ISoP NEWS

Feb 2019

Message From the President

By Justin Wilkins

ISoP: 2019 and beyond

2019 is going to be a pivotal year for ISoP. We have a number of significant changes coming down the road, the result of a lot of time and planning by our Board and our teams of volunteers. ISoP is growing from the equivalent of a plucky startup into a mature scientific society: by 2023 we intend to cement our role as the premier organization advancing the discipline of pharmacometrics globally, actively championing the expanding role of pharmacometrics in protecting and improving human health.

We announced our Five-Year Strategic Plan at ACoP9 in San Diego, our blueprint for this transformation. It was kicked off by our Past President Jin Jin during her presidential term in 2018, developed by teams of volunteers from a wide range of backgrounds in academia and industry – Working Group led by Mike Heathman and a Steering Committee led by former ISoP president Brian Corrigan. The Five Year Strategic Plan is composed of five pillars – *Scientific Expertise and Innovation*, focusing on encouraging research and innovation in our field; *Influence*, focusing on increasing the role of pharmacometrics in decision-making within drug discovery, development and clinical practice; *Education*, focusing on improving consistency, quality, and availability of educational resources for society members in every stage of their careers; *Tools and Resources*, focusing on increasing visibility and facilitating development of and access to pharmacometric tools, as well as open science resources in our field; and *Internationalization*, focusing on the global expansion of our activities and membership – which rely on *Organizational Effectiveness*, the foundation upon which all pillars depend. Planning is now largely complete, and we intend to launch the implementation phase in Q1 2019. Each of these components will be run by a Working Group: we're going to need volunteers to help us!

The first noticeable result of our plans will be the transformation of our website, the first step in a general overhaul of our communications. Also launching soon, it will receive a complete facelift to reflect the needs of our maturing society and the feedback we received from you, our membership in last year's survey. At the same time our new year-round mobile app will be ready – it's currently having its first outing supporting the 20th PAGANZ meeting in Auckland, New Zealand!

Preparations for our tenth ACoP meeting, to be held this year in Orlando, Florida from October 20 to 23 and chaired by Mirjam Trame, are already well underway and we hope you will be able to join us for our diamond anniversary. ACoP is also traditionally the time we present our awards and fellowships for the year: an important aspect of our society is recognition of achievements at all levels. Each year's winners are chosen from a pool of people nominated by you, our membership – please take the time to do so when the call comes! Before then, we have a number of local events planned for the next few months, starting with ISoP New England in Boston on the evening of 20 February.

Highlights In this Issue **Page**

Message From the President (Continued)

Our SIGs and Committees continue to thrive. Of particular note, the first in a series of new webinars organized by the Education Committee under the leadership of Gauri Rao and Samer Mouksassi was a great success (and we intend to continue to deliver material of this caliber going forward). The revamped Communications Committee chaired by Pete Bonate continues to be tremendously effective, and the first regular inter-SIG meetings have taken place.

Finally, we're very pleased to be deepening our cooperation with our sister society ASCPT in 2019, as we explore ways to further refine our joint operations and develop new and exciting scientific and educational collaborations.

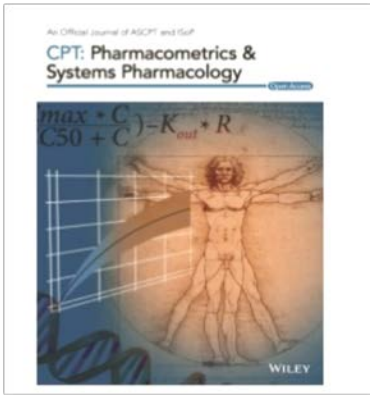
This is going to be a very exciting and busy year for ISoP, as we focus on laying the groundwork for reinventing ourselves over the next five years. We have so much planned – not just the flashy news I've mentioned above, but much, much more, as we make less visible, but no less important changes, to how we operate as a society. We intend to change our world, and we hope you'll be with us as we do.

Justin Wilkins

President, ISoP
February 2019

News from CPT: Pharmacometrics & Systems Pharmacology

France Mentré Editor-in-Chief



France Mentré, MD, PhD, is the new Editor-in-Chief of *CPT: Pharmacometrics & System Pharmacology* (*PSP*) since October 2018. Given the success of *PSP*, she proposed to keep the same spirit and management and to perform only smooth changes in the Editorial Team. All the previous members of the Editorial Team accepted to continue: Lena Friberg, PhD, Uppsala University, as Deputy-Editor-in-Chief, Stephen Duffull, PhD, University of Otago, Douglas Lauffenburger, PhD, Massachusetts Institute of Technology, Lang Li, PhD, The Ohio State University College of Medicine, Donald E. Mager, PhD, PharmD, University of Buffalo, Vikram Sinha, PhD, Merck & Co. Inc., Ping Zhao, PhD, Bill & Melinda Gates Foundation as associate editors. Two new associate editors accepted to join the team in order to expand the scope of expertise: Jonathan French, ScD, from the Metrum Research Group, to cover statistics, and Eric Sobie, PhD, from Icahn School of Medicine at Mount Sinai, to cover systems pharmacology.

The first vision for the journal, is to obtain more articles from outside the United States (US) and the European Union (EU). Indeed, out of the 97 publications in 2017, 90% came from the US or the EU (54% and 36%, respectively). We will actively reach out to PMX groups from several areas of the world and ask them to write perspectives, editorials and original research articles, as publication fees for original research is waived for articles from developing countries.

The second vision is to welcome more articles and tutorials on methods and software in pharmacometrics (PMX) and quantitative system pharmacology (QSP), so that the journal will be a natural reference for new (and existing) members of our ever growing community. In February 2019 we launched a new virtual issue: "Methods and Software Tools" which already has 113 articles. We have also invited authors of popular software in the field to write tutorials, and many have accepted.

Given the growing importance of model-informed drug discovery and development (MIDD), in January we launched a new virtual issue, "Regulatory MIDD", which has 17 publications. Notably, it includes the article from the Office of Biostatistics and Clinical Pharmacology, Center for Drug Evaluation, of the China National Medical Products Administration, published in December 2018, as well as articles from the European Medicines Agency, the US Food and Drug Administration, and Japan's Pharmaceuticals and Medical Devices Agency.

In addition to the recently launched "Regulatory MIDD", and "Methods and Software Tools" virtual issues, the Editorial Team also decided to soon launch the following virtual issues: "Biomedical Informatics", "Statistics and PMX" and "Pregnancy".

AMERICAN CONFERENCE ON PHARMACOMETRICS

Planning for ACoP10 is underway! The Tenth American Conference on Pharmacometrics (ACoP10) will be held October 20th to 23rd, 2019, at the Rosen Shingle Creek Hotel in Orlando, Florida.

