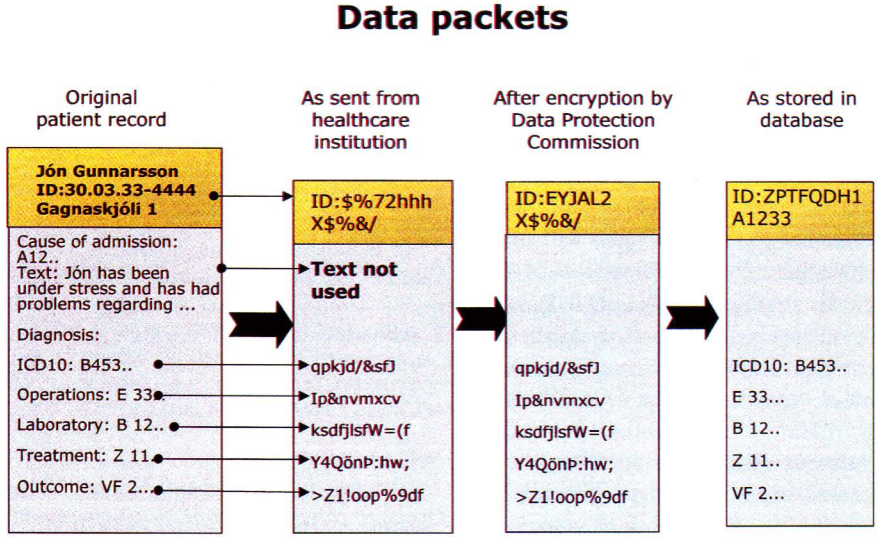


Figure 1. Overview over The Decode genomic research approach (see text).

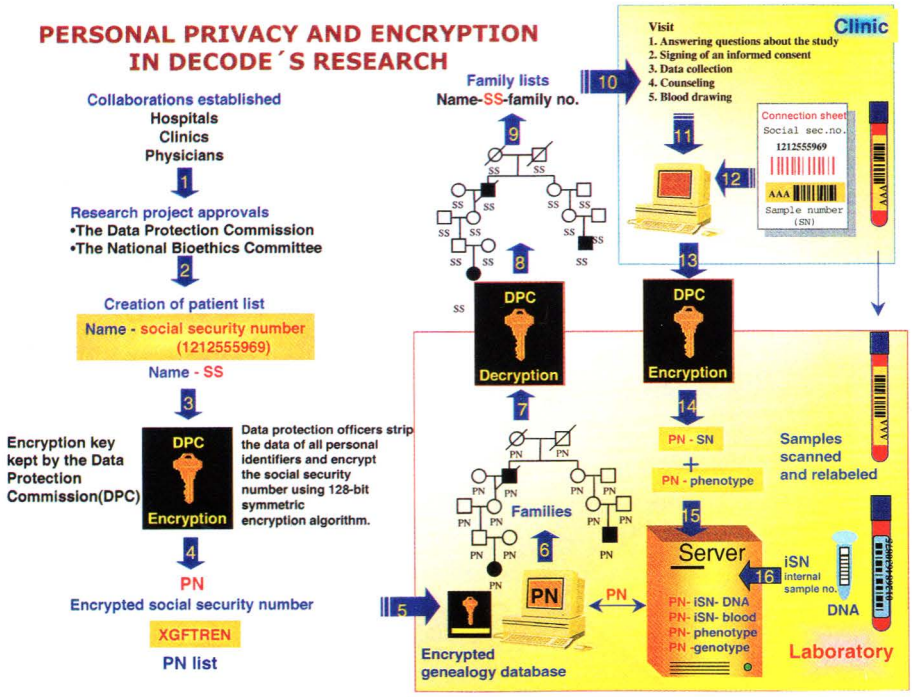


Figure 2. The proposed transport of data from healthcare institutions to the Icelandic Healthcare Database.

Since there has been little inward migration, most of Iceland's current inhabitants are descendants of this circumscribed genetic pool of founders. As a result there is an increased likelihood that differences between healthy and afflicted individuals are in fact genetic variations and not solely random variations resulting from diverse racial or ethnic backgrounds.

A computerized genealogy database has been constructed and includes all 270,000 living Icelanders and 330,000 of their ancestors. Those genealogy attributes, as well as Iceland's high-quality healthcare system, offers unique resources to identify genes associated with a multitude of common diseases. Research based on this unique population, can provide powerful insights into the pathogenesis of disease. The identification of disease susceptibility genes can provide very specific information that may revolutionize both how diseases are diagnosed and how novel and more specific drug targets and other treatment modalities are generated.

In its research Decodes forms a collaboration with a group of medical specialists and other healthcare workers around each disease project and a protocol is written. An encrypted genealogy database is used to cluster patients with a particular disease into large, extended families, sometimes containing hundreds of individuals. After a permission for each research project has been granted by the Data Protection Commission and the National Bioethics Committee, an encrypted patient list is generated. The actual contact with the patients and relatives is solely the responsibility of the collaborating doctors and no names or information on participants are available to Decode as blood samples are encrypted through a third party encryption. Each project therefore begins with the clinical characteristics of a common disease and from there the researchers work backwards to discover its genetic basis.

Through large-scale genotyping, Decode's scientists generate genetic 'fingerprints' of each chromosome and then compare those of related patients. The chromosome that contains identical fingerprints in the patients, marks the approximate location of the disease gene. By performing high-resolution DNA analysis, using denser markers, within this location, the region containing the gene is narrowed down further. Any gene discovered

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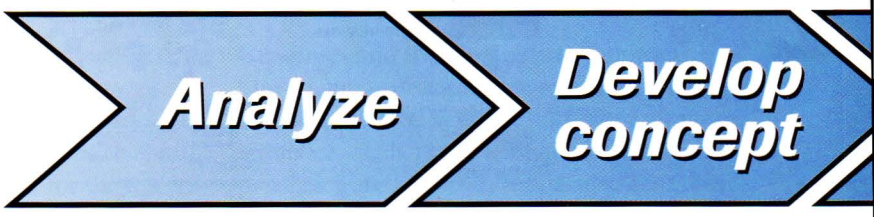

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within this location is screened for mutations by comparing the DNA sequence of healthy and affected individuals.

In its population genomics program, Decode has established collaborations in over 30 selected diseases with close to 100 clinical collaborators. Cooperation with pharmaceutical companies, biotechnology firms and other healthcare-related businesses has been developed and contracts made for funding of certain diseases. In others, the company is pursuing internally funded research programs to discover genetic causes in a number of disease areas.

