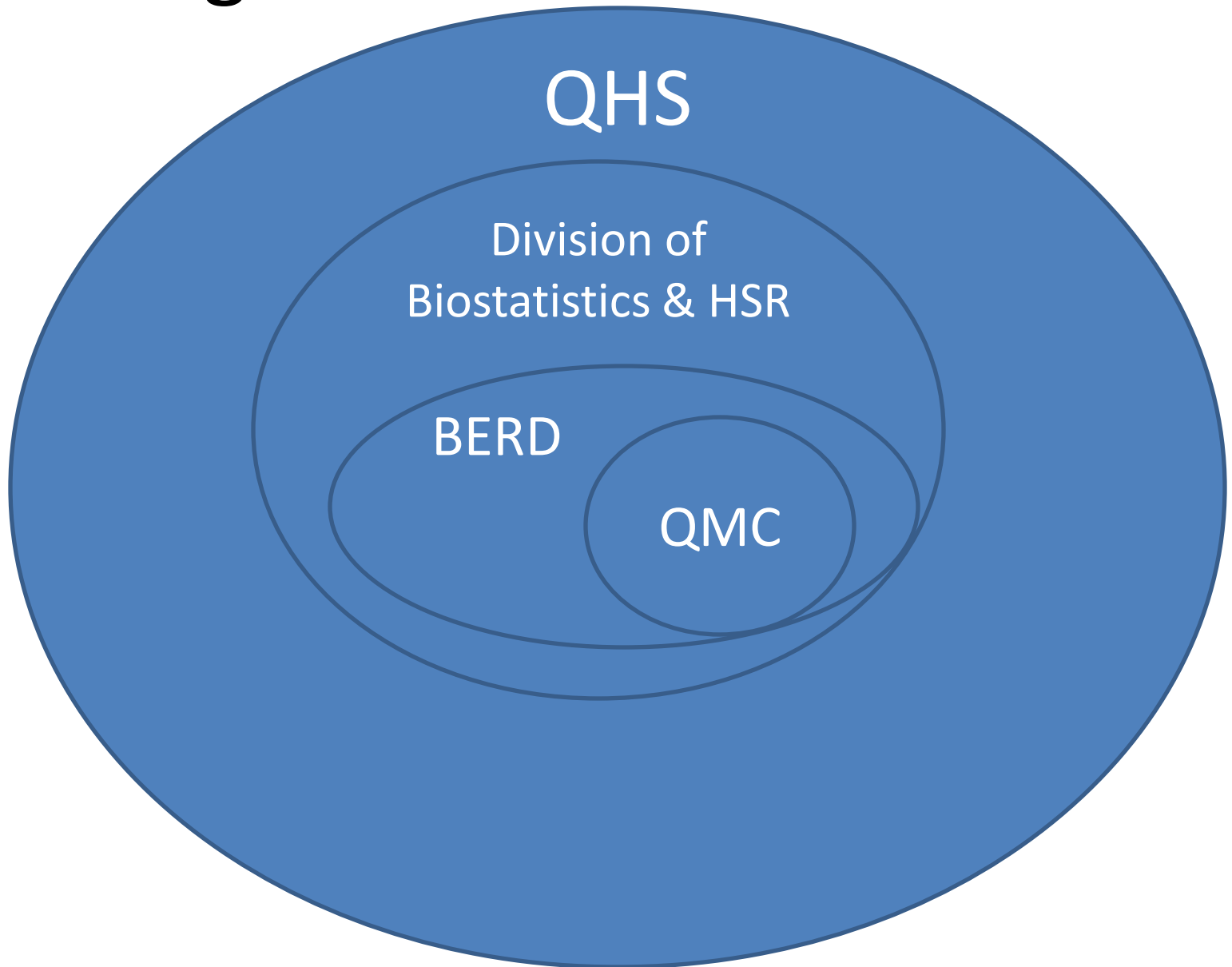


UMass Center for Clinical & Translational Science (CCTS) Seminar Series – Biostatistics, Epidemiology & Research Design (BERD)

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.

