Report to the Long Range Plan Steering Committee

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Executive Summary

Applied biostatistical research plays a vital role in bridging the gap between abstract statistical work and day-to-day statistical practice. Historically, NSERC has been very successful in supporting applied statistical research and training. However, recent efforts to avoid funding duplication between NSERC and CIHR run the risk of creating a funding gap and jeopardizing the future of biostatistical research and capacity-building in Canada.

1 Introduction

The purpose of this document is to provide input from the perspective of biostatisticians to NSERC's long range plan for mathematics and statistics, focusing particularly on the importance of cross-disciplinary research within biostatistics and the resulting implications for funding. We begin by describing the role of cross-disciplinary work within the field, and then describe how this can create funding barriers. These barriers exist both for faculty and for students. Within the Discovery Grant program there is a lack of clarity over what applied work NSERC is willing to fund, and consequently a danger that recent efforts to avoid duplication between NSERC, CIHR and SSHRC may create a funding vacuum for biostatistics. Within scholarship competitions entire biostatistical graduate programs have been deemed ineligible because they sit within a parent program that focuses on health research. We argue that while NSERC has historically been successful at supporting biostatistics research and training, recent changes threaten to jeopardize the future of both research and capacity-building in our field.

2 Science: highlights, cross-disciplinary work, and funding barriers

One of the highlights of biostatistics research is that the findings are often directly applicable. For example, a biostatistician who has worked on methods for causal inference will often have the op-

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portunity to apply these methods immediately, because it was a practical example that highlighted the need for the research. Thus, biostatistical research will often directly impact the way research is done in other disciplines.

Biostatistics is by nature cross-disciplinary. Clinicians are unlikely to adopt new statistical methods or experimental designs of their own accord, as they do not typically read the statistical literature. However if, for example, a trialist often faces a particular issue and a biostatistician who is a trusted collaborator has developed a new experimental design to address that issue, the trialist is much more likely to adopt the method. Once it has been used successfully and the results published in the medical literature, other trialists will become aware of the method and have an example of its success. Conversely, the methodological issues encountered in clinical research raise important statistical questions and lead to meaningful advances in statistical knowledge. Thus good biostatistics depends on good relationships with clinical colleagues in which there is a mutual interest in one another's research.

Within biostatistics there is, of course, a continuum. On the one end of the spectrum you might have people who are developing experimental designs and data analytic models in the abstract, while at the other end there are people who are concerned only with particular clinical problems and who are not concerned with general methodology as it might be applied elsewhere. **We need both general abstract work and work on particular problems**. Work in the abstract creates a body of methods that have the potential to be widely applicable, but without work on particular clinical problems it risks being irrelevant and impractical. Conversely, work on particular problems is directly applicable, but can be hampered without a body of general work on which to draw.

Given this continuum, it may be difficult to delineate a firm boundary between what biostatistical research is or is not strictly eligible for NSERC funding. Good applied statistics is characterized by collaboration and interplay with clinical colleagues, so the so-called overlap boundary may be hard to operationalise. For example, the guidelines for biostatistical methods (MS16, within Mathematics and Statistics) in the Discovery Grant program currently state that "research involving clinical trials is not eligible for NSERC support", while the topics under "MS16-biostatistical methods" include "design of clinical trials". Whilst we would hope that this apparent contradiction is intended to convey the idea that while NSERC is not interested in funding actual clinical trials, it is interested in funding general methodology concerning the principles of design of clinical trials, this is currently unclear. Similarly, "survival analysis; longitudinal and life-history analysis" are listed under MS16, however "applied research for disease treatment, diagnosis or prevention" is not considered eligible. Would NSERC consider funding research into the methods for longitudinal data analysis that focuses on the particular issues that arise when studying disease treatment amongst human beings (loss to follow-up, intermittent measurement, informative censoring)? Similar questions apply to each of the other items listed under MS16, and further examples are given in the appendix. This ambiguity has been a concern to many of us. Moreover, wherever the line is drawn between theoretical and applied work, the resulting boundary is likely to be somewhat arbitrary.

3 Research funding - existing infrastructure, recent changes, and funding gaps

Historically, NSERC research funding has been flexible, tied to a program of research rather than to a specific project. The major use of research funding is to fund trainees, and this flexibility allows us to provide students with a stipend while they identify a research topic within the supervisor's program and apply for their own funding, usually through OGS or NSERC. However, recent efforts to avoid overlap between what is funded by NSERC, CIHR and SSHRC raise the possibility that because of its cross-disciplinary nature, biostatistics research may "fall between the cracks" and in effect be denied by all three agencies. Biostatistical work is rarely funded by CIHR, as it does not usually address a clinical question but rather looks at statistical methodology in a more general and technical way. The same is true for SSHRC. **The effort to avoid duplication coupled with the lack of clarity over what applied work NSERC is willing to consider may create a funding void if not handled carefully**.

4 Training

The emerging funding gap for applied statistical research applies to our trainees as well. Entire programs have been deemed ineligible for NSERC funding. For example, our graduate program is titled "Health Research Methodology", and offers biostatistics as a field of specialization. Some of our students in the biostatistics stream have been told they were ineligible to apply to NSERC for scholarships because the parent program focuses on health research. The students own research plans apparently did not enter into the decision. There is already a shortage of statisticians able to work effectively with clinical researchers, and moving funding away from applied statistics can only exacerbate this. There are few other avenues for funding for our students, as typically their research is viewed as falling under the umbrella of mathematics and statistics rather than the health sciences, and so they are not eligible for CIHR funding.

5 Summary

In summary, applied biostatistical research plays a vital role in bridging the gap between abstract statistical work and day-to-day statistical practice. In the past NSERC has been very effective at supporting biostatistical research and training, however recent changes in the way applied statistical research is handled run the risk of creating a funding gap and jeopardizing the future of biostatistical research and capacity-building in Canada. Efforts to avoid funding duplication need to be coupled with efforts to avoid funding exclusion.

A Eligibility and ineligibility criteria in the NSERC Discovery Grants Program

Listed as eligible under MS16 (biostatistics) within mathematics and statistics	Listed as ineligible	Examples of ambiguities
1. Survival analysis 2. Life history analysis 3. Longitudinal analysis 4. generalized linear mixed models 5. case control studies 6. quantitative methods in health sciences 7. meta-analysis 8. physiological models 9. epidemiological methods 10. infectious disease models 11. statistical methods for health policy research 12. design of clinical trials	1. Research involving the refinement of already existing technology for facilitating clinical therapies or health delivery systems. 2. Applied research for disease treatment, diagnosis or prevention 3. Research involving clinical trials (as defined by the International Conference on Harmonisation (ICH) Guidelines to Good Clinical Practice).	Research into statistical methods for cost-effectiveness evaluation to inform health policy around funding for refinements of existing technology (***Eligible under criterion 11, ineligible under criterion 1***) Development of methodology for handling the informative censoring patterns that emerge when conducting long-term follow-up of patients after an initial course of treatment (***Eligible under criterion 1, ineligible under criterion 2***) Development of stochastic infectious disease models designed to evaluate vaccination programs (***Eligible under criterion 10, ineligible under criterion 2***) Developing priors for between-study heterogeneity in a Bayesian meta-analysis (***Eligible under criterion 7, ineligible under criteria 2 and 3***)