Estimating the value of an internal biostatistical consulting service

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SUMMARY

Biostatistical consulting is a service business. Although a consulting biostatistician’s goal is long-term collaborative relationships with investigators, this is the same as the long-term goal of any business: having a group of contented, satisfied customers. In this era of constrained resources, we must be able to demonstrate that the benefit a biostatistical consulting group provides to its organization exceeds its actual cost to the institution. In this paper, I provide both a theoretical framework for assessing the value of a biostatistical service and provide an *ad hoc* method to value the contribution of a biostatistical service to a grant. Using the methods described, our biostatistics group returns more than $6 for each dollar spent on institutional support in 1998. Copyright © 2000 John Wiley & Sons, Ltd.

1. INTRODUCTION

Biostatistical consulting is a service business. I assume here that the biostatistical consulting group acts as an internal consulting service, providing service to a single organization, with multiple potential clients within the organization. Like other service businesses, the long-term viability of the biostatistical consulting group depends upon many factors including: identifying an appropriate niche; marketing itself successfully to its customers; providing quality service of value to its customers; and being supported for the services the group provides. Marquardt [1] observes that even in an internal consulting group, the statistical consultant is an entrepreneur.

The amount of resources provided by the organization determines what services, if any, are available from the consulting group without charge to clients. At one extreme is unlimited institutional support. Under such a model, the biostatistics consulting group would provide support without charge both for a large clinical trial involving extensive data management and data analysis, and to an investigator needing some help in doing a Fisher’s exact test for

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a manuscript. At the other extreme, a biostatistics consulting group could work on a strict fee-for-service basis, with support available only for the appropriate fee. In this model, the investigator doing a large study would provide many resources to cover the services needed for the study, and the investigator doing a Fisher’s exact test would need to provide a modest amount. In the middle would be a consulting service providing all eligible users some ‘free’ or ‘core’ or ‘institutional’ support while charging for additional services. The precise definition of what is covered as ‘free’ services, however, means that the biostatistics group could be very close to the unlimited support model, or very close to the fee-for-service model. A major factor influencing how much support an institution provides is the institutional culture itself, which is very slow to change and unlikely to be changed by the biostatistics consulting group alone. In this paper, I assume that the institution has adopted the middle model, with some core support subsidized by the institution available without charge to all eligible users, and fees charged for additional services. It is not my purpose to argue the appropriateness of this decision nor to discuss the issues involved in setting an appropriate level for core services.

The biostatistical consulting literature focuses on the key roles of communication and interpersonal relationships in the art of consulting [1–12]. There are also articles on the organization of statistical groups in general [13–15], case studies of specific organizations [16–18], and articles focusing on specific practical aspects of biostatistical consulting [19–21].

Although one would anticipate that estimating the value of an internal consulting group to an organization would be a common and important question, there does not appear to be any publicly available literature on this topic in any field. Even with the assistance of a senior research librarian, supported by the research staff of Dialog®, I have been unable to locate any published papers on this issue for any field. One referee suggested additional search topics, but these again failed to retrieve any relevant literature.

Marquardt [22] provides criteria for evaluating an individual statistical consultant in industry. The first of the eleven criteria listed is ‘impact on the success of the company’ which frequently ‘can be quantified in terms of dollars’. Even when work leads to an ‘indirect and distant payo!’ he states that ‘consultant supervision must assess the impact on the success of the company’.

A similar approach can be adopted to estimate the value of the services provided by a biostatistics consulting group. This will provide the ‘benefit’ information for a cost-benefit analysis of the core activities of such a group. Although the appropriateness of specific items may be debated, estimating the cost of the service will generally be easier.

In Section 2, I discuss theoretical methods to determine the true value of the different services available from a biostatistical consulting group. Since accurate estimates are unavailable for the major contribution, study design, in Section 3 I propose an ad hoc method to value the biostatistical contribution to grants and contracts. These approaches are illustrated with several examples from my own consulting group in Section 4. Finally, in Section 5 I discuss some practical issues in making a cost-benefit analysis.

2. THEORETICAL VALUE ASSESSMENT

Table I is a detailed list of services available from a biostatistics consulting group within an academic medical centre. Additional services might be available in another environment. Many services, particularly those relating to grant development, may not be as relevant in other settings, or may be described differently. In Table I, I indicate why the service is of value and provide
Table I. Theoretical methods to assess value of services.