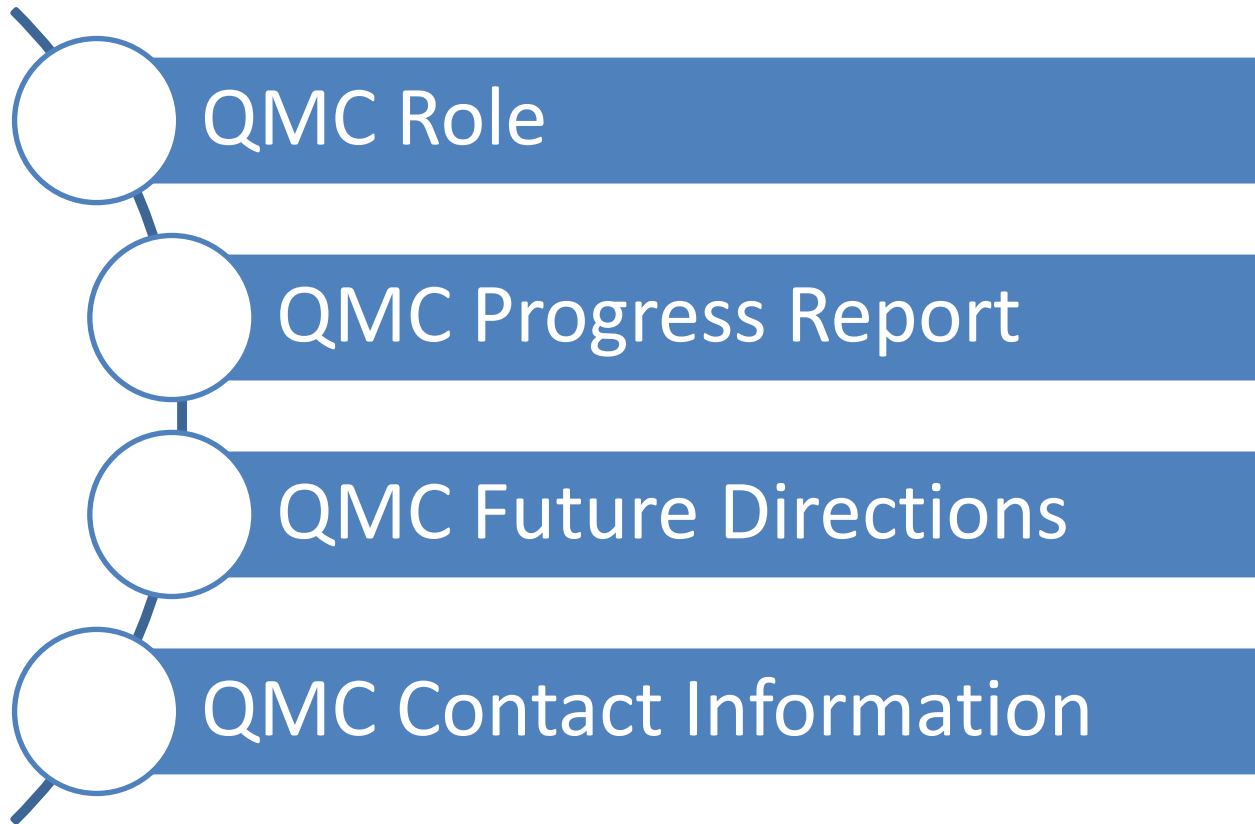
Director

Quantitative Methods Core

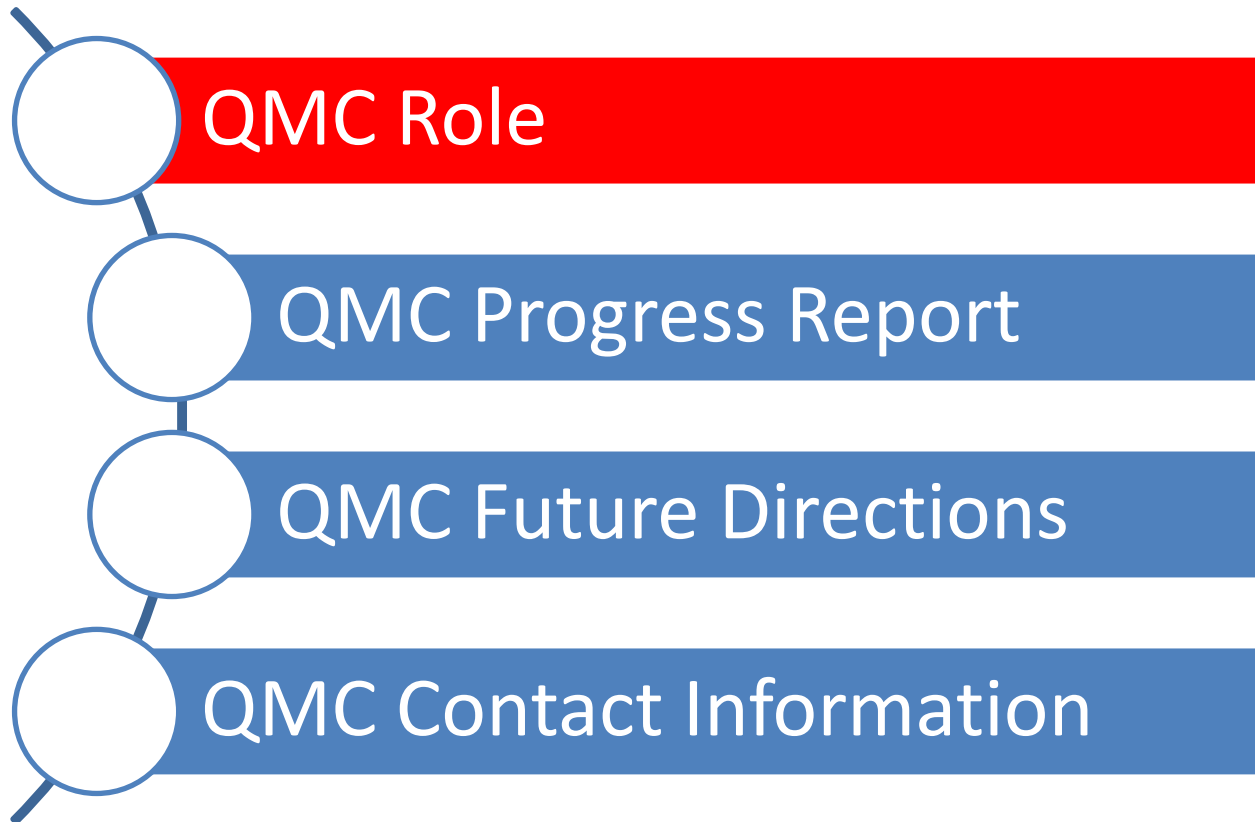
December 2, 2011



Purpose



Purpose



