Clinical Pharmacy-2013

OMICS Group Conferences
Accelerating Scientific Discovery

International Summit on
Clinical Pharmacy & Dispensing

November 18-20, 2013 San Antonio, Texas, USA

The new pharmacokinetics, therapeutic drug monitoring, and optimal drug dosage individualization (DDI): Social, hospital, economic, and cultural considerations

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Abstract

Current pharmacokinetic (PK) teaching in many pharmacy schools is often done at the level of "Basic PK" for those who will use this training for patient care. It still often uses 1 compartment linear models, and fits data by linear regression on the logarithms of the serum concentrations. However, much has gone on the last 40 years. Maximum aposteriori probability (MAP) Bayesian analysis has made significant improvements in patient care, reducing mortality, morbidity, patient stay in hospitals, and costs, especially for digoxin, lidocaine, aminoglycosides, vancomycin, busulfan, and cyclosporine,These improvements, though, have had difficulty being incorporated into the mainstream of medical care for several reasons. The most important has been, I believe, that the training of clinical pharmacists in dosage individualization has fallen off, and MAP Bayesian methods seem now to be taught as "Advanced PK" – this at a time when the need for such tools for patient care has increased greatly. In addition, "big pharma" will have nothing to do with such use, and to them DDI is the kiss of death.I do not know a single medical school in the world that trains physicians to dose drugs well in clinical settings, in large part because no one is trained to teach them. These skills also need to be integrated into the hospital setting in a useful way. Currently hospital pharmacists do their best they can with their limited training and lack of influence with the physicians, who know much less.Nurses and phlebotomists need to be trained to record accurately the times when doses are given and blood samples drawn. Bar codes are attractive but costly, and it is so easy to look at the wall clock and record (military time) when events take place. Many new developments in PK have taken place. Nonparametric population (NP) population PK/PD modeling estimates not only parameter means and standard deviations, but the **entire** parameter distributions. This permits multiple model (MM) **maximally precise** dosage regimens for the first time. This can be as important in reducing the variability of patient response on a dosage regimen as discovering an important clinical covariate such as creatinine clearance. NP Bayesian analysis again permits maximally precise MM regimens for the future, in addition to being able to show the hospital pharmacist the increased precision with which the patient is now known. In other words, it is now possible to see for the first time exactly how much benefit the TDM has done for the patient and his subsequent care.New developments in the mathematical aspects of PK and PD modeling and dosage design are the cutting edge of new math, which is always changing. It is impossible for anyone who is not a practicing mathematician to understand them. However, their logic is quite clear. Good graphics display results to anyone who runs the clinical software. These new tools are designed specifically for use in the hospital at the bedside with a laptop computer, or even an Ipad, to access a laptop and do the job, both getting the data from the hospital EMR at first, and putting it into it after the job is done. Many exciting things are happening in medical and pharmacy education, patient care, hospital administration, and the improvement of the economics of medical care. Let's get going and make it happen!.

Biography

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.Dr. Jelliffe's interest is now in nonlinear PK/PD population modeling of multiple interacting drug systems, optimally coordinated combination MM dosage regimens for patients, and in methods using the dose itself as an active partner to learn about the patient optimally while having to treat him/her at the same time. 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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