Your Planning Committee is hard at work to bring you a variety of scientific programming, poster presentations, social activities, and networking opportunities. Here are some highlights for what's in store:

- In accordance with the theme of the conference "Modeling without Borders," we are convening for the first time a "Sponsored Investigator Session," to which we invited three international speakers hailing from low- and middle-income countries to share their research, goals, and their unique scientific perspective with us.
- We have more exciting news for you as we are thrilled to introduce our new "Roller Coaster Sessions." Stay tuned!
- By popular demand, the Innovative Communication session will be back, with a new twist at ACoP10. You don't want to miss it!
- The Pre-Conference on Sunday, October 20th, "Clinical Pharmacometrics: Bringing Models to Patients," co-chaired by Navin Goyal, PhD, and Elizabeth Lakota, PharmD, PhD, will discuss the application of pharmacometrics in clinical practice, enabling the translation of pre-clinical and clinical findings to patient care settings. As such, the preconference is focused on bringing together pharmacometricians with clinical interest and clinicians with an interest in pharmacometrics to foster a community of clinical and computational scientists to pursue the mission of bringing models to patients.
- ACoP10 Programming Committee, chaired by Nahor Haddish-Berhane, PhD, is planning for an exceptional series of scientific sessions consistent with the conference theme, "Modeling without Borders," reflecting ISoP's 2019 objectives of "globalization and collaboration" among pharmacometrics groups, methods, and tools, and its impact on Global Health. A special thank you to all members who submitted symposium and tutorial proposals. Your contributions will make for another year of exciting scientific programming.

- ACoP's free post-meeting tutorials, including the Student Tutorial Workshop, will be held on the morning of Thursday, October 24th, with post-conference workshops beginning that afternoon and continuing on Friday, October 25th.

- Planning your travel? Last year's extension of conference days received positive feedback as it allowed for additional sessions and more networking time. Given the extension's tremendous success, ACoP10 will continue to run until early evening on Wednesday, October 23rd.
- **The Call for Abstracts is now open through April 15th.** Our Abstract Committee, led by Luning (Ada) Zhuang, PhD, is already looking for new ways to highlight the many outstanding scientific abstracts that are contributed by our community each year. Visit the ACoP website for more information.
- ACoP's free post-meeting tutorials, including the Student Tutorial Workshop, will be held on the morning of Thursday, October 24th, with post-conference workshops beginning that afternoon and continuing on Friday, October 25th.

Last but not least: the **Call for Nominations for ISoP Awards and Fellows will open soon on March 15th.** Please take the time to recognize your colleagues for their innovative science and outstanding leadership in the field of pharmacometrics.

Please mark your calendars and be sure to register early! ACoP has been selling out prior to the Early Bird registration over the last couple of years.

We look forward to seeing you in Orlando!

On behalf of the ACoP10 Programming Committee,

Mirjam N. Trame, PharmD, PhD –
ACoP10 Conference Chair

Member Spotlight on Mark Lovern

Vice-President
Certara Strategic Consulting

By Peter Bonate

Tell us about yourself?

I have been working in or around the pharmaceutical industry for more than 20 years. Most of that time was spent in consulting companies, but I also spent about 5 years at bona fide pharmaceutical companies. In my off hours, I love to cook and entertain. It has been said that I know how to throw a great party.

How did you get into pharmacometrics?

Like many others within our field, I was not formally trained as a pharmacometrician. My undergraduate degree was environmental science, and my doctorate was in biomathematics. My segue into the pharma world was my first job at Quintiles, where I was a PK scientist. From there, I went to Pharsight where I started out as a software support technician. I spent several years at Pharsight and eventually grew into a pharmaco-metric consulting role through on-the-job learning.

You've worked in both industry and consulting. What are the differences between the two?

In my view, all pharmacometricians, regardless of whether they work at pharma companies or consulting companies, are consultants. This is because we are generally in the position of being the decision influencer, rather than the decision maker. Having said this, the business cycle at consulting companies tends to be shorter. In pharma, a pharmacometrician might work on the same development program for several years.

In consultancy, our projects usually do not last more than a year, and may be as short as a few weeks.

What is a typical day like for a consultant?

It depends on the consultant's level. Earlier in my career, I spent most of my time doing hands-on analysis for weeks or even months on-end. These days, I generally consult on a multitude of projects in which my junior colleagues are performing the bulk of the analysis. So, I spend a lot of time on the phone or Webex in 1 hour blocks.

What advice do you have for someone considering a career as a PMx consultant?

Don't just be great at analyzing data. If you want to have an impact, you also have to be a great communicator. Most of the decision makers in the pharma industry are not modelers, and have very little time or interest in understanding the vagaries of our discipline. So, I can't emphasize enough how important it is to provide those folks with the information they need in a manner that is clear, accessible, and relatable.

If someone were to ask you, Why should I join ISoP, what would you tell them?

It is the only international professional society specifically by and for pharmacometricians. In addition to its national meeting, the American Conference on Pharmacometrics, ISoP sponsors numerous regional events and workshops throughout the year. Joining ISoP is unquestionably the best means of connecting with the global community of pharmacometricians.

What has been the toughest modeling problem you've encountered and how did you solve it?

The biggest challenges I have faced in my career have not been with the modeling. They have always been those of communication. Last year, I came across a great quote by George Bernard Shaw: "The greatest challenge in communication is the illusion that has actually occurred." I think that is particularly true of the field of pharmacometrics, in which we so often need to communicate our ideas to non-modelers. Unfortunately, I don't think this is a problem that ever truly gets solved. It's more of a journey.

What do you think pharmaco-metrics will look like in 10 years?

The importance of quantitative systems pharmacology (QSP) will continue to grow. As QSP models become more robust, they will be increasingly used for predicting therapeutic targets, potential safety risks, etc. The formation of collaborative multi-institutional consortia will likely prove necessary in order to generate the massive quantities of experimental data needed to inform QSP models.

We will continue using the classical PK and PKPD models we have traditionally used for data description, but the model development process will likely be augmented and largely automated through the application of artificial intelligence. There will be increasing emphasis on coupling pharmacological models together with health economic outcomes models. Pharmacometric models have shown their worth in helping drugs get approved, but that's not enough anymore. Payers need to be convinced that they should buy new drugs, and that requires an economic rationale. The increasing emphasis on competitive positioning will also drive greater use of public information sources and application of techniques such as model-based meta-analysis to synthesize and contextualize the available information.

What have I forgot to ask you?

My three great heroes are Johnny Cash, Austin Powers, and Bugs Bunny. I am not deterred by two of the three being fictional characters, or that one is an animated rabbit that looks great in drag.

Papers Worth Reading

by The ISoP Publications Committee
(Angela Birnbaum, Peter Bonate, David D'Argenio, Ashwin Karanam, Shaun Kumar, Jin Niu, Ana Ruiz, & Catherine Sherwin)

Clements JD, Perez Ruixo JJ, Gibbs JP, Doshi S, Perez Ruixo C, Melhem M. Receiver Operating Characteristic Analysis and Clinical Trial Simulation to Inform Dose Titration Decisions. CPT Pharmacometrics Syst Pharmacol. 2018 Nov; 7(11): 771-779. doi: 10.1002/psp4.12354. Epub 2018 Oct 15. (Suggested by Angela Birnbaum).

Choosing optimal doses to be used in clinical trials for potential new therapies is difficult as data can be limited. The ability to identify relevant doses is further complicated when the difference between concentrations that are efficacious and those causing toxicity are narrow. Add to these issues the need to not overshoot or undershoot a target dose for approval and variability within subjects and the task is even more daunting. Quantitative methods that can improve selection of optimal doses especially for drugs with narrow therapeutic indexes provides a means to explore dose titration schemes that might not be otherwise be considered possible due to safety concerns. This paper explores the use of combining Receiver Operating Characteristic (ROC) Analysis and Clinical Trial Simulation (CTS) in optimizing dose titration algorithms. The authors simulate five PK-related scenarios using different degrees of variability added to a base scenario with low variability.

