REFLECTIONS ON STATISTICAL EDUCATION, PRACTICE, AND OPPORTUNITIES FOR LEADERSHIP

Lisa LaVange, PhD
ASA President
Professor and Associate Chair

ASA New Jersey Chapter/
Bayer Workshop
Bayer Campus
Whippany, NJ
November 2, 2018
Outline

- Leadership opportunities in statistical practice
  - Industry
  - Academia
  - Government
- Training – statistics and data science
- ASA Leadership Institute
LEADERSHIP OPPORTUNITIES

All Employment Sectors
My Career

- Non-profit research (1976 – 1994)
- Large CRO (1996-2001)
- Academia (2005 – 2011)
- Academia (2018 to date)
- Retirement...?
Leadership Opportunities in Industry

Examples

• Large research institutions (e.g., RTI, Quintiles) are often matrix organizations
  • Management positions with assigned leadership roles – e.g., director, vice-president
  • Additional leadership opportunities through multi-disciplinary project teams

• Pharma opportunity to lead a development team (esp. in small pharma)
  • Drug supply
  • Non-clinical studies
  • Clinical development
  • Strategic planning (e.g., market research)
  • External communication – scientific, regulatory, business
Leadership Opportunities in Academic Research

- Collaborative research
  - R01 grants led by subject matter expert
  - Coordinating center grants for multi-site studies

- UNC Biostatistics has the oldest continuously funded NIH coordinating center (1971)
  - Clinical trials and trial networks
  - Epidemiology studies (longitudinal cohort studies)
  - Patient registries

- Coordinating Center PI is an important member of the study’s steering committee
  - Usually the sole statistical voice among other disciplines

- Challenge is to build consensus for and ensure adoption of:
  - Most appropriate trial design and analysis plan
  - High quality study conduct, data collection, safety reporting, etc.
  - Efficient data sharing, publications, dissemination of results
Leadership Opportunities in Academic Research

Examples

- PI for Coordinating Center of Hispanic Community Health Study/Study of Latinos
  - Epidemiology study of risk factors and health outcomes in cohort of 16,000 US Hispanics/Latinos
  - As voting member of Steering Committee, led initiative to apply household-based area probability sampling methods for recruitment of cohort – met with much resistance!
  - Impact of sampling design on recruitment, retention, and data analysis required continued leadership to carry to completion

- PrecISE – NHLBI funded trial network to study targeted therapies in severe asthma
  - Different designs optimal for different questions, e.g., select treatment(s) for further study or determine which treatment is better for a given subgroup or identify the subgroup most likely to benefit from treatment
  - Obtain consensus among statisticians while also obtaining buy-in from clinicians
Opportunities to Lead at FDA

- Leading within the Office of Biostatistics
  - Growing the workforce
  - Training and mentoring statistical reviewers
  - Educating and influencing reviewers of other disciplines
- Owning statistical policy
  - Through guidance development and dissemination
  - Through internal discussions with other disciplines
- Leading innovation
  - Precision medicine
  - Smart use of non-standard trial designs and data sources
- Influencing decisions (when quantitative reasoning is critical)
“...Give priority to provisions that present the greatest opportunity for FDA to foster innovation and integrate advances in biological sciences, engineering, information technology, and, to most directly improve the Agency’s product review tools and processes.”

The 21st Century Cures Act (Cures Act), signed into law on December 13, 2016, is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.

“...“Expert FDA staff with expertise in statistics, data science, meta-analysis, clinical outcomes research, and other areas will develop the framework and methodologies for evaluating the use of real world evidence
Precision Medicine

• Personalized medicine is getting the right product to the right patient (and in case of a drug or biologic) at the right dose

• Key challenge is to identify targeted subgroups at the right stage

• FDA statisticians have long been involved:
  • Diagnostic device evaluation (CDRH)
  • Enrichment study designs (CBER and CDER)
  • Master protocols/platform trials (CBER, CDER, CDRH)
  • Biomarker validation and qualification (CDER)

• As medicines (or their targets) become more precise, traditional clinical trials become more difficult to conduct and/or less efficient

• Collaborative research paradigms, such as master protocols, are of increasing interest, as a result
Master Protocols

• Multiple diseases, multiple patient subgroups (biomarker-defined), and/or multiple therapies studied under one, over-arching protocol

• FDA’s advocacy has had an influence
  • Support of programs like I-SPY 2, Lung MAP, PREVAIL II, ADAPT, DIAN-TU
  • Path for patient advocacy groups to become involved, often driving collaborations

• NIH research a natural home for master protocols
  • Long history of supporting comparative effectiveness research
  • Goal of inference is to influence the practice of medicine
  • Treatment algorithms tailored to individual patients using machine learning methods
  • Real-world data presents challenges, e.g., mobile health data, EHRs, claims data
Master Protocols to Study Multiple Therapies, Multiple Diseases, or Both

Janet Woodcock, M.D., and Lisa M. LaVange, Ph.D.