<table>
<thead>
<tr>
<th>Service</th>
<th>Why the service is valuable</th>
<th>Potential methods to assess the value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design support</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Design assistance for grants</td>
<td>Improved quality increases likelihood of receiving grant/contract</td>
<td>Randomized study (see Section 2.1)</td>
</tr>
<tr>
<td>and contracts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Design assistance for other</td>
<td>Improved quality of study increases chance that study will be successful (for example,</td>
<td>Cost for outside services</td>
</tr>
<tr>
<td>studies</td>
<td>answer question posed; be publishable</td>
<td>(see Section 2.2)</td>
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<td></td>
<td></td>
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<tr>
<td><strong>Implementation support</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support for a grant or</td>
<td>Essential to completing the grant or contract</td>
<td></td>
</tr>
<tr>
<td>contract*</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Saves investigator time (for example, for investigator to determine answer on their own)</td>
<td>• Cost for outside services</td>
</tr>
<tr>
<td></td>
<td>• Reduces chance of errors or misinterpretation</td>
<td>• Awarded amount from grant/contract including institutional overheads</td>
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<tr>
<td></td>
<td>• Reduces chance of public embarrassment (for example, when incorrect analysis/interpretation detected in a published article)</td>
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<td></td>
<td></td>
<td>• Cost for outside services</td>
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<td></td>
<td></td>
<td>• Time costs for investigator to perform research plus cost of errors</td>
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<td></td>
<td></td>
<td>(see Section 2.3)</td>
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<td></td>
<td></td>
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<tr>
<td>Support for a study (not a</td>
<td>• Saves investigator time</td>
<td>• Cost for outside services</td>
</tr>
<tr>
<td>grant/contract)†</td>
<td>• Provides access to more sophisticated/informative techniques</td>
<td>• Awarded amount from grant/contract including institutional overheads</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>• Saves investigator time</td>
<td>• Time costs for investigators to perform own work plus cost of errors</td>
</tr>
<tr>
<td></td>
<td>• Improves quality of manuscript, making it more likely to be accepted</td>
<td>• plus cost of loss of knowledge from less efficient/informative statistical techniques</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Awarded amount from grant/contract including institutional overheads</td>
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<td></td>
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</tr>
<tr>
<td>Assistance in preparation of</td>
<td>• Saves investigator time</td>
<td>• Cost for outside service</td>
</tr>
<tr>
<td>manuscripts for publications</td>
<td>• Improves quality of manuscript, making it more likely to be accepted</td>
<td>• Time cost for investigator plus value of earlier/increased chance of</td>
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<td></td>
<td></td>
<td>acceptance of manuscript</td>
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<tr>
<td>Written responses to referee’s</td>
<td>• Saves investigator time</td>
<td>• Cost for outside service</td>
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<tr>
<td>criticisms</td>
<td>• Avoids unnecessary or inappropriate revisions</td>
<td>• Time cost for investigator plus value of increased chance of acceptance</td>
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<tr>
<td></td>
<td></td>
<td>of manuscript</td>
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<tr>
<td>Study salvage</td>
<td>• Provides some results from the effort and resources previously devoted to the study</td>
<td>• Cost for outside service</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Total value of grant/contract including indirect costs (if funded)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Total resources expended on study including time costs (if not formally funded)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Service</th>
<th>Why the service is valuable</th>
<th>Potential methods to assess the value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Training</strong></td>
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</tbody>
</table>
| General courses or lectures | • Improves quality of investigators, increasing their productivity  
• Provides training needed as part of specific training programmes | Cost for outside training courses |
| Specific courses or lectures | • Improves quality of investigators, increasing their productivity  
• Provides training needed as part of specific training programmes | • Cost for specialized training course, if available  
• Cost for outside group to develop and provide course |
| **Miscellaneous activities** | | |
| Service on committees such as institutional review board, institutional animal use committee, compliance and auditing committees | • Provides scientific and statistical reviews of issues, improving quality of committee deliberations  
• Helps meet mandate to minimize the use of animals in research by ensuring appropriate study design | • Cost for outside service  
• Time costs for investigators related to lower scientific quality/productivity plus value of time for institutional officials with improved compliance and monitoring activities |
| Co-ordinating institutional purchases of statistical software | • Saves individual investigators time  
• Reduces cost of software through group purchases | Time costs for investigators to investigate and purchase material plus cost saving over cost of multiple purchases (both direct, to investigators, and institutional, for processing fewer orders) |
| Existence of biostatistical support | Improves chances of recruiting new professionals and retaining current professionals  
Availability for inclusion in training grants, fellowship programmes etc. increases chance of grants/programmes being approved | Surveys of potential recruits and current professionals  
Randomized study (see Section 2.1) |

*Implementation of a grant or contract could include any or all of the following: development of manual of procedures; data form design; database development; data entry; quality control including data audits; routine and special monitoring reports; support for Data Safety and Monitoring Board; interim analyses; interim and ad hoc projects and manuscripts; final (planned) data analysis and manuscripts; secondary and subsidiary analyses and manuscripts.

