HKCP ALUMNI BULLETIN

Issue-X, June- 2013

From the Editors Desk:

Dear Alumni,

It's always a good time to release the tenth issue of Alumni bulletin. On behalf of HKCP I appreciate your overwhelming response by attending the convocation ceremony of batch 2012 students. We expect the same in future programmes arranged by the institute. Please extend your co operation to strengthen the Alumni Association by actively participating in the activities specially arranged by Alumni Association of HKCP.

The alumni bulletin is full of activities and events as well as an article explaining a career as a statistician in the field of pharmacy by Mr Shrikant Boharupi, Faculty - Department of Pharmaceutical Chemistry. The article explains about the biostatistics and its importance in the field of pharmacy. The biostatistician should have a combination of education/training and experience sufficient to implement the principles articulated in this guidance. He plays a crucial role in the areas of clinical research:- Protocol Development & Design, Data Management, Study Implementation, Study Monitoring, Data Analysis & Reporting. Also responsible for defining study endpoints, sample size calculation, interim analysis monitoring plans and the hypothesis and testing procedures which are defined in the Statistical Analysis Plan (SAP). In each of these responsibilities, the biostatistician has additional considerations.

The research updates section includes the news about development of a drug on neuropathic pain caused by a lesion of the peripheral or central nervous system as this type of pain frequently persists, even following normal repair of the injured tissue. In a clinically significant proportion of cases, the neuropathic pain becomes chronic, severely debilitating, and extremely difficult to treat. It will be a great hope for the patients suffering from peripheral neuropathic diseases such as multiple sclerosis, herpes zoster related neuropathy, HIV related and cancer related neuropathy.

As ever we always work towards giving you more and more of news about college, do send us your views and suggestions.

With best wishes

SushrutaMulay.

President- Alumni Association

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Campus News:

- Seminar was arranged by M Pharmacy Sem II students on 1st and 3rd June 2013 as per the curriculum of M. Pharm. It was evaluated by senior faculties and the Principal of HKCP.

- Training programme(Good Laboratory Practices) was arranged for the whole staff of college as well as for M Pharm students about safe handling of instrumentations in Analytical and instrumentation laboratory and slides presentation by Dr Kamlesh Soni, Mrs Jaya Agnihotri, Mrs Archana Bele, Mrs Parimal Kotkar, Mrs Ojaswi Ghadge, Mr Amol Borade and Mr Yuvraj Unale (Application Scientist).

- A one day workshop on Emotional Intelligence was organized on 27th June as Faculty Development Programme at H. K. Campus. The speaker was Dr.Vipul Vyas, Principal Oriental College of Commerce and Management. The workshop was focused especially on understanding emotional intelligence and application of this knowledge in teaching. The different components of emotional intellengence discussed were Self Awareness, Self Management, Self Confidence and Self Efficiency, Empathy and Self Motivation.

Final year student's achievement:

The following students of HKCP were qualified GPAT examination in this year.

SR. NO.	NAME	GPAT RANK
1	FIRDAUSS FAROOQUI	297
2	GAURAV ANDHANSARE	577
3	SARVESH RANGNEKAR	2032
4	ABDUL HAFIZ AB	2032
5	DHANIK PATEL	2607
6	RUDRAKSH JOSHI	2934
7	ANUPAMA VALVI	3634
8	KHUSHBOO JETHWA	7883

Publications of HKCP:

- **Overcoming interferences in endotoxin Detection Assays by Sushruta Mulay and Dr Anubha khale in PHARMATIMES April 2013 issue.**

M Pharm New Syllabus:

Highlights of the new syllabus are:

- **Comprises of IV semesters.**
- **Semesters III and IV as research projects.**
- **Credit Based System.**
- **Continuous internal assessment.**
- **Sessional tests.**
- **Integrated learning involving tutorials.**
- **Group discussions and assignments.**
- **Field Work.**

COURSE STRUCTURE

M. Pharm.

Semester I (For All Branches of Study)

No.	Title of the subject	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage		
									CIA		ESE
		C/E/S		L	I.L	P	T	P	ST	IA	
1	Modern Pharm. &Med. Chem.	C	4	3	1	-	3	-	15	10	75
2	Modern Pharmaceutics	C	4	3	1	-	3	-	15	10	75
3	Modern Pharmacology	C	4	3	1	-	3	-	15	10	75
4	Modern Pharmaceutical Analysis	C	4	3	1	-	3	-	15	10	75
5	Study of Natural Products	C	4	3	1	-	3	-	15	10	75
6	Seminar	C	4		4	-	-	-	-	100	-