High-quality evidence is what we use to guide medical practice. The standard approach to generating this evidence—a series of clinical trials, each investigating one or two interventions in a single disease—has become ever more expensive and challenging to execute. As a result, important clinical questions go unanswered. The conduct of "precision medicine" trials to evaluate targeted therapies creates challenges in recruiting patients with rare genetic subtypes of a disease. There is also increasing interest in performing mechanism-based trials in which eligibility is based on criteria other than traditional disease definitions. The common denominator is a need to answer more questions more efficiently and in less time.

A methodologic innovation responsive to this need involves coordinated efforts to evaluate more than one or two treatments in more than one patient type or disease within the same overall trial structure.\(^4\) Such efforts are referred to as master protocols, defined as one overarching protocol designed to answer multiple questions. Master protocols may involve one or more interventions in multiple diseases or a single disease, as defined by current disease classification, with multiple interventions.
Adaptive Designs for Clinical Trials of Drugs and Biologics

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document, contact (CDER) Scott N. Goldie at 301-796-2055, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologies Evaluation and Research (CBER)

September 2018
Clinical/Medical

Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologies Evaluation and Research (CBER)
Oncology Center of Excellence (OCE)

September 2018
Procedural
Master Protocols – NIH application

- PrecISE – Precision Medicine in Severe, Exacerbation Prone Asthma network
- Adaptive platform trial conducted under a master protocol
- 6 novel interventions identified for study
  - Early futility testing to drop interventions
  - Add other interventions, as they become available
- Randomization probabilities based on biomarker-defined subgroups of patients targeted by each intervention
- Precision medicine interim analysis to refine definition of target subgroup
  - Refine cut-point delineating biomarker + and – patients
  - Refine the biomarkers themselves
- Final precision medicine analysis to identify best course of treatment among overlapping subgroups using machine learning methods
• FDA Reflection paper on E6, E8
• Proposal to
  • Revise E8 (R1)
  • Renovate E6
• Office of Biostatistics:  
  • Co-authored reflection paper  
  • Leading E8 revision

ICH Reflection on “GCP Renovation”: Modernization of ICH E8 and Subsequent Renovation of ICH E6

12 January 2017

ICH is inviting public review and comment on a reflection paper on Good Clinical Practice (GCP) "Renovation", which contains the ICH proposal for further modernization of the ICH Guidelines related to clinical trial design, planning, management, and conduct. The scope of the proposed renovation includes the current E8 General Considerations for Clinical Trials and further revision to the E6 Guideline for Good Clinical Practice, which is already undergoing modernization with the recent production of ICH E6(R2).

The reflection paper is available for download via the following link:

• Reflection paper on GCP Renovation

The goal of the potential renovation is to provide updated guidance that is both appropriate and flexible enough to address the increasing diversity of study types and data sources that are being employed to support regulatory and other health policy decisions, as appropriate. The underlying principles of human subject protection and data quality would remain. ICH’s decision to invite stakeholder comment on the proposed renovations at this early stage, ahead of guideline development efforts, recognises the considerable stake and relevant expertise in the research community beyond ICH.

The seeking of stakeholder comment on the current reflection paper is seen as a first step in an enhancement of the ICH process with respect to public consultation for the revision of ICH E8 and E6. The GCP Renovation reflection paper outlines additional steps that are also being considered to enhance stakeholder engagement.
ICH E8 General Considerations for Clinical Trials

1999 guideline describes:
- Phases of drug development
- Features of trial design
- Importance of protecting safety of participants

Expert working group formed for revision; two meetings held to date
- Target date of 1st quarter 2019 for draft guideline available for public comment
- Statistician is rapporteur; EWG includes variety of disciplines

Revised document:
- Introduces quality by design approach; critical to quality factors managed proportionate to risk
- Expands types of trial designs beyond RCTs
- Expands data sources to include real-world data*

*Jarow, LaVange, and Woodcock, JAMA, 2017
Other Initiatives

- PDUFA VI
  - Complex Innovative Designs – pilot program
  - Analysis data standards
  - Patient-focused drug development
  - Real-world evidence
- Pediatric trials – new approaches
- Catching up with academia—dynamic treatment regimes and machine learning
TRAINING