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

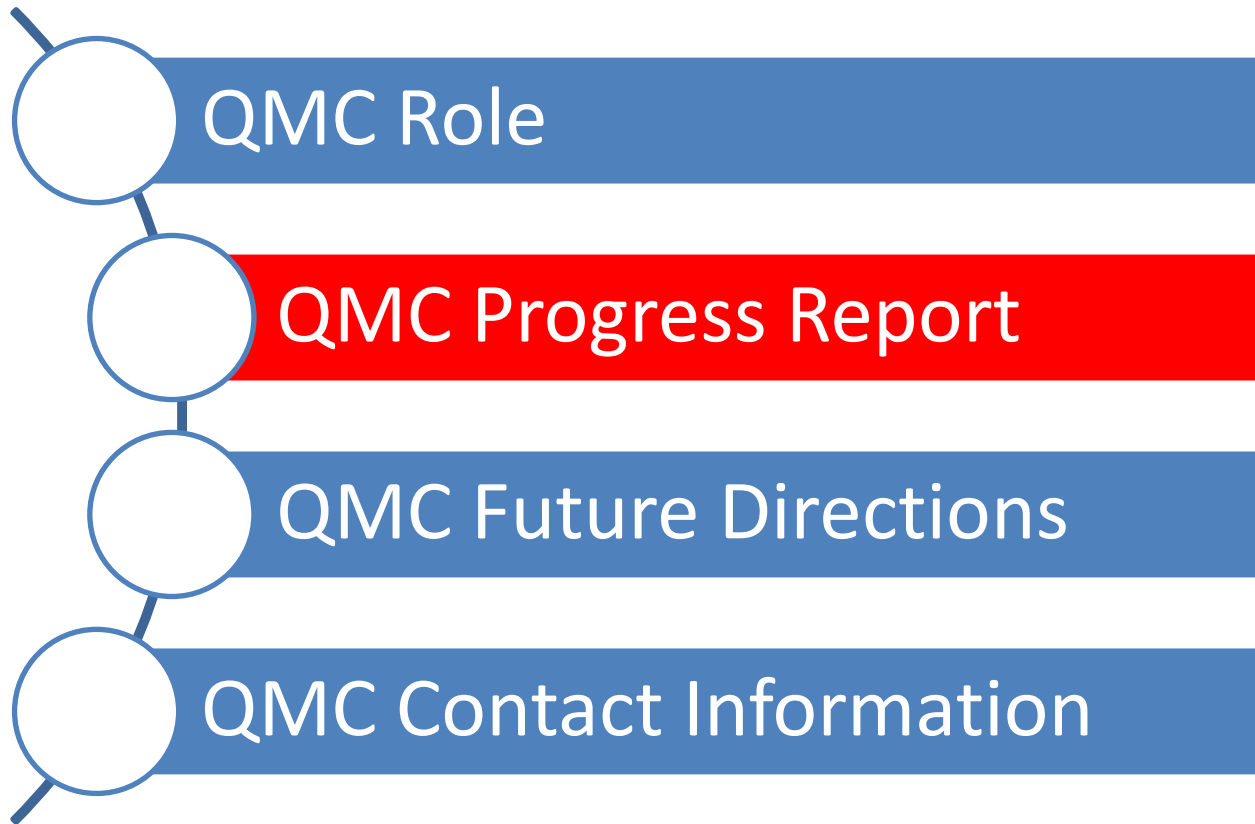
Study Conduct

- 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