In those projects the company utilizes leading-edge bioinformatics and fully integrated computer systems developed with proprietary software for genetic studies. The company operates one of the world's most technologically advanced genotyping operations, capable of generating more than 3 million genotypes each month.

It is to be expected that drug target identification that is based primarily on expression and functional studies will be less specific than using the genetic approach, that may identify the mutated gene of a molecular pathway in the pathogenesis of the disease. The information generated in this way can enable prediction of which patients are susceptible to a positive or adverse reaction to existing drugs. It can also identify genes involved in specific diseases, screen compounds and help develop specific drugs for the disease.

The work is progressing very well. The acceptance by the Icelandic people has been outstanding as well as project participation. The forthcoming results will further attest to the feasibility of research based on the characteristics of the Icelandic population. The cooperation with the governing bodies of personal data protection and science ethics has generated new methods and approaches in data security in research to be copied by others. All this research is done with the participants informed consent.

The Icelandic Healthcare Database (IHD)

In December of 1998 the Icelandic parliament passed the law on healthcare database in Iceland. Decode Genetics is the sole contender to be granted the license to build and operate the database for the next 12 years. The database will contain health information derived from hospitals and primary care centers in addition to private institutions, thus generating holistic health information on participants. An assumed consent is applied in building this database and the data is unidentifiable as defined by the law. People can opt out and refrain from participation at any time.

The data security is to be subject to very strict regulations with triple encryption, including a "one way" encryption, strict admission criteria and surveillance. The Data Protection Commission, The National Bioethics Committee, an Operation Supervisory Committee and a special Database Science Ethics Committee will monitor the operation and approve research proposals of the IHD.

The genealogy database, constructed by an informed consent from participants, and genotypic database will be separate from the IHD but a license can be granted by the above mentioned appropriate Commissions for temporary linking during processing of certain previously approved queries.

A healthy discussion has taken place about the making of this database for various reasons. The discussion has included items such as privacy protection, informed consent, the freedom of scientific research and scientist have even discussed such less scientific matters as business prospects and laws on commercial competition.

The dispute has crystallized out many important aspects about conduct of research in general in Iceland and internationally. This discussion has already brought about considerable improvement in research conduct for the protection of personal data and patients rights in general in Iceland.

When the IHD is compared to many of the currently operated databases internationally, it turns out that assumed consent in fact is the rule rather than exception. Detailed discussions about this form of consent have not taken place anywhere else to the same extent as in Iceland, but my prediction is that as people in other countries become more aware of the presence of such databases, they will demand the same discussion as has already taken place in Iceland. The Icelandic Healthcare Database will contain information on longitudinal disease progression, treatments and treatment response as well as direct and indirect cost of treatment and cost-effectiveness. The IHD

will, when fully operational, contain more information than is now common practice in present databases but with the progress of electronic medical records we'll see the progress towards such databases facilitated elsewhere as well.

The Icelandic Healthcare database in connection with Decode's genealogy database and molecular genetic information, will represent a powerful instrument to discover new knowledge about human disease and its management. Coupled with genealogical and genetic data, the genetic pattern of various diseases can be elucidated further, as well as the relationship between genetics and pharmacological response.

The use of the IHD will give the opportunities i.a. to:

- Assist healthcare providers in tailoring the treatment of individuals according to the genetic basis of disease and treatment response.
- Enable healthcare providers and payers to analyze and single out the most cost-effective treatment for various diseas and provide the highest quality treatment.
- Construct models for developing disease management programs.
- Provide pharmaceutical researchers with a chance to use both a macroscopic and microscopic approach (i.e. healthcare data with genetic data) to understand the origins of complex diseases and find more specific drug targets.

To build a useful databank widespread coope-ration is needed. Not only from the people and the customers of the healthcare system but also from healthcare workers and directors and boards of healthcare institutions. Confidence in the project and its executioners by the people need to be strengthened and cooperation from healthcare workers must be secured. With the introduction of new medical record systems the opportunity to standardize recordkeeping will further emerge in Iceland. A change of working habits can only be expected to take place if the workers will gain something from the change in their daily work or it will give them new research opportunities. This work will therefore only be successful if both parties benefit from cooperation. The possibilities for that to happen are in fact good but an extensive introduction and later contract talks should be forthcoming.

There has been some worries that scientific freedom will be compromised be the IHD. On the contrary the IHD will in fact generate increased possibilities for scientists at the cooperating institutions to conduct research. Not only will the new record keeping systems facilitate in-house research but the addition of the IHD will also be for their benefit. Data privacy will also be greatly enhanced by replacing research conducted by chart review done on paper records with research based on data from electronic medical records.

Decode Genetics has brought about for the Icelandic healthcare system and the Icelandic science world a new era of progress and new ideas. It has already proven its point about genetic research in Iceland. The plans on IHD, a health informatics based research, are well on the way with the goal to help analyze disease patterns, such as the interplay between genes and environment, treatment and outcome.

It is quite natural that such major changes in a certain part of a society will not be met with universal applause. Independent polls have though shown that over 80% of the nation support the genetic research. The participation is even greater, suggesting an even more widespread support by patients and their relatives, people who really know the effect of disease and ill health. In similar polls, 11% of the nation claim that they will opt out from the IHD. So far only about 6% have done so, even after a full year of advertising and activist groups urging people to opt out.

The discussions that have stemmed from the IHD about ethics in science and patients rights have been extensive and will benefit not only Icelandic patients but will have and have already had repercussions internationally. They have been focused on the importance of human rights but also on the need to do medical research to ensure progress in science and healthcare. The balance between those two needs to be struck.

Decode Genetics is therefore pleased with the support its research and future plans have received from the Icelandic nation. The company is also proud of the discussion its work and plans have generated. Not many matters of such complexity and so widely debated have gained between 80 – 90% support within a whole nation. That fact is reassuring during , at times, heated but very useful, debate.

For further information see: www.decode.is

Platelet flowcytometry: limitations and possibilities

YASH PAL AGRAWAL
Division of Laboratory Medicine, Massachusetts General Hospital, USA and Department of Clinical Chemistry, University of Kuopio, Finland.

Introduction

Flow cytometry (FCM) has matured as an art and discipline. The research applications of FCM continue to develop at a brisk pace. The application of FCM to newer clinical applications is decidedly slower. This is inpart due either to reimbursement issues whereby "experimental " tests cannot be billed for or due to the lack of robustness/documented benefit of the assay procedure required for clinical decision making. I thus like to divide clinical FCM tests into 3 levels where the first tier comprises universally practiced clinical applications such as leukemia-lymphoma immunophenotyping. A considerable amount of published reviews are available on these applications and these applications are not further discussed. The second tier comprises potentially reimbursable applications that are clinically useful if the possible caveats and limitations are understood. The information regarding the clinical utility of this group of tests is less well defined in the literature and some of the key issues involved in platelet analysis are reviewed. The third tier comprises the group of interesting new clinical research applications that are by definition of an experimental nature with no established clinical utility (Tarnok et al, 1999; Drouvalakis et al, 1999).

