

Expanding Leadership and Substantive Skills of Statistical Agency Personnel – Panel Discussion

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BASIC CONCEPTS AND SKILLS

My observations, so far

Based on a career spanning industry, academia, and government

- Leadership opportunities are out there for statisticians
- As a profession, we are often viewed as supporting, rather than leading, scientists or policy makers
- This needs changing
- But to do so requires increased awareness, training, and skill building, often on-the-job

Some basic concepts

- Leadership and influence:
 - “Leadership is a process whereby an individual *influences* a group of individuals to achieve a common goal”
 - “Influence is the sine qua non of leadership. Without influence, leadership does not exist.”
- Trait vs. process
 - Defining leadership as a process rather than as a set of innate qualities → leadership is available to everyone, not just a pre-determined few

Ref. Northouse (2010)

Some basic concepts

- Assigned vs. emergent leadership*
 - “Leadership that is based on occupying a position in an organization is assigned leadership...Yet the person assigned to a leadership position does not always become the real leader in a particular setting.”
 - Emergent leadership is acquired “through other people in the organization who support and accept that individual’s behavior...it emerges over a period through communication.”
- Communication behaviors of emergent leaders include “being verbally involved, being informed, seeking others’ opinions, initiating new ideas, and being firm but not rigid.”**

* From Northouse (2010)

**From Fisher (1974)

Some basic concepts

- Emergent leadership, cont.
 - Personality plays a role – traits include intelligence and confidence
 - Gender- or other biased perceptions may occur
 - Social identity theory may be in play – how well does the person reflect the group's identity?
- Assigned or emergent leaders are engaged in leadership—both influence others to achieve results

Statistical leadership

- Statistical leadership
 - May involve leading a team, department, division, office, or other organizational unit consisting primarily of statisticians – *usually assigned*
 - May involve leading a multi-disciplinary team – *often emergent*
- Both (assigned and emergent) are important
 - Both provide a way for statisticians to influence others in accomplishing meaningful goals
 - Both require skills fundamental to effective leaders
 - Both encompass a variety of leadership styles

Skills

- Statistical knowledge and skills are essential, but
- In-depth understanding of content area is, as well
- To have a seat at the decision-making table
 - Both are needed for statisticians to be scientific collaborators, not just consultants
- Formal educational training is just the beginning
 - Field is always evolving
 - Staying current while on the job can be challenging
 - Learning how to think, to problem-solve is critical in keeping up

Skills -- communication

- Effective communication
 - Requires being able to express yourself in a way that does not detract from the logic and science of your work
 - When successful, both parties sufficiently understand the science of the other's discipline
- As a statistician, you communicate to a variety of audiences in a variety of circumstances
 - Must be able to account for differing points of view
 - Must have ability to speak to others with different and varied skill sets, interests, and knowledge

Communication



"We know that communication is a problem, but the company is not going to discuss it with the employees."



Statistical Leadership

TRAINING AND OPPORTUNITIES

Statistical Leadership

- UNC Biostatistics course in Statistical Leadership
 - Co-Developed and taught in 2011 with Bill Sollecito, PhD
 - Designed for doctoral students with work experience and nearing graduation
 - Motivation based on the number of UNC Biostatistics graduates currently in leadership positions in academia, industry, and government
- Course format
 - Concepts and skills of leadership
 - Guest lecturers from different employment sectors
 - Serve as role models
 - Present real-world problems for students to ‘work’

Leadership Training

- Essential components*
 - Vision and strategic thinking
 - Basic management skills – communication, delegation, etc.
 - Transformational leadership, empowerment, and innovation
 - Personal leadership styles
 - Project team leadership; organizational leadership
 - Conflict resolution
 - Ethics; service to the profession and to society
 - Leadership as lifelong learning

**Curriculum from Biostatistics 844, University of North Carolina at Chapel Hill, Fall, 2011*

Statistical Leadership: Preparing Our Future Leaders



Photo by Michella Dabner
Leadership in Biostatistics students at The University of North Carolina. From left: Margaret Polinkovsky, Alison Wise, Jennifer Clark, Beth Jablonski Horton, Annie Green Howard, and Michael Huszay.

