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Best Practices for Biostatistical Consultation and Collaboration in Academic Health Centers

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Best Practices for Biostatistical Consultation and Collaboration in Academic Health Centers

Short Title: Best Practices for Biostatistical Consultation and Collaboration

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Abstract:

Given the increasing level and scope of biostatistics expertise needed at academic health centers today, we developed best practices guidelines for biostatistics units to be more effective in providing biostatistical support to their institutions, and in fostering an environment in which unit members can thrive professionally. Our recommendations focus on the key areas of: 1) funding sources and mechanisms; 2) providing and prioritizing access to biostatistical resources; and 3) interacting with investigators. We recommend that the leadership of biostatistics units negotiate for sufficient long-term infrastructure support to ensure stability and continuity of funding for personnel, align project budgets closely with actual level of biostatistical effort, devise and consistently apply strategies for prioritizing and tracking effort on studies, and clearly stipulate with investigators prior to project initiation policies regarding funding, lead time, and authorship.

Keywords: biostatistics, collaboration, consultation, funding, prioritization

Introduction

Many biostatisticians at academic health centers (AHCs) are devoting increasing amounts of time to consulting and collaborating with other investigators. For example, among the Biostatistics, Epidemiology and Research Design (BERD) units at 62 Clinical and Translational Science Award (CTSA) sites across the country, the percentage that provided biostatistical support to over 300 projects during the year more than doubled between 2011 and 2013, from 9.1% to 24.2%. While the rapidly changing biomedical research environment and the corresponding increase in demand for biostatistical expertise spurs growth of the biostatistics field, it can also make it challenging for biostatistics units to provide support in a way that is effective, efficient, sustainable, and professionally rewarding.

A number of excellent articles and textbooks have been published over the years on various aspects of biostatistical consulting and collaboration. Lesser and Parker (1995) discuss allocation of the biostatistician's time and effort in consultations and collaborations. Moses and Louis (1984) and Geller (2011) address the importance of effective communication about scientific issues and research roles. Arndt and Woolson (1991) propose strategies for avoiding common problems in consulting organizations and Welty et al. (2013) discuss ways to develop and support centralized biostatistics units.

The current AHC environment, however, raises new challenges for biostatisticians engaged in consulting and collaboration. Given the increasing importance of biostatistics in all aspects of research, from study design to the publication of results, the demand for biostatistical collaborators often exceeds the supply at many institutions. In addition, emerging technologies in fields such as genomics, proteomics, and imaging require highly specialized and sophisticated

methodological expertise that is far beyond the background and training of most biostatisticians. Biostatistics units are also getting larger and more diverse in scope, and hence, more administratively and financially complex. Moreover, the financial complexity is exacerbated by the increasingly difficult and competitive extramural grant funding environment that results in the need for alternative sources of support for unit personnel. Finally, as the concept of team science gains traction and biostatisticians assume bigger roles in the research process, strategies and policies are needed to assure equitable funding and acknowledgement of individual efforts.

The CTSA-based BERD units recently considered these important issues. Based on the collective experience in leading and participating in biostatistics cores and other shared resources, we developed best practices guidelines and recommendations for biostatistics units to be more effective in providing biostatistical support, and in fostering an environment in which unit members can thrive professionally. We focus on the following three key areas: 1) funding sources and mechanisms; 2) providing and prioritizing access to biostatistical resources; and 3) interacting with investigators. Our recommendations are intended primarily for those involved in the development, leadership, and administration of a biostatistics unit. We use the term “unit” loosely to include any organizational cluster of biostatistical scientists that support the research enterprise of an AHC.