For FCM laboratories the challenge then is to continually survey the literature in search for newer diagnostic tests to better serve their patients as well as to push forward the FCM diagnostic armentarium. In this brief review I discuss some of the key issues concerning analysis of reticulated platelets and platelet antibodies.

1.1 Platelet flow cytometry:

In general, one has to be extremely careful when using platelet FCM protocols for clinical applications (Michelson, 1996). One of the major difficulties in the analysis of platelets for clinical use is the problem of artifactual activation of platelets. It is important to be aware of this especially when using washed platelets or platelet rich plasma as opposed to FCM of platelets from whole blood. In this respect attempts have been made to reach consensus on the issues concerning the collection of blood, choice of anticoagulants, fixation of specimens and data analysis by the European Working Group on Clinical Cell Analysis (Schmitz et al, 1998).

1.2 Clinical indications for measurement of reticulated platelets: Thrombocytopenias arise from three pathophysiologic mechanisms (Kienast and Schmitz, 1990). Deficient production, accelerated destruction or abnormal pooling of platelets. Abnormal pooling could be due to hypersplenism in the presence of splenomegaly. The usual clinical problem in the evaluation of thrombocytopenias is however the distinction between deficient production versus accelerated destruction of platelets. This is best studied by an evaluation of the bone marrow where the presence of an increased numbers of megakaryocytes would imply increased peripheral blood destruction of platelets and a paucity signify that the thrombocytopenia is due to a decreased production of megakaryocytes. Bone marrows aspirates are however a painful procedure and thus there is a need for a non-invasive test to identify the mechanism of thrombocytopenia.

Correspondence: Docent Yash Pal Agrawal, Massachusetts General Hospital, Division of Laboratory Medicine, Gray-Jackson 249, Fruit Street, Boston, MA 02114, USA Tel: 1-781-648-4645 E-mail: yashagrawal@hotmail.com

The measurement of platelet-associated immunoglobulins is one such method and these are discussed in detail later. An alternative test is the measurement of reticulated platelets. These are immature platelets (Ault and Knowles, 1995), which contain RNA and are analogous to reticulocytes (reticulated erythrocytes). Reticulated platelets are increased in conditions characterized by a high platelet turnover such as ITP (Kienast and Schmitz, 1990) and decreased in conditions characterized by bone marrow failure. For these reasons elevation of reticulated platelets precedes the rise in platelet counts during recovery from chemotherapy (Romp et al, 1994).

1.3 Issues in measurement of reticulated platelets: Reticulated platelets are commonly stained with derivatives of thioflavin T such as thiazole orange (TO) since it is excitable at the 488 nm laser wavelength available in most flow cytometers and also the dye permeates the cell membrane without the need for permeabilization. TO provides an approximately 3000-fold enhancement of fluorescence upon binding to RNA. The main difficulty with the assay has been that the binding of TO to RNA is not entirely specific and depending on the protocol used TO could also bind to other nucleic acids and even accumulate in dense granules of platelets. Thus an ideal protocol should identify the cell type which is being studied, and use appropriate controls during method development and preferably during the assay itself to exclude non-specific staining. The recent protocol by Matic et al, 1998 meets these criteria. They identify platelets by GPIb staining and show that pretreatment of sample with RNAse abolishes staining whereas exposure to thrombin degranulates platelets without a decrease in TO staining.

The other issue in the use of reticulated platelets as a surrogate marker for ITP are the observations (Ault et al, 1992) in a murine ITP model and in patients with elevated platelet associated immunoglobulins that the reticulated platelet count correlates best with the state of thrombopoiesis when the platelet counts are above 50,000/ul.

This somewhat limits the utility of the assay. Platelet kinetic studies show that once the platelet count dips to below 50,000/ul the platelet lifespan is less than 3 days and by extrapolation is 1-2 days at counts of 20,000/ul. At this point the survival of normal platelets will approximate the duration of time that a reticulated platelet is identifiable by its RNA content and reticulated platelets will constitute a significant proportion of the circulating platelets. They would thus become a major target for destruction and thus result in a decrease in the absolute levels of reticulated platelets.

2.1 Platelet antibodies:
Immunoglobulins or antibodies may bind to platelets due to a variety of reasons. These include a) autoantibodies against platelet glycoproteins as in chronic ITP, b) platelet specific antibodies, c) anti-HLA antibodies d) non-specific binding via platelet F_c receptors. I will briefly summarize the role of flowcytometry in the measurement of these antibodies.

2.2 Key issues in chronic ITP:
In chronic ITP the autoantibodies can bind to a variety of glycoproteins though binding to GPIIb/IIIa and GPIb/IX is the most common (Wadenvik et al, 1998). The detection of platelet-associated immunoglobulin by flowcytometry is a relatively straightforward procedure. The problem is that many patients with non-immune thrombocytopenias also show platelet surface immunoglobulins. The assay thus has a low specificity since we are unable to distinguish the specific binding of antibodies to platelet glycoproteins such as GPIIb/IIIa from binding via F_c receptors on platelets (Winiarski, 1998). To solve this problem attempts have been made to measure antibodies against the specific platelet glycoproteins involved such as GPIIb/IIIa or GPIb (McMillan et al, 1987). In these assays lysates of patient platelets are used as the source of antigen and after suitable incubation with patient plasma that presumably contains antibodies, the antigens are detected using known anti-glycoprotein antibodies. While these assays can identify the specific IgG antibodies against the involved glycoprotein in many cases, it is to be realized that the assays will miss those platelet glycoprotein antibodies not being screened (e.g. rarer antibodies such as against GPIV), as well as IgM and IgA class antibodies, Fc receptor mediated binding and HLA class I antibodies. Thus, an intuitive approach may be to initially screen by FCM

for platelet surface antibodies and then identify the specific glycoproteins involved by using monoclonal antibody specific immobilization of platelet antigens (MAIPA). Such an approach may not be fruitful since in a study of 65 chronic ITP patients comparing FCM analysis of intact platelets with a ELISA based examination of platelet lysates (Stockelberg et al, 1996) both techniques identified approximately 45 % of patients with ITP. In addition, several patients positive by one assay were negative by the other assay and the authors concluded that both the assays have their merits and demerits. In another study, conventional FCM for surface immunoglobulins when comparison to MAIPA had only a limited role in the diagnosis of ITP (Joutsi and Kekomäki, 1997). In selected cases it may however be useful to analyze platelets by fluorescence resonance energy transfer (FRET) on a flowcytometer as discussed below.