When you think of statistical leaders, what examples come to mind? Do you think of a preeminent researcher, a department head, or an elected officer in our association? All these are important, but an even greater variety of leaders is essential to the vitality and visibility of our profession. In this month's column, I discuss why we need more statistical leaders and ways we can develop future leaders.

Why Is Statistical Leadership Critical?

writing an editorial letter advocating for data-based policy decisions is a statistical leader, as is a manager working with human resources staff to define the job responsibilities of statisticians in a company or government agency.

Along with influencing others, leadership is about helping others succeed. A university professor coaching a student on how to give an effective presentation is a statistical leader, as is an experienced industrial statistician guiding a younger colleague through multiple revisions of a paper.



Robert Rodriguez

AmStat News Feb 2012

← President's Corner

UNC Course ↓

Preparing Biostatisticians for Leadership Opportunities

Lisa LaVange, William Sollecito, David Steffen, Lori Ewerts, and Michael Kosorok

A new course on statistical leadership, offered by the department of biostatistics in the Gillings School of Global Public Health at The University of North Carolina at Chapel Hill, was launched last fall. The course was the result of a year-long planning effort initiated by department chair, Michael Kosorok, and a planning committee of senior faculty led by professor William Kalsbeek.

The motivation for offering a course in leadership was two-fold. First, the planning committee determined that many UNC biostatistics graduates held leadership positions throughout academia, government, and industry. Providing a course in leadership would ensure graduates were well-equipped to meet the challenges they would face when tapped for such a position. Second, the committee determined the concepts of organizational leadership and skills required to become an effective leader were not covered in any other course.



Leadership in Biostatistics students discuss strategic planning during a break out session. From left: Margaret Polinkovsky, Daniela Sotres-Alvarez (faculty member auditing the course), and Alison Wise.

Leadership opportunities at FDA

- FDA wide: 300+ statisticians
 - CDER's Office of Biostatistics: over 170 and climbing
 - Office is comprised of 7 divisions, each with 3-4 teams
- Leadership opportunities at FDA:
 - Serve as Team Leader, Division Director, or Deputy within the biostatistics organization
 - Serve as Thought Leader within CDER for a specific area of statistical policy and/or methods
 - Participate in FDA Advisory Committee meetings
 - Represent the office on internal and external working groups and committees

Summary

- Lots of opportunities for statisticians as leaders
 - Of groups of statisticians
 - Of multi-disciplinary teams
- Leadership skills can be acquired, but training is needed
- Leadership is influence—whether assigned or emergent
- Effective communication is essential to having influence
- I encourage you to speak up (in areas where you are comfortable with your expertise), exert your influence, and move your organizational teams forward. You may be surprised at the impact you can have!

