Perspective: Strategies for Developing Biostatistics Resources in an Academic Health Center

Leah J. Welty, PhD [assistant professor],
Department of Preventive Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois

Rickey E. Carter, PhD [associate professor and section head of clinical sciences],
Department of Health Sciences Research, and director, Biostatistics, Epidemiology, and Research Design Key Function Committee of the Clinical and Translational Science Award Consortium, Mayo Clinic Center for Translational Science Awards, Mayo Clinic, Rochester, Minnesota

Dianne Finkelstein, PhD [professor of medicine (biostatistics)],
Harvard Medical School, and Department of Biostatistics, Harvard School of Public Health, and chief of biostatistics unit, Massachusetts General Hospital, Boston, Massachusetts

Frank E. Harrell Jr., PhD [professor and chair],
Department of Biostatistics, Vanderbilt University School of Medicine, and director, Design Biostatistics and Research Ethics Program, Vanderbilt Institute for Clinical and Translational Research, Nashville, Tennessee

Christopher J. Lindsell, PhD [professor],
Department of Emergency Medicine, and co-director, Biostatistics, Epidemiology, and Research Design, Center for Clinical and Translational Science and Training, University of Cincinnati, Cincinnati, Ohio

Maurizio Macaluso, MD, DPH [professor and director],
Division of Biostatistics and Epidemiology, Cincinnati Children's Hospital Medical Center and co-director, Biostatistics, Epidemiology, and Research Design, Center for Clinical and Translational Science and Training, University of Cincinnati, Cincinnati, Ohio

Madhu Mazumdar, PhD [professor],
Division of Biostatistics and Epidemiology, Department of Public Health, and director, Research Design and Biostatistics Core, Clinical and Translational Sciences Center, Weill Cornell Medical College of Cornell University, New York, New York

Paul J. Nietert, PhD [professor],
Division of Biostatistics and Epidemiology, Medical University of South Carolina, and director, Biostatistics, Epidemiology, and Research Design Program, South Carolina Clinical and Translational Sciences Institute, Charleston, South Carolina

Robert A. Oster, PhD [associate professor],

Division of Preventive Medicine, Department of Medicine, and co-director, Biostatistics, Epidemiology, and Research Design Program, Center for Clinical and Translational Science, University of Alabama at Birmingham School of Medicine, Birmingham, Alabama

Brad H. Pollock, PhD, MPH [professor and chair],
Department of Epidemiology and Biostatistics, and director, Biostatistics, Epidemiology, and Research Design Core, Institute for the Integration of Medicine and Science, University of Texas Health Science Center at San Antonio School of Medicine, San Antonio, Texas

Paula K. Roberson, PhD [professor and chair],
Department of Biostatistics, and director, Biostatistics and Research Design Component of the Translational Research Institute, University of Arkansas for Medical Sciences College of Medicine, Little Rock, Arkansas

James H. Ware, PhD [Frederick Mosteller professor], and
Department of Biostatistics, and associate dean for clinical and translational science, Harvard School of Public Health, Boston, Massachusetts

Biostatistics, Epidemiology, and Research Design Key Function Committee of the Clinical and Translational Science Award Consortium

Abstract

Biostatistics—the application of statistics to understanding health and biology—provides powerful tools for developing research questions, designing studies, refining measurements, analyzing data, and interpreting findings. Biostatistics plays an important role in health-related research, yet biostatistics resources are often fragmented, ad hoc, or oversubscribed within academic health centers (AHCs). Given the increasing complexity and quantity of health-related data, the emphasis on accelerating clinical and translational science, and the importance of conducting reproducible research, the need for the thoughtful development of biostatistics resources within AHCs is growing.