2.3 Clinical background to HLA and anti-platelet specific antigen antibodies:

Management of thrombocytopenic patients who are refractory to platelet transfusions can be a diagnostic problem. This may be due to alloimmunization and/or the presence of platelet reactive antibodies against human platelet antigens (HPA). In addition, fever, sepsis, bleeding and splenomegaly can be other confounding factors. Multiple studies show that the incidence of alloimmunization is 50-90 % after transfusions with non-leukocyte depleted blood as opposed to 0-28 % when using leukodepleted platelets (Novotny et al, 1995). In the TRAP study 3-5 % of patients formed alloantibodies and as much as 6-11 % developed antibodies against platelet glycoproteins (Slichter et al, 1997). In another study using apheresis platelets 23 % of patients developed antibodies against HLA antigens, 2 % against HPA and importantly of the patients alloimmunized to HLA antigens 9 % also had antibodies against HPA (Kickler et al, 1990). HPA's such as PI^A, Bak, PI^E, Ko, Br, PI^t, Pen may also be of importance in neonatal alloimmune thrombocytopenia purpura and posttransfusion purpura. The identification of HLA and HPA antibodies can have therapeutic implications with reference to need for HLA matched transfusions, splenectomy etc.

2.4 Key issues in HLA versus HPA antibodies:

The problem of distinguishing HLA from HPA antibodies can be approached in multiple ways depending on the clinical situation. The simplest approach is to look for the presence of platelet surface immunoglobulin, which has been shown to correlate with the platelet, corrected count increment (Rosenfeld et al, 1985). This approach may be adequate if ITP is not clinically suspected. Another approach is to do a platelet cross-matching procedure by FCM and to look for platelet reactive antibodies without distinguishing HLA from HPA antibodies (Gates and MacPherson, 1994). Such an FCM approach (Köhler et al, 1996) correlates highly with the MAIPA technique as well as with lymphocytotoxicity based assays and offers a high sensitivity and specificity. However, in certain conditions such as neonatal alloimmune thrombocytopenias it may be important to distinguish maternal HLA from HPA antibodies. The easy and inelegant method is to first identify the presence of platelet surface immunoglobulin. This is followed by treating the platelets with an acid-chloroquinine reagent to strip the HLA antigens. Any remaining reactivity is due to HPA antibodies (Marshall et al, 1994). This method requires a careful testing of the acid-stripping conditions. A more intellectually challenging approach is to use FRET flow cytometry.

3.1 Fluorescence resonance energy transfer (FRET):

The theory and wide range of clinical and research applications for FRET have been reviewed (Szollosi et al, 1998). FRET involves the radiationless transfer of energy from an excited donor molecule to an acceptor molecule under favourable conditions. In simplistic terms, once the donor fluorochrome is excited it rapidly achieves a higher vibrational state and then drops to the lowest vibrational level of the excited state. The molecule can then either decay radiatively by fluorescence or if a suitable acceptor fluorochrome is available nearby then it will not decay but rather transfer its energy to the acceptor fluorochrome. The acceptor fluorochrome will then achieve a higher vibrational level and subsequently decay radiatively (fluorescence). Two conditions must be met for this to occur. Firstly, the fluorochromes must be such

that the emission wavelength of the donor fluorochrome must be excitatory to the acceptor molecule. Secondly, the acceptor molecule must be in close vicinity (< 10 nm) to the donor fluorochrome since the rate of energy transfer is inversely proportional to the sixth power of the distance between the donor and acceptor molecules. A conceptual illustration is shown (Fig.1). If FRET occurs the intensity of donor fluorochrome is quenched (double labeled cells) compared to donor fluorochrome alone in channel 2. Conversely, the fluorescence intensity of acceptor fluorochrome is increased (double labeled cells) as compared to acceptor fluorochrome alone in channel 3. To obtain the efficiency of FRET, it is enough to calculate donor emission quenching according to the equation below (Koksch et al. 1995).

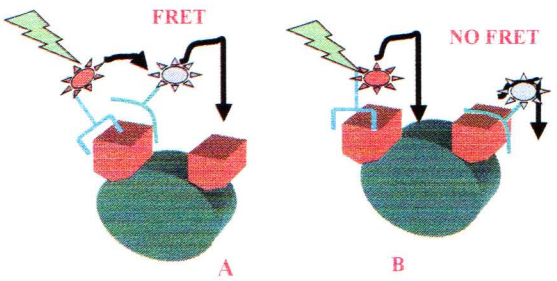

Figure 1: *Fluorescence resonance energy transfer (FRET). In (A), both the donor and the acceptor fluorochromes are closeby and FRET occurs. In (B) the donor and acceptor fluorochrome molecules are distant and FRET does not occur. FRET is inversely proportional to the sixth power of the distance between the two fluorochromes. Also the acceptor fluorochrome must be excitable by the emission wavelength of the donor but not directly at the excitation wavelength of the laser.*

$$E=1-(I_{2D+A} + I_{2A})/I_{2D}$$

E = Efficiency, D = Donor, A = Acceptor

I_2 = Fluorescence intensity in channel 2

I_{2D+A} = Fluorescence intensity of double labeled cells in channel 2

I_{2A} = Fluorescence intensity of acceptor labeled cells in channel 2

3.2 Key issues in FRET by flow cytometry:

FRET analysis can be useful in the broad characterization and differentiation of HLA class I antibodies from those directed against platelet glycoproteins or even discriminate those bound via platelet Fc receptors (Koksch et al. 1995). The antibodies against glycoproteins could be against glycoproteins such as GPIIb/IIIa or to their polymorphisms (HPA's). Typically platelets are incubated with the patient's plasma (containing the antibodies) together with unlabelled murine antibodies with known specificity (e.g. GPIIb/IIIa). In a second step the murine antibodies as well as the human antibodies are detected using secondary antibodies labeled with the donor (PE) or acceptor (Cy5) fluorochromes. If FRET occurs one can assume that the patient's antibodies react at an epitope very close to the added murine antibody and thus the identity of the human antibody can be inferred. While the above technique may appear complex it is worth noting that in most instances calculating FRET efficiency is not necessary since a visual examination of the superimposed (donor fluorochrome alone and with possible quenching) intensity curves is adequate. Koksch et al. indicate that direct staining gives essentially similar results as with the indirect staining method and in addition quantitative information regarding the antigen expression is also obtained. An important consideration is the donor-acceptor fluorochromes that can be used. One of the best is the PE/Cy5 combination since the spectral overlap can easily be corrected in the presence of FRET. Another consideration is the possible cross-reactivity of the goat anti-human and goat anti-mouse immunoglobulin sera when using indirect methods. This should be minimal with appropriate choice of sera. The authors also claim suitability for cross matching of stored platelets without loss of activation dependent antigens in the presence of suitable buffers.