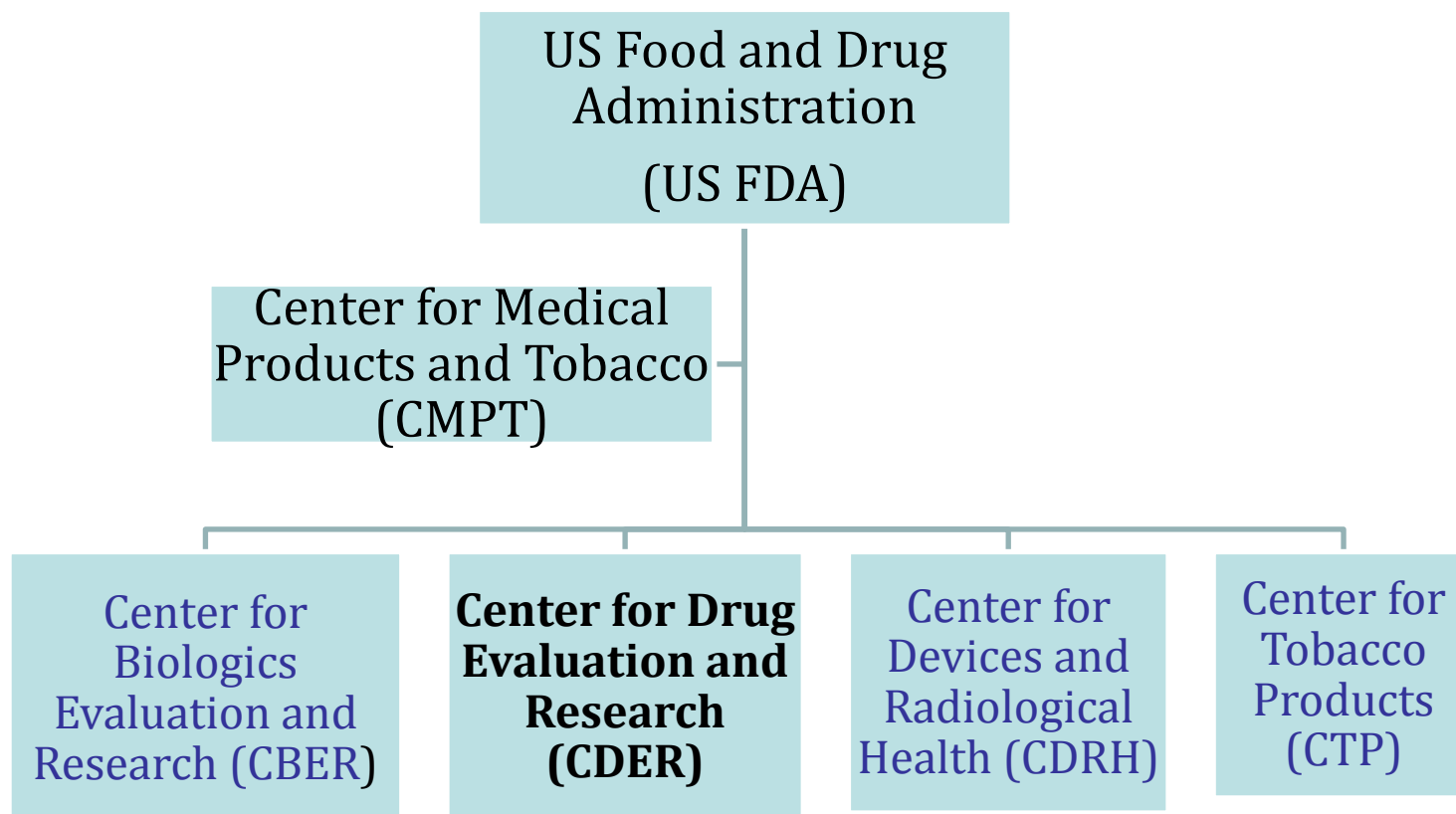
References

- *Leadership: Theory and Practice* by Peter G. Northouse, 5th edition, Sage (2010)
- *Managing Scientists* by Alice M. Sapienza, 2nd edition, Wiley (2004)
- *Small group decision-making: Communication and the group process* by BA Fisher, McGraw-Hill (1974)