In this article, the authors identify strategies for developing biostatistics resources in three areas: (1) recruiting and retaining biostatisticians; (2) efficiently using biostatistics resources; and (3) improving biostatistical contributions to science. AHCs should consider these three domains in building strong biostatistics resources, which they can leverage to support a broad spectrum of research. For each of the three domains, the authors describe the advantages and disadvantages of AHCs creating centralized biostatistics units rather than dispersing such resources across clinical departments or other research units. They also address the challenges biostatisticians face in contributing to research without sacrificing their individual professional growth or the trajectory of their research team. The authors ultimately recommend that AHCs create centralized biostatistics units, as this approach offers distinct advantages both to investigators who collaborate with biostatisticians as well as to the biostatisticians themselves, and it is better suited to accomplish the research and education missions of AHCs.

Science is built upon rigorous observation and experimentation. Biostatistics--the application of statistics to understanding health and biology--provides powerful tools for developing questions, designing studies, refining measurements, and analyzing data. A biostatistician's unique contribution to a research team is his or her ability to quantify uncertainty in and generate sound inferences from data. Because of the increasing complexity and quantity of health-related data, the need for biostatistical expertise on research teams is expanding and evolving.

The role of biostatistics is fundamental to the conduct of research, yet biostatistics resources are often fragmented, ad hoc, or oversubscribed in academic health centers (AHCs).

Although many experienced investigators value collaborating with biostatisticians, biostatistics is sometimes regarded as an ancillary service, rather than as an academic discipline.[1] As a result, some AHCs scatter biostatisticians throughout their clinical departments and research units. Other AHCs, however, have centralized biostatistics units. While groups that act primarily as consultants provide a valuable service, they fail to maximize the contributions that biostatisticians can make to research. Even when biostatistics resources are well developed and integrated into the research enterprise, the growing demand for their expertise may strain institutional resources.

In this article, we aim to raise awareness of the need for the thoughtful management of biostatistics resources in AHCs and recommend strategies for AHCs to take a focused and systematic approach to developing these resources. We propose strategies for developing biostatistics resources in three specific areas: (1) recruiting and retaining biostatisticians; (2) efficiently using biostatistics resources; and (3) improving biostatistical contributions to science. Our proposed strategies are relevant to all AHCs, from those with few or dispersed resources to those that already support a centralized biostatistics unit. AHCs that create and support centralized units in the form of departments, divisions, or centers, however, will be better positioned to implement our proposed strategies.

Leaders within AHCs are in positions to develop these biostatistics resources; yet, we also direct our recommendations to investigators with large research programs and senior biostatisticians who are interested in building capacity and improving collaborations. In addition, our recommendations pertain not only to biostatisticians collaborating with physician investigators but also to those collaborating with investigators in the other health sciences, such as nursing, pharmacy, dentistry, public health, allied health sciences, and basic science. Furthermore, we offer guiding principles instead of detailed examples; because AHCs vary in size, mission, composition, and culture, the logistics of any example may be well suited to some institutions but irrelevant to others. We encourage interested readers to contact us for specific examples of how we have implemented these strategies at our own institutions.

Our recommendations are based on our collective experiences. Several of us lead biostatistics units, others are junior members of growing units, and still others are isolated biostatisticians in clinical departments. We conceived and refined these strategies with input from the biostatistics, epidemiology, and research design community within the National Institutes of Health Clinical and Translational Science Awards program.

Recruiting and Retaining Biostatisticians

Statisticians, especially those with strong communications skills, are in demand across a range of industries.[2,3] Yet, statisticians in AHCs also must be interested in health-related research.[4] As a result, there is currently a shortage of biostatisticians qualified to meet the needs of AHCs.[5] Efforts to attract and retain well-qualified biostatisticians should be a priority for AHCs.

Identifying qualified biostatisticians

We recommend that a senior biostatistician, rather than a clinician or investigator, recruits new faculty biostatisticians. Senior biostatisticians are uniquely positioned to define the skills, experience, and training necessary to address the AHC's research needs. For example, a clinical department's self-perceived need for a full-time doctoral-level biostatistician may be better filled by a statistical programmer with oversight from a doctoral-level biostatistician (who the department supports at less than 100% full-time equivalent [FTE]). Senior biostatisticians have the professional networks to identify candidates, and candidates

are more likely to respond to announcements distributed by biostatistics units rather than by clinical departments. When evaluating candidates, senior biostatisticians have the disciplinary expertise that clinicians, other investigators, and many search firms do not. Just as most biostatisticians would not adequately be able to evaluate candidates for a clinical position, most clinicians lack the knowledge required to identify biostatisticians with the appropriate technical background and experience.