The five alternative scenarios included were a) high residual unexplained variability (RUV), b) high Interoccasion variability, c) high Interindividual variability (IIV), d) combined high RUV+IIV) with a sigmoidal maximum effect PK/PD relationship, and e) probability of toxicity characterized by a shallow slope for a hypothetical compound A which had a dosing window of 5-10 mg b.i.d. IIV on half-maximal effective concentration was expressed using an exponential error structure.

The authors use the scenarios to demonstrate how safety and efficacy criteria with subject-level exposure data can be utilized to establish a quantitatively justified dose titration algorithm. This approach of combining ROC and CTS-based analyses can be used as a quantitative approach for achieving the desired balance of safety and efficacy for drugs with narrow therapeutic window in all stages of drug development. The overall conclusion of the simulations is a single C_{trough} sample may be useful for PK-based titration schemes for drugs with sufficiently low IOV or RUV.

Polli JR, Engler FA, Balthasar JP. Physiologically Based Modeling of the Pharmacokinetics of "Catch-and-Release" Anti-Carcinoembryonic Antigen Monoclonal Antibodies in Colorectal Cancer Xenograft Mouse Models. J Pharm Sci 108: 674-691, 2019 (suggested by David D'Argenio).

The first application of physiologically based pharmacokinetic (PBPK) models to endogenous antibodies is that of David Covell and his colleagues at the NIH in the mid-1980s. Their work built on the conceptual foundation for understanding the distribution of substances in the body presented in the iconic work of Teorell in the 1930s, the publication of the first circulatory models for drug distribution by Bellman and Kalaba at the RAND Corporation in the early 1960s, and the formal development and application of PBPK models by Bischoff, Dedrick and colleagues starting in the late 1960s. Since the mid-1990s, Balthasar and his group, at the Center for Protein Therapeutics at the University at Buffalo, have been at the forefront of PBPK model development for monoclonal antibodies.

The recent publication from this group by Polli *et al.* cited above, represents the evolution of their platform model to monoclonal antibodies with pH-sensitive target release (catch-and-release antibodies – CAR). Their model incorporates endosomal space sub-compartments to characterize the pH-dependent rate processes of mAb binding to the target and to FcRn. Application of the model to a standard pH-sensitive target release anti-carcinoembryonic antigen (CEA) monoclonal, predicted a dramatic increase in tumor selectivity (increasing mAb tumor exposure relative to plasma exposure). Sensitivity analyses identified several important determinants of the disposition of CAR mAbs, including the rate constant of mAb-CEA dissociation in acidified endosomes. Future application of the model may allow *a priori* assessment of the utility of pH-sensitive target release mAbs developed for binding to a range of target molecules.

Did You Know?

Old versions of the newsletter are posted on the ISoP Website:

https://insp.memberclicks.net/isop-newsletter

If you've read an interesting paper tell us why and send it to the ISoP Newsletter for publication. Items can be emailed to peter.bonate@astellas.com.

Update from the Clinical Pharmaco-metrics SIG

by Marc Scheetz

The Clinical Pharmacometrics SIG finished a successful inaugural year under the leadership of Dr. Elizabeth Lakota. The SIG grew to 106 members with the mission to synergize collaborations between pharmacometricians and clinicians. The SIG was active at international conferences throughout the year with scientific sessions at the following societies' annual meetings: 1) the International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDMCT), 2) the American College of Clinical Pharmacology (ACCP) 3) the International Society of Pharmacometrics (ISoP), and 4) the American Society of Health-System Pharmacists (ASHP). The IATDMCT scientific session focused on new novel bedside tools and overcoming the hurdles to implementing these tools. The SIG also presented a Post-Congress Workshop which taught the clinician audience the concepts behind bedside pharmaco-metrics. At ACCP, Drs. Michael Neely, Amelia Deitchman, Sirj Goswami, Justin Bader, and Liz Lakota presented various software tools which allow for the application of pharmacometrics at the bedside. At ACoP, Drs. Dan Wright, Amelia Deitchman, Steve Duffull, Marjorie Imperial, and An Vermeulen discussed use of clinical pharmacometrics beyond pharmacokinetics in optimizing patient outcomes. At ASHP, Drs. Michael Neely, Nik Onufrak, Janel Long-Boyle, and Marc Scheetz highlighted pharmacometric links to the patient bedside with real world success stories. In the next year, the SIG is especially interested in member driven activities and suggestions for sessions at ACCP and ACoP. People with interest are welcome to contact the SIG at clinical.pmx.sig@go‑isop.org.

Update from the QSP SIG

By Eric Sobie and the Leadership Team

The Quantitative Systems Pharmacology Special Interest Group (QSP SIG) aims to advance the development and utilization of safe and efficacious medicines through the application of QSP modeling and simulation. We work towards this overarching goal through efforts that promote the discipline of QSP, advance QSP scientific approaches, and provide resources for practitioners. The QSP SIG Leadership Team currently comprises: Eric Sobie, Chair, Brian Schmidt, Chair-Elect, Christina Friedrich, Vice Chair, John Burke, Communications Director, Valeriu Damian, Past Chair, and Panteleimon Mavroudis, Secretary. The QSP SIG has many events planned for 2019. Some of these continue previous efforts whereas others represent brand-new efforts to advance the discipline.

The QSP SIG plans to host two mini-symposia that will bring together scientists and trainees for networking and communication of cutting-edge science. We hope that one will take place in southern New Jersey, and the other in the San Francisco Bay area. We have developed new Working Groups within the QSP SIG that bring together experts in a specific sub-discipline of QSP for periodic meetings and collaborative projects such as webinars, review articles, and community surveys. These efforts help to define the state of our science intended to cut across industry, academic, and regulatory boundaries. Finally, we will sponsor several events at ACoP10, including a student award, the Meet the SIG Luncheon, and a social event at which several poster presentations will be highlighted. We're trying to keep the new QSP website [https://sites.google.com/view/isopqspsig] up to date (please note that it is a Google Site, and may not be allowed on all company firewalls). Please email Pantelis Mavroudis (pmavrud@gmail.com) and John Burke (john.burke@ appliedbiomath.com) for content (like events).

The QSP SIG plays an active role in the programming for ACoP10. Thank you for submitting QSP focused sessions to the QSP SIG for feedback, and we look forward to your abstract submissions before April 15! Through these efforts we intend to raise the profile of QSP and highlight its value in drug research and development. Please feel free to share your feedback and advise, and we are all looking forward to a great 2019 (see you at ACoP10)!!!