Statistics and Data Science
Training Statisticians

- Probability and statistical inference
  - Theory and application
- Specialty areas, e.g., clinical trials, statistical genetics, Bayesian statistics, sample surveys, etc.
- Data Science and Machine Learning
- Leadership
29 Bootcamp entries

http://datascience.community/bootcamps
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Get Course Syllabus
582 entries in college/university degree programs

http://datascience.community/colleges
Top 23 Schools with Data Science Master’s Programs

Looking to freshen your résumé and improve your earning potential? You’re in exactly the right place at exactly the right time. According to Glassdoor, there are over 15,000 jobs in the analytics and data science fields as of January 2018. In response, universities have been looking to improve their existing degree data and analytical programs and to create entirely new degrees offerings, both online and on-campus. We’ve listed 23 of these programs below.

Choose the Best Masters in Data Science Program For You

1st Master’s program in Advanced Analytics

https://analytics.ncsu.edu/
UNC MPH Program Launches in 2019

Public Health Data Science Concentration

Scientific discoveries made by the Gillings School’s Dr. Michael Kosorok, left, were put into practice by pediatric pulmonologist Dr. George Retsef-Bogart. The result was better hospital care and better health for children with cystic fibrosis.

About

Accurate interpretation and use of data is crucial to understanding health needs and devising and implementing comprehensive, evidence-based solutions.

The Public Health Data Science concentration—one of the first applied data science programs situated within a school of public health—will give you the skills and knowledge to employ cutting-edge data science tools and, in turn, respond to pressing public health issues and advance effective solutions.
ASA AND DATA SCIENCE
SPECIAL INVITED LECTURES

ASA President’s Invited Address
TUESDAY, 8:00 PM

Deming Lecture
TUESDAY, 4:00 P.M.

DR. DENNIS GILLINGS
Chairman and Chief Executive Officer
Quintiles Transnational Corporation

DR. GEORGE E. P. BOX
Professor Emeritus, University of
Wisconsin and ASA Past President

ASA Presidential Address
TUESDAY, 8:00 PM

Fisher Lecture
WEDNESDAY, 4:00 P.M.

DR. W. MICHAEL O’FALLON
Mayo Clinic
ASA President

DR. INGRAM OLHIN
Stanford University
ASA and Data Science

- ASA statements and curriculum guidelines state three foundational components:
  - Mathematics
  - Statistics
  - Computer Science

- July 2017 Board Meeting
  - Met with NY Data Science Academy to discuss their program, curriculum, evaluation, and job placement
  - Discussed among Board members the possibility of accreditation in data science to ensure adequate statistical training
  - Similar to Pstat accreditation program
  - AMS having similar discussions

- April 2018 Board Meeting
  - Broad discussion on data science and ASA’s role in the field
  - Consensus reached that statistical leaders will be working with, managing data scientists going forward
ASA Statement on the Role of Statistics in Data Science

1 OCTOBER 2015 10,488 VIEWS 13 COMMENTS

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The rise of data science, including Big Data and data analytics, has recently attracted enormous attention in the popular press for its spectacular contributions in a wide range of scholarly disciplines and commercial endeavors. These successes are largely the fruit of the innovative and entrepreneurial spirit that characterize this burgeoning field. Nonetheless, its interdisciplinary nature means that a substantial collaborative effort is needed for it to realize its full potential for productivity and innovation. While there is not yet a consensus on what precisely constitutes data science, three professional communities, all within computer science and/or statistics, are emerging as foundational to data science: (i) Database Management enables transformation, conglomeration, and organization of data resources, (ii) Statistics and Machine Learning convert data into knowledge, and (iii) Distributed and Parallel Systems provide the computational infrastructure to carry out data analysis.

Certainly, data science intersects with numerous other disciplines and areas of research. Indeed, it is difficult to think of an area of science, industry, commerce, or government that is not in some way involved in the data revolution. But it is databases, statistics, and distributed systems that provide the core pipeline. At its most fundamental level, we view data science as a mutually beneficial collaboration among these three professional communities, complemented with significant interactions with numerous related disciplines. For data science to fully realize its potential requires maximum and multifaceted collaboration among these groups.