For some investigators or department chairs, maintaining control over hiring may outweigh the advantages of having a senior biostatistician direct a search. In such cases, we recommend a respected partnership between the investigators or department chairs and the senior biostatistician, in which both parties offer evaluations of the candidates and the investigators' evaluation is seen as central to the ultimate decision. Feedback from different perspectives--including on the candidates' methodological training as well as his or her collaborative potential--will result in higher-quality hires with better chances for retention.

Creating an attractive environment

Opportunities for academic advancement are important considerations for biostatisticians selecting a position. Too often, however, investigators or clinical department chairs expect biostatisticians to fill what they perceive as a service role. Such mismatches in expectations will negatively affect hiring and, ultimately, retention. AHCs will find it easier to recruit and retain biostatisticians to an academic home that has a strong identity, spurs intellectual growth, values methodological contributions to health-related research, and offers a clear and appropriate path for promotion. These attributes are readily fostered within a centralized biostatistics unit. Junior biostatisticians must have senior biostatisticians to advise them on effective collaboration strategies and professional development. Biostatisticians, particularly those building careers, recognize that isolation from other biostatisticians who may act as mentors--as occurs when a single biostatistician is hired within a clinical department--may limit their opportunities for advancement.

To retain biostatisticians, AHC leaders must align their promotion criteria with the independent contributions that biostatisticians make to interdisciplinary research. If being promoted requires receiving external funding as a principal investigator and a substantial portfolio of senior-author publications, an AHC cannot expect to retain biostatisticians whose primary focus is collaboration. Several AHCs have redefined their promotion criteria to better recognize the substantial intellectual contributions that co-investigators make to research.[6,7] AHCs with centralized biostatistics units may be best able to retain biostatisticians because the unit leaders then are responsible for providing appropriate career development opportunities and have influence on appointments and promotions.

Biostatisticians will gravitate toward a unit with a strong leader. Ideally, such a leader should possess broad biostatistics knowledge, an impressive record of methodological and collaborative research, and exceptional communication skills. Given the variety of disciplines in an AHC, the leader of the biostatistics unit also must enjoy collaboration and possess a generalist biostatistician's skills. We strongly caution AHCs against recruiting junior faculty to start biostatistics units. Not only do junior biostatisticians lack the necessary research and administrative experience, but as the first member of a unit, they also lack guidance from senior biostatisticians and have limited ability to mentor new faculty recruits. The premature assumption of a leadership role may negatively affect the growth of the biostatistics unit in addition to individual careers.

Efficiently Using Biostatistics Resources

The advancement of new technologies in areas as diverse as imaging, nucleic acid sequencing, and electronic health records is outpacing the development and dissemination of applicable statistical methods.[8] Thus, the need for the efficient use of biostatistics resources is increasing.

Specialization

Just as physicians specialize, most biostatisticians focus on one or two statistical areas. The skills and knowledge pertaining to adaptive clinical trials, predictive modeling, and comparative-effectiveness research, for example, all differ. Doctoral programs in biostatistics cover widely used methods, and any well-trained biostatistician can support entry-level research in any number of areas. However, complex projects require specialized expertise. For example, biostatisticians who specialize in clinical trials can recommend the most appropriate study designs and suitable sample sizes, and those who specialize in imaging data are experts in extracting signal from noise. Centralized biostatistics units comprised of complementary specialists can accommodate the disparate needs of the AHC and will be well positioned to contribute to a variety of current and future health-related problems.