Semester II (Branch wise)

No.	Title of the subject	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage		
									CIE		ESE
		C/E/S		L	I.L	P	T	P	ST	IA	
1	Biostatistics and Research Methodology	C	4	3	1	-	3	-	15	10	75
2	Core Subject 1	C	4	3	1	-	3	-	15	10	75
3	Core Subject 2	C	4	3	1	-	3	-	15	10	75
4	Elective 1	E	4	3	1	-	3	-	15	10	75
5	Elective 2	E	4	3	1	-	3	-	15	10	75
6	Experimental Techniques in Pharmaceutical Sciences	C	4	-	-	8	6	-	15	10	75

Introduction of new faculty

Name	**Mr. Amol U. Borade**
Educational Qualification	M. Pharm. Pharmaceutics
Work Experience	Teaching : 1 years Industrial : 2 Years
Email	amol.borade@hkcp.eudu.in borade.amol@gmail.com
Area of Specialization	Pharmaceutics, NDDS
Subjects taught	UG level: Physical Pharmacy, Pharmaceutics PG level: Advanced Pharmaceutics, Bio-pharmaceutics, Technology of Cosmetics
Awards, Credentials, Professional affiliations	- Registered with Indian Pharmaceutical Association (Life member) - Life member of APTI (Association of Pharmaceutical Teachers of India) - Qualified GATE-2005 Examination with 83.00 percentile
Research Grants received	-
No. of papers published	-
No. of presentations	**1)** **Podium** presentation presented on "Formulation and Optimization of Ferrous Fumarate Sandwich Tablets Designed to Achieve Renewable Mucoadhesion" at **58TH IPC, Mumbai**. **2)** **Podium** presentation delivered on "A Novel Dosage Form Design Approach to Overcome the Obstacle of Rapid Mucus Turnover and Achieve Prolonged Gastric Residence" at **58TH IPC, Mumbai**. 3) Poster presentation delivered on "Measurement of Mucoadhesion: A Modified *Ex-vivo* Method Aimed at Improving the Correlation between *Ex-vivo* and *In-vivo*Mucoadhesive Performance" at **11TH APTI-2006, Bangalore**. 4) Research paper selected on "Designing and Characterization of **Solid Lipid Nanoparticles** Loaded with Terbinafine Hydrochloride" held on 7th July 2007 at 34th annual international symposium of **Controlled Release Society, CA, USA**. 5) Research paper selected on "Preparation and Evaluation of Etoposide Liposomes" at **PSWC-2007, Amsterdam, Netherlands**. 6) Poster presentation delivered at 7th international symposium on advances in technology and business potential of new drug delivery systems, **Controlled Release Society -I, Mumbai**.
Projects carried out	-
Training programmes / workshops/conferences attended	- One day National Seminar on *"Advances in instrumentation & analytical techniques"* organized by H. K. College of Pharmacy on February-2013, Mumbai, India

Photo Gallery:

Staff Development Programme – Dr Kamlesh Soni

Faculty Development Programme- Speaker Dr. Vipul Vyas

Success Secrets Series:

Article by: Mr. Shrikant Boharupi

Importance of biostatitics in analysis

Biostatistics is the application of statistics to a wide range of topics in biology. The science of biostatistics encompasses the design of biological experiments, especially in medicine, agriculture and fishery; the collection, summarization, and analysis of data from those experiments; and the interpretation of, and inference from the results. A major branch of this is medical biostatistics, which is exclusively concerned with medicine and health.

Introduction to Statistics in *Pharmaceutical Clinical Trials* is an ideal introduction to statistics presented in the context of clinical trials conducted during pharmaceutical drug development. This novel approach both teaches the computational steps needed to conduct analyses and provides a conceptual understanding of how these analyses provide information that forms the rational basis for decision making throughout the drug development process. The growth of the pharmaceutical industry over the past decade is astounding, but the impact of this growth on statistics is somewhat confusing. While software has made analysis easier and more efficient, regulatory bodies now demand deeper and more complex analyses, and pharmacogenetic/genomic studies serve up an entirely new set of challenges. For more than two decades, *Statistics in the Pharmaceutical Industry* has been the definitive guide to sorting through the challenges in the industry,. Basic Statistics and Pharmaceutical Statistical Applications explores types of variables, random sampling, probability, measures of central tendency, and hypothesis (or significance) testing, discusses regression analysis, nonparametric tests, and power determination, and examines study designs, confidence intervals, dissolution testing, and bioequivalence.