Funding Sources and Mechanisms for Biostatistical Support

The support that a biostatistics unit provides on a project can be funded by a variety of sources and mechanisms depending on both institutional policy and the biostatistician’s role on the study as either a consultant or collaborator. As a consultant, the biostatistician provides short-term guidance and advice about study design, statistical methods, and/or statistical

software for a specific problem and may perform some routine analyses (Lesser and Parker, 1995; Fenn Buderer and Plewa, 1999). In contrast, the collaborating biostatistician is an active and pivotal member of the scientific team who is involved in all phases of research. As a result, the collaborator typically acquires significant knowledge about the field of research, often through work on several related projects over a period of years (Geller, 2011; Moses and Louis, 1984). In this section, we review the different sources and mechanisms for funding biostatistical consultation and collaboration and discuss the advantages and disadvantages of each approach.

Core grant support

One major source of funding for biostatisticians is a core or infrastructure grant. Examples include National Cancer Institute (NCI) designated Cancer Center Support Grants, Center for AIDS Research Grants, Specialized Programs of Research Excellence Grants, and Clinical and Translational Science Awards. These grants tend to be funded in 5 year cycles and personnel participating in the biostatistics cores may receive anywhere from 5% to 100% of salary support depending on their role. In addition to study design and statistical analysis, the biostatistician's range of responsibilities in the core often includes protocol development and review, educational and training activities, and new methods development when necessary. Investigators using the core are usually not directly charged for the services provided, which is beneficial to those with little or no independent research funding. However, the perception that this type of biostatistical support is 'free' can result in unrealistic expectations regarding the time and effort that the core can devote to any particular project. Investigators may also be disincentivized from including sufficient funding for biostatistics in their own research grants. Many cores consequently set limits on the hours of support that are provided without charge,

e.g., 5 – 10 hours, and then request funding for additional effort either on a fee-for-service or percent effort basis. Others use vouchers and retainers that can be used to obtain a specific number of hours of biostatistical support per project or per investigator.

Research grants

Another primary source of funding is the investigator-initiated research grant, such as the R01, which typically provides percent effort support for a biostatistician to assume a well-defined collaborative role on the project. This arrangement fosters long-term collaborations that are beneficial for a biostatistician's career, often generating multiple published papers in a specific area and motivating related methodological research. The level of effort to include in a grant for biostatistical support should be clearly aligned with the scope of the work, and should account for any methodological development, data management and statistical programming that may also be needed for the project.

We emphasize that when biostatisticians are on multiple grants at a low percent effort, they are less able to focus on a specific substantive area and make meaningful contributions to the research. This can adversely affect the quality of the science as well as the biostatistician's career development and satisfaction. Under-budgeting the biostatistician's effort can also negatively impact how the grant is evaluated by funding agency reviewers who are aware of the importance of sufficient biostatistical support in a project's success. In cases where a low level of funding (e.g. less than 5% effort) is unavoidable due to budgetary constraints, we encourage the explicit use of cost-sharing to ensure that the work can be accomplished. Some units use the fee-for-service mechanism rather than percent effort for research grants when the expected amount of biostatistical effort is very low (e.g. less than 5% per year).

Support from collaborating academic units

Collaborating academic units, such as clinical departments that need biostatistical support on an ongoing basis, are becoming an important and stable source of funding for biostatistics units. Such funding may support a percentage of a doctoral level biostatistician's salary, and in some cases, also that of a master's level biostatistician or graduate student. This type of collaborative arrangement yields similar benefits to investigators as core support, especially to junior investigators who are trying to establish a research program. Biostatisticians are usually expected to not only provide expertise on the academic unit's research projects, but also to participate in valuable educational activities such as attending journal clubs, mentoring residents and fellows, and giving lectures on biostatistical topics. On occasion, the collaborating units may also be willing to provide funding for methodological research. In lieu of partial salary support for a collaborating biostatistician, some academic units establish a separate fund which investigators use to access biostatistical support on a fee-for-service basis. Regardless of the approach, agreements between units should be carefully negotiated and put in writing so that all parties are clear about roles and expectations. In addition, since the amount of support needed is not always obvious in the beginning, biostatisticians should document on an ongoing basis their activities and effort, and review these periodically with the collaborating academic unit to ensure that the funding level is commensurate with the workload.