An investigator collaborating with a single biostatistician from a centralized biostatistics unit benefits from the collective expertise of the entire unit. Even when a biostatistician's methodological interests align with an area of health-related research, the research will generate questions outside that biostatistician's expertise. In a centralized unit, biostatisticians may find the answer with a colleague down the hall; when biostatisticians are isolated, they often must solve the problem alone, frequently reinventing methodologies that others already have developed--a process that is both inefficient and prone to error. The leader of a centralized biostatistics unit also can recognize redundant efforts and ensure that biostatisticians capitalize on the collective expertise of the unit.

In addition, biostatisticians work more effectively by specializing in one or two health-related research areas. This occurs naturally when a biostatistician is well integrated in a research team. A biostatistician focusing on a particular disease learns the disease characteristics, treatment types, efficacy measures, and expected complications. Building this knowledge requires patience and commitment from both the biostatistician and his or her collaborators, but it is essential for appropriately developing study designs and conducting data analyses. Biostatisticians may even become scientific leaders within a health-related research area. Although biostatisticians in clinical units may be more readily immersed in a specific research area, their investment in the subject matter ultimately will contribute more to the success of the collaboration than the proximity of their offices to those of the other investigators.

Appropriate use of doctoral- and master's-level skills

Efficiently using biostatistics resources requires that AHC leaders recognize the training biostatisticians need to engage in different activities, such as study design, data management, data analysis, proposal development, and manuscript preparation. While doctoral-level biostatisticians often possess data management skills, master's-level biostatisticians and database or statistical programmers do as well, and they are sometimes more proficient and often less expensive. If isolated doctoral-level biostatisticians are responsible for all data-related matters, they will engage disproportionately in data management and programming, spending less time on study design, statistical analysis, and proposal development--areas for which their expertise is pivotal. Many successful

biostatistics units maintain a ratio of about 1:2 or 1:3 doctoral-level to master's-level personnel. The appropriate allocation of effort for individual projects may vary more widely--more master's-level effort may be needed for a large trial with a straightforward design but extensive data management, for example, while relatively more doctoral-level effort may be needed for a small trial with a complicated design and fewer observations. If a research group employs a single biostatistician, they may find it less effective to employ a master's-level biostatistician than a doctoral-level one for the following reasons: (1) doctoral-level biostatisticians are more likely to have expertise in study design; (2) proposals with a doctoral-level biostatistician as a co-investigator will be reviewed more favorably than those with a master's-level biostatistician; and (3) although some master's-level biostatisticians work independently, most require doctoral-level oversight. In addition to their ability to work independently, doctoral-level biostatisticians should be available to manage the work of and mentor master's-level colleagues.

Infrastructure

Biostatisticians require extensive, specialized software and hardware that can be expensive. Software licenses and high-speed computing typically are not available except within centralized biostatistics units, and costs for such equipment are rarely recouped in grant budgets. These resources (e.g., site licenses, shared computing clusters) are less expensive on a per-user basis when AHCs maintain them centrally. Once the number of biostatisticians at an institution reaches a critical mass, the group also needs technical and administrative support. The presence of a centralized biostatistics unit formally addresses this need for technical and administrative support.

Funding to maintain and replace such specialized software and hardware is critical to the success of a biostatistics unit. Capital expenditures for larger purchases (e.g., server clusters) should be viewed as expenditures similar to those for laboratory equipment. Ongoing costs, such as annual license renewals, are difficult to include as line item expenses in research proposals because they may be used for multiple research projects. Centralized biostatistics units may cover these costs by either accounting for them in indirect and overhead rate calculations, implementing a recharge or fee-for-service mechanism to "rent" the software and hardware to research projects, or drawing from the operating margins of the AHC (e.g., clinical revenues). AHC leaders also can attribute the fees for some software and hardware to direct costs, prorating the use of core infrastructure across multiple grants; however, this practice limits the availability of these resources only to those projects funded by the specific grants.