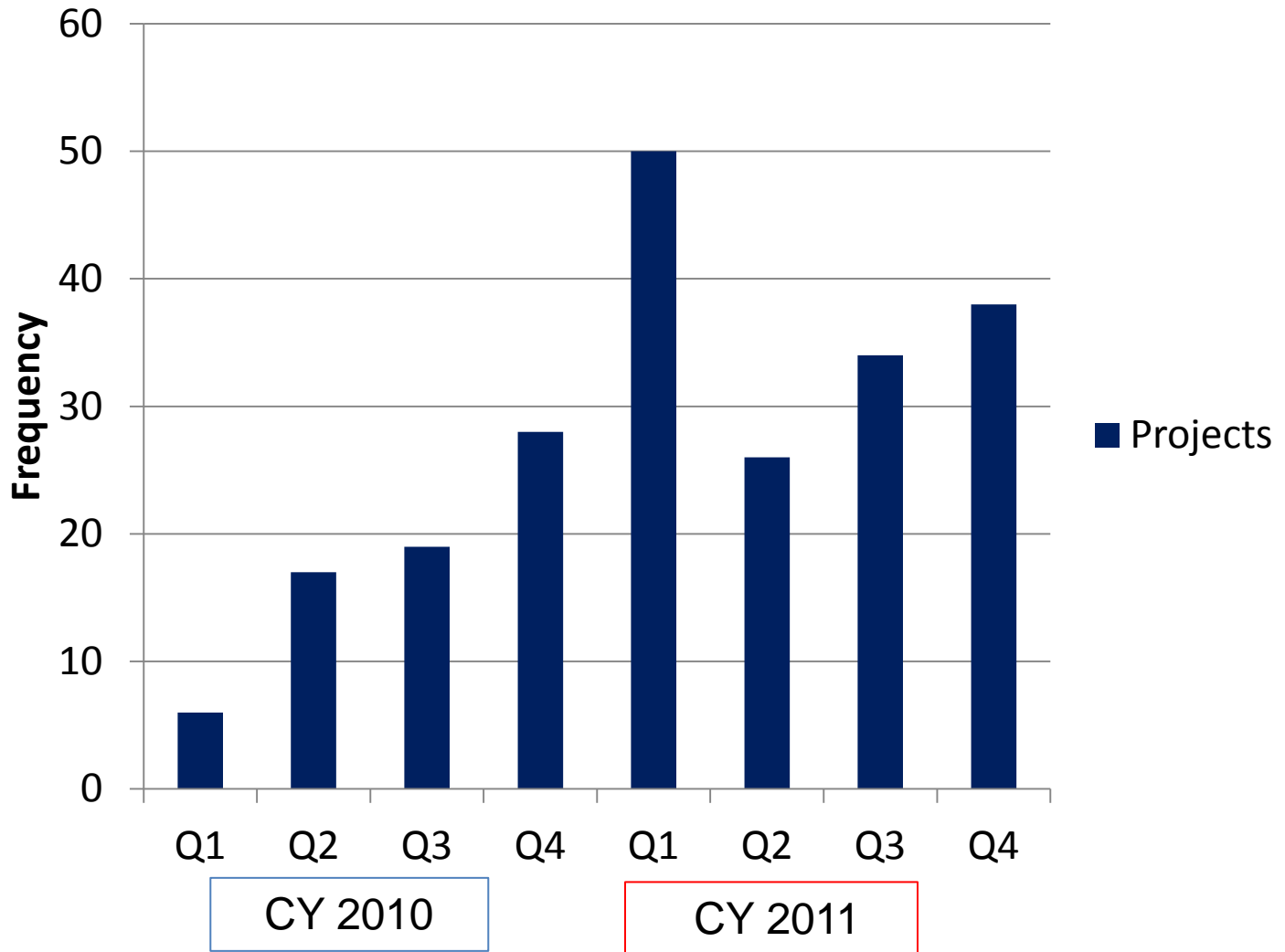
Progress Report

- 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

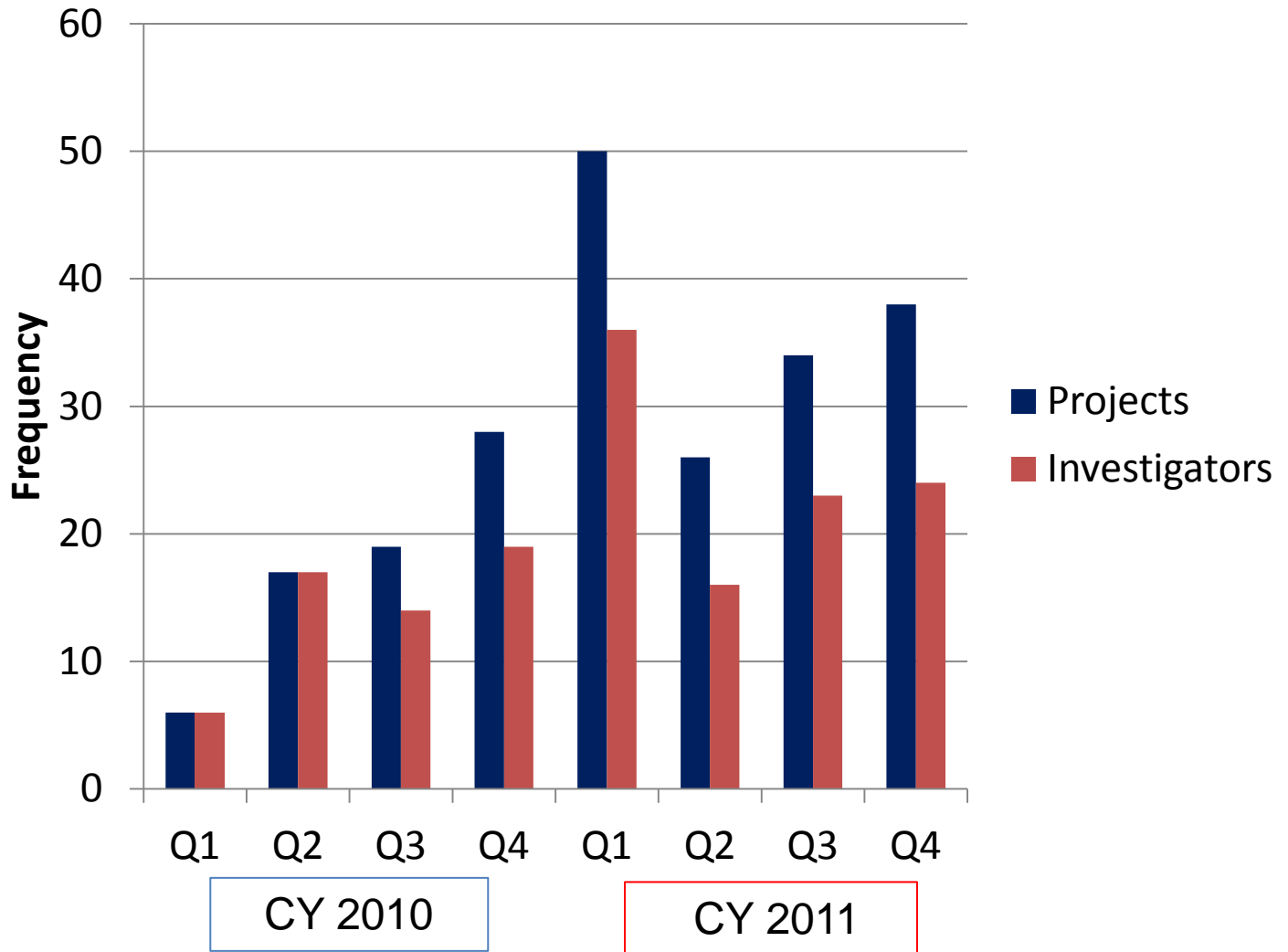