Institutional support

Institutional support, which we define here as broad infrastructure funding from a school, college, academic hospital, or university, is critical to establish and maintain a sustainable biostatistics consultation and collaboration unit, and to fund activities not covered by grants or

other funding sources. Such activities include the analysis of unfunded pilot studies to generate preliminary data for a grant application, other aspects of grant proposal development (design, analysis plan, and sample size justification), recruitment of new biostatisticians, mentoring junior biostatisticians, and managing fluctuations in external support (Welty et al., 2013).

Successfully negotiating for institutional support involves more than simply requesting a specific level of funding. First, tracking and presenting metrics, such as number of hours spent developing grants or helping junior investigators, provide concrete evidence of level of demand. Second, describing compelling examples that show the impact of the support provided, such as the funding of a large program project grant or a junior investigator's first successful R01, can help in negotiating for funding. Ultimately, the value of the institutionally supported biostatistical infrastructure should be demonstrated by clearly articulating the expected return on investment for the institution, both monetarily (i.e., grant funding) and in terms of academic productivity.

Comparison of percent effort and fee-for-service reimbursement mechanisms

The percent effort mechanism can be a stable source of funding that is conducive to the development of long-term collaborations and requires less administrative effort for the biostatistician than other funding arrangements. However, it is necessarily limited to investigators who have large grants or other resources that allow for partial salary support for a biostatistical collaborator. Problems can also arise if there is long-term misalignment between the percent effort supported and the actual biostatistical effort required across multiple projects, and these issues may be difficult to rectify in the absence of other resources that can help bridge the difference.

Fees generated from fee-for-service or hourly billable systems are an alternative funding mechanism. The fee structure is often tiered depending on the level of biostatistical expertise required. Rates can also vary for the type of task performed (statistical analysis, data management) and type of client (e.g., intramural or extramural). When a fee-for-service mechanism is used for federal grants, the fee structure must be compliant with the U.S. Office of Management and Budget Office's Circular A-21 principles (http://www.whitehouse.gov/omb/circulars_a021_2004), including the key principle that federal grants must be charged at the lowest prevailing rate for any client for the same type of service.

One advantage to the fee-for-service mechanism is that there is a clear link between the work done and the funding of that effort. Another advantage is that a wider range of investigators and types of projects can be supported and consequently, the biostatistics unit may gain more exposure to and experience with new techniques. Managing the work flow can be more challenging with a fee-for-service approach, however, and it is a less stable source of funding for the biostatistician. Furthermore, time tracking and bookkeeping require dedicated processes and an efficient reimbursement model. Another potential drawback is that some investigators meet less frequently if they are required to pay for these activities, and may not obtain advice during the critical study design phase. Paying for biostatistical support by the hour can also give some investigators the erroneous impression that the biostatisticians are not providing independent intellectual contributions to the work and therefore do not need to be acknowledged as co-authors. Factors contributing to a successful fee-for-service system include personnel who enjoy the challenges and stimulation of working efficiently on multiple projects, clients who appreciate the scientific value of the biostatistical support they receive, generation of

co-authored publications, and meaningful rewards and recognition for faculty and staff who provide this type of service. For example, some units give “Consultant of the Year” awards or reward consulting activities by providing funds for methodological research.

The advantages and disadvantages of the fee-for-service and percent effort mechanisms are summarized in Table 1. Ittenbach and DeAngelis (2012) also provide a detailed comparison of the two mechanisms and how they might be combined into a comprehensive framework.