The statistician designs the experiments and trials, analyses the data and interprets the results so that health care professionals can have the necessary information at their fingertips when they need it. The pharmaceutical industry is a successful and rapidly growing world-wide industry. It contributes significantly to the economies of the many countries all round the world where it is located, both as a major employer and as an export earner. Its continuing success rests on it rising to the many and diverse challenges faced in today's health care sector. Pharmaceutical statisticians are at the forefront in meeting many of these challenges; they have a vital role to play in the health care of the entire population. The process of a statistical test can be divided into seven steps: (1) establish the research question, (2) formulate a hypothesis, (3) select an appropriate test, (4) sample correctly, (5) collect data, (6) perform the test, and (7)make a decision.

Selecting the most appropriate test

In order to select the correct statistical test, the most important aspect is to define the types of variables being analyzed. Each variable (also referred to as a factor) needs to be defined with respect to both the type of measurement scale involved and whether or not the researcher has control over that specific variable. A nominal scale represents categories (e.g., males versus females,control group versus experimental group). Each observation is required to fall into one of the mutually exclusive and exhaustive categories.Factors measured on nominal scales are sometimes referred to as discrete variables, and the outcomes are reported as frequency counts or percentages.In contrast, interval and ratio scales represent quantitative data that can be measured, and there is relative positioning with no gaps or interruptions in the continuum (e.g.,height, weight, percents,cholesterol level, blood pressure). The difference between interval and ratio scales is that the former has no true zerovalue. Factors that are measured using interval and ratio scales are often referred to as continuous variables. For continuous variables, the most commonly used measures of central tendency would be the sample mean and standard deviation. A fourth scale, ordinal measures, falls between discrete and continuous scales. This type of scale represents information that has ascending or descending order, but the difference between units is not necessarily the same. Examples of ordinal scales would include stages I–IV for tumors and 0–10 Apgar scores for assessingthe health of newborns. When there is a large number of divisions on the ordinal scale or multiple subscales are combined, they may be treated as interval or ratio scales. An example would be the Epworth sleepiness scale.3 The total scores on the Epworth scale can vary from 0 to 24, but results can be classified nominally as normal (0–10), sleeping disorder (11–17), and sleep apnea (18–24). Each of the eight questions on the Epworth scale can be rated on a 0–3-point scale. For example, one question assesses sleepiness in the situation of "sitting and talking to someone" and the only possible ordinal responses are0 = would never doze or sleep 1 = slight chance of dozing or sleeping
2 = moderate chance of dozing or sleeping 3 = high chance of dozing or sleeping Multiple questions can be combined to create an overall score ranging from 0 to 24 that could be treated as ordinal or ratio data. For ordinal variables, the measures of central tendency would be the sample median (50th percentile) and dispersion as the 25th and 75th percentiles.

Independent versus dependent variables.

Some variables are controlled or determined by the researcher. These are referred to as independent or predictor variables.For example, if a pharmacist researcher wishes to compare three hydroxymethylglutaryl–coenzyme A (HMG- CoA) reductase inhibitors on a hospital formulary, the three products chosen (different manufacturers)would be the researcher controlled independent variable.However, individual patient responses to the three different products(e.g., change in total cholesterol levels after six months of therapy) are beyond the researcher's control. The change in cholesterol level would be considered either a response variable or a dependent variable (dependent on the level of HMG-CoA reductase inhibitors received). The result measured for the dependent variable is associated with the classification (or level) of the independent variable. In this example, there is a discrete independent variable with three levels or possibilities (drugs A, B, and C) and an associated continuous dependent variable (change in cholesterol). The most appropriate inferential statistic for this scenario would be the one way analysis of variance, as will be seen below. The types of variables involved will dictate this choice in statistical test to be performed.

Dealing with random error

Systematic error, or bias, is minimized by good study design and care in collecting and recording observations.

Uncertainty or random error always exists with inferential statistical tests and exists as two types:

(1)rejecting the null hypothesis (*H*0)when it is true and

(2) failing to reject *H*0 when it is false.

These are labeled as type I errors (□ □or *p*) and type II errors (□), respectively. A complete discussion of hypothesis testing has been presented in a previous article. When performing a statistical test, the researcher can never be 100% certain of the results because results from a small subset (sample) are being used to predict a larger population. The traditional acceptable level for type I error is less than 5%, or a *p* value of less than 0.05. Therefore, in published reports in which authors reject *H*0, they will usually cite a corresponding *p* value of less than 0.05.The smaller the *p* value, the more confident the researcher is in his or

her decision to reject *H*0. At the same time, a type II error rate of 20% or less is usually acceptable and is a complement to the statistical power of the test results (1 – □).As a consequence of the statistical test, *H*0 can be rejected in favor of the alternative (research) hypothesis with less than a certain probability of being wrong in making this decision. However, if the researcher fails to reject *H*0, *H*0 is not proven; there is simply not enough evidence to reject it.