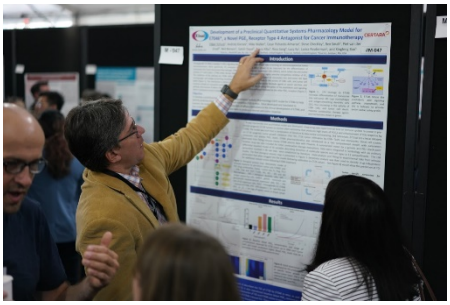
ISoP Webinar: Delay Differential Equations Based Models in NONMEM

By Wojciech Krzyanski

Models using delay differential equations (DDEs) are getting increasingly popular in analysis of data exhibiting delays. Many pharmacometric software (Phoenix NMLE, Monolix, MATLAB, Berkeley Madonna, R) support DDE solvers to facilitate DDE based model development. Recently, a DDE solver has been implemented in a pre-released version of NONMEM 7.5 as ADVAN16. On January 18th ISoP hosted a webinar titled "Delay Differential Equations Based Models in NONMEM" that was presented by Dr. Wojciech Krzyzanski, University at Buffalo. The webinar was hosted by Dr. Sameer Mouksassi and had Dr. Robert Bauer as a panelist. The objective of this presentation was to introduce basic concepts underlying DDE based models and show how they can be developed using ADVAN16. ADVAN16 is based on a Fortran program RADAR5 (https://www.unige.ch/~hairer/software.html) developed by Drs. Nicola Guglielmi and Ernst Hairer to solve stiff differential-algebraic equations with state dependent delays. RADAR5 was implemented to NONMEM 7.5 by Dr. Robert Bauer as ADVAN16 and ADVAN17.

The webinar provided a brief overview of new syntax features of ADAVN16 and examined performance of this new DDE solver using three DDE models. Individual simulation and comparison of results with MATLAB dde23 DDE solver was demonstrated by the rheumatoid arthritis model (Koch et al., J Pharamcokinet Pharamcodyn 39:55 (2012)). Estimation of parameters from individual data was exemplified by tumor growth inhibition in xenograft mouse model (Koch G et al. J Pharmacokinet Pharmacodyn 41: 291-318, 2014), and estimation of population parameters was done using simulated data for RBC response to erythropoietin treatment described by Budha et al. (AAPS J 13:650-661, 2011). (FOCE, LAPLACE) was discussed.

The diference in performance of expectation maximization methods (IMP, SAEM) and methods that require calculation of derivatives with respect to model parameters. The webinar was concluded with Q&A invoking discussion of topics such as difference between transit compartment and DDE models, lag-time vs. DDEs, and implementation DDEs for systems at steady-state in NONMEM 7.5 ADAVN17. A copy of webinar slides is available at [http://discuss.go-isop.org/t/updated-january-18th-12-30-est-webinar-delay-differential-equations-based-models-in-nonmem/1234/8?u=samermouksassi].



ISoP NE Local Event

The ISoP New England Local Group will host its first event of 2019. Peter Bonate, member of the ISoP Board of Directors, will give an informative presentation to the local pharmacometric community. His talk will highlight ways you can immediately improve your communication skill set. Please join us for an evening of learning and networking. Registration is required as food and beverages will be served.

Date: Wednesday, February 20, 6:00-8:00 pm
Location: Takeda auditorium, 35 Landsdowne Street, Cambridge, MA
Presentation: "Clear Communication - 5 things to immediately improve your presentations"

Update from the Mathematical & Computational Sciences (MCS) SIG

By Peiying Zuo

The Mathematical & Computational Sciences (MCS) Special Interest Group (SIG) was actively engaged in the ACoP 2018 meeting. A program session titled "**Pharmacometrics in Big Data Era - Mission possible to find the needle in a haystack**" was endorsed by MCS SIG covering the applications of mathematical and computational methods in drug development.

MCS SIG also successfully hosted a "Meet the SIG" luncheon, which was open to all attendees at the meeting. Some of the steering committee met in person at this event and introduced themselves to other attendees with warm welcome messages to encourage more people join this dynamic interest group. During the one-hour luncheon, two speakers were invited to share their interesting research work that was related to the mathematical and computational sciences. Dr. **Linda Petzold**, Distinguished Research Professor at the University of California at Santa Barbara, spoke about her interesting research over her 40-year career and particularly about stochastic simulation, how it applies to biological modeling, and how you can get started doing your own stochastic simulation with a free open-source software package her group has developed, **StochSS**.

For the first time, the MCS SIG gave an award for an ACoP poster abstract that featured mathematical or computational sciences. This year's award winner was **Itziar Irurzun-Arana**, of the University of Navarra in Spain. Itziar is a PhD student in the Pharmacometrics and Systems Pharmacology Group in the School of Pharmacy.

ACOP Highlights

In addition to presenting a poster titled "Optimization of drug delivery in the treatment of prostate cancer using optimal control methods" during the regular poster sessions, Itziar also gave a short talk during the luncheon on this poster, which involves the optimization of the release profile for a drug from sustained release formulations matching the multi-objective therapeutic needs.

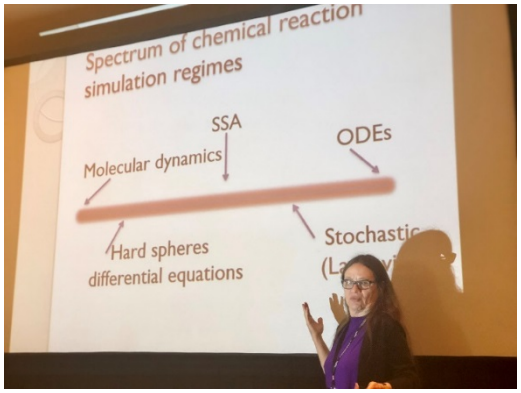
To highlight outstanding posters with mathematical and computational sciences content, an **MCS Poster Walk** was hosted by the MCS SIG leadership. Poster attendees met with MCS SIG leaders at the posters and followed them as they walked through the MCS section and announced highlights of the three outstanding posters, which were as follows:

- PW-1: The effect of monoclonal antibodies pharmacokinetics on tumor cells dynamics: A bifurcation analysis, presented by **Amirhossein Hajihosseini** (University of Florida)
- PW-2: A Machine Learning, Genetic Algorithm Based Approach to Model Selection for Tumor Growth, presented by **Sihang Liu** (University of Buffalo)
- PW-3: Determining the structure of a quantitative systems pharmacology (QSP) model for azathioprine metabolism, presented by **Vijay K. Siripuram** (University of Otago)

Based on the positive attendance and feedback received on the MCS SIG events at ACoP 2018, similar activities are being planned for the ACoP 2019 meeting. People with an interest in this SIG are welcome to join and/or participate in the related events at future meetings.

This year's chair of the MCS SIG, **Helen Moore** of AstraZeneca, was pleased with the turnout at the MCS SIG events at ACoP. Helen said "Dr. Petzold is a world-class researcher whose work is widely used in biopharma software. Her engaging talk about cutting-edge computational techniques that our field could adopt immediately was well-received. It seems clear that relevant quantitative content is valuable to the community, and we plan to continue to provide that."

Suggestions for future speakers or topics can be submitted to mcs_sig@go-isop.org .



