Methods for maximally precise individualization of drug therapy

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This workshop is intended for physicians, pharmacists, clinical toxicologists and biomedical scientists with an interest in Therapeutic Drug Monitoring (TDM), and in optimal individualization of drug therapy for best patient care. Prior experience in clinical pharmacokinetics will be an advantage. Participants will be introduced to the USC Best dose clinical software, which will be compared and contrasted with other approaches. This library of software tools now provides maximally precise methods for clinical therapeutic drug management.

Objectives and Expectations:
1. Describe the General approach to Target-Oriented, Model Based, and Individualized Drug Therapy.
2. Discuss the Clinical capabilities of Nonparametric Population Modeling, and compare it with similar parametric approaches.
3. Explain the need for using assay standard deviation rather than CV% in reporting lab errors.
4. Explain Multiple Model, maximally precise, Dosage Design.
5. Describe the Interacting Multiple Model (IMM) method of sequential Bayesian individualization of Pharmacokinetic Models, and when and how to use them.
6. Summarize the features of models of bacterial growth and kill
7. Explain the new approaches to optimize TDM protocols for best learning about the patient while treating him/her at the same time.
8. Discuss improved outcomes using Bayesian adaptive control.
9. Apply these concepts to optimize practical therapy with Aminoglycosides, Vancomycin, Digoxin, and other drugs.

Individualized Drug Therapy: Example of Antimicrobial Therapy – Dr. Noreddin

Tools for Optimizing Individualized Drug Therapy - Dr. Jelliffe

Tool #1 – Nonparametric Population Pharmacokinetic/dynamic Models
Tool #2 – Multiple Model (MM) Dosage Design
Tool #3 – Correct Description of assay errors – reciprocal of assay variance, Not CV%
Tool #4 – Estimating Creatinine Clearance from changing, not stable, Serum creatinine measurements
Tool #5 – Optimizing protocols for Therapeutic Drug Monitoring
Tool #6 – Optimizing Individualized therapy of acutely ill and Unstable ICU patients.

Improved outcomes with Individualized Therapy – Dr. Jelliffe, Dr. Noreddin

Biography

Ayman Noreddin received his PhD in Pharmaceutical Sciences from the University of the Pacific, California and received research training as a visiting scholar at the Department of Medicine, Stanford University. He had Post-doctoral fellowship (Pharmacokinetics and Pharmacodynamics of Antimicrobials), Department of Medical Microbiology, University of Manitoba followed by an American College of Clinical Pharmacy postdoctoral fellowship (Infectious Diseases). His research interest includes Pharmacokinetic/Pharmacodynamic modeling of anti-infective and anti-cancer therapy, clinical simulation and Monte Carlo analysis and bacterial resistance in biofilm studies. He has outstanding records of scientific and academic accomplishments with multiple research funding, numerous publications in highly prestigious journals and various presentations in both national and international conferences. He served as a scientific reviewer for the NIH as well as other national and international research institutions.

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Roger Jelliffe MD, FCP, FAAPS, developed the first computer software for individualizing drug dosage regimens in 1967. He was the first to relate renal drug elimination to creatinine clearance. He developed the first method for estimating creatinine clearance when serum creatinine is changing. He founded the USC Laboratory of Applied Pharmacokinetics in 1973, and the USC*PACK and more recent MM-USCPACK clinical software for individualizing drug dosage regimens most precisely. His laboratory developed the Resource for Population Modeling at the San Diego Supercomputer Center, the nonparametric adaptive grid (NPAG) population modeling approach, and Multiple Model (MM) design of maximally precise dosage regimens. This is now the Bestdose clinical and Pmetrics research software. We have developed three new methods of Bayesian analysis for individual patients. This adds great capability and safety in managing unusual patients. He is author or co-author of 132 peer reviewed publications, has mentored over 100 visiting scientific scholars, 1 sabbatical scholar, 2 Master’s Students, 3 Ph.D candidates, and 3 mini-sabbaticals.

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