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Biostatistics, Epidemiology & Research Design (BERD)

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*Et al.*

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UMass Center for Clinical & Translational Science (CCTS) Seminar Series – Biostatistics, Epidemiology & Research Design (BERD)

Arlene Ash, Ph.D.
Chief, Division of Biostatistics and Health Services Research
BERD Director
December 2, 2011
Organizational Structure
Quantitative Methods Core –
A Progress Report

Bruce A. Barton, Ph.D.
Director
Quantitative Methods Core
December 2, 2011
Purpose

- QMC Role
- QMC Progress Report
- QMC Future Directions
- QMC Contact Information
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Quantitative Method Core Mission

• To provide the highest caliber of professional expertise to researchers in the design, conduct, analysis, and reporting of medical research

• Established within Division of Biostatistics and Health Services Research in the Department of Quantitative Health Sciences
QMC Services

• Analysis of existing data
• Study design
• Grant preparation
• Data management
• Data and safety monitoring
• Study conduct
Analysis of existing data

- Prep data for analysis
- Can accept almost any format (e.g., Excel)
- Work with you to determine best analytic approach and actually run the analyses
- Help with tables, listings, figures
- Help with write-up
  - I.e., Stat methods and Results sections
Study design

- Randomized clinical trials
- Cohort studies
- Case-control studies
- Retrospective studies
- Quasi-experimental designs
- Single- or multi-center
- Adaptive and accelerated designs
- Clustered designs
Grant preparation

- Sample size/power
- Analysis plans
- QA/QC
- Data management plans
- Data and safety monitoring
- Data/resource sharing
- Innovation, innovation, innovation
- Review and editing
- Key statistical personnel
Data Management

• Design and implement systems for data entry, data processing, and integration with statistical programming

• Multiple approaches
  – REDCap
  – Fax-Entry
  – QuickBase

• Developing area
Data and Safety Monitoring

• RCTs require Data and Safety Monitoring Boards (DSMBs)
• Observational studies require OSMBs
• Both single center and multi-center studies
• Large and small
• Developing area
Study Conduct

• Currently providing services as described above
• Future area for development
• Eventually evolve into a Data Coordinating Center (DCC)
• DCCs (independent) required for multi-center studies
Other services

- Epidemiology
- Informatics
- Health services research
- Outcomes research
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Progress Report

• Unofficial start – 2/1/2010
• Official start – 5/1/2010
• Substantial – and rapid – growth
• Staffing has grown to accommodate
• Review of what we have done and who is the QMC
Progress Report – As of 11/30/2011

• Initial investigator meetings: 155
• Initial project meetings: 218
  – Currently, about 1/3 of new projects are with “repeat” investigators
• Departments involved: 28
  – Divisions involved: 20
  – Includes animal labs, cell biology, molecular biology, pathology
Project Meetings by Quarter

- Frequency

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Projects
Project Meetings by Quarter

![Bar chart showing frequency of project meetings by quarter for CY 2010 and CY 2011. The chart compares the frequency of projects and investigators across quarters.]
Project Meetings by Quarter

- **Frequency**
- **Projects**
- **Investigators**
- **Repeat**

**CY 2010**

**CY 2011**
Progress Report - Results

• Purpose of Meeting
  – Grant Applications: 82 (38%)
  – Analysis: 78 (36%)
  – Study Design: 35 (16%)
  – Study Support: 17 (8%)

• Articles/Abstracts Submitted: 32
Progress Report - Results

• Grants submitted: 82
  – NIH R-level grants: 55
  – NIH K-level grants: 6
  – NIH P-level grants: 3
  – Foundations/Other: 14
  – CTSA: 4
Progress Report - Results

- U Mass Cross-Campus Collaborations: 6
  - U Mass Lowell: 3
  - U Mass Boston: 1
  - U Mass Dartmouth: 2
Progress Report - Education

• QMC Seminars/Workshops
  – 1\textsuperscript{st} and 3\textsuperscript{rd} Tuesday each month at 12 noon in AC7-211
  – Cover wide variety of topics:
    • Clinical trial evolution
    • Power analysis for genetic studies
    • Bootstrap (non-parametric) confidence intervals
    • Multiple testing
    • Probability sampling in health research
    • Better statistical graphics workshop (January)
Current Faculty

• Bruce Barton, Ph.D.
Current Faculty

- Bruce Barton, Ph.D.
- Arlene Ash, Ph.D.
- Stephen Baker, M.Sc. P.H.
- Julia (Hua) Fang, Ph.D.
- Phil Gona, Ph.D. (12/15/2011)
- Sharina Person, Ph.D.
- Sowmya Rao, Ph.D.
Current Staff

• Connie Barysaukas, M.S.
• Aimee Kroll-Desrosiers, M.S.
• Stephen Kurtz, M.S.
• Dane Netherton, Ph.D.
• Recruiting additional statisticians and database programmers
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QMC – The Future

• Continue basic approach with expanded services
  – Particular interest in finding a health economist, a “Quality of Life-ist”, and a statistical geneticist
  – Many applications could/should have a Specific Aim in one or more of these areas
  – Experience exists, but not the obvious credentials
QMC – New Frontiers