Although support for other studies might include any or all of the activities listed in footnote *, normally only data management, data analysis and interpretation of results are requested.

a method to assess the value of each specific service in an ideal world where all data could be obtained, and discuss these methods further below.

2.1. Assessing the value of design support

If biostatistical support were generally available and the support clearly shown in grants, then biostatistical support would not increase the chance of success for an individual grant, since total
resources available for grants are limited. Instead, the lack of biostatistical support would significantly reduce the chance of success, since biostatistical support would be assumed for all grants. If some institutions and investigators do not, for whatever reason, provide or include biostatistical support in grants, however, then the value of biostatistical support in the design of the study would be reflected in the improved chance of the grant's being funded or the contract approved. As any biostatistician would tell an investigator, the best study to assess the true impact of statistical assistance on the success rate of grants would be a rigorously designed randomized study.

Many features would be needed for a valid study. I list several of them only to show that such a study would not be feasible. First, the study would need to be randomized. Some protocols would need to be assigned to get statistical review and support before submission, and others would be submitted without statistical review and support. This would need to be done independent of whether the investigator came seeking support or not. Otherwise, the impact of statistical interventions might be muted because those grants that would most benefit from statistical review are often those least likely to request such assistance.

Second, the study would need to involve a large number of investigators. This would ensure that the projects being randomized reflect the range of grants for:

(a) overall quality;
(b) specific research topics; and
(c) specific funding source to which the grant is submitted.

All three of these areas have substantial impact upon the chance of funding for a specific proposal, given the variation in funding for different research areas and from different sponsors.

Third, the study would need to enroll a large number of biostatisticians with a range of academic training, prior collaborative experience, and experience in grant preparation to ensure that the results represented the quality of biostatisticians in general, and not merely the abilities of a specific individual or group.

Finally, the protocols would all need to be initially screened, so that they could be stratified by the necessary involvement within the project. Some basic levels would be:

(a) 'thinking through a study' in which the entire design and proposal are developed jointly, as expected in a long term collaborative relationship;
(b) involvement at a later stage, after a draft of the protocol is completed, but while there is still an opportunity for the statistician to have a major impact upon the overall study design, hypotheses, etc., and to provide appropriate statistical material for the grant, which might include sample size, data management and data analysis text; and
(c) preparation of appropriate statistical material, but without significant need or ability to alter the overall study design.

Both (b) and (c) may need to be stratified further by how much material is needed, for example, basic material (such as a paragraph on sample size and a paragraph on data analysis) or extensive material (such as an extended justification of the sample size, data management or complex data analysis plan.)

If this theoretical study were successfully completed, one could compare the overall success rate between grants with statistical support to the success rate of grants without statistical support. The per cent difference would be a measure of the improvement attributable to biostatistical support. This difference, multiplied by the 'total value' of all the grants submitted, would be an
indication of the dollar value of biostatistical support. The amount used as the ‘total value’ might be the total cost, or include only direct or indirect costs.

2.2. Costs of outside biostatistical consultants

Biostatistical consultants may charge in many different ways. Three basic approaches, however, are likely to account for a substantial majority of cases:

(a) charging on an hourly basis;
(b) charging on a project basis, which may be calculated by considering the type and amount of work involved, possibly with a discount from the hourly rate; or
(c) charging on a retainer basis, with a fixed fee for either unlimited support to an investigator/group, or up to a specified limit of support with additional time billed at an agreed rate.

The standard hourly rate for an outside consultant is determined by many factors, including:

(a) the desired annual salary;
(b) the related fringe benefit costs (for example, additional social security taxes related to self-employment, health, disability, life insurance and pension plans);
(c) actual costs related to consulting (for example, office space, advertising, computing equipment, meetings, professional expenses etc.); and
(d) the expected number of ‘billable hours’ during a year.

Unlike a salaried employee, who is assured of being paid regularly, a consultant must allow for the fact that much time is spent trying to get projects, rather than doing projects; 1000 billable hours per year would be a high estimate for most consultants unless extremely successful. If the rate for fringes and actual costs related to consulting were 50 per cent (a conservative value for most organizations), hourly charges would be $75 for a $50000 salary level (a master's level statistician) and $150 for a $100000 salary level (a senior doctoral level statistician).