The Statistical Analysis Plan (SAP) includes a detailed description of the targeted study population and statistical methodology to be used, methods of computation of all analysis variables, handling of missing values and outliers, handling of multiplicity issues, identification of primary and secondary analysis variables, identification of analysis populations and subsets, and methods to ensure blinding and control of Type I error rate for any interim analyses. The SAP also includes templates or formats for proposed summary tabulations of the data and data listings to be included in the clinical study report. The SAP includes data definitions for all analysis data sets not already described in the Data Management Plan.

The biostatistician authors a test programming code for preparation of tables, listings, and figures, and performance of statistical analysis of the study data according to the SAP. The biostatistician performs an independent statistical review of the clinical database and provides review comments for resolution to the CDM prior to database closure. After the authorized database lock, the biostatistician merges the randomization codes, and develop the planned tables, listings, and figures & perform an independent audit of the tables, listings, and figures, to confirm their correspondence and agreement with the SAP and the study database.

Research Updates

A New Drug to Manage Resistant Chronic Pain

Apr. 30, 2012 — Neuropathic pain, caused by nerve or tissue damage, is the culprit behind many cases of chronic pain. It can be the result of an accident or caused by a variety of medical conditions and diseases such as tumors, lupus, and diabetes. Typically resistant to common types of pain management including ibuprofen and even morphine, neuropathic pain can lead to lifelong disability for many sufferers.

Now a drug developed by Tel Aviv University researchers, known as BL-7050, is offering new hope to patients with neuropathic pain. Developed by Prof. Bernard Attali and Dr. Asher Peretz of TAU's Department of Physiology and Pharmacology at the Sackler Faculty of Medicine, the medication inhibits the transmission of pain signals throughout the body. In both in-vitro and in-vivo experiments measuring electrical activity of neurons, the compound has been shown to prevent the hyper-excitability of neurons -- protecting not only against neuropathic pain, but epileptic seizures as well.

The medication has been licensed by Ramot, TAU's technology transfer company, for development and commercialization by BioLineRx, an Israeli biopharmaceutical development company.

Targeting potassium for pain control:

Voltage-gated K^+ channels (Kv) are one of the important physiological regulators of membrane potentials in excitable tissues, including nociceptive sensory neurons. Since the opening of K^+ channels leads to hyperpolarization of cell membrane and a consequent decrease in cell excitability, several Kv channels have been proposed as potential target candidates for pain therapy. In this review, we focus on common changes measured in the Kv channels of several different trigeminal neuropathic/inflammatory pain animal models, particularly the relationship between changes in Kv channels and the excitability of trigeminal ganglion (TRG) neurons. We also discuss the potential of Kv channel openers as therapeutic agents for trigeminal neuropathic/inflammatory pain, such as mechanical allodynia.

According to Prof. Attali, the medication works by targeting a group of proteins which act as a channel for potassium. Potassium has a crucial role in the excitability of cells, specifically those in the nervous system and the heart. When potassium channels don't function properly, cells are prone to hyper-excitability, leading to neurological and cardiovascular disorders such as epilepsy and arrhythmias. These are also the channels that convey pain signals caused by nerve or tissue damage, known as neuropathic pain.

With few treatment options available for neuropathic pain, Prof. Attali set out to develop a medication that could bind to and stabilize the body's potassium channels, controlling their hyper-excitability and preventing the occurrence of pain by keeping the channels open for the outflow of potassium. This novel targeting approach has been recently reported in the journal *PNAS*.

Inducing calm in the neurons:

Understanding the mechanism that controls these channels has been crucial to the development of the drug. By successfully controlling the excitability of the neurons, Prof. Attali believes that BL-7050 could bring relief to hundreds of millions of patients around the world who suffer from neuropathic pain. The medication will reach the first phase of clinical trials in the near future.In pre-clinical trials, BL-7050 was tested in rats experiencing both epilepsy and neuropathic pain and was found to be efficient in protecting against both when taken as a pill. While on the medication, rats were no longer affected by stimuli that had previously caused pain. Measures in the electrical activities of neurons also revealed that the medication was able to induce "calm" in the neurons, inhibiting pain pathways.