4.1 Other clinical platelet assays:

For the sake of completion it is worth mentioning the use of FCM for diagnosis of heparin induced thrombocytopenia (Gordon, 1997) as well as in the analysis of storage pool disorders (Wall et al, 1995; Thom et al, 1995). These conditions are however more frequently diagnosed using other assays.

In conclusion, some of the current thinking on clinical FCM of platelets along with the possibilities and limitations has been presented.

References:

1. Ault KA, Rinder HM, Mitchell J, Carmody MB, Vary CPH, Hillman RS: The significance of platelets with increased RNA content (reticulated platelets). Am J Clin Path 98:637-646, 1992.

2. Ault KA, Knowles C: In vivo biotinylation demonstrates that reticulated platelets are the youngest platelets in curculation. Exp Hematology 23:996-1001, 1995.

3. Drouvalakis KA, Neeson PJ, Buchanan RRC: Detection of anti-phosphotidylethanolamine antibodies using flow cytometry. Cytometry 36:46-51, 1999.

4. Gates K, MacPherson BR: Retrospective evaluation of flowcytometry as a platelet cross-matching procedure. Cytometry 18:123-128, 1994.

5. Gordon N, Thom J, Cole C, Baker R: Rapid detection of hereditary and acquired platelet storage pool deficiency by flow cytometry. Brit J Haematol 89:117-123, 1995.

6. Joutsi L, Kekomäki R: Comparison of the direct platelet immunofluorescence test (direct PIFT) with a modified direct monoclonal antibody-specific immobilization of platelet antigens (direct MAIPA) in detection of platelet associated IgG. Brit J Haematol 96:204-209, 1997.

7. Kienast J, Schmitz G: Flow cytometric analysis of thiazole orange uptake by platelets: A diagnostic aid in the evaluation of thrombocytopenic disorders. Blood 75:116-121, 1990.

8. Kickler T, Kennedy SD, Braine HG: Alloimmunization to platelet-specific antigens on glycoproteins IIb-IIIa and Ib/IX in multiply transfused thrombocytopenic patients. Transfusion 30:622-625, 1990.

9. Koksch M, Rothe G, Kiefel V, Schmitz G: Fluorescence resonance energy transfer as a new method for the epitope-specific characterization of anti-platelet antibodies. J Immunol Meth 187:53-67, 1995.

10. Köhler M, Dittman J, Legler TJ, Lynen R, Humpe A, Riggert J, Neumeyer H, Pies A, Panzer S, Mayr WR: Flow cytometric detection of platelet-reactive antibodies and application in platelet cross-matching. Transfusion 36:250-255, 1996.

11. Marshall LR, Brogden FE, Roper TS, Barr AL: Antenatal platelet antibody testing by flow cytometry-results of a pilot study. Transfusion 34:961-965, 1994.

12. Matic GB, Chapman S, Zaiss M, Rothe G, Schmitz G: Whole blood analysis of reticulated platelets: Improvements of detection and assay stability. Cytometry (Clin Comm Cytometry) 34:229-234, 1998.

13. McMillan R, Tani P, Millard F, Berchtold P, Renshaw L, Woods Jr VL: Platelet-associated and plasma anti-glycoprotein autoantibodies in chronic ITP. Blood 70:1040-1045,1987.

14. Michelson AD: Flow cytometry: A clinical test of platelet function. Blood 87:4925-4936, 1996.

15. Novotny VMJ, van Doorn R, Witvliet MD, Claas FHJ, Brand A: Occurrence of allogeneic HLA and non-HLA antibodies after transfusion of prestorage filtered platelets and red blood cells: A prospective study: Blood 85:1736-1741, 1995.

16. Romp KG, Peters WP, Hoffman R: Reticulated platelet counts in patients undergoing autologous bone marrow transplantation:an aid in assessing marrow recovery. Am J Hematol 46:319-324, 1994.

17. Rosenfeld CS, Bodensteiner DC: Detection of platelet antibodies by flow cytometry. J Clin Path 85:207-212, 1986.

18. Schmitz G, Rothe G, Ruf A, Barlage S, Tschöpe D, Clemetson, KJ, Goodall AH, Michelson AD, Nurden AT, Shankey TV. European working group on clinical cell analysis: Consensus protocol for the flow cytometric characterization of platelet function. Thromb Haemost 79:885-96, 1998.

19. Slichter SJ et al: Leukocyte reduction and ultraviolet B irradiation of platelets to prevent alloimmunization and refractoriness to platelet transfusions. N Engl J Med 337:1861-69, 1997.

20. Stockelberg D, Hou M, Jacobsson S, Kutti J, Wadenvik H: Detection of platelet antibodies in chronic idiopathic thrombocytopenic purpura (ITP). A comparative study using flow cytometry, a whole platelet ELISA, and an antigen capture ELISA. Eur J Haematol 56:72-77, 1996.

21. Szollosi J, Damjanovich S, Matyus: Application of fluorescence resonance energy transfer in the clinical laboratory: routine and research. Cytometry (Comm Clin Cytometry) 34:159-179, 1998.

22. Tarnok A, Mahnke A, Müller M, Zotz RJ: Rapid in vitro biocompatibility assay of endovascular stents by flow cytometry using platelet activation and platelet leukocyte aggregation. Cytometry (Comm Clin Cytometry) 38:30-39, 1999.

23. Tomer A: A sensitive and specific functional flow cytometric assay for the diagnosis of heparin-induced thrombocytopenia. Brit J Haematol 98:648-656,1997.

24. Wadenvik H, Stockelberg D, Hou M: Platelet proteins as auto antibody targets in idiopathic thrombocytopenic purpura. Acta Paediatr Suppl 424:26-36, 1998.

25. Wall JE, Buiks-Wilts M, Arnold JT, Wang W, White MM, Jennings LK, Jackson CW: A flow cytometric assay using mepacrine for study of uptake and release of platelet dense granule contents. Brit J Haematol 89:380-385, 1995.