Progress Report – As of 11/30/2011

- 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

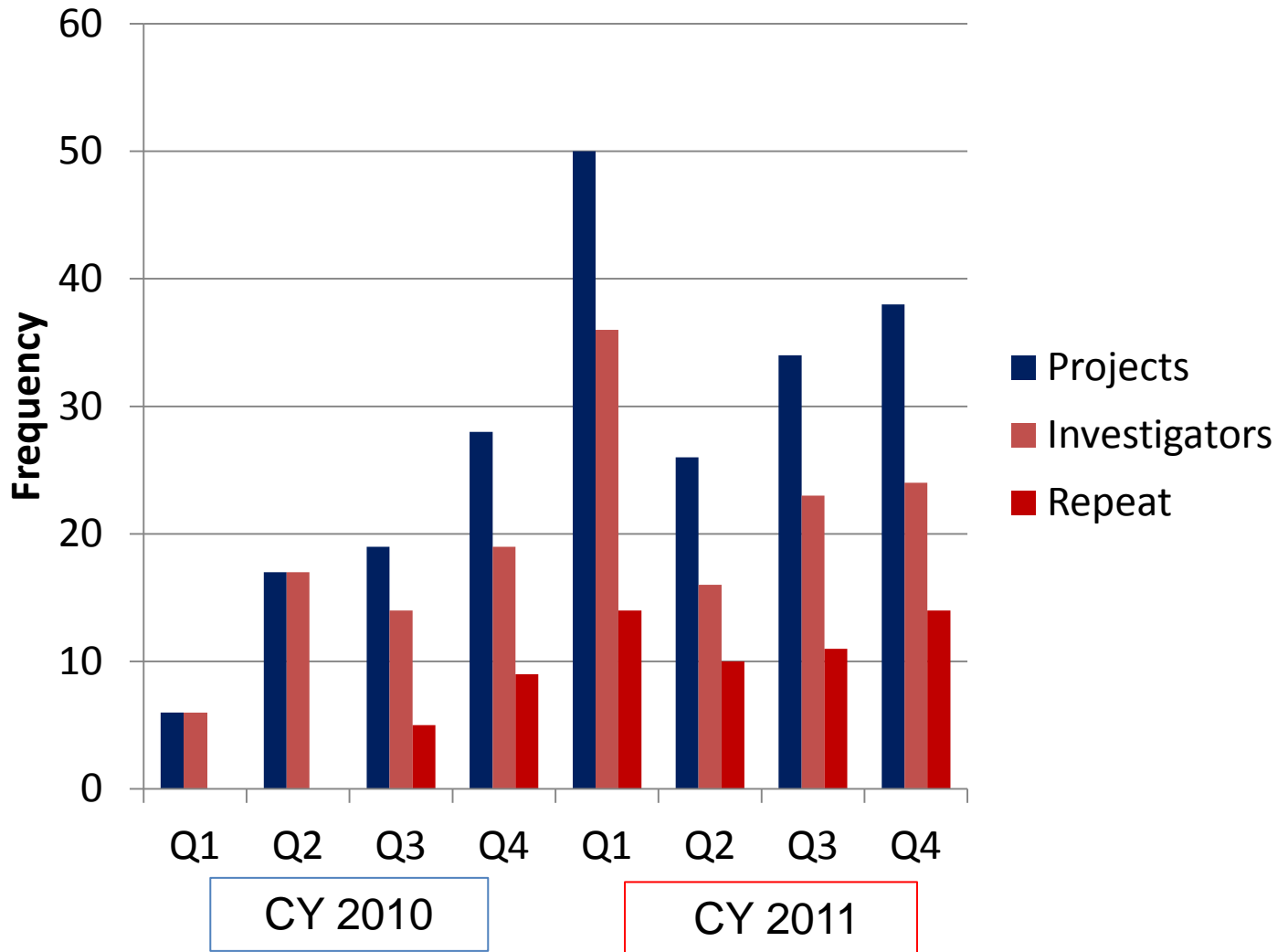
Project Meetings by Quarter



Project Meetings by Quarter



Project Meetings by Quarter



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
 - 1st and 3rd 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.