Key Recommendations

An effective funding model for a biostatistics unit requires a diverse portfolio that includes some or all of the sources and mechanisms described above. This results in greater stability and flexibility to accommodate different types of projects and funding levels. The benefits of a mixed funding model apply at the individual level as well; biostatisticians who are funded by several mechanisms will not only have the opportunity to engage in a broader range of research and other activities such as training and mentoring, but also have more job satisfaction and security over the long run. We emphasize the importance of careful budget negotiations (discussed further below) to ensure that sufficient resources are available to support the work and personnel needed to accomplish the relevant aims. While the goals of any biostatistics unit include fiscal sustainability, we stress that a baseline level of ongoing institutional support is essential to underpin key activities that add value yet are not directly funded by grants and fee-for-service activities.

Formal tracking and evaluation of metrics for consulting and collaboration activities should be used to document productivity for funding providers, i.e., return on investment, and to justify requests for additional resources when needed. Consideration must be given at the unit

level to determine how detailed the tracking needs to be. Tracking may be as simple as filling out a paper-based form, to using web-based systems with phone or calendar-based application interfaces. As with most systems, however, simplicity and convenience generally result in greater usage by unit personnel. A comprehensive description of evaluation metrics for consultation, collaboration, education, and mentoring can be found in Rubio et al. (2011).

Providing and Prioritizing Access

To efficiently meet the growing demand for biostatistical support in AHCs, decisions need to be made about which types of support are offered, to whom they are offered, how to provide target clients with access, how to prioritize access, and how to assign projects to unit personnel. These decisions are largely influenced by the institutional environment, as well as the biostatistics unit's mission, size, and funding, but are necessary for limited time and resources to be optimally allocated. Below we review the general decision making process and offer guidance on the factors that could be considered when developing an implementation plan.

Outreach and Access

The simplest ways to broadly advertise a unit's activities include leveraging modern technologies for communication: e-mail, online brochures, digital signage in building lobbies and other public areas, and institutional research websites. Websites provide a convenient way to instruct investigators on how to access a unit and effectively work with a biostatistician. Electronic portals¹ also allow for more information to be gathered about projects for triaging

¹ Examples available on www.CTSpedia.org under Contribute/Links and Resources

purposes. We note that while intake forms provide an initial level of information, further inquiry about the investigator's needs is best addressed through a conversation, whether by e-mail, telephone or in person.

Examples of more low tech but direct outreach include presentations about biostatistical resources at departmental, research, and faculty meetings; participation in educational seminars for trainees at every level; attending journal clubs hosted by collaborating units; and volunteering to serve on institutional review boards and internal grant review panels. A biostatistics unit leader may also arrange meetings with other academic unit leaders to discuss collaborative activities and expertise, and then follow up with an email which summarizes the available biostatistical support and that can be forwarded to the rest of the faculty in the academic unit.

Other effective and increasingly common activities for outreach and facilitating access to biostatistical support include walk-in clinics, interdisciplinary design studios and hands-on computing labs. Walk-in clinics offer very brief biostatistical consultations (e.g., 15-20 minutes per consult) with the potential for referrals to other appropriate personnel as needed². These walk-in consultations are an efficient way to handle simple statistical questions, but may also develop into long-term collaborations. Some biostatistics units (e.g., Vanderbilt, Indiana University, and University of Michigan) participate in interdisciplinary study design meetings or “studios” that include a biostatistician as well as clinical and basic science researchers, coordinators, regulatory experts, and biomedical informatics specialists (Byrne et al., 2012; Denne et al., 2013). These studios are not only educational but also clearly demonstrate the

² Examples available on www.CTSpedia.org under Contribute/Links and Resources

value of a team approach to the investigator. Several biostatistics units run computing labs and analytic clinics that offer investigators access to computers with appropriate statistical software and guidance with basic data analysis.