These fees may seem high to many individuals, since consulting work is often considered ‘extra money’ rather than being treated as an alternative occupation. If actual hourly costs are calculated within an institution, taking into account the institutional overhead and fringe rates, space charges and general support expenses, one will find that these estimates are reasonable and may even be low.

2.3. Assessment of other costs

It is true that many investigators would do the work themselves rather than pay an outside biostatistical consultant these charges. However, there is a cost when the investigators do the work, although often the cost is neglected. Doing the work themselves, or having staff do the work (a common option in an academic medical environment) implies less time available for other activities, some of which might be far more productive than the cash saved. Moreover, given that neither the investigator nor the investigator’s staff is expert at doing statistics, it is likely that they will spend far more time on a project than a statistician would. Even if all the work is done by the investigators in their ‘free time’, the time could still have been used for personal activities such as playing with children or spending time with a significant other. Although quantifying the economic impact of these activities in one’s life is probably impossible, having a life outside work does allow one to be more productive at work.
If the work is being done by a staff member, then the investigator is paying both a salary and at least fringe benefits for the staff member. Assuming a low-level staff member at $25000/year, fringes at 25 per cent, and 1547 productive hours a year (to allow for vacation, sick leave, coffee breaks etc.), this gives an hourly cost of $20.20/hour. If this person takes 3–4 times as long to do the work as a statistician would take, then that implies the actual cost is similar to a master’s-level statistician. In addition, the master’s-level statistician could provide a more sophisticated analysis when appropriate. Potentially, such an analysis would provide more insight into the data than a basic analysis would give.

If a unit is large enough for individual statistical staff to focus on specific research areas there would be less potential for the investigator’s staff to reduce costs, since the statistical staff would have clear ideas on how to analyse the data and present the results. This would make their work more efficient, thus reducing the cost for the statistical work. Potentially, the investigator would also save time when discussing the project with the statisticians. This benefit would be most marked for individual small projects, in which the time involved for a statistician to learn the goals of the project, obtain some background in the subject area, and determine the type of analysis may account for a substantial fraction of the total work on a project. Thus, the cost comparison above may substantially underestimate the relative efficiency of a trained statistician compared with the investigator’s staff in a focused environment such as a cancer centre.

Moreover, the investigator’s staff would be unlikely to be as conscious of data problems or of appropriate analysis techniques as a master’s-level statistician, increasing the chance of error. Such errors have a cost. Although these costs are largely intangible, there may be long-term consequences to the career of an investigator who develops a reputation for careless mistakes. For example, a referee having reviewed a manuscript and found substantial errors is unlikely to hurry to review a new manuscript and likely to be more critical in reading the investigator’s work.

There is also the benefit of completing work quicker. Although often not critical, quick completion may have important implications when applying for promotions, new positions and new grant applications. Placing a monetary value on this benefit is virtually impossible, however. Assessing the value of other benefits, such as improved compliance, would be even harder to quantify, and are not discussed further.

### 3. PRACTICAL APPROACHES FOR ASSESSING VALUE

#### 3.1. Valuing contributions to grants

Given the difficulties in organizing the randomized study outlined in Section 2.1, the contribution of biostatistical support to a grant is unlikely to ever be objectively assessed. Therefore, an ad hoc procedure is necessary. Table II summarizes the proposed procedure, incorporating both the level of the contribution and the importance of biostatistics to the accomplishment of the overall grant. Note that Table II does not refer to specific statistical aspects of the grant (for example, support for data management and analysis in a clinical trial) for which the biostatistics group is compensated. Direct compensation needs to be deducted from the total value attributed to the biostatistical group to calculate the extra value provided. In addition, the assessment may need to be done separately for each of the major components of the grant. For example, a biostatistics consulting group might only be involved in a specific component (such as the clinical study) and not in any of the mechanistic studies in the grant application. In that case the value contributed is based on the total value of the clinical study alone, not the whole project.
Table II. *Ad hoc* approach to valuing the contribution of biostatistics to a grant*.