Dr. Linda Petzold during her presentation at the 2018 MCS "Meet the SIG" luncheon

ISoP Board of Directors and Award Winners Reception

ISoP Award Winners:

Stacey Tannenbaum, Leadership Award (top left);
Wenping Wang, Innovation Award (top right);
Mats Karlsson accepting for Anne-Gaelle Dosne, Technical Manuscript Award (middle left);
Daniele Oullet, Fellow (middle right);
Yaning Wang, Fellow (bottom left);
David Z. D'Argenio, Sheiner Award (bottom right)

Winners of the Innovation in Communication Session

All photos courtesy of Songmao (Ben) Zheng

A Conversation with Pharmacometrics Africa

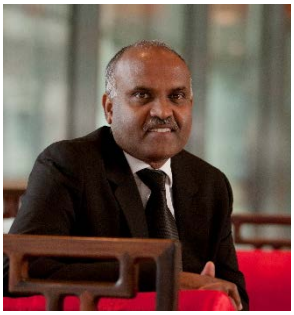
Interview by Peter Bonate

Respondents: Colin Pillai, Steve Kern, Paolo Denti, Aida Kawuma, and Emmanuel Chigutsa

Introduction Peter Bonate (PB):

Quantitative clinical pharmacology is well established in most parts of the world, but the low- and middle-income countries (LMIC's) are under-represented. To address this need, a team of pharmacologists have started a new organization known as Pharmacometrics Africa. I asked some of them to tell us more about their vision for the future:

First, tell us about yourselves:



Colin Pillai (CP):): I've worked as a clinical pharma-cologist in both academia and pharma, but my passion is connecting global resources with those who have limited access. I'm part of the team that founded Pharmacometrics Africa, in addition to running a consultancy that advises funders, research institutes and pharma on programs to strengthen science in LMIC's.

Paolo Denti (PD): I am a professor of pharmacometrics at the University of Cape Town, where I lead a diverse and young team of pharmacometric modelers. Our research mostly focuses on infectious diseases like tuberculosis and HIV.

Steve Kern (SK I am the Deputy Director of Quantitative Sciences at the Bill and Melinda Gates Foundation and am responsible for quantitative analyses that support program strategies for therapeutic projects that the foundation funds.

Aida Kawuma (AK): I am a pharmacist, doctoral student and the program manager for Pharmaco-metrics Africa. I oversee this ambitious capacity development program that will include hosting the World Conference on Pharmacometrics (WCoP) 2020 in Cape Town. I am also excited to expand on the training activities initiated by my mentor, Jackson Mukonzo from the Department of Pharmacology at Makerere University, Uganda.

Emmanuel Chigutsa (EC): I am a pharmaco-metrician who trained in Cape Town, South Africa and Harare, Zimbabwe and am currently a team leader at Eli Lilly responsible for model-based analyses in drug development and regulatory submissions.

PB: So, what is Pharmacometrics Africa and how does it fit in with the global Pharmacometric community?

CP: Pharmacometrics Africa was born out of a lack of such a convening platform on the African continent. We have real data, pressing open questions and motivated students, faculty and healthcare professionals eager to collaborate and learn but no focal point for them to do so.

AK: When I was an undergraduate student, it was very difficult to get access to the wider pharmacometric community outside of our small team in Kampala, Uganda. There is a huge desire to collaborate and grow our understanding with students such as myself but we often don't know where to turn to.

PD: I am hoping that by hosting the 2020 WCoP in Africa, we can show to the broader pharmaco-metric community the scientific challenges that attracted me to Cape Town, and how fulfilling and meaningful it is to apply our modelling skills to global healthcare challenges that so dramatically affect the lives of million in the poorer regions of the World.

At the same time, we want to share our experience of fostering a pharmacometric community in a limited-resource setting. We believe that pharmacometrics is unique in the sense that it is a cutting-edge applied science which needs relatively low resources. All one needs is a computer, a brain, and access to the right expertise and mentoring. The first two items are widely available on the continent, and we, as Pharmacometrics Africa, aim to fill the latter two gaps by fostering collaborations and linking up African pharmacometricians with each other and the rest of the global community.

PB: What is its relationship to the World Conference of Pharmacometrics?

CP: Pharmacometrics Africa is a not-for-profit organization that will co-host WCoP 2020 together with the University of Cape Town (UCT) – but has the wider remit of building capacity and capabilities.

EC: WCoP 2020 can be a catalyst to contribute to pharmacometrics in Africa long after the conference ends. The expectation is that Africa will appear more vividly on the 'Pharmacometrics map' and the footprint set by WCoP 2020 will rapidly expand after the global pharmacometrics community realizes what can be achieved in Africa.

PB: Tell us about what you want to achieve with Pharmacometrics Africa.

PD: Our vision is to increase the number of quantitative clinical pharmacology scientists in Africa. We want to achieve this by assisting in the creation of a training and collaboration network, both within Africa and with the rest of the global pharmacometric community.

We will also focus on locally generated data, thus achieving another objective: improving our understanding of dose-exposure-response relationships of how existing and new drugs are used in under-served African populations. This can help policy-makers and improve treatment.

SK: I would expect that this program strengthens the nascent centers of excellence such as the group at UCT and Makerere University and draws in other groups that we may not know of. These could form central hubs for local country networks of excellence, and encourage new centers, drawing in local, regional and international collaboration to increase the visibility of African pharmacometricians.

PB: Why is it necessary to start something like this and why Africa?

EC: There is only a small number of trained pharmacometricians in Africa, but with a large potential to expand. Africa also suffers disproportionately from a huge burden of infectious diseases which are often treated using older medicines developed at a time without robust methods of dose selection and dose optimization. Therefore there is plenty of room to improve doses of drugs to increase their effectiveness and safety. In addition, the growing prevalence and recognition of non-communicable diseases present an additional threat to patients.

The use of pharmacometrics offers an opportunity to improve the way available and new medication can be used to improve patient treatment outcomes and reduce the burden of disease on the continent.

Training opportunities in the field of pharmacometrics on the African continent are few and far between. I was fortunate to make contact with the group at the University of Cape Town and get access to the global network that Paolo and the clinical team had cultivated. More recently I learned of the group at Makerere University – and how both these teams have been hosting training events to build capacity for pharmacometrics in Africa. With both these units established within teaching hospitals, there is direct contact with the most pressing diseases affecting Africa and a vibrant culture of clinical research units. They are ideally poised to lead the way in bringing acceptance and harnessing the opportunity pharmacometrics offers to the continent.

PB: Does this imply that there is no need elsewhere?

CP: NO. In fact, there is need everywhere, since our science is still relatively new – we just felt that this was more acute in Africa, and it is the home base for some of us. We do want to collaborate with other groups especially those in LMIC's in the future.

PB: So can you tell us concretely what you will do?

AK: We will develop and offer training activities suited for different levels of interest in pharmacometrics. From undergraduate students who might be contemplating a post-graduate degree in this and associated fields to doctoral or post-doctoral level scientists who are applying modelling techniques in their specialized research fields. We will also raise awareness of the opportunities for applying quantitative methods among healthcare professionals.

We have structured our training into 3 approaches

Webinar Seminar Series

- Presenting topics of global health relevance with open access resources and materials. Our inaugural webinar on malaria vaccine modelling is available via our website at www.pmxafrica.org.

On-line training courses

- 10 to 12-week university-level courses with subject matter experts as faculty and tutors, including live and recorded weekly tutorials with all course content transferred to local host universities.

Face-to-face workshops

- Located in various African countries to maximize attendance by local scientists.