26. Winiarski J: Measurement of platelet antibodies: where do we stand ?. Acta Paediatr Suppl 424:51-53, 1998.

Styrelsen för Föreningen för Klinisk Kemi i Finland 2000

Ordförande:
Sjukhuskemist Päivi Laitinen, FD
Endokrinologiskt laboratorium
Uleåborg universitetssjukhus
FIN-90220 Uleåborg
Tel: +358,8,3154430
Fax: +358,8,3154451
E-post: paivi.laitinen@ppshp.fi

Vice ordförande:
Överläkare Tiina Mäki, MD
Laboratoriet
Jorvi Sjukhus
Åbovägen 150
FIN-02740 Esbo
Tel: +358,19,8611
Fax: +358,19,8615900
E-post: tiina.maki@jorvi.ushp.fi

Sekreterare:
Sjukhuskemist Jaana Toivanen, FM
Klinisk-kemisk avdelning
Västerbottens centralsjukhus
FIN-94100 Kemi
Tel: +358,16,243643
Fax: +358,16,243657
E-post: jaana.toivanen@lpks.fi

Ekonom:
Sjukhuskemist Matti Laitinen, FD, Docent
Klinisk-kemisk avdelning
Kuopio universitetssjukhus
FIN-70210 Kuopio
Tel: +358,17,173159
Fax: +358,17,173200
E-post: matti.laitinen@kuh.fi

Medlemmar:
Doktor Jarkko Ihalainen, MD
Hematologiskt laboratorium
Mejlans sjukhus
Helsingfors Universitetscentralsjukhus
FIN-00290 Helsingfors
Tel: +358,9,47174474
Fax: +358,9,47174065
E-post: jarkko.ihalainen@huch.fi

Doktor Tomi Koski, MD
Klinisk-kemisk avdelning
Tammerfors universitetssjukhus
FIN-33520 Tammerfors
Tel: +358,3,2474997
Fax: +358,3,2475554
E-post: tomi.koski@tays.fi

Huvudkemist Kari Mattila, Docent
Centrallaboratoriet
Åbo universitetssjukhus
FIN-20520 Åbo
Tel: +358,2,2611912
Fax: +358,2,2613920
E-post: kari.mattila@tyks.fi

Styrelsen för det isländska sällskapet för laboratoriemedicin

Elín Ólafsdóttir, læge, MSc (formand)
Department of Clinical Biochemistry
Landspitalinn, University Hospital
IS-101 Reykjavik
Tlf: +354 560 1838
Fax: + 354 560 1810
E-post: elino@rsp.is

Ólöf Sigurdardóttir, læge, PhD
Department of Clinical Chemistry
Reykjavik Hospital, Fossvogi
IS-108 Reykjavik
Tlf: +354 525 1000
Fax: + 354 525 1472
E-post: olsi@shr.is

Leifur Franzson, cand. pharm.
Department of Clinical Chemistry
Reykjavik Hospital, Fossvogi
IS-108 Reykjavik
Tlf: +354 525 1000
Fax: + 354 525 1472
E-post: leifurfr@shr.is

Gunnar Sigurdsson, professor i medicine, dr.med.
Department of Medicine
Reykjavik Hospital, Fossvogi
IS-108 Reykjavik
Tlf: +354 525 1000
Fax: + 354 525 1552
E-post: gunnars@shr.is

SFKK:s styrelse 2000

Vid SFKK's årsmöte 1 december 1999 valdes följande styrelse och revisorer:

Ordförande	Elvar Theodorsson, Laboratoriet för klinisk kemi, Universitetssjukhuset, 581 85 LINKÖPING Arb tfn o fax 013-22 32 95, alt fax 013-22 32 40 E-mail elvar.theodorsson@klk.liu.se
Vice ordförande	Lennart Nordström, Klin kem lab, Centralsjukhuset 651 85 KARLSTAD Arb tfn 054-10 60 52, fax 054-15 18 40 E-mail lennart.nordstrom@centrala.liv.se
Sekreterare och riksstämmesekreterare	Bodil Olander, Klinisk kemi, Danderyds sjukhus, 182 88 DANDERYD Arb tfn 08-655 72 42, fax 08-753 02 83 E-mail bodil.olander@kem.ds.sll.se
Skattmästare	Rosanne Forberg, Klin kem lab, Centrallasarettet, 721 89 VÄSTERÅS Arb tfn 021-17 35 49 alt 48, fax 021-17 36 00 E-mail rosanne.forberg@ltvastmanland.se
Vetenskaplig sekreterare/ redaktör	Per Simonsson, Klin kem avd, Universitetssjukhuset MAS, 205 02 MALMÖ Arb tfn 040-33 14 59, fax 040-33 62 86 E-mail per.simonsson@klkemi.mas.lu.se
Ledamot	Britta Landin, Kem kem lab C174, Huddinge sjukhus, 141 86 HUDDINGE Arb tfn 08-585 812 36, fax 08-585 812 60 E-mail britta.landin@chemlab.hs.sll.se
Ledamot	Kurt Karlsson, Klin kem lab, Regionsjukhuset 901 85 UMEÅ Arb tfn 090-785 12 72, fax 090-77 81 97 E-mail kurt.karlsson@klinkemi.umu.se
Suppleant	Per-Olof Forsberg, Avd f klinisk kemi, BLS 371 95 KARLSKRONA Arb tfn 0455-73 45 61. 0455-73 45 70 (exp), fax 0455-824 05 E-mail per-olof.forsberg@ltblekinge.se
Suppleant	Anders Larsson, Avd för klinisk kemi, Akademiska sjukhuset 751 85 UPPSALA Arb tfn 018-66 42 71, fax 018-55 25 62 E-mail anders.larsson@clinchem.uas.se

Förförande idéer – avhandling om ackreditering och kvalitetssäkring

PER SIMONSSON
Klinisk kemisk avd, Universitetssjukhuset MAS Malmö, Sverige

Gudbjörg Erlingsdóttir, Förförande idéer – kvalitetssäkring i hälso- och sjukvården, Företagsekonomiska institutionen, Ekonomihögskolan, Lunds universitet 1999.

Det skrivs många avhandlingar i klinisk kemi. Det är glädjande. Men det skrivs sällan några avhandlingar *om* klinisk kemi. Det är synd. Men nu har Gudbjörg Erlingsdóttir vid företagsekonomiska institutionen vid Lunds universitet gjort ett intressant försök. Hennes studieobjekt är vår ackreditering.

Nu är inte Gudbjörg Erlingsdóttir primärt intresserad av dokumentstyrning eller metodvalidering. Egentligen är hon inte intresserad av kvalitetssäkring alls. Hon skriver sin avhandling om sjukvårdens kvalitetsarbete under 90-talet utifrån ett organisationsteoretiskt perspektiv. Hur växer sig en spirande idé stark och blir en etablerad institution?