Centralization

With a centralized biostatistics unit, investigators requiring some biostatistics support may subscribe to a portion of a biostatistician's time. Then, investigators need not commit to a full-time position, and biostatistics expertise is available to investigators who would otherwise go without. Having a critical mass of biostatisticians within a centralized unit provides protection against losing expertise during transitions in employment and changes in funding levels, and investigators have fewer concerns about continuity of funding or recruiting biostatisticians. A centralized biostatistics unit with dedicated institutional support (i.e., "hard money") can manage: (1) fluctuations in external support; (2) recruitment of new biostatisticians in anticipation of future needs; and (3) transitioning newly hired biostatisticians to a research team through training under senior leadership.[9-11] Theoretical estimates and empirical observations suggest that institutional dollars spent to support a centralized biostatistics unit have high return on investment.[12] In addition to internal biostatistics resources being less expensive and better integrated than outside consulting services, the improvements in study design that result from using internal resources may

increase both opportunities for additional funding and the likelihood of conducting studies that directly address specific aims. A study by Parker provides a more extensive discussion of this issue.[12]

In addition, AHCs can directly fund centralized biostatistics units to support research and education more broadly. When biostatisticians are not supported solely by external funding, they may participate in institutional activities, such as teaching, mentoring, or other service activities. Biostatisticians may serve on institutional review boards (IRBs), mentor career development grant awardees, or teach workshops on a variety of topics (e.g., sample size determination, emerging trends in clinical trial design, or ethical practices in data analysis). These activities all enrich the research culture of an AHC by making biostatistics expertise broadly available.

A centralized biostatistics unit must carefully manage its shared resources to ensure that biostatistics expertise is readily available and appropriately leveraged throughout the AHC. Although it may be inefficient for only a few groups within an AHC to have biostatisticians, it is also inefficient for biostatisticians to divide their time amongst many disparate projects.[13] In the extreme, excessive sharing of biostatistics resources will result in the "tragedy of the commons"--oversubscribed biostatisticians who are unable to meaningfully contribute to any specific project.[14] Departments or groups with dedicated biostatisticians are not immune to this problem, especially if they have many faculty members, trainees, and sizeable research projects, or underestimate the time required to conduct data analyses.

Formal and thoughtful creation of a centralized biostatistics unit can help to curtail such oversubscription. Some AHCs discourage biostatisticians from collaborating on projects for less than 10% effort. Others suggest that biostatisticians maintain one or two larger collaborations and spend a limited portion of their time on smaller projects (e.g., no more than three projects with 10% effort each). Successful models for the allocation of percent effort and number of projects will vary because they must account for each biostatistician's experience, specific project requirements, and available supporting resources (e.g., master's-level programmers and postdoctoral biostatisticians). Such models must also balance biostatisticians' other competing demands, such as teaching, institutional service, administrative duties, and other professional activities. Because the demands on biostatistics resources are many and varied, AHCs should adopt institutionally tailored policies that prioritize the use of biostatistics resources commensurate with institutional goals. No single formula exists for the optimal distribution of biostatistics resources. Instead, we recommend that such resources be allocated after a thoughtful discussion of priorities, expectations, and resources among investigators, biostatisticians, and AHC leaders.

A centralized biostatistics unit offers many advantages to an AHC in terms of efficiency, but biostatisticians and their senior leaders must be responsive to investigators. Knowing how to communicate with investigators about timelines and competing demands is a critical skill for biostatisticians in a centralized unit. However, competing demands are ubiquitous, and no investigator wants to feel that a biostatistician--in whom he or she has invested resources and relies on for expertise--is not fully invested in a project because the biostatistician is in a different department or because he or she receives less than 100% funding from the investigator. Some investigators may prefer to hire an isolated biostatistician to have more control over his or her time, despite the inefficiencies in such a relationship. Instead, we recommend that biostatisticians have: (1) secondary appointments in the department of their primary and long-term collaborators; (2) one or two areas of medical expertise; and (3) adequate supporting resources, such as master's-level statistical programmers to quickly perform routine statistical tasks.