Prioritization

Considerations for prioritization

Biostatistics units should specify clear algorithms to prioritize requests rather than leave it to individual members to decide on a case-by-case basis. First and foremost, prioritization strategies must be consistent with the priorities of the unit's funding sources. For example, for biostatistics cores of NCI designated cancer centers, cancer investigators engaged in peer-reviewed funded research take precedence over unfunded investigators. In other instances, junior investigators may have priority. When a biostatistics unit provides support to multiple investigators in a clinical department, a senior member of that department could help triage projects based on the department's goals and priorities. Specific questions to consider in devising strategies for prioritization and access include, but are not limited to, the following:

1. Is this a high impact project?

The quality of the science and the project's potential to have an impact on the field should be key considerations in any prioritization strategy. For example, analysis of a randomized clinical trial of a novel agent should have higher priority over a retrospective chart review that will only add incremental knowledge, or grant proposals may take priority over an abstract for a conference. In biostatistics core grant renewals, funding agencies increasingly want to see examples of high

impact science that was supported by the core and evidence of the “value added” to the research, in addition to the usual productivity metrics.

2. Is there funding for the biostatistical effort required for the project?

Priority should clearly be given to activities for which funding is provided, whether from a research grant, core grant, or clinical department. The exception to this is support for grant proposal development. This type of effort is generally not funded by the PI of the grant, but applications that include the potential for funding the biostatistician and/or affiliated personnel may be given higher priority than those for which no funding for biostatistical support is sought.

3. Is the project likely to result in a co-authored publication?

Co-authorship on papers is important not only for the career advancement of biostatistics unit personnel but also for demonstrating the overall productivity of the unit and its contributions to the institution’s research missions. The budgetary needs of the unit and priorities of the funding agency, however, may influence the decision to take on a project without publication potential (e.g., pilot study).

4. Does the unit have biostatisticians with the expertise needed for the project?

The emergence of “-omics” technologies, new imaging modalities, advanced electronic medical record systems, and other sources of “Big” data, as well as new fields such as comparative effectiveness research, raise unique methodological challenges. If a project requires statistical expertise not available in the biostatistics unit, it could be referred to other biostatisticians within or outside the institution. Alternatively, a motivated member of the unit interested in expanding their range of statistical skills or methodological research areas could learn the requisite analytic approaches. The PI should be informed, however, that this will require extra time and perhaps

funding for the collaborating biostatistician. Institutional or unit funding would be appropriate when it is likely that the expertise acquired will have applications to future projects. In contrast, the investigator should provide the funding when the methodological needs are highly specific to that one project.

5. Is this support for a student project?

Some biostatistics units have funding arrangements specifically to help students. In the absence of such arrangements, appropriate funding needs to be identified as with any other project. Regardless of funding source, having the input of the student's faculty mentor should always be a prerequisite for biostatistical support so that the scientific goals of the project and any methodological issues are clearly understood by all parties. If students are required to conduct their own statistical analysis, they should be encouraged to undertake any necessary biostatistics training and to include a faculty biostatistician on their mentoring committee to supervise the analysis.

Project assignment

Once a project is identified as a priority, the next step is to identify a biostatistician to work on it. If there is already an established relationship between the researcher and a specific biostatistician, then the logical assignment would be for that individual to handle the project. Many units have a project manager who is responsible for reviewing new requests and making assignments. Others delegate projects to biostatisticians on a rotational basis or have them volunteer based on interest, expertise, and availability. Biostatistics post-doctoral or graduate students may be assigned projects as part of their applied training. Unless they have prior

consulting or collaborative experience, however, they should be paired with a more senior biostatistician who can provide the proper oversight. Some institutions formalize this arrangement by establishing consulting labs that give biostatistics trainees the opportunity to interact with investigators and help with projects under the supervision of a senior biostatistician.

Key Recommendations:

There are many approaches for providing and prioritizing access to biostatistical support, but the unit's policies and processes should be clear, consistent, fair, and transparent for both the biostatistics unit members and the investigators seeking support. A summary of considerations is provided in Table 2.