För så har det skett med ackrediteringen. Från Sahlgrenska pilotförsök för ett decennium sedan, via några entusiasters grundarbete tillsammans med SWEDAC och nu ett system som engagerar merparten av Sveriges lab. Under denna korta tid har de idéer som fanns inom sjukvården kring 1990 blivit till lag. Det krävs nu att systematisk kvalitetssäkring finns i alla svensk sjukvård. Utvecklingen från idé till institution har därmed gått snabbt.

Gudbjörg Erlingsdóttir gjorde fältstudier vid Universitetssjukhuset i Lund 1994-5. Utrustad med anteckningsbok och en socialantropologs nyfikna blick studerade hon två somatiska avdelningar samt kliniskt kemiskt laboratorium. Dåvarande chefen Göran Fex gav henne fritt tillträde till laboratoriets alla delar och hon kunde se ackrediteringsarbetet inifrån. Hon ville studera hur de nya kvalitetsidéerna slog rot i verksamheten.

Inom klinisk sjukvård gjorde man då ett – temporärt – försök med King´s Funds Organisationsgranskning, ett rätt övergripande kvalitetssystem som initierades av sjukhusledningen. På kliniskt kemiskt laboratorium, däremot, hade man själv initierat en ackrediteringsprocess, inspirerade av andra labkollegors framgångsrika ansatser.

Gudbjörg Erlingsdóttir ger en för klinisk kemi i allmänhet (och lab i Lund i synnerhet) positiv bild. Medan somatikens system var toppstyrt och svårt att applicera på vardagen visade sig ackrediteringen förståeligt. EN 45 001 ansluter till företagskulturen i klinisk kemi, vana som vi är vid att mäta och dokumentera. Hon visar också i sin avhandling en bild av stort engagemang från många på lab.

Det är givande att läsa en utomståendes reseskildring från våra rätt besynnerliga hemtrakter. Om hur BMA samlas kring en maskin som påminner om en framkallningsapparat och som också går under namnet Kodak. Hur arbetet hos oss är organiserat, hur självständiga och icke-hierarktisk hon trots allt uppfattar arbetet i vår disciplin. Igenkännandets leende spelar ofta på läsarens läppar. Som när hon skrivet om läkarna på lab: "i övrigt var läkarna mestadels en frånvarande chef som trots allt hade det slutgiltiga ansvaret".

Anmeldelse af Spri rapport 461: "At påverka praxis - klinisk kemi i primärvården".

PER GRINSTED
almen læge og praksiskonsulent på Afdeling KKA (klinisk biokemi) Odense, Danmark

Spri-rapport 461, ISSN 0586
Pris: 110 Skr exkl moms
Hälso- och sjukvårdens utvecklingsinstitut
Hornsgatan 20, Box 70487
107 26 Stockholm
http://www.spri.se

Sverige og Spri har gjort det igen

Spri rapporten er forbilledlig for al klinisk kemi i primærsektoren og i samarbejdet mellem primær- og sekundærsektoren i Norden.

Spri rapporten er overskuelig og pædagogisk skrevet med relevante afsnit og med flotte referencer. Rapporten giver sit største udbytte ved at læse den i sin helhed, hvilket også er overkommeligt.

På baggrund af den udvikling, der gælder diagnostiske metoder specielt i primærsektoren, er det livgivende at stifte bekendtskab med denne rapport og den bør være "lærebog" i alle de nordiske lande i de bestræbelser, der er på at udbygge samarbejdet mellem almen praksis og sygehuslaboratorierne. I rapporten tages der fat såvel på kvalitetssikringen som på hele efteruddannelsesproblematikken. Det, der er utrolig spændende med Spri rapporterne, er, at man tør vove sig ind i at påpege, hvilke analyser der skal minimeres i ordinationsantal og hvilke analyser der foreslås at blive øget i antal i den daglige klinik.

Denne Spri rapport er en fortsættelse og ajourføring af Spri rapporten 422 "Klinisk kemi i primärvården", som tidligere er udgivet.

I rapporten påpeges det vigtige i, at der som led i efteruddannelsen bygges på medicinske nøgletal og at efteruddannelsen hviler på gensidig tæt samarbejde mellem specialisterne og almen lægerne.

Et yderligere centralt punkt i rapporten er diskussionen omkring, hvor vanskeligt det er at implementere kundskaber. Det påpeges, hvor vigtigt det er, at kundskaberne bygger på evidensbaseret viden, hvor det overhovedet er muligt, at implementeringen skal være en naturlig integreret del af hvert enkelt vårdprogram. Alle, der arbejder med udvikling indenfor sundhedsvæsenet, ved, hvor vanskeligt det er at implementere ny viden - at ændre adfærd (beteende). I rapporten lægges der vægt på, at der gennem samarbejde, koordinering og efteruddannelse skal ske en påvirkning af den medicinske praksis for at kunne bibeholde god kvalitet i sundhedsvæsenet med de tiltagende økonomiske stramninger, der sker. Der påpeges i rapporten, hvor væsentligt det er, at alle forstår, hvilke faktorer der har betydning for lægernes medicinske beslutningsproces. Rapporten vil være et godt baggrundsmateriale, når der lokalt i hvert enkelt land skal arbejdes med kvalitetsudvikling og kvalitetssikring.

Rapporten giver eksempler på forskellige udviklingstendenser, som er foregået forskellige steder i Sverige.

Det centrale i rapporten er beskrivelsen af, hvordan man påvirker daglige rutiner såvel indenfor som udenfor sygehusvæsenet. Alle tidligere undersøgelser har vist, at der er en utrolig variation og spredning mellem de enkelte almen læger, mellem specialister indenfor samme speciale og mellem forskellige sygehuse. Forskelligheden dækker hele spektret indenfor ordinationsmønster, rekvireringen af laboratorieanalyser, udskrivning af medicin, ordination af røntgenundersøgelser osv.

De 4 væsentligste faktorer, der påvirker dagligе rutiner, omtales og diskuteres. De 4 hovedfaktorer er:

• De patientrelaterede faktorer.
• De faktorer, der er relateret til ressourcerne og organisationen.
• De faktorer, der er relateret til behandlingstraditionerne.
• De lægebundne faktorer. Det drejer sig primært om den enkelte læge er sygdoms- eller patientorienteret.

Som tidligere omtalt vil denne Spri rapport være en central informationskilde for alle de personer, der arbejder med laboratoriekonsulentordninger. I Danmark skal der udarbejdes kvalitetssikringssystemer og laboratoriekonsulentordninger i alle regioner og her vil Spri rapporten være et værdifuldt grundlag.