Curriculum Guidelines for Undergraduate Programs in Data Science


Keywords
curriculum, statistics education, computer science education

Abstract

The Park City Math Institute 2016 Summer Undergraduate Faculty Program met for the purpose of composing guidelines for undergraduate programs in data science. The group consisted of 25 undergraduate faculty from a variety of institutions in the United States, primarily from the disciplines of mathematics, statistics, and computer science. These guidelines are meant to provide some structure for institutions planning for or revising a major in data science.
Success, Opportunities, and Challenges for Statistics and Biostatistics in the Data Science Era

A Report of the July 2016 NSF-Sponsored Workshop for Chairs of Departments of Biostatistics and Statistics
ASA AND LEADERSHIP TRAINING

The ASA Leadership Institute
Leadership Training

- Curriculum*
  - Vision and strategic thinking
  - Communication
  - Diversity
  - Ethics
  - Basic management skills and financial literacy
  - Transformational leadership, empowerment, and innovation
  - Personal leadership styles
  - Organizational leadership and culture
  - Conflict resolution
  - Decision making and decision analysis

*Curriculum from Biostatistics 844, University of North Carolina at Chapel Hill, Fall, 2018
ASA Leadership Institute

2018 Presidential Initiative

1. Support development of leaders of statistics groups/organizations – *assigned leadership*

2. Support development of leaders of multi-disciplinary groups -- *emerged leadership*

3. Offer elements of statistical leadership to leaders of other disciplines
• **Michael Rappa** – Goodnight Director and Distinguished University Professor, Institute for Advanced Analytics at North Carolina State University

• **Bob Rodriguez** – Senior Director in SAS Research and Development and former ASA President

• **Aarti Shah** – Senior Vice President and Chief Information Officer and former Vice President of Biometrics and Advanced Analytics at Eli Lilly and Company


• **Debbie Hughes** – Vice President for Higher Education and Workforce Development at the Business and Higher Education Forum

**ASA LEADERSHIP INSTITUTE Steering Committee**
ASA Leadership Institute

• Steering Committee met Jan. 23 to brainstorm about initiatives

• Identified three points in a statistician’s career for leadership training:
  • Pre-career
  • Early- to mid-career
  • Mid- to late-career

• Different objectives at each stage

• Different opportunities for engagement
2018 Launch – Three Initiatives

• Pre-career: Future Leaders Program
  • 5-student teams recruited through ASA student chapters
  • Coaching provided to solve a leadership challenge problem
  • Present solutions to ASA Board in April 2019

• Early- to mid-career:
  • Extend current JSM short course to offer more in-depth training
  • Open to JSM 2018 workshop registrants plus past cohorts
  • Learning opportunities planned in-person and via web

• Mid-late career:
  • Engage ‘C-suite’ leaders to understand organizational needs
  • Identify resources to provide for members seeking to take the next leadership step
  • Roundtable co-sponsored by BHEF to include executives from industry, academia, and government
Leadership Challenge

Overview

Teams with five members will take on a leadership problem. At least 2 members of the team must be students during the challenge period. The remaining members of the team must have a graduation date after January 1, 2018.

At least one member of the team must attend the kick-off at JSM 2018.

Six teams will be selected to compete in the challenge.

Each team will be assigned a coach.

Each team will select a representative to present the team’s solution to the ASA Board of Directors at their April 2019 meeting.

Each member of the winning team will receive a $500 travel scholarship to attend a 2019 or 2020 ASA meeting.

All participants will receive complimentary ASA membership for 3 years.

Applications are due by July 20, 2018.

5 Teams Selected; Met with coaches at JSM; Webinar Series planned for fall/winter
Mid-Career Leadership Training

- Pilot-test as year-long follow-up to JSM 2018 Leadership Workshop
- 3 Modules offered between Fall 2018 and Spring/Summer 2019

1. Cultural Competency in Leadership
2. Decision making and decision analytics
3. Communicating with the C-Suite, or Executive Presence for Statisticians
Mid-Career Workshops

- 20 Attendees
  - 8 from JSM 2018 Leadership Course
  - 12 alums from prior JSM courses
- Guest speakers from FDA and Industry
- Focus on diversity and leadership
C-Suite Roundtable

Convene C-suite executives from industry and academia to provide insight into their organizational leadership models and training needs, and ultimately champion ASA activities.
Summary

• Data science permeates all aspects of statistics, from education to employment
• Leadership opportunities abound, as a result
• Presidential initiative to develop an ASA Leadership Institute
  • Supports membership at all career stages
  • Provides a home for ASA professional development offerings
  • Is sustaining
  • Strives to become a recognized resource in leadership training, for statisticians and beyond
• Choose to Lead!