USC Workshop, Los Angeles, July 30-31, 2004.

AN INTRODUCTORY AND ADVANCED HANDS-ON COURSE IN THERAPEUTIC DRUG MONITORING AND MODEL-BASED, GOAL-ORIENTED INDIVIDUALIZED DRUG THERAPY.

FRIDAY & SATURDAY, JULY 30-31, 2004. FINAL PROGRAM

This course is intended for physicians, pharmacists, clinical toxicologists and biomedical scientists, at a beginning or advanced level, who have an interest in population pharmacokinetic and pharmacodynamic modeling and in therapeutic drug monitoring and optimal individualization of drug therapy for patient care. Prior experience in clinical pharmacokinetics will be an advantage. Participants will be introduced to the USC*PACK software programs which can be used both for therapeutic drug monitoring as well as for parametric and nonparametric population PK/PD and physiological modeling.

Location: Computer Classroom, 3rd floor, USC School of Pharmacy, 1985 Zonal Ave, Los Angeles, CA. For more information, and for registration, contact

Roger Jelliffe, MD, USC School of Medicine,
2250 Alcazar St, Los Angeles CA 90033,
tel 323-442-1300, fax 323-4442-1302, email jelliffe@usc.edu

Registration Form - I wish to register to attend the USC Workshop

Registration fee: $495.00 for those in academia or hospitals, $695 for those in industry. Amount sent: $_____
I will_____Will not_____attend the Get - Together Dinner Friday night
I will_____Will not bring _____guest(s)

We can handle checks and foreign travelers checks in US dollars, and electronic bank transfers (please ask for info). We can handle credit cards through Paypal. Sorry, no purchase orders.

Please make checks to: Laboratory of Applied Pharmacokinetics

Name of Registrant _____
Institution_____
Address_____
City, State, Zip_____
Country_____
Phone (____)_____Fax (____)_____
Email _____

Please print and fax this form to 323-442-1302, or return it, with your check, to:

Roger W. Jelliffe, M.D.
Laboratory of Applied Pharmacokinetics, USC School of Medicine
2250 Alcazar Street, CSC 134-B, Los Angeles, CA 90033
Phone (323)442-1300, Fax (323) 442-1302. Email jelliffe@usc.edu

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Please register early. First come are first served. Registration is limited to the spaces available. Cancellations must be received by July 15, 2004, to obtain a refund.

I would _____ would not _____ also like to receive information about the USC software.

Objectives and Expectations:

After this conference, the participant should:

1. Be able to understand the basic pharmacokinetic behavior of drugs in patients.
2. Be able to design optimal initial individualized dosage regimens of drugs to hit selected target goals most precisely.
3. Be able to enter and store patient data of doses, TDM serum concentrations, etc., and to make an individualized model of drug behavior in that patient.
4. Be able to develop an adjusted dosage regimen based on the patient's individualized model.
5. Understand how to apply these techniques to therapy with other TDM drugs such as Vancomycin, Digoxin, anticonvulsants, and drugs for AIDS, cancer, and transplants.
6. Understand the basic concepts of parametric and nonparametric population PK/PD modeling.
7. Know how to develop the error polynomial for a drug assay, to fit each data point by an optimal measure of its credibility.
8. Be able to make population models of common drugs
9. Understand the basic concepts of multiple model dosage design.

Faculty:

Dr. Roger Jelliffe, USC Laboratory of Applied Pharmacokinetics, Los Angeles CA, Course coordinator.
Dr. David Bayard, Senior Scientist, Guidance and Control Section, Jet Propulsion Laboratory, Pasadena CA
Dr. Paul Beringer, USC School of Pharmacy, Los Angeles CA, Course Co-coordinator.
Dr. Robert Leary, San Diego Supercomputer Center, San Diego, CA
Dr. Michael Neely, USC Laboratory of Applied Pharmacokinetics, Los Angeles CA
Dr. Alan Schumitzky, Department of Mathematics, USC

Speaker Disclosures

Dr. Beringer receives grant/research support from Pharmacia.

Drs. Beringer, Jelliffe, Neely, and Schumitzky are on the faculty of the University of Southern California*.

Drs. Bayard and Leary do not have any financial relationships to disclose.