Information about how to contact the unit, the scope of biostatistical support offered, funding options, and conditions and priorities of access, should be available to researchers and unit members via, at minimum, a website. Multiple ways to access biostatistical support are needed not only to alleviate bottlenecks in times of acute demand, but also so that work can be efficiently distributed among the unit members and handled by the personnel with the right skill set for each project. The use of social networking sites and other technologies for facilitating communication, scheduling appointments, and collaboration were not addressed here, but may be explored as additional ways to increase efficiency in resource utilization and time management. Any technological approaches, however, should be combined with effective in-person outreach methods such as meetings with departmental faculty, walk-in clinics, and design studios.

Interacting with Investigators

The key to any successful professional relationship is clear communication regarding expectations, and this is no less true in the interaction between biostatisticians and investigators. In this section, we address how biostatisticians can discuss with investigators specific project related issues such as delineation of responsibilities, funding, authorship, and project completion times. We also address broader topics relevant to relationships with investigators such as resolving conflicts, improving communication skills and providing biostatistical support using a team based approach.

Negotiating Funding

The amount of funding for the biostatistician should be negotiated up-front so all parties are in agreement about the cost and scope of support for the project. The time required for a project is often underestimated, especially when meetings, ancillary studies, and the need for new methods are not considered. In addition, budgets should appropriately reflect the substantial effort needed in the early planning stages of the project and during data collection (e.g. monitoring data capture, quality control and completeness) so that the majority of funds are not relegated to the final year.

The biostatistician and the investigator should also be in agreement about the course of action to take in the event of a budget cut or change in the scope of work. Options include: 1) a proportional cut that is shared by the entire research team across the board; 2) no cut for biostatistics if the scope of biostatistical work is not affected, e.g., a reduction in the size of a clinical trial that does not affect the analytic plan; 3) a disproportionately higher cut for

biostatistical support, such as when an analytically intensive specific aim is dropped or substantially simplified; 4) a reduction in the scope of work (e.g., omitting certain analyses); or 5) supplemental funding from institutional or other sources. Regardless, the goal in any budgetary negotiation is to achieve a level of funding consistent with the actual effort required. Finally, budgetary agreements should be documented in writing to avoid potential conflicts and misunderstandings between the biostatistician and the investigator.

Setting project deadlines

Unit policies should explicitly specify the need for ample lead time for a biostatistician to provide high quality support on a project. Generally, collaboration on grant proposals should be started at least six weeks before the submission deadline. Too often, requests have an immediate due date (a few days or even ‘today’). Although it may be difficult and may require moderation by the unit leader, a last minute request should ideally be declined to reinforce to the investigator the need for sufficient time to thoroughly understand and rigorously address the methodological aspects of a study. Importantly, declining last minute requests that arise due to poor planning will preserve resources for projects that were submitted in a timelier manner and that therefore have a higher likelihood of success.

To manage expectations regarding timing of completion of data analyses, an agreement about the scope of work should be reached with the investigator following the initial meeting. We recommend that the biostatistician draft a plan which briefly summarizes the background and statistical approach, and then review this with the investigator prior to starting the analysis. Once underway, periodic progress updates should be provided to the investigator, especially

when unexpected methodological problems occur that may cause delays or when additional analyses prompted by discoveries during the initial analysis phase are needed. Timelines and funding associated with any extra work that is required on a project should be negotiated separately from the original agreement.

Discussing authorship

Authorship should also be explicitly discussed early in the research process. Standard criteria for authorship, available in the International Committee of Medical Journal Editors' Uniform Requirements for Manuscripts Submitted to Biomedical Journals <http://www.icmje.org/recommendations/>, indicate that a biostatistician who: 1) contributes to conception and design, analyzes the data, provides a description of the biostatistical methods, and/or assists in the interpretation of the results; 2) drafts or revises the work; 3) approves the final version; and 4) agrees to be accountable for the work, will meet authorship criteria. Financial considerations must be kept separate from authorship. Parker and Berman (1998) articulate that "*The basis of financial support should be the time and effort spent on a project and the basis for authorship should be whether the biostatistician has made a scientific contribution to the project.*" In some situations, it may be appropriate for the biostatistician to decline authorship such as when a biostatistician has not met the minimum authorship criteria or is not in a position to accept responsibility for the content of the work. Having the authorship policy of the biostatistics unit posted on the unit's website and available as a handout can facilitate communication with investigators, and is helpful for junior biostatisticians who may feel inhibited about addressing these issues with more senior colleagues. Some biostatistics units require investigators to agree to this policy prior to receiving biostatistical support.