We will make significant progress prior to WCoP2020.

PB: Where is your funding coming from?

SK: Our goal is to make the training events to be as cost neutral to the delegates as possible.

Pharmacometrics Africa has received a grant from the Bill & Melinda Gates Foundation that will also allow a limited number of young scientists to attend WCOP and the training programs.

CP: We are actively looking for more funders.

PB: So how and why did you get involved in this exciting project?

EC: I recognize that there are many bright Africans who are talented, full of potential and who are looking for ways to apply their mathematical expertise and clinical acumen. All they need is somebody to believe in them, just like other people believed in me and gave me a chance. This is how the rest of the world works and Africa is no exception. As an African and knowing where I come from, it is my duty (and pleasure) to do whatever I can to promote pharmacometrics in Africa before I can expect others to do the same. I have had conversations with African pharmacometricians in the diaspora who share a similar perspective and we were considering ways to promote pharmacometrics in Africa. In this case Pharmacometrics Africa was a logical avenue. The energy and enthusiasm of young African scientists makes even brief contact with them very fulfilling personally. Sometimes it is just this brief contact that could be the missing piece to set a bright student off to an exciting career making significant contributions in pharmacometrics and addressing health challenges in Africa.

PB: And as a natural extension of the previous question – please tell us how others could get involved?

PD: The ways to get involved are numerous. One can opt to give a webinar, volunteer to teach at one of our face-to-face workshops, host a young pharmacometrician in your organization, share training materials, supervise or co-supervise a graduate or doctoral student or donate funds to support our work or scholarships for students.

AK: Please visit our website, www.pmxafrica.org for updates on all our activities and don't hesitate to contact any one of us.

News from the Journal of Pharmacokinetics & Pharmacodynamics

William Jusko, Editor-in-Chief

A highly interesting article was published by de Witte et al. in the August 2018 issue of *JPKPD*. While target binding has become well appreciated in influencing the pharmacokinetics and pharmaco-dynamics of biologics, consideration of the role of *kon* and *koff* for small molecule drug-receptor binding has gone largely neglected. Swinney (2008) has pointed out and listed a number of drugs that exhibit slow to extremely slow dissociation rates from their targets as identified by studying their binding kinetics. Discerning this mechanism as a rate limiting step is difficult without in vitro data for support. Thus it is likely that alternative models have been employed in analysis of data with such hysteresis. de Witte et al. nicely explored an array of target binding and effect compartment models to assess the PK and EEG effects of morphine in rats. They appropriately concluded that, "Drawing mechanistic conclusions from successfully fitting one of these two models should be avoided". As the target binding model can be informed by in vitro measurements of *kon* and *koff*, such data should be sought more often in seeking more useful PK/PD models with mechanistically relevant pharmacologic parameters.

References:

W. E. A. de Witte, V Rottschafer, M Danhof, P H van der Graff, L A Peletier, and E C M de Lange, Modeling the delay between pharmacokinetics and EEG effects of morphine in rats: Binding kinetic versus effect compartment models, J Pharmacokin Pharmacodyn 45: 621-635 (2018).

D C Swinney, Applications of binding kinetics to drug discovery: Translation of binding mechanisms to clinically differentiated therapeutic responses, Pharm Med 22: 23-34 (2008).

FDA 2018 By the Numbers

59 novel medicines approved

32% of NMEs approved were deemed first-in-class

43 were designated in one or more expedited approval categories, including approvals for 14 breakthrough therapies

34 new approvals for patients with rare diseases

The ISoP Newsletter Needs Contributors

Please contact Peter Bonate at peter.bonate@astellas.com if you are interested.

Is It Time to Learn a New Programming Language?

By Peter Bonate

The first computer programming language I learned was Basic in 1978 (yes, I am that old), when I was in high school. While an undergraduate in college, I learned Pascal and Fortran, and in graduate school I learned SAS. When I started my first job at Eli Lilly I learned Gauss and Matlab, but eventually settled on SAS and became a SAS guru. In the early 2000s I saw that people were starting to switch to R. So I too started to learn R, but I had a difficult time with it and soon started calling it the Devil's Language. That's right assignment "<-" operator, I'm looking at you. Anyways, I resisted as long as I could but a few years ago I had to buckle down and learn R, which I now feel quite comfortable with. I think I have 10 to 15 years left in my career (hopefully). Will I end my career using SAS and R? History would say 'no'. Should I learn a new programming language and, if so, which one should I chose and when should I start learning it?

When you only know one programming lamguage it's like the old adage, "If all you have is a hammer, everything looks like a nail." This is so true because I've seen people perform simple logistic regression using NONMEM. Why? There are easier options than NONMEM. They did it that way because NONMEM is what they knew.

There are lots of reasons to learn new languages. The first one is that it allows you new ways to think about how to solve a problem. You may realize that one language is better at solving a problem than another, like using SAS for logistic regression instead of NONMEM. Problem solving then becomes finding the right tool for the job.

Another reason is that learning another programming language lets you appreciate the differences between them. For instance, R uses 1-based vector indexing, Python used 0-based indexing. So if you have a vector x=[1,2,3,4,5] then x[1] will give you {1} in R, but will give you {2} in Python. Further, to slice a vector you use x[start:stop] in R but you use x[start:exclude] in Python. In other words to extract {1,2,3} from the vector you would use x[1:3] in R, but x[0:3] in Python. Wait, shouldn't it be x[0:2] in Python since it uses 0-based indexing? No, because the stop reference in Python is really an 'exclude' index, i.e., exclude x[3] from the slice. The first time I heard of this I thought "what the hell?" What kind of crazy thinking is that? I still think it's insane but it lets me appreciate R a little more. On the other hand, coding is Python is so easy to read, it's almost like pseudocode. Learning a second programming language allows you to see the advantages and disadvantages of both.

Lastly, learning a new language keeps things fresh and interesting, like taking a break from the daily grind, and allows you to add something more to your resume.

Now that you have decided to learn a new computer language, which one should you learn? There are so many options. Within Pharma, there are a couple of main contenders: SAS, R, Julia, Matlab, and Python. There are strong advocates for each. In Stack Overflow's 2018 Developer's Survey (1), R was the 19th most popular language, Matlab was the 6th most dreaded programming language, and Julia was the 17th most loved language. Python was the most wanted and 3rd most loved language. In the Tiobe Annual Programming Survey (2), which is based on number of search engine queries for the year, Python was voted the language of the year for 2018, R moved from 8 to 12th, a downward move for the first time, while Matlab moved from 12th to 8th. Julia didn't crack the top 20. In both surveys, SAS was nowhere to be seen. Knowing both SAS and R, I can say that if you know R, SAS will be easy to learn and in terms of statistical analysis is the industry leader.

Which language is right for you? It really depends on what you want out of it. I eventually decided to learn Python because I wanted to learn artificial intelligence techniques and right now Python is the go-to language for that. But if I had wanted to learn how to do easier statistical analyses, and I had access to it, SAS would have been a better choice. If I was in the Quantitative Systems Pharmacology area, Matlab may have been a better choice. Julia is being developed to be a faster and easier alternative to R. Some academic centers, like the University of Maryland, are building Julia libraries to replace R libraries for nonlinear mixed effects modeling. So maybe Julia should be the next step. In the end, you have to do what's right for you.