Improving Biostatistical Contributions to Science

Biostatistics is a rapidly changing field. Using methods tailored to a research question, rather than tools previously developed for alternate purposes, results in increased precision and power for analyses.

Continuing education for biostatisticians

A centralized biostatistics unit can provide continuing education for its faculty in statistical methodology and practice that other clinical departments cannot, and it can offer regular access to seminars and journal clubs, and informal conversations with other biostatisticians-- all of which strengthen biostatisticians' knowledge and value as collaborators. A centralized unit also may dedicate financial resources to biostatisticians attending conferences, webinars, or short courses in emerging areas of the field. For example, an increasingly important goal for biostatisticians (and investigators) is conducting reproducible research, in which statistical programming and documentation is sufficient so that others may replicate the results. Specialized software that automatically embeds statistical estimates, graphics, and tables in manuscripts is fast evolving, and exposure to these tools from colleagues or outside courses will improve biostatisticians' ability to conduct reproducible research. Biostatisticians affiliated with a centralized unit also remain current in professional standards and areas of research by learning from each other and participating in continuing education activities.

Professional activities

Biostatisticians with strong professional qualifications provide the maximum benefit to research teams. AHCs benefit when they provide resources for biostatisticians to: (1) prepare their own manuscripts and proposals; (2) present at conferences; and (3) participate in peer review. These activities, in turn, all benefit biostatisticians' collaborators. For example, biostatisticians who are first authors and publish methodological research will be stronger co-investigators on research proposals. The time allocated to biostatisticians for teaching or administrative responsibilities should not diminish the time allocated for these other professional activities.

The time reserved for biostatisticians to participate in methodology research varies across institutions--some AHCs consider 20% effort the minimum. Funding for this time may come from institutional support, indirect costs, clinical revenues, consulting income, or grants that include biostatistical aims. When biostatisticians are fully engaged as collaborators with their investigator partners, research and development are fundamental activities for both parties. In such instances, biostatisticians should develop the statistical methodology that is relevant to that particular research project, and investigators should include sufficient allocation for such methodological research in their grant budgets. Investigators also should be aware both that the process for constructing and writing a methods paper is fundamentally different, and can be more time consuming, than writing a clinical research paper and that peer review times may be longer.[15] In turn, biostatisticians must be accountable for the time and resources provided for them.

Collaboration versus consultation

Biostatisticians need to be true collaborators with vested interests in the success of research projects, from beginning to end. Too often, investigators perceive doctoral-level biostatisticians as technicians, not independent contributors. Aspects of data management may be classifiable as a service, but much of the research process--including the delineation of data requirements and database design--requires an independent intellectual contribution. In addition, the interpretation of results is nuanced; establishing a thorough data analysis

plan requires more than identifying the type of dependent variable and a list of independent variables and covariates. Although any trained biostatistician can perform basic power calculations, only one who is immersed in an area of research will be able to design an efficient study that directly addresses its specific aims. Doctoral-level biostatisticians have a unique skill set that makes them integral parts of research teams. Their contributions are typically independent and implemented without supervision. Regardless of the structure of an AHC's biostatistics resources, ultimately, the science benefits when biostatisticians function as collaborators. Limiting biostatisticians to the role of consultant or service technician undermines their capacity to advance science.

Biostatistics literacy and education

Effective communication between investigators and biostatisticians is only partially accomplished by biostatisticians' familiarity with an area of research; investigators also must become familiar with biostatistics. Investigators who are aware of the assumptions and pitfalls of the statistical methods used to generate scientific evidence in their field will be more informed consumers of the literature and will have additional motivation to conduct better research--from study design to data analysis and interpretation of findings.

Biostatisticians must ensure that the biostatistics education they provide investigators meets high standards. Such education is continuous and occurs at many junctures--from one-hour consultations to formal classes to multi-year collaborations. Many AHCs now support master's-level programs in clinical research that include instruction in biostatistics. Biostatisticians necessarily play an important role in meeting the educational needs of the health-related research community in this area, but isolated biostatisticians have limited ability to contribute to such endeavors. Centralized biostatistics units provide a natural home for educational programs in biostatistics and research design. For example, many biostatistics units offer seminar series and conferences that are beneficial to both investigators and methodologists. Furthermore, biostatisticians in centralized units are well positioned to mentor students in these programs, who then can contribute to data management, statistical analysis, and methodological research as part of their training.