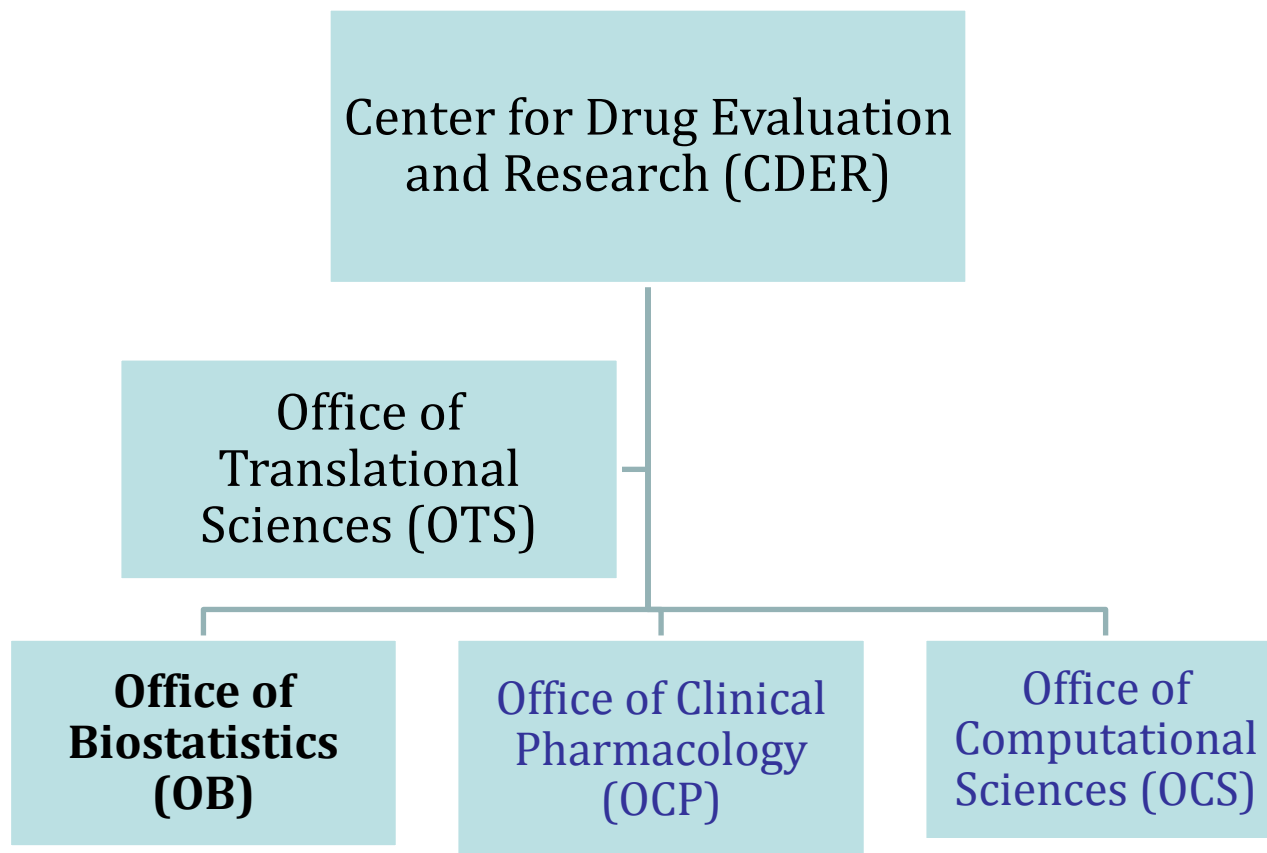


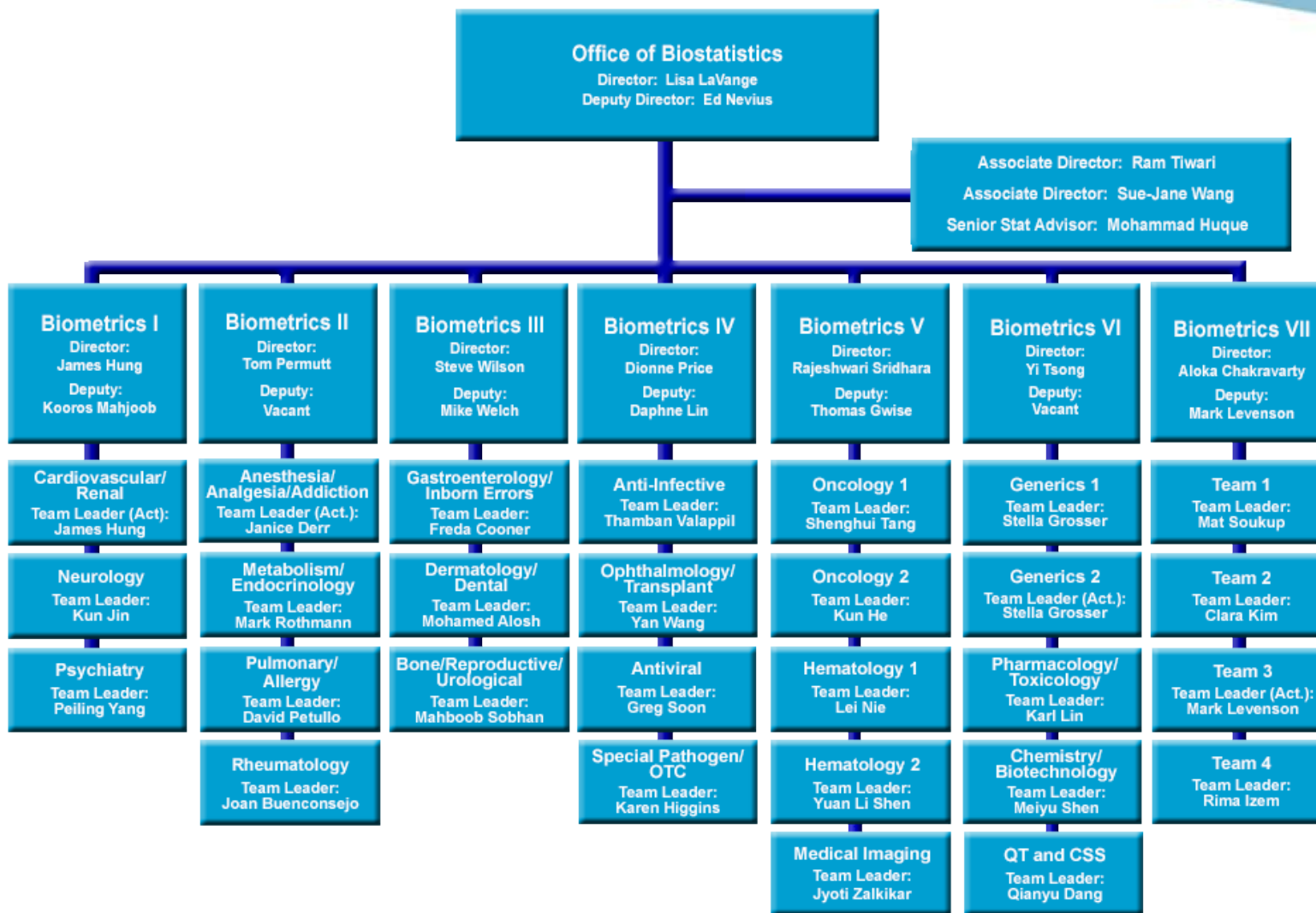
BACK-UP SLIDES

Office of Biostatistics



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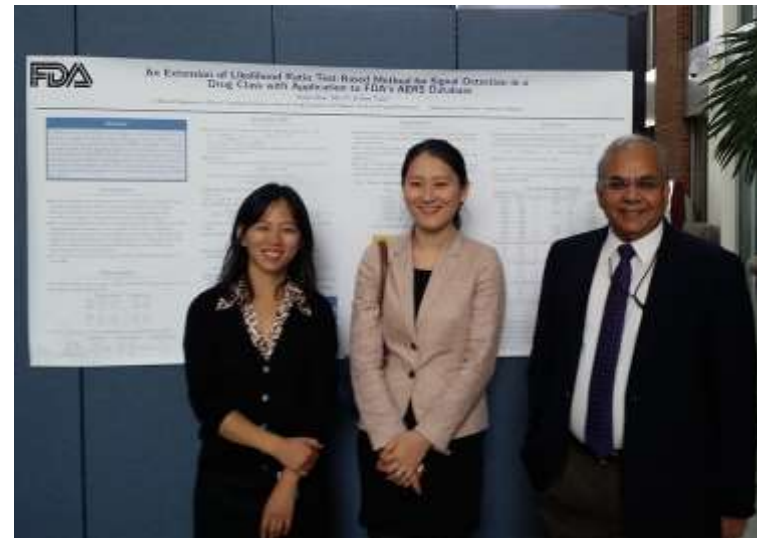




2014 OB Regulatory Science Day

Friday, September 19, 2014
Building 66 Room G512/514





Office of Biostatistics

- Consistent with CDER'S Strategic Plan 2013-2017, we promote
 - **Consistency** in application of statistical methods across medical divisions, while also factoring in therapeutic considerations
 - **Transparency** and reproducibility of regulatory reviews
 - **Clarity** of statistical policy as applied to regulatory submissions

2013 Metrics

- 175 statisticians and support staff
 - 300+ statisticians FDA-wide
 - Planned growth to 205 (in CDER)
- ~ 300 statistical reviews (efficacy, safety, equivalence)
- ~1600 IND/protocol reviews (~600 unique INDs)
- 60 peer-reviewed publications
- Over 50 external presentations

Office of Biostatistics

- **Vision statement:**

The Office of Biostatistics is recognized for excellence in the application and communication of statistical science in drug regulation and development. We play a central role in promoting innovative, science-based, quantitative decision-making throughout the drug development life-cycle.

- **Mission statement:**

Provide CDER and other internal and external stakeholders with statistical leadership, expertise, and advice to foster the expeditious development of safe and effective drugs and therapeutic biologics for the American people. Protect the public health by applying statistical approaches for monitoring the effectiveness and safety of marketed drugs and therapeutic biologic products.