Dec 2nd, 12:00 PM

Biostatistics, Epidemiology & Research Design (BERD)

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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

QHS

Division of Biostatistics & HSR

BERD

QMC
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
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
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

Q1  Q2  Q3  Q4  Q1  Q2  Q3  Q4

CY 2010

CY 2011

Projects
Project Meetings by Quarter

- Frequency of meetings by quarter and year.
- Two years compared: CY 2010 and CY 2011.
- Categories: Projects, Investigators, Repeat.

Bar chart showing the trend of project meetings across quarters for both years.
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\(^{st}\) and 3\(^{rd}\) 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 Barysauskas, M.S.
- Aimee Kroll-Desrosiers, M.S.
- Stephen Kurtz, M.S.
- Dane Netherton, Ph.D.
- Recruiting additional statisticians and database programmers
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
Purpose

- QMC Role
- QMC Progress Report
- QMC Future Directions
- QMC Contact Information
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?