• Data management
  – Based on both REDCap system and new “Fax-Entry” system
  – REDCap system has been described in this forum earlier this fall
  – Fax-Entry system based on Teleform software to design, publish, and process CRFs
  – Essential element is to integrate elements of a system into the “stream of research”
QMC - Data Management Progress Report

• REDCap systems routinely designed and implemented as are Fax-Entry systems

• Currently, 8 projects use (or are about to use) QMC Data Management – with numerous grant applications proposing to use a QMC system

• Challenge is to build the infrastructure
QMC – New Frontiers

• Data and Safety Monitoring Board Reports
• All RCTs – and observational studies – must now have a DSMB/OSMB
  – Leads to the requirement for substantive reporting
  – Includes study conduct, safety, and possibly efficacy
• Specialized programming to turn DSMB/OSMB reports into production
QMC – Data Monitoring

• Produce hard-copy/PDF reports for distribution
• Integrate with cube ("drill-down") technology to provide additional information if DSMB members request
• Formal interim analyses if study requires
• Integrated with QMC Data Management systems to provide direct data access
QMC Data Monitoring Progress Report

• Currently, providing Data Monitoring for two studies with one more about to start
• Numerous grant applications propose to use QMC Data Monitoring
• Hiring statistical staff experienced in this type of programming to develop standard, yet flexible, approaches to data monitoring
QMC – Final Frontier

• Data Coordinating Center activities for Multi-Center Studies
  – Study documents
  – Data management systems
  – Systems integration (randomization, drug and specimen inventory management, ePRO systems)
  – Logistics
  – QA/QC
  – Data and Safety Monitoring
  – Analysis and Reporting
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What to expect

• Meet with a faculty-level biostatistician
• Discuss what you need with informed discussion of options
• Formulate an Action Plan
• Form a collaboration to get your project done in the best possible way
• Teamwork!!!
• Polished final product
How to Contact the QMC

• E-mail (easiest): QMC@UMassMed.edu
• URL: www.UMassMed.edu/QHS/QMC.aspx
• Phone: 6-8798 (Kelley Baron)
• Set up a time to meet and talk about what help you might need
• Send out an Information Sheet to gather some information about your project before we meet
Cost

• Partially supported by the CTSA
• Junior investigators and short consults are generally at no cost (CTSA)
• Grant applications are generally at no cost assuming QMC staff/support included in grant budget
• Long-term analyses projects need to be supported – various mechanisms
• P01 program/project grants – let’s talk
Questions?

• Now or later
Dept. of Quantitative Health Sciences – Background and Status

Catarina Kiefe, PhD, MD
Chair, Dept. of Quantitative Health Sciences
December 2, 2011
Dept of Quantitative Health Sciences (QHS)

– QHS, an academic dept with a broad mission

– Includes all CCTS Biostatistics, Epidemiology, and Research Design (BERD) Specific Aims and much more
QHS: The Youngest UMMS Dept

• Conceptualized by UMass leadership in 2007, during CTSA planning

• Viewed as pivotal in
  – Strengthening T2+ translational research
  – Providing expertise campus-wide in the quantitative health sciences: statistics, epidemiology, “and more”
  – Providing a model for “breaking down silos” and collaborative research
QHS History

- Inaugural Chair and Vice-Chair arrive on campus June 2009
- 4 Division Chiefs recruited by October 2009
- Strategic planning retreat held Spring 2010
- Quantitative Methods Core opens May 2010
- UMCCTS funded July 2010
QHS Vision

• **Vision:** We will be leaders in the science of moving from discovery to improving individual and population health

• **Values:**
  – Science that makes a difference
  – Integrity and scientific excellence
  – Collective creativity
  – Diversity and mutual respect
  – Social justice through improved health
QHS Senior Faculty

• Chair: Catarina Kiefe, PhD, MD
• Vice-Chair: Jeroan Allison, MD, MScEpi
• Division Chiefs:
  – Arlene Ash, PhD: Biostatistics and Health Services Research
  – Rob Goldberg, PhD: Epidemiology of Chronic Disease and Vulnerable Populations
  – Tom Houston, MD, MPH: Health Informatics and Implementation Science
  – John Ware, PhD: Outcomes Measurement Science
• Director, Quantitative Methods Core: Bruce Barton, PhD
QHS Current

• 33 Primary Faculty total
  • Goal: Steady state of about 40 Primary
• 23 Faculty with QHS primary salary commitment (18.8 FTE):
  – 7 Professors, 6 Assoc Profs, 8 Asst Profs, 2 Instructors
  – Average 76% effort extramurally funded
• 3 Adjunct/voluntary Faculty
• 26 secondary faculty from 12 Depts/Divs
QHS Teaching and Enrichment

• Masters of Science in Clinical Investigation
  – Targets mostly MDs becoming clinician-scientists
  – Being reorganized; Goldberg, Director

• Doctoral Program in Clinical and Population Health Research
  – Transitioned to home in QHS
  – Currently ~6 new students/year
  – MD/PhD track to be expanded
Questions?