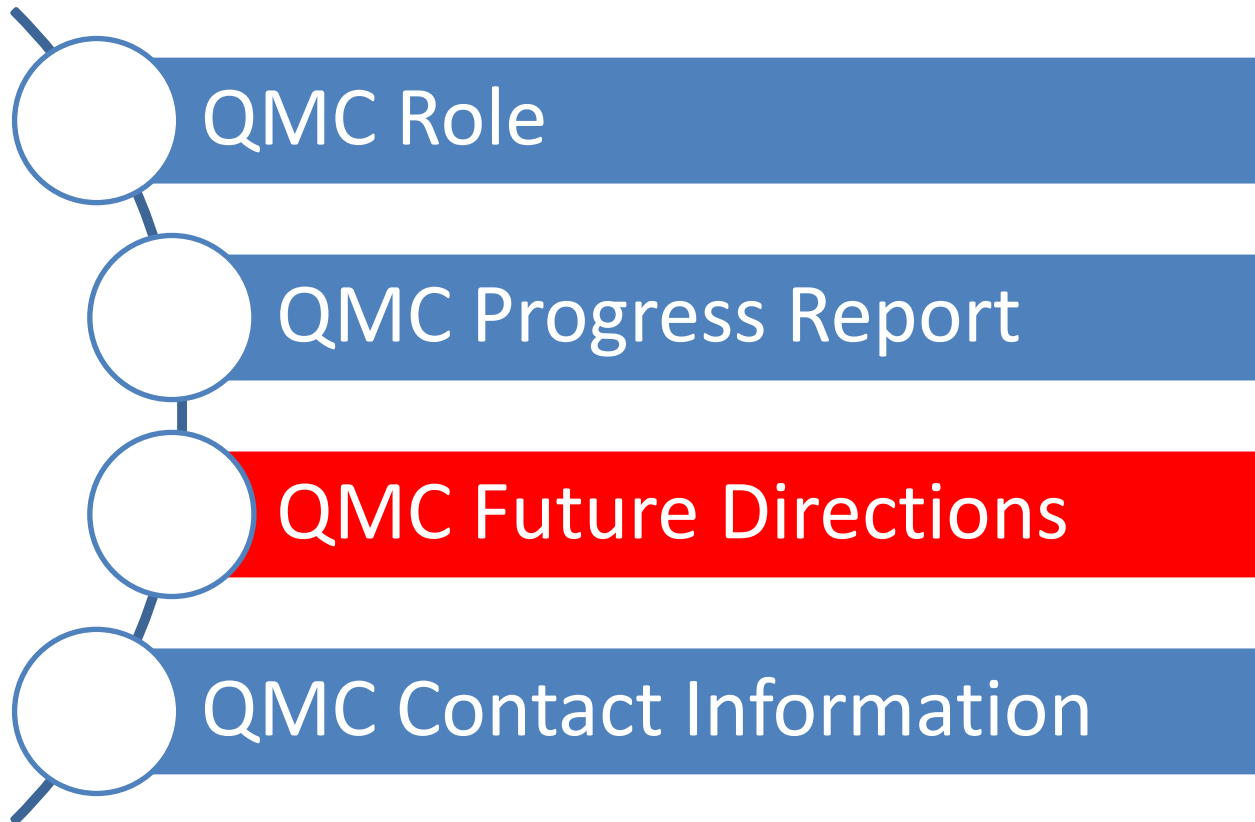
Current Faculty

- 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

Purpose



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

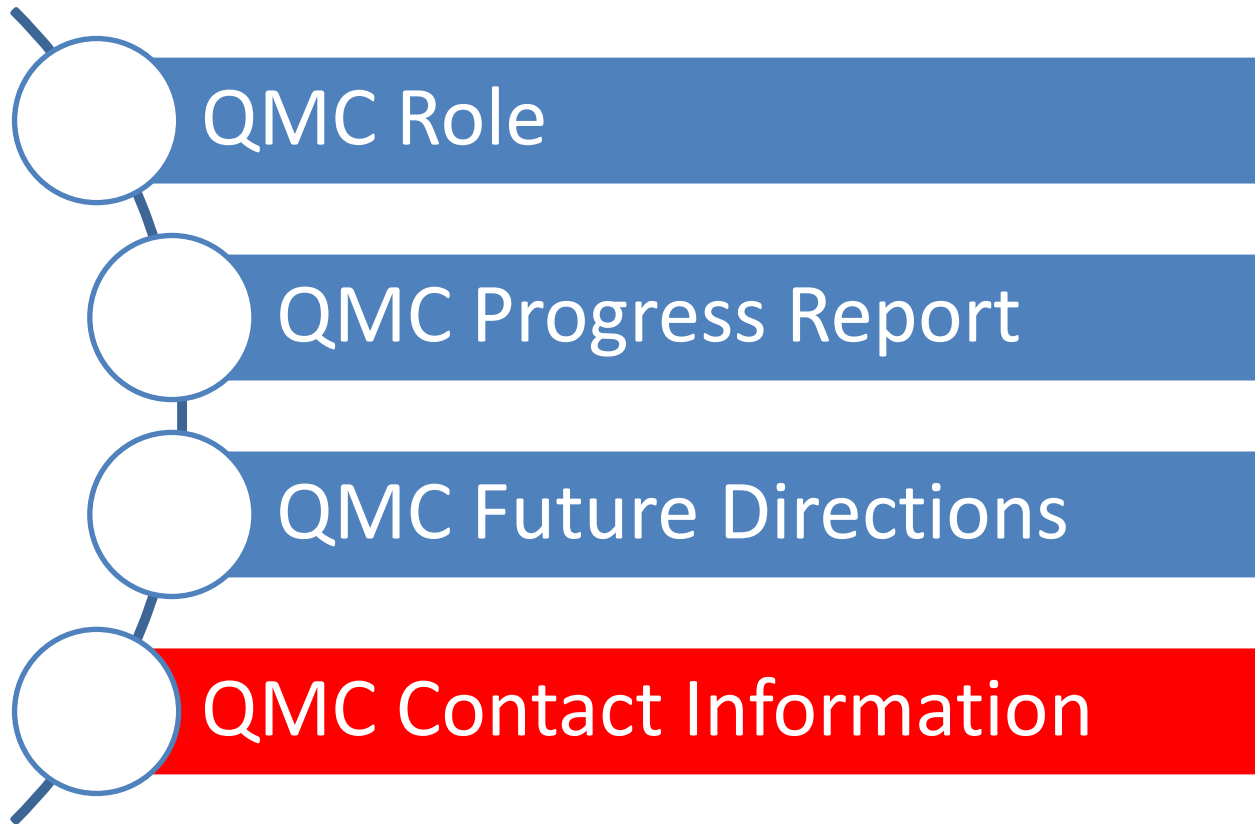
QMC Data Monitoring Progress Report