Research data operations

Biostatisticians are often responsible for research data operations. Their roles may include: (1) defining data elements and designing research databases; (2) establishing criteria for and enforcing data quality control procedures; (3) ensuring that monitoring components are integrated into database applications; and (4) optimizing efficient data workflows. Centralized biostatistics units are well positioned to capitalize on faculty members' past experience and knowledge of infrastructure when setting up data operations for new projects. Even if data management activities are housed within other units, biostatisticians may have oversight to ensure that a study's data management plan will result in high quality, complete data that unambiguously address the study aims.

In addition, biostatisticians can have a lasting impact on clinical and translational research infrastructure by ensuring that data collected to address the primary hypotheses of one study can be used to conduct the secondary analyses for other investigations. For example, data collected through a clinical trials consortia can be used for hypothesis-generating historical cohort analyses. Biostatisticians in larger centralized units will be better able to "future-proof" research infrastructure by using uniform database architectures and design principles that facilitate the reuse of data for unintended but related purposes.

Additional Considerations for Developing and Supporting Centralized Biostatistics Units

With a growing emphasis on clinical and translational research and evidence-based medicine, integrated research teams are increasingly becoming essential in AHCs. The unprecedented quantity and complexity of health-related data requires that biostatisticians be key collaborators on research teams. In this article, we have outlined strategies for developing and supporting biostatistics resources at AHCs, including recruiting and retaining biostatisticians, efficiently using biostatistics resources, and improving biostatistical contributions to science. A centralized biostatistics unit--with strong biostatistics leaders--may be an essential evolution of the current fragmented model, as it has distinct advantages.

Even well-developed centralized biostatistics units with strong leaders face continuing challenges. In this article, we have argued that biostatistics units should include faculty who are: (1) individually recognized for their academic excellence; (2) recognized as key members of collaborative research teams; (3) effective statistical consultants; and (4) efficient managers of data resources, finances, and personnel. Although a centralized biostatistics unit as a whole may deliver all four of these elements, individual faculty members can be pulled in competing directions if they are expected to fulfill all four roles themselves. Conversely, faculty who limit themselves to one or two of these roles may not meet institutional criteria for promotion (e.g., if they focus on acting as consultants and oversee data management), or they may fail to meet their institution's research needs (e.g., if they focus exclusively on individual achievement).

In this article, we have not directly addressed all the challenges to developing and supporting centralized biostatistics units. AHCs that include multiple legal entities, schools, or institutions may find it difficult to centralize biostatistics resources due to administrative hurdles. For example, the required allocation of overhead in a subcontract may prevent a biostatistician in a medical school from collaborating with a clinician in a hospital. Until such administrative hurdles are removed, AHCs may prefer to maintain several centralized biostatistics units, in which case, co-location may overcome some of the barriers we have described. We also have heard of instances in which the recruitment package for an investigator includes the hiring of a dedicated biostatistician. An alternative to this scenario would be for the AHC to support the investigator's access to equivalent resources within a centralized biostatistics unit. Finally, because biostatistics units rely on institutional support, they may be vulnerable to changes in leadership, internal politics, or weak business models.

We recommend that future research use metrics, such as those proposed by Rubio and colleagues[16], to evaluate biostatistical collaborations, track the evolution of biostatistics units, and identify specific mechanisms and structures that effectively support the biostatistical needs of AHCs. Just as the demand for patient-centered, integrated health care has galvanized the integration of physicians from multiple specialties into teams, so too should the growing complexity and importance of health-related research galvanize the thoughtful and careful structuring of biostatistics units as key elements in a successful research enterprise.

Acknowledgments

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