<table>
<thead>
<tr>
<th>Level of contribution to grant</th>
<th>Specific activity</th>
<th>Per cent contributed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fundamental changes: contributions to at least two of: overall aims, study design and overall</td>
<td>Biostatistics and data management a key component†</td>
<td>33</td>
</tr>
<tr>
<td>organization</td>
<td>Biostatistics and data management ancillary to main aims of the study, so that</td>
<td>25</td>
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<tr>
<td></td>
<td>the grant could be done without such support</td>
<td></td>
</tr>
<tr>
<td>Substantial reshaping and refocusing: contributions to at least two of: overall aims, study</td>
<td>Biostatistics and data management a key component†</td>
<td>25</td>
</tr>
<tr>
<td>design and overall organization or</td>
<td>Extensive material for study design, statistical considerations</td>
<td></td>
</tr>
<tr>
<td>Fundamental change in only one area†</td>
<td>Limited material for study design, statistical considerations</td>
<td>10</td>
</tr>
<tr>
<td>Revisions: contributions to at least two of: overall aims, study design and overall</td>
<td>Biostatistics and data management a key component†</td>
<td>15</td>
</tr>
<tr>
<td>organization of grant or Substantial changes in only one area†</td>
<td>Extensive material for study design, statistical considerations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Limited material for study design, statistical considerations</td>
<td>10</td>
</tr>
<tr>
<td>Preparation of specific material for a grant, but revisions to at most one area</td>
<td>Biostatistics and data management a key component†</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Extensive material for statistical considerations</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Limited material for statistical considerations</td>
<td>2</td>
</tr>
<tr>
<td>Convincing investigators to stop work on a futile grant</td>
<td>Value of investigator’s time</td>
<td></td>
</tr>
</tbody>
</table>

*Per cents given assume no other group provides contributions to the overall study proposal.

† As a ‘key component’ the grant would not be fundable no matter how meritorious it was without biostatistics and data management support. Examples in which a biostatistics and data management group would be a key component include (a) a large clinical trial, which could not be done without such support; and (b) a proposal with sophisticated statistical modelling as a primary aim.

‡ Although it is unlikely either fundamental or substantive changes would involve only one of the three areas listed, these situations are included for completeness.

§ Although it is unlikely biostatistics and data management would be a key component but would not make at least substantial improvements to several areas of the grant, these situations are included for completeness.

3.2. Rationale for *ad hoc* approach

A grant consists of many parts, including:

(a) a well-defined and important question;
(b) an available population to study the question;
(c) an appropriate study design to answer the question;
(d) appropriate data collection methods to obtain the needed information, including laboratory and clinical examinations, etc.; and
(e) an appropriate method to summarize the results and draw conclusions.
As a basic principle, the investigator puts together a package that includes the idea for the study (item (a)) and the necessary resources for the study (specifically, patients and measurements; items (b) and (d)). Without at least a basic idea of these prerequisites, there is no study to develop. Usually an investigator comes to a biostatistics and data management group having already identified certain key components of the study, at least in broad outline, including the patient population and the specific laboratory and clinical examinations being done. As such, the detailed laboratory methods, physical examinations, and other examinations being done, although critical to the study proposal, are part of the package brought by the investigator as the investigator's part of the value of the proposal.

I have arbitrarily set the minimum value for this contribution as 50 per cent, recognizing that for a well-designed proposal the investigator contributes a much higher proportion. Occasionally a biostatistician might find an investigator's proposal so ill-focused that the investigator is contributing even less than this. Usually I would invest minimal resources helping such an investigator improve the grant, on the assumption that there was little I could do to improve the proposal and that my efforts would be better spent on other proposals. Thus, I have assumed that the most that biostatistics, together with other contributors, can claim credit for is 50 per cent of the grant. Usually, however, the only other group adding value to the overall proposal is biostatistics, since most other groups focus on their detailed area of expertise, not the study as a whole. Obviously, when several groups are adding value to the proposal, then the biostatistics group's contribution may need to be reduced. For example, when one of the investigator's colleagues suggests a major revision to the focus of the study, then the contribution of the biostatistics group may need to be reduced.

3.3. Valuing major contributions to grants

Regrettably, there is often little relationship between the amount paid for biostatistics and data management and biostatistics' contribution to the grant. Some types of grants will involve extensive data management and data analysis, even though the intellectual contribution of the biostatistics group will be relatively straightforward (although important). An obvious example is a randomized clinical trial, in which standard and well-developed methods are used for study design, data management and data analysis. In such a case the intellectual contribution might be small although the budget for biostatistics and data management might be substantial.

In contrast, other grants may involve major contributions to the overall logic of the grant and the overall study design, but few data are collected and data analysis is simple. Such a grant would provide little direct support for the biostatistics group because its role is focused on advising the investigator rather than in actual data management and data analysis activities. An example would be the design of a complicated animal study in which the final analysis, however, could be reduced to ANOVA and post hoc pairwise comparisons.

When the biostatistics group makes a major contribution to the overall proposal, this needs to be recognized as a major contribution to the grant. Such contributions include providing a focus to a proposal, modifying the basic study design, organizing the proposal to be coherent and understandable, and so forth.