- 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



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

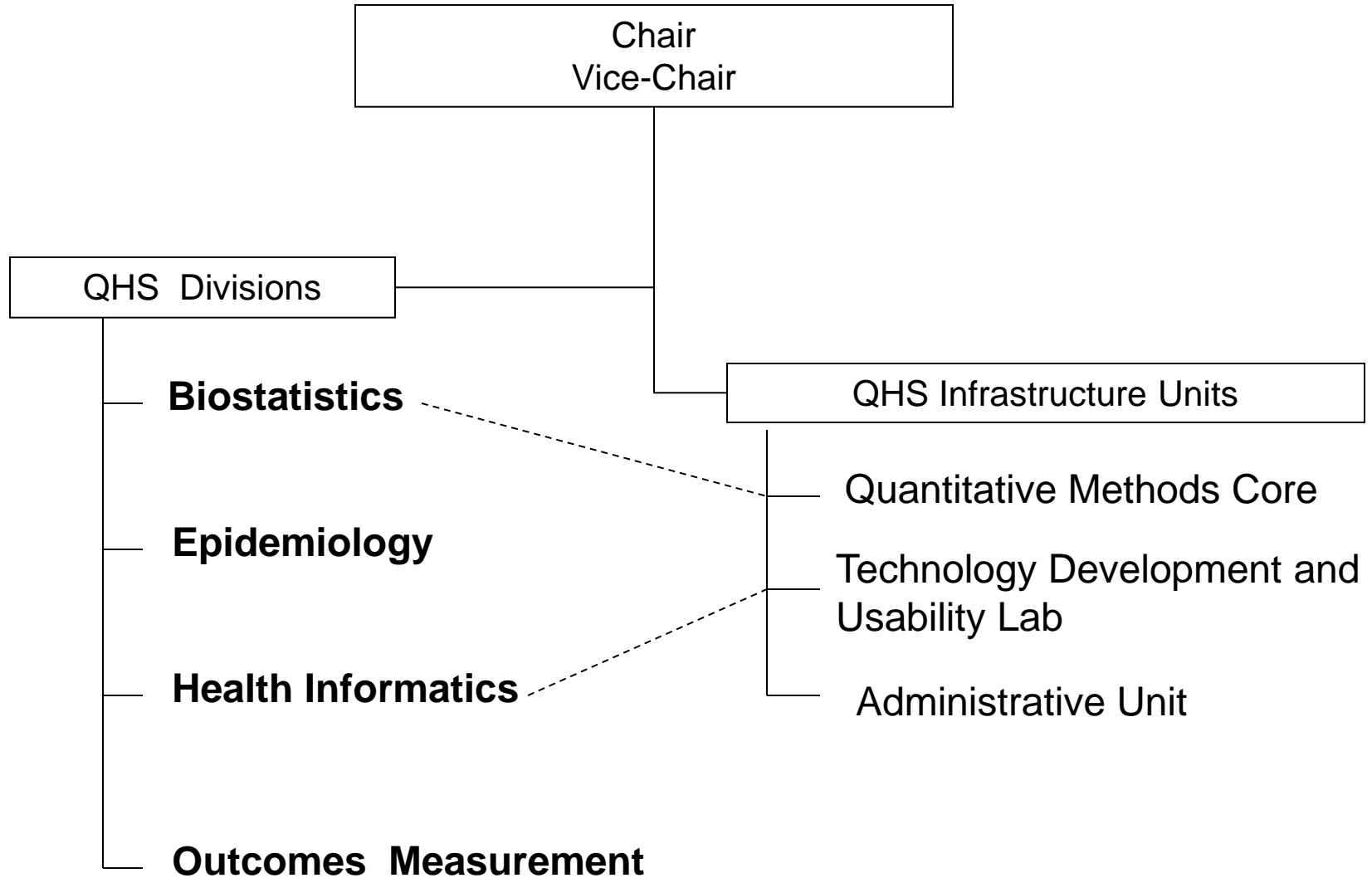
QHS History

- 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



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?