Evaluation of Recent Research Grant Applications to the National Institutes of Health in the Area of Pediatric Nephrology

ANTONIA C. NOVELLO¹

General Medicine B Study Section, Physiological Sciences Review Section, Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205

ABSTRACT. To assess the National Institutes of Health extramural activity in the area of pediatric nephrology research, the rate of submission of grant applications to the National Institutes of Health and available indicators of the quality of these applications were analyzed. This was accomplished by utilizing the grant application files of the Division of Research Grants' Statistics and Analysis Branch with the help of the Reports, Analysis and Presentation Section. Applications reviewed during the period 1980-1983 (May 1980 to January 1984 Council dates) were evaluated, and data from the 10 Study Sections most frequently involved with the review of nephrology applications were tabulated. Results showed that the number of pediatric nephrology applications submitted was quite low, whereas the approval rate was good for those that were submitted. (Pediatr Res 19: 1139-1142, 1985)

Abbreviations

NIH, National Institutes of Health FY, fiscal year IRG, initial review group DRG, Division of Research Grants

Despite a prospective investigator's best efforts, success in obtaining Federal funds to conduct biomedical research is influenced by several factors, only some of which are under the investigator's control. Over the past several years a doubling of approved but unfunded applications, a lowering of the cutoff points at which applications are being funded, and a slowing in the growth of Federal funds for biomedical research have occurred. The number of competing research project grant applications (R01, P01, R22, R23, R43, R44, U01 projects) has risen dramatically-from 8,596 in FY 1972 to 16,798 in FY 1983, an increase of 95%. The number of applications recomended for approval and thus eligible for award has grown at an even greater rate, increasing from 6,141 in FY 1972 to 14,479 (136%) in FY 1983. The number of actual awards, however, has fluctuated greatly, from a low of 2592 new and competing renewal proposals to a high of 5944, averaging somewhat more than 5000 in the last several years. In FY 1972, approximately 50% of the approved or eligible competing research grant applications were

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Reprint requests Dr. Antonia C. Novello, Executive Secretary, General Medicine B Study Section, Division of Research Grants, Westwood Building, Room 322, 5333 Westbard Avenue, NIH, Bethesda, MD 20205.

¹ Executive Secretary, General Medicine B Study Section, Physiological Sciences Review Section, Division of Research Grants, National Institutes of Health, Westwood Building, Room 322, 5333 Westbard Avenue, Bethesda, MD 20205; Clinical Associate Professor of Pediatrics, Georgetown University, Washington, DC. funded. By FY 1983, the award rate had fallen to 37.2%, although the NIH still managed to fund over 5000 project grants.

In FY 1983 the figure of 5388 was an increase of 361 awards or 7.2% from the previous year. Similarly, despite the lower award rate, new principal investigators have consistently entered the NIH system at a healthy rate, as evidenced by the fact that from FY 1978 through FY 1982 an average of 28.5% of the principal investigators on competing research project grants were new investigators.

Despite an apparent healthy trend in the number of approvals of all competing applications to the NIH, the American Society of Pediatric Nephrology Council has been concerned with the number and rating of pediatric nephrology applications. It appeared to members of the Society that only a few pediatric nephrologists were actively engaged in research, and there was a perception that those who submitted competing applications received priority scores in the unfundable range. It was believed that low scores resulted from not having a Pediatric Study Section and from evaluation by nonpediatrician reviewers. The DRG was asked to examine these concerns.

Before reporting on an analysis of the problem of pediatric nephrology proposals, a brief examination of the basic process of NIH peer review of research grant applications may be advantageous. Currently there are 66 chartered IRGs in DRG (referred to as Study Sections) established according to scientific disciplines. In addition, there are approximately 33 other groups in the different Bureaus, Institutes, and Divisions of NIH. When the DRG receives an application which does not fit the assignment guidelines of an IRG, it is sent to a specially convened review panel known as a Special Study Section.

Each IRG is composed of 15–20 members from the biomedical research community. All have the necessary scientific expertise as well as an interest in serving; in addition, all are currently active in research, have mature judgment, balanced perspective, objectivity, and are able to work effectively in a review group setting. Most of these researchers come from medical schools (56.6%) and other higher education organizations (25%), with the remainