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
Purpose

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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

Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

Projects
Investigators

CY 2010 CY 2011
Project Meetings by Quarter

Frequency

Q1  Q2  Q3  Q4  Q1  Q2  Q3  Q4

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 Barysauskas, M.S.
• Aimee Kroll-Desrosiers, M.S.
• Stephen Kurtz, M.S.
• Dane Netherton, Ph.D.
• Recruiting additional statisticians and database programmers
Purpose

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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
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
Department of Quantitative Health Sciences (QHS) Org Chart

Chair
Vice-Chair

QHS Divisions

Biostatistics
Epidemiology
Health Informatics
Outcomes Measurement

QHS Infrastructure Units

Quantitative Methods Core
Technology Development and Usability Lab
Administrative Unit
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?