References:

1.) Stack Overflow Developer's Survey (https://insights.stackoverflow.com/survey/2018/).

2.) TIOBE Index for 2019. (https://www.tiobe.com/tiobe-index).

Communication Corner

By Peter Bonate

The Job Presentation in Pharma

When you interview for a job in Pharma you are often required to give a seminar on some work you have done in the past. Usually these last an hour, which is to include time for questions. I have sat through countless boring, scattered or poorly delivered ones and I am here to tell you a secret: *to my knowledge no one has ever gotten a job because of their seminar but I have seen many <u>not</u> get the job because of their seminar*. You see, there is no upside to a job presentation, all there is is downside. But time and again, interviewees come in poorly prepared, not having practiced, using material that was often thrown together at the last minute.

Job seminars are not the same as a scientific seminar. Yes, the audience wants to see something novel, but most don't expect to see anything new due to intellectual property considerations. I doubt anyone has gotten legal approval to present their work to a competitor during a job interview. Instead, compounds are often blinded or the work that is presented was done years ago on dead compounds. In some cases, work done in graduate school is presented. And that's ok because the real objective of the job seminar is to evaluate YOU in front of a crowd and see how you handle questions.

As a hiring manager let me give some advice to all those looking for a new job:

1.) **Know your audience**. Learn who will be at your seminar. Is it just pharmacometricians or will other scientists, like clinical pharmacologists and physicians, be present? Ask the hiring manager for the job what level of detail do they want you to go into because the presentation you make to pharmacometricians should be different than the one you make for a mixed audience.

Once you know your audience, tailor your presentation for them. What is it you want the audience to know? If they leave remembering one thing, what is that one thing? Take the time and effort to do a good job. Show that you are invested enough to care in the quality of your work.

2.) **Prepare**. The preparation you do beforehand is reflection of the quality of work you will do later. It is very obvious to an audience if a presentation was put together at the last minute. Respect your audience and don't do that.

Lastly, make sure you have enough material to fill the allotted time. On the flip side, don't be the person who says "I know this is a lot of slides. Let's see how much we get done."

3.) **Practice**. This may seem obvious but most people fail to practice for their job seminar. Instead you get comments like "what did I want to say here". Practicing will also reveal how cohesive a presentation is. Is what you are saying making sense? Is the presentation too long or short? Do you need to spend more time in a section because it isn't making sense? Remember what the purpose of the job presentation is – it's to evaluate your communication skills.

Don't forget your first impressions. It usually only takes a few minutes for people to make their mind up about you and whether they are truly going to listen to you. These first minutes are crucial. Make eye contact. Smile. If you have technical problems, make a joke about it. Once things get started, start strong. Practicing will help you create those powerful first moments of a presentation.

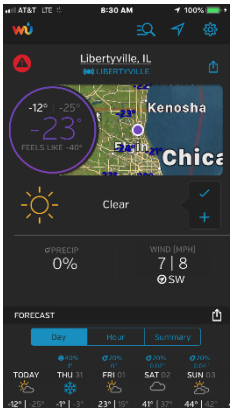
4.) **What was your role**? In some cases, it's easy to see what the presenter's role was in the presentation. If they are the pharmacometrician then they probably did the modeling. Sometimes though scientists come in and present study results and modeling results together. In the Q&A it becomes apparent they did not do the modeling work but were presenting the work of others. This is bad.

Part of working in a company is collaboration. Presenting someone else's work as your own is somewhat deceptive. Showing how you collaborated in a team presents you in a positive light. Remember, it's not just about you. When I think back about some of the people I've hired, I don't really remember what they talked about. What I remember is how they presented. How they made me feel. I can look at every one of my staff and tell you whether they did a good job at their presentation, whether they were nervous, or whether they displayed confidence. And for the people that we didn't hire, they are often discussed in terms of what they did wrong. "Do you remember so-and-so? Their presentation was so bad." There have been many times when I hired someone who gave a bad presentation because of their technical skills, but what I have learned is that often their bad job seminar skills carry directly over to the presentations they make for their job. Now, *I am to the point where I would rather hire an average pharmacometrician with great communication skills* than a great pharmacometrician with average communication skills. So, please do everyone a favor, take a little time to create a memorable job presentation. It can only help you land that job you want.

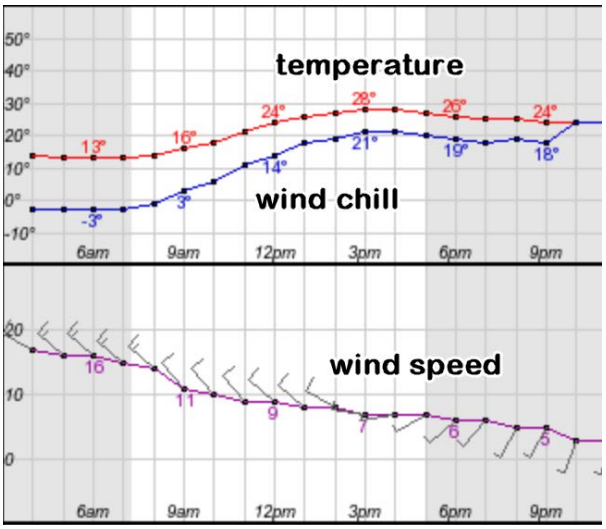
Did You Know?

What's the Deal with Wind Chill?

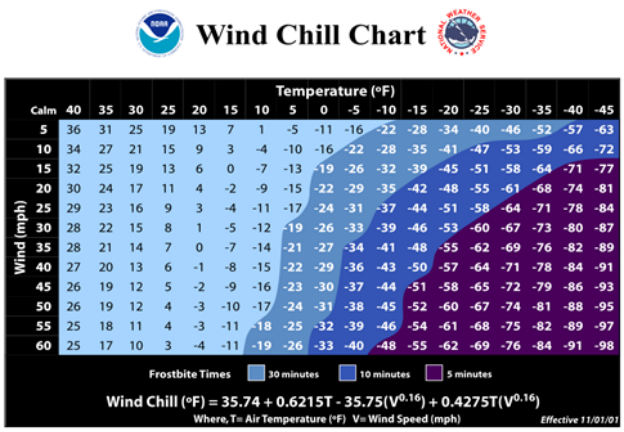
Reprinted from Decision Science News

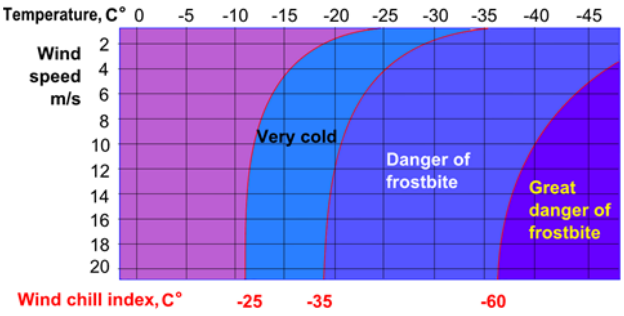


Editors note: On January 30th of this year, the Midwest in the United States was gripped by some of the most brutal, freezing temperatures it ever experienced because of a polar vortex reaching down from the Arctic. Temperatures around -25°F (-32°C) with wind chills of near -50°F were not uncommon. This blog post came out a couple of days before and I thought it would be interesting to our readers. Our thanks to Dan Goldstein, editor of Decision Science News (http://www.decisionsciencenews.com/), for allowing us to reprint the blog in its entirety.