Similarly, if the proposal would not be seriously considered without the inclusion of the biostatistics consulting group, or another similar resource, then the biostatistics group should be recognized as a key component of the grant. For example, a proposal for a multi-centre clinical
trial without material on data collection, management, and analysis and an experienced biostatistics and data management group would not be a viable proposal.

These two aspects do not necessarily overlap. Thus, in Table II, I propose that the biostatistics group would be credited with 33 per cent of the value of the grant when the biostatistics group both makes a fundamental contribution to the study grant and is a key component. The biostatistics group receives less credit when it makes a fundamental contribution to the grant but is not a key component (25 per cent). When the biostatistics group is a key component of the project but does not make a fundamental contribution, it receives less credit, ranging from 10 per cent to 25 per cent, depending on the importance of its intellectual contribution to the grant.

These estimates are based on the following assumptions:

(a) the lack of even a single key component would almost certainly prevent a grant from being funded;
(b) the investigator would have most key components (patients; measurements) identified as part of the proposal;
(c) fundamental contributions by the biostatistics group substantially increase the probability of a grant’s being funded; and
(d) no other group is making fundamental contributions to the overall aims, design and development of the protocol.

Thus, although these values may appear large, I do not believe that they are unreasonable.

The value estimated for lesser contributions to a grant follow from these upper limits, and is intended to reflect the intellectual contribution to the overall quality of the grant and the increase in the probability that it will be funded.

3.4. Valuing contributions for other activities

For virtually all other items listed in Table I the cost of an outside service doing the work is a reasonable measure. If this work is done by a mix of senior and junior staff, then it would be reasonable that the senior staff would provide all the design work and would supervise junior staff in a ratio of one hour senior time to three hours junior time for other activities such as data management and analysis. Moreover, providing a discount to the hourly charges in this evaluation would be appropriate, since the institution is, to some extent, a single large client, although multiple individuals are receiving support from the biostatistics group. The size of the discount would depend upon how much work is provided but could not be more than 33 per cent and still cover costs. A discount approaching this size would be appropriate only if multiple FTEs were used for this activity.

Training is a special case, since many commercial training programs are available. Although estimating the actual commercial cost for a specific course is difficult, many commercial training courses are offered in the range of $300–600/student/day. Again, quantity discounts are often available, so a reasonable value for training might be $200/student/day in basic statistics while training in advanced statistics, or special topics, might be $500/student/day. A local course also avoids travel expenses and time spent traveling to the course, which would further increase the direct financial value of the course to the institution. Moreover, a local course can be focused on the specific needs of the students, unlike most commercial training courses, and could even include examples relevant to the students, although the direct financial benefits of a course would not include such non-monetary values.
4. CASE STUDY: THE BIOMETRICS CENTER AT THE BETH ISRAEL DEACONESS MEDICAL CENTER

This section provides several examples of how different contributions would be valued. I begin with four illustrations of how the contribution to specific grants can be assessed; the dollar figures are rounded for convenience. The actual value used for a real calculation is discussed in Section 5.

(a) For an R01, the biostatistics group provided fundamental contributions to the proposal, including study design and organization for one of the three major aims. The group doing the study had its own internal data management activity so no work would be done by the biostatistics group and the biostatistics group would not be a key component of this grant. Given the fundamental contributions to the proposal for this aim, the biostatistics group should be credited with 25 per cent of the value of this section of the grant. For a grant with a value of $1000000, with this aim being 50 per cent of the total value, the biostatistics group’s contribution would be $125000 (25 per cent of 50 per cent of 1000000). After deducting the $2000 paid to the biostatistics group for consultation, the total value of our contribution is $123000.

(b) For a mentored training award, the biostatistics group provided fundamental contributions to the proposal, including focusing specific aims into identifiable objectives, reorganizing the basic set of clinical studies into a coherent whole, etc. No other group was involved in improving the original proposal. Although the biostatistical group has only a relatively small direct role in the study, based on its fundamental contributions to the proposal the biostatistics group should be credited with 25 per cent of the value of the grant. For a grant with a value of $500000, this would be $125000 less the actual amount paid to the biostatistics group ($20000), for a total contribution of $105000.

(c) For an RFA, the biostatistics group prepared extensive data management and data analysis sections for a grant and did extensive computer work to justify the specific (very small) sample sizes being used. This material was summarized for the body of the grant and the full material used as an appendix in the grant application. The biostatistics group also made significant revisions to the overall logic of the study and organization of the proposal. Laboratory collaborators of the investigator made substantial revisions to the laboratory component of the study (specific tests used) but did not seem to make substantial revisions to the overall study design. The overall design of the grant, however, was not fundamentally changed nor was biostatistics and data management a key component of the project. Because of the level of the contribution (revisions to two or more specific areas) and the extensive amount of material provided for this grant, the biostatistics group should be credited with 10 per cent of the value of the grant. For a grant with a value of $1000000, this would be $100000 less the actual amount paid to the biostatistics group for consultations ($15000), for a total contribution of $85000.