* None of the faculty receive money from the donations made to obtain a license to use the USC*PACK and the MM-USCPACK software.

Continuing Education Information

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of American Association of Clinical Chemistry (AACC) and the University of Southern California Laboratory of Applied Pharmacokinetics. AACC is accredited by the ACCME to provide continuing medical education for physicians.

AACC designates this educational activity for up to fifteen (15.0) Category 1 credits towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spends in the educational activity

This program is also approved by AACC for up to fifteen (15.0) Category 1 ACCENT© credit hours towards the Clinical Chemist's Recognition Award. The AACC is an approved provider of continuing education for the states of California, Florida, Louisiana, Montana, Nevada, North Dakota, Rhode Island, and West Virginia.

Friday July 30 - Beginning: Basic Concepts, Building Blocks, and Tools

8:30 AM - Registration
9:00 AM - Welcome - Dr. Jelliffe
9:15 AM – PK Building Blocks - Ways of fitting pharmacokinetic data – Dr. Jelliffe
- Linear Regression
- Nonlinear Regression
- MAP Bayesian fitting
- Multiple Model (MM) Bayesian
- Parametric Population Modeling
- Nonparametric Population Modeling

10:00 AM – PK Building Blocks - Evaluating Creatinine Clearance Dr. Jelliffe
10:15 AM – PK Building Blocks - Determining the Assay Error Pattern – Dr. Jelliffe

10:30 AM BREAK

10:45 AM - PK Building Blocks - Bayes' Theorem – its use with parametric and nonparametric PK/PD models - the Bayesian scenario of planning, monitoring, and adjusting drug dosage regimens for patients. - Dr. Jelliffe
11:15 AM – PK Building Blocks - When to get serum samples for TDM – Dr. Jelliffe
11:30 AM - Introduction to the new MM-USC*PACK Nonparametric Bayesian Clinical Program for Optimally Precise Tracking of Drug Behavior and Optimally Precise Dosage.
A Patient on Gentamicin
11:45 AM - Modeling diffusion into endocardial vegetations, and the postantibiotic effect - Dr. Jelliffe
12:00 noon - Modeling bacterial growth and kill - Dr. Jelliffe.

12:30 PM – Lunch

1:30 PM – Parametric and Nonparametric Population Modeling – Dr. Schumitzky
2:15 PM - A Survey of Population PK Methodologies - Dr. Leary
3:00 PM – Multiple Model Dosage Design – Dr. Bayard

3:30 PM Break

3:45 PM –Antifungal Therapy and TDM – Dr. Michael Neely
4:15 PM - General Guidelines for making, validating, and comparing population PK/PD Models – Dr. Jelliffe
Weighting the data appropriately. Fitting the data – comparing methods.
Validating models – what does this involve?
Comparing patient populations – how to do this. Likelihoods, correlations.
4:45 PM – Comparing Results – Parametric and Nonparametric Methods – Dr. Jelliffe
5:30 PM – Adjourn

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A Friday evening get - together and dinner at the USC Faculty Center

No - host cocktails ---------- 6:00 PM

Dinner ---------- 7:00 PM

Our Guest Dinner Speaker

"Azithromycin Therapy in Patients with Cystic Fibrosis"

Dr. Paul Beringer
USC School of Pharmacy

Saturday July 31 - Advanced: Hands-on Population Modeling and Patient Care

8:30 AM – Bioavailability of Oral Linezolid in Tube Fed Patients - Dr. Beringer
9:00 AM – Hands on:The Nonparametric Population Program - Dr. Jelliffe
The new NPAG: NPEM with an Adaptive Grid
Amikacin further. Using gamma, ranges. Evaluating the results: the log-likelihood function, and descriptors of dispersion :
The 2 and 3-D plots of the marginal and joint marginal PDF's
Linking Nonparametric Models to Multiple Model Adaptive Control
Deriving individual Bayesian posterior patient parameter joint densities
Relationships between parameters and covariates

10:30 AM - Break

11:00 AM – Hands-on: Using the BOXES program to make large and nonlinear PK/PD Models – Dr. Jelliffe
11:15 AM – Hands-on: Big NPEM: Modelling Piperacillin - Dr. Jelliffe
Using gamma, ranges