Twenty years ago, a German colleague asked me what the deal was with wind chill. I guess they didn't have it in Germany. I explained it was an attempt to communicate how it feels when there is a low temperature combined with wind. But my colleague wanted to know how they get the values in charts like these:





If you look closely at the Wind Chill Chart in the left-column, it gives the formula for wind chill. It looks pretty hairy but it's just a function of two things: wind speed and temperature. The windchill in Fahrenheit is just:

35.74 + .6251 * temp – 35.75 * windspeed^.16 + .4275 * temp * windspeed^.16

(Note that windchill is only defined for temperatures below 50°F and wind speeds above 3 mph.)

But where does this equation come from? This brochure has the answer. Researchers put sensors on people's faces and had them walk in wind tunnels:

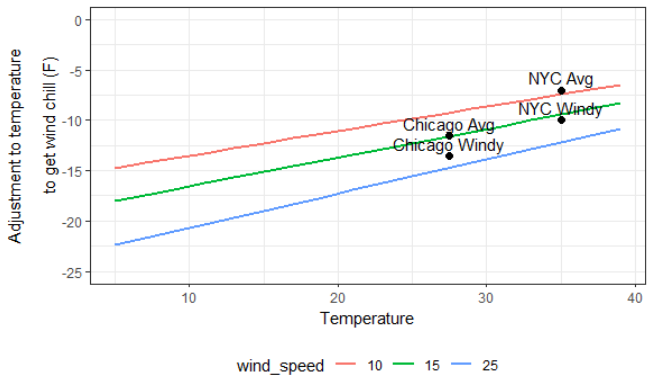
> During the human trials, 6 male and 6 female volunteers were placed in a chilled wind tunnel. Thermal transducers were stuck to their faces to measure heat flow from the cheeks, forehead, nose and chin while walking 3 mph on a treadmill. Each volunteer took part in four trials of 90 minutes each and was exposed to varying wind speeds and temperatures. The NWS Wind Chill Temperature (WCT) index uses advances in science, technology, and computer modeling to provide an accurate, understandable, and useful formula for calculating the dangers from winter winds and freezing temperatures. The index does the following:

- Calculates wind speed at an average height of 5 feet, the typical height of an adult human face, based on readings from the national standard height of 33 feet, typical height of an anemometer
- Is based on a human face model

- Incorporates heat transfer theory based on heat loss from the body to its surroundings, during cold and breezy/windy days
- Lowers the calm wind threshold to 3 mph
- Uses a consistent standard for skin tissue resistance
- Assumes no impact from the sun, i.e., clear night sky

A common misunderstanding is to assume that the wind can make something colder than the outside temperature. That can't happen. Wind just speeds up the chilling process.

Ok, this is all fine, but we wanted a chart that would 1) make it easier to see the effect of the wind speed and temperature and 2) show the wind chill effect for typical February weather in New York and Chicago. We coded up the following:



Note that in this chart, the Y axis isn't the temperature, it's the difference between the outside temperature and the windchill: the number of degrees you need to subtract.

So, when the wind is 10 miles per hour (red line), and the temperature is 25 degrees (x axis value of 25), the effect of wind chill is to lower the perceived temperature by 10 degrees (y axis value of -10), but at the same temperature when the wind is 25 miles per hour (blue line), wind lowers perceived temperature by about 16 degrees.

A useful takeaway is that with average winds and average temperatures, the effect of windchill is to lower the perceived temperature by about 7-12 degrees.

(BTW, if you like this stuff, you might enjoy our post on the heat index.)

Want to mess around with the code? It's posted in the next column.

R Code:

```
library(tidyverse)

#Wind speeds from the percentile bands in
#https://weatherspark.com/y/23912/Average-Weather-
in-New-York-City-New-York-United-States-Year-Round

#https://weatherspark.com/y/14091/Average-Weather-
in-Chicago-Illinois-United-States-Year-Round

#weather.gov wind chill chart at
https://www.weather.gov/safety/cold-wind-chill-
chart

get_wind_chill = function(temp,wind){
   35.74 + 0.6251*temp - 35.75 * wind^0.16 +
      0.4275 * temp * wind^.16 }

toC = function(F) {(F - 32) * 5 / 9}

speeds = c(10,15,25)

mini_df = data.frame(temp=c(35,35,27.5,27.5),
                     wind=c(10,16,14,22),
                     lab=c("NYC Avg",
                           "NYC Windy",
                           "Chicago Avg",
                           "Chicago Windy") ) %>%
  mutate(wind_speed=factor(wind, levels = speeds),

wind_chill=round(get_wind_chill(temp,wind),0))

df = expand.grid(temp=seq(5, 40, by = 2),
        wind=speeds) %>%
        mutate(wind_speed =
             factor(wind, levels = speeds),
               wind_chill =
              round(get_wind_chill(temp,wind),2))

p = ggplot(df, aes(x=temp,
                   y=wind_chill-temp,
                   group=wind_speed,
                   color=wind_speed) )
p = p + geom_line(size = 1)
      + ylim(c(-25,0))
      + theme_bw()
      + labs(x = "Temperature",
             y = "Adjustment to temperature\n
                   to get wind chill (F)")
p = p + geom_text(show.legend=FALSE,
           data=mini_df,
           aes(x = temp,
               y = wind_chill - temp + 1.25,
               label=lab,
               group=NULL,
               color=NULL) )
p = p + geom_point(show.legend=FALSE,
                   data=mini_df,
                   size=2,
                   aes(x=temp,
                       y=wind_chill-temp,
                       group=NULL,
                       color=NULL) )
       + theme(legend.position = "bottom")
ggsave(plot=p,
       file="windchill_chicago_nyc.png",
       width=6, height=4)
```


WCoP
World Conference on Pharmacometrics
CAPE TOWN 6-9 April 2020
wcop2020@gmail.com
www.go-wcop.org

aaps Workshop

AAPS Forum to Connect Predictive Modelers

Increasing Modeling's Collective Impact on PharmSci

May 6-7, Hyatt Regency Boston Harbor, Boston, MA

Visit us at **https://www.aaps.org/modeling**

to learn more and see the agenda, which features several

familiar names from the ISoP community!

Join us at the AAPS Forum to Connect Predictive Modelers -- share and learn together as a collective and unified pharmaceutical sciences modeling community!

This event will bring together predictive modelers from academic, industry and regulatory environments. The goal of this program is to identify opportunities to work together going forward to provide a more comprehensive and influential quantitative basis for decision making within our institutions. Great science happens when great scientists come together!

Join us as we think outside the box and use our collective knowledge to explore:

- Tools, techniques, and the language driving predictive modeling today
- Modeling philosophy and best practices
- Ways to strategically communicate modeling results
- Future directions and new frontiers of predictive modeling
- Opportunities for collaboration, efficiency, and cross-discipline learning

Lend your modeling expertise, learn from your peers, and help formulate a more comprehensive and quantitative basis for decision making within our research organizations!