Educating investigators and biostatisticians

Biostatistical consulting and collaboration provide opportunities for mentoring and educating researchers in study design, statistical analysis, and reproducible research. Deutsch et al. (2007) discuss the need and opportunity for specialized biostatistical instruction during one-on-one consulting sessions. Ambrosius and Manatunga (2002) describe the use of short courses to familiarize physician-researchers with biostatistical methods that commonly appear in the medical literature, and to enable them to have a productive collaborative working relationship with a biostatistician. Similarly, leaders of biostatistics units should encourage their personnel to develop a basic understanding of the content area of the scientific research by reading articles, asking relevant questions, participating regularly in research meetings, and even attending conferences specific to the content area (ideally with encouragement and funding from the investigator).

Resolving conflicts

Issues or misunderstandings between investigators and biostatisticians sometimes occur despite efforts to minimize them. When the fault lies with an investigator who is not properly funding or crediting the biostatistical work, it is essential that the biostatistician have the support and guidance of unit leadership. If direct communication between the investigator and biostatistician does not resolve the issue, the next step should be for the biostatistics unit leader to have a conversation with the investigator and in some cases, also with the leader of the investigator's unit. In rare cases, the biostatistics unit head may need to make the decision that

the investigator can no longer be supported, or the local Office of Research Integrity or Ethics Committee may have to be contacted to aid in conflict resolution.

Improving communication skills

The most successful consultants and collaborators have not only a strong methodological background but also excellent oral and written communication skills. Although these skills come naturally to some individuals, others need to actively develop them via training and experience. Unit leadership should encourage junior biostatisticians to shadow a senior biostatistician during research meetings and consultations to observe best practices in action, such as how to provide constructive criticism or convey bad news about a study (e.g., an idea is not feasible or results are inconclusive). They should also be encouraged to take advantage of the frequent meetings, workshops, or sessions at professional conferences devoted to consulting and collaboration issues. Importantly, training should begin prior to practicing. Tobi et al. (2001) identified core competencies required for biostatistical consulting and collaboration, which include applied statistics, methodology, epidemiology, communication, computational science, and personal effectiveness. Both didactic and practicum courses focusing on fundamental aspects of consultation and collaboration, including eye contact, body language, use/non-use of statistical jargon, and dealing with critical conversations in an effective manner, should be further developed within degree programs as students train for a biostatistical career. If English is a second language, supplemental courses in language and writing skills should be encouraged. The unit could also make available access to a professional English editor to assist with manuscript and grant writing.

Using a 'Team Science' approach for biostatistics

A best practice for collaborating on large projects is through a team of biostatisticians with complementary expertise and various levels of experience and education. The rationale is that while every research endeavor includes some routine statistical design and analysis, many also require the implementation of complex statistical methods, or even the development of new methods. In addition, an inexperienced junior biostatistician may not feel comfortable or confident working alone with investigators of higher professional academic rank. The team approach ensures that there is oversight and support from a senior biostatistician, and efficient use of resources and skill sets. The team science approach is also effective for core and other large grants (e.g., program projects) since these often require the expertise of both collaborating and methodological biostatisticians. As studies and technologies become more complex, new techniques need to be developed to address the resulting design and analytic challenges. The inclusion of methodological researchers in the statistical team not only strengthens a research core/program, but can also lead to the development of future methodological grant applications based on the data.