(d) For another R01, the biostatistics group prepared extensive material on sample size, data management and data analysis for a multi-centre clinical study. The design, however, was little changed from the initial design proposed by the investigator at the first meeting. Although the biostatistics group made significant improvements to the overall organization of the grant, we made only minor contributions to the basic study design or to the hypotheses. Thus, the biostatistics group should be credited with 15 per cent of the value of the grant, since we made a substantial contribution to one area and are a key component of
the grant. For a grant with a value of $1000000, this would be $150000 less the actual amount paid to the biostatistics group ($75000), for a total contribution of $75000.

Other aspects of our contributions to the institution include:

(e) training of approximately 40 individuals a year in general statistics and/or study design, with the equivalent of a one day course, at $200/student/day, for a value of $8000;
(f) specialized seminars for different groups, approximately four per year, averaging 10 individuals, equivalent to about seven individuals attending a specialized one-day course, at $500/student/day, for a value of $3500;
(g) 200 total hours of internal consulting on data management and data analysis would have a cost of $375/four hours (one hour of senior time at $150/hour plus three hours of junior time at $75/hour), for a total value of $18750. Given that this is only 20 per cent of one person's estimated billable hours, only a small discount, if any, would be given by an outside consulting group.

Overall, we have estimated that the core services provided a value of more than $4 per dollar spent in 1996 and in 1997, and more than $9 per dollar spent in 1998. The figure in 1998 is primarily due to one very large grant, in which the principal investigators agree that the biostatistics group's contribution to the value of the grant was at least the percentage claimed by us. As this figure is extremely large, within the institution we claim only that we provide a value of more than $6 per dollar spent for institutional support in 1998.

5. PRACTICAL ISSUES

There are many practical issues involved in evaluating the contribution to grants and contracts, the major ‘value added’ service provided by a statistics group. These include:

(a) the value attributed to the grant;
(b) whether value is added for all grants or only for funded grants; and
(c) the per cent contribution of the biostatistics group for various contributions to a grant, which in turn is based on the maximum percentage that biostatistics can contribute to a grant.

Although all these decisions could be considered arbitrary, the approach adopted here has been reviewed and approved by the Biometrics Center Advisory Committee, which consists of clinical, laboratory and health policy investigators, and institutional officials.

I use total direct costs for the value of the grant. As these are expenses, it might be argued that direct costs provide no benefit to the institution itself, and that only indirect expenses (that is, ‘overhead’) should be counted. However, the overhead rate varies substantially depending upon the source of funds. For NIH grants, the type of grant also influences the per cent overhead paid. As I believe that the contribution provided to a grant should be calculated independent of the source of funds or the type of application being submitted, total direct cost appears more suitable. Direct costs could be further refined by limiting the calculation only to certain items, for example, salaries, or excluding specific items, for example, subcontracts or equipment. Given the uncertainties involved in valuing the per cent contribution of the biostatistics group to each specific grant.
itself, however, it does not appear that these refinements are worthwhile. My focus on direct financial value ignores the non-economic value of the grant. Depending on the grant, these non-economic benefits might include increased public prestige for the institution, improved competitiveness for future grants, and increased ability to attract or retain investigators. Although these non-economic benefits may subsequently lead to substantial long-term financial benefit to the institution, because of the difficulty in quantifying them they are not considered in my analysis. In another environment one might want to use a different measure of value (for example, total of direct and indirect costs; indirect costs only), and possibly even attempt to estimate and include non-economic benefits in the total value of a project.

The theoretical study described in Section 2.1 would provide an overall estimate of the incremental funding due to biostatistical support. The increase in value attributable to biostatistical support is approximately the change in the average per cent funding rate times the total value of all the grants submitted. This change in per cent funding rate is likely to be a small percentage of the total submitted, given the low funding rate for most grants. One could develop an alternative ad hoc approach that used a small percentage and applied it uniformly across all grants submitted. I believe, however, that it is more practical to consider the value contributed only to funded grants, and to use a grant-specific percentage reflecting how much biostatistics contributed to the total quality of the grant. This reflects the realities of academic life in which only funded projects, not grant submissions, are valued. Similarly, although the intellectual contribution to an internal study may be the same as for a funded grant, I do not attribute any direct financial value to the assistance given for the internal study since it does not bring in external funds to the institution. In another environment, however, internal studies may be the primary focus of the biostatistics group and would need to be included in the cost-benefit analysis.