Til sidst i rapporten gennemgås så de enkelte analyser set i lyset af, hvilke analyser der skal mindskes i antal og hvilke analyser der bør nyde fremme og som bør øges i antal for at få bedst mulig faglig viden af laboratoriemedicin.

Spri rapport 461 kan så absolut anbefales til alle indenfor klinisk kemi, som arbejder tæt sammen med primærsektoren. På samme måde er Spri rapporten værdifuld læsning for de almen læger, der har involveret sig i kvalitetsudvikling og kvalitetssikring indenfor laboratoriemedicin, og her skal laboratoriemedicin forstås bredt, idet bl.a. også klinisk mikrobiologi er indbefattet.

Spri rapporten vil få min varmeste anbefaling til brug i alle de nordiske lande.

Möteskalender

Ansvarig: Ilkka Pentillä, Kuopio, fax +358 17 17 32 00

e-post: ilkka.penttila@uku.fi

Möten i Danmark
11. 2. 2000
DSKK møde nr. 357: Biokemiske markører ved akut myokardiesyndrom.
Frederiksberg Hospital, København
Information: http:/www.dskk.dk

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Information: http:/www.aacc.org /meetings/default.stm

Möten i Finland
11.2. – 12.2. 2000
Labquality Days 2000, Marina Congress Center, Helsinfors
Information: e-post: ritva.huovinen@labquality.fi

6.4. – 7.4. 2000
FKKF:s vårmöte: Aktuella och bestående hormonanalyser, Fiskartorpet, Helsingfors
Information: e-post: päivi.laitinen@ppshpfi

6.5. - 10.5. 2000
27th Symposium on Calcified Tissues, Tampere, Finland; CongCreator CC, P.O.Box 762, FIN-00101 Helsinki, Finland, fax: +358,9,492810,
e-post: secretariat@congcreator.com,
http://www.congcreator.com/calcified-tissues

Möten i Norge
4.6.-8.6.2000
XXVII Nordiske kongress i klinisk kjemi, Bergen
Information: Kongressekretariat, Travel Planners of Scandinavia AS, Bergen, Norway, fax +47,55,231768, e-post:harald.riisnaes@travel-planners.no, http://www.uib.no/med/lkb/kongr.html

Möten i Sverige
16. 3. – 17.3. 2000
Equalis anvädarmöte, hematologi
Information: e-post: kristoffer.hellsing@equalis.se

23.3. – 24.3. 2000
Equalis användarmöte, klinisk mikrobiologi
Information: e-post: kristoffer.hellsing@equalis.se

6.4. – 7.4. 2000
Equalis användarmöte, koagulation
Information: e-post: kristoffer.hellsing@equalis.se

4.5. – 5.5. 2000
Equalis användarmöte, proteinanalyser
Information: e-post: kristoffer.hellsing@equalis.se

10.5. – 12.5. 2000
SKKK:s vårmöte i klinisk kemi, Huddinge
Information: Bodil Olander, fax +46,8,7530283, e-post: bodil.olander@kem.ds.sll.se

25.6. - 29.6. 2000
XII International Symposium on Atheroslerosis, Stockholm
Information: Bodil Olander, fax +46,8,7530283, email: bodil.olander@kem.ds.sll.se

29.11. – 1.12. 2000
Riksstämman 2000, Göteborg
Information: Bodil Olander, fax +46,8,7530283, email: bodil.olander@kem.ds.sll.se

Innehåll i Klinisk Kemi i Norden Volym 11, 1999

Artiklar och meddelanden

Bokanmälan

Från NFKK och dess styrelse

Från de kliniskt kemiska föreningarna i Norden

Innehållsförteckning

Kollegialt

Kongresser och möten

Produktnyt

Nordisk förening för Klinisk Kemi (NFKK)

NFKK har som syfte att verka för utvecklingen av klinisk kemi, särskilt nordiskt samarbete inom forskning, utveckling och utbildning. Den består av medlemmarna i de vetenskapliga föreningarna för klinisk kemi i Danmark, Finland, Island, Norge och Sverige. Verksamheten i NFKK bedrivs i olika arbetsgrupper och kommittéer, t ex arbetsgruppen för utbildningsfrågor. Föreningen har det vetenskapliga ansvaret för Scandinavian Journal of Clinical and Laboratory Investigation (SJCLI) och står dessutom för arrangerandet av de nordiska kongresserna i klinisk kemi.

Styrelsen består av Ebba Nexø (ordförande) och Holger J. Møller (sekreterare) samt från Danmark: Sten Sørensen, Hvidovre och Palle Wang, Kolding; från Finland: Marjaana Ellfolk, Helsingfors och Päivi Laitinen, Uleåborg; från Island Leifur Franzson, Reykjavik och Elin Olafsdottir, Reykjavik; från Norge: Kristian Bjerve, Trondheim och Petter Urdal, Oslo; från Sverige: Per Simonsson, Malmö och Gunnar Skude, Halmstad .

Styrelsens adress är:

NFKK, Klinisk Biokemisk Afdeling KH, Århus Kommunehospital, DK-8000 Århus C, Danmark, tel +45 89 49 30 82, fax +45 89 49 30 60

TILL MANUSKRIPTFÖRFATTARE

Bidrag till KLINISK KEMI I NORDEN sändes i två exemplar till den nationella redaktören, som finns angiven på omslagets andra sida. Manuskripten skall vara maskinskrivna och följa de instruktioner som angetts i Vancouver-avtalet (Nordisk Medicin 1988; 103:93–6). Språket skall vara nordiskt.

Meddelanden och korta inlägg skrives helst fortlöpande, medan längre artiklar med fördel delas i avsnitt med en kort överskrift.

Tabeller skrives på särskilda ark tillsammans med en text, som gör tabellen självförklarande.

Figurer måste vara av tekniskt god kvalitet med text och symboler tillräckligt stora för att tåla förminskning. Till varje figur skrives en förklarande text.

Litteraturhänvisningar numreras i den ordning de anges i texten och skrives som i följande exempel.

Sandberg S, Christensen NB, Thue G, Lund PK. Performance of dry-chemistry instruments in primary health care. Scand J Clin Lab Invest 1989; 49:483–8.

Innehållet i de insända artiklarna kommer inte att genomgå vanlig granskning med referee-system. Redaktionskommittén kommer emellertid att värdera alla manuskript innehållsmässigt och redaktionellt och eventuellt föreslå ändringar.

FYRIS-TRYCK AB, UPPSALA