12:00 Noon Lunch

1:00 PM – Hands-on session – Determining the Assay Error Pattern
1:15 PM – Hands-on session - Estimating Creatinine Clearance without the Urine Specimen
1:30 PM - Hands-on session - Making an NPAG Model of Amikacin – Dr. Jelliffe
2:15 PM - Hands-on session: Making a Michaelis-Menten NPAG Model of Piperacillin – Dr. Jelliffe

3:00 PM – Break

3:15 PM - How to Plan, Monitor, and Adjust Individualized Drug Dosage Regimens for Patients.
Set a target goal for each patient according to the need for the drug.
Aminoglycosides 10 and 1, or 20 and 0.5
Vancomycin trough 10
Digoxin – really a 2 compartment model
Clinical effect correlates better with tissue than serum concentrations
How to manage this problem clinically
Serum troughs usually 0.9 ng/ml
Peripheral peaks usually 7.0 ug/kg
Patients with atrial fibrillation need more
3:30 PM – Hands-on session: Two Patients on Digoxin
4:15 PM – Hands-on session: Case Studies in Aminoglycoside Therapy
5:00 PM - Hands-on session: Case Studies in Vancomycin Therapy
5:30 PM – Adjourn

More general information

The course will be given in the third floor Computer Classroom of the USC School of Pharmacy on the USC Health Sciences Campus, 1985 Zonal Ave., Los Angeles CA 90033. Note that the USC Health Sciences Campus is not downtown at the USC main campus, but rather is near the Los Angeles County/USC Medical Center. It is near the corner of Zonal Ave and Biggy Street on the map.

Go to our web site. (www.lapk.org. Click on ”About us”, scroll down to “Contact information”, then to “Map and Directions”. You may wish to fly to Burbank rather than LAX. It is closer and less congested. Rent a car or get a van at the airport. It will be cheaper than taxi fares.

As to accommodations, it is probably best to stay either downtown, at the Bonaventure, Omni, or Sheraton Grande, or in Pasadena. I live in Pasadena, close to the Saga Motel, 1633 Colorado Boulevard. Its phone number is 626-795-0431, and fax number is 626-792-0559. It is about $65.00 per night single, or $75.00 double, and has a nice continental breakfast, free. If you make a reservation, by fax, for example, mention "Dr. Jelliffe's USC Workshop" to get that rate. I can easily pick you up in the morning and take you to and from the workshop, and be your wheels, unless you would also like to have your own car.

From the Saga to the USC Health Sciences Campus, go West on Colorado Blvd. to Arroyo Blvd., then South to Glenarm, where it becomes the Pasadena Freeway. Take the freeway Southwest for about 7 miles, then turn South on Route 5, the Golden State Freeway. Get off at Mission (2nd off-ramp). Turn left under the freeway, go about 3 traffic lights, turn right on Zonal, then left on Biggy St. (in front of the large parking structure) then right into that large parking structure. Tell the parking attendant you are here for the PK Workshop. Parking should be free. Walk East to the large open area, then turn right to the John Stauffer Pharmaceutical Sciences Center (the USC School of Pharmacy). Take the elevator to the basement, turn to the East, and the computer classroom is the first door on the right.

If you would also like to obtain the USC*PACK programs, they can be separately obtained at the workshop, and we will be happy to help you install them and get them going on your machine during the breaks in the workshop. Note that not all programs run on Windows XP. All programs run on Windows 95, 98, and NT.

The USC*PACK and MM-USCPACK software is made available by license from the University. The requested donations for these two packages, whether or not you are already a USC*PACK user, are:

Hospital or Academic Institution	Commercial or Industry
$595.00	$895.00

We are anxious to have your feedback. Please speak up at any time during the course. Please write, call me at 323-442-1300, or email me (jelliffe@usc.edu) if you have any questions or problems. If you should need to cancel, you must do so by July 15, 2004, to obtain a refund. We look forward to seeing having you with us.

Sincerely,

Roger W. Jelliffe, M.D., Professor of Medicine,
Paul Beringer, Pharm.D., Associate Professor of Clinical Pharmacy
Course Coordinators