Key Recommendations:

There are several ways in which biostatistics unit leadership can promote productive interactions during consultations and collaborations. They should first make sure that all personnel have a clear understanding of the unit's project related policies and have been instructed on how and when to discuss them with investigators. Funding for biostatistical support should be addressed during the first meeting between the biostatistician and the

investigator. Early in the research process, all parties should also come to agreement on the scope and timing for completion of biostatistical tasks, as well as authorship issues. Where possible, biostatistics unit policies should be posted on websites or included in consulting agreements so investigators are well informed about these issues. In addition, we emphasize that consultations and collaborations should be viewed as opportunities for biostatisticians to mentor and educate clinicians about key statistical concepts. We underscore the importance of strong communication skills to effectively interact with other investigators and recommend that a team science approach be taken for larger projects where multiple biostatisticians at various levels are assigned to tasks best suited to their skill set. Finally, we strongly recommend that the leadership of any biostatistics unit take a proactive role in moderating any conflicts that arise.

Discussion and Conclusions

While biostatistical consultation and collaboration are without a doubt both extremely valuable to the research enterprise, these activities nevertheless remain undervalued at many institutions and can impact how biostatisticians are evaluated for promotions. Fortunately, recent changes in how some federal funding agencies are assessing in grant applications the strength of institutional commitment to a project should help shift culture and attitudes. For example, one of the review criteria specified in the current guidelines for P30 Cancer Center Support Grants is whether team science is formally recognized in the institution's promotion and tenure policies. In addition, a framework for evaluating scientists collaborating in team-based research using the case study of a biostatistician has recently been published (Mazumdar et al., in press 2015). While proper institutional recognition of and credit for a biostatistician's collaborative contributions are essential to encourage biostatisticians to participate in multi-disciplinary team

science and to retain them, a supportive research environment in a well-organized and robust biostatistics unit is also essential. The unit should have sufficient funding from multiple sources, clear access and prioritization strategies, and best practices for interactions with investigators, while encouraging the continued growth and professional development of its members. Such strategies will help consulting and collaborating biostatisticians to have stable, fulfilling and successful careers in AHCs, and to have a greater impact on the institution's research programs and ultimately, on the advancement of science.

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Table 1: Summary of Advantages and Disadvantages of Percent Effort vs. Fee-for-service Mechanism

Percent effort:

Advantages:

- More stable source of funding for the biostatistician
- Administratively easier to implement
- Biostatistical support more likely to be provided throughout all phases of the research project (such as design phase).
- Fosters long-term collaborations and motivates related methodological research

Disadvantages:

- Limited to investigators with larger grants and other sources of funding
- Long-term misalignments between percent effort and actual effort across multiple projects can be difficult to rectify

Fee-for-service:

Advantages:

- Clear link between work provided and funding of that effort
- Biostatistical support is available to a wider range of investigators and types of projects

Disadvantages:

- Less stable source of funding for the biostatistician
 - Time tracking/bookkeeping requires dedicated processes and an efficient reimbursement model.
 - Investigators tend to meet less frequently with a biostatistician and may not obtain advice during the critical study design phase
 - Investigators can have the impression that the biostatisticians do not need to be acknowledged as co-authors
-

Table 2: Summary of Considerations for Providing and Prioritizing Access

Outreach and Access:	<ul style="list-style-type: none"> - Emails, brochures, digital signage, web sites - Presentations at departmental, research, and faculty meetings, educational seminars, journal clubs, volunteering to serve on review boards/panels, meetings with leaders of other units - Walk-in clinics, interdisciplinary studios, computing labs
Prioritization:	<ul style="list-style-type: none"> - Is it consistent with guidelines of funding agencies? - Is this a high impact project? - Is funding available for the biostatistical effort required for the project? - Is the project likely to result in a co-authored publication? - Does the unit have expertise needed for the project? - Is this support for a student project?
Project Assignment:	<ul style="list-style-type: none"> - Use of a project manager to review new requests and match them with an appropriate biostatistician - Assignment by rotating schedule or through volunteers - Assignment to post-docs or graduate students as a part of their training and to supplement staff support