Another major assumption is the per cent contribution attributable to the biostatistics group for a specific grant. The basic assumption is the maximum value that a biostatistics group may contribute to a grant. Once this upper limit is set, then the other proportions are determined based on the relative contribution to the maximum valuable attainable. Under appropriate circumstances, I believe that a biostatistics group should be credited with as much as 33 per cent of the value of the grant. Although one could argue that the biostatistical group could claim as much as 50 per cent if the investigator contributes only 50 per cent, personally I am uncomfortable claiming such a high percentage. Others might argue that since the investigator provides the basic idea, the investigator deserves nearly all the credit for a grant, independent of the improvements suggested by others. Certainly, the biostatistics contribution to a well-formulated, well-organized and well-presented study will be much less than 33 per cent. However, many grants have little chance of being funded because of problems such as a faulty study design or a poorly presented application. When this occurs, it seems appropriate that a major fraction of the value of the grant should be credited to those who salvage the proposal. Usually, only the biostatistics group provides such assistance to an investigator. The Biometrics Center Advisory Committee felt that this maximum contribution of 33 per cent was reasonable, as do institutional officials who have reviewed internal cost-benefit analyses. The maximum potential contribution may be different at other institutions.

Although I have presented a fixed percentage for each type of activity and level of contribution, this is a simplistic solution. Fixed percentages imply that all statisticians add the same value for each specific type of activity. In reality, the value added will vary across statisticians, with some statisticians having greater skill or experience in improving grants than others.
Moreover, the value added by a specific statistician is likely to vary depending on the subject matter of the grant and the statistician’s knowledge of the subject area. As such, a full solution would probably require both statistician specific and statistician - subject matter specific rates for the value contributed to the grant. In addition, it is often not clear whether a contribution is truly fundamental or only substantial, for example, or whether material is extensive or limited. Furthermore, as indicated in example (a) in Section 4, the specific per cent contribution may vary for different sections of the grant. Thus it is often necessary to develop a specific per cent contribution for each individual grant.

Unless one feels that one is making only a small contribution to the proposal (for example, at the revision level or simply text for the grant), one might wish to discuss the allocation of credit when the grant is submitted. This is particularly important when assessing the contribution to a major grant (for example, centre projects) or when a substantial contribution is being claimed. Occasionally the investigator and the statistician disagree about whether the level of contribution is fundamental, substantive, or merely a revision to a grant. I have had substantial disagreements about the level of contribution only on protocols that were largely developed by my group because the initial version was extremely weak. Retaining a copy of the original proposal prepared by the investigator and the final version submitted is usually ample documentation for outside review, should any questions arise. It is interesting that many of our strongest collaborators credit the biostatistics group with a bigger contribution than I feel we have made. In these cases, I prefer to use my own more conservative valuation.

The cost-benefit analysis can be refined in several ways. First, one could produce an analysis separately for each type of activity, for example, one for design support, one for training, and one for other activities. Although I have not done this formally, it is clear from the example that the major contribution is to external grants. The tangible benefits for both training (items (e) and (f) in Section 4) and data management/analysis on an hourly basis (item (g) in Section 4) are relatively small.

One can also perform a sensitivity analysis for the cost-benefit analysis, calculating a range for the potential benefit provided by biostatistics. Such a calculation could incorporate a range of assumptions about the per cent of value contributed to grants and contracts and about the value of other contributions, for example, the cost for external services of various types. This calculation could also incorporate different value metrics, for example, using total costs or only indirect costs, instead of direct costs. Such a calculation could also include the value of the intangibles provided by the biostatistics group. Although this would provide a range of benefits for the cost-benefit analysis, the resulting range would not be a confidence interval in any statistical sense and potentially would be very wide. For example, a rough calculation would suggest a cost-benefit ratio ranging from about $3 to over $20 per dollar spent on core activities in 1998 for the BI-Deaconess Biometrics Center.

Finally, when making such an analysis, it is critical that the results do not overstate the case. No matter how talented one individual is, it is unlikely that one individual can fundamentally affect many unrelated protocols concurrently. To affect a protocol fundamentally, one needs both to understand the material well, to have thought about it, to have spent time with the investigator working through the revisions, and usually doing extensive writing. Such work is very taxing, both in time and energy. Biostatistics contributes more than enough to justify its existence and support by an institution. To understimate our value and be considered plausible is far better than to claim a benefit so large, although accurate, as to raise suspicions that we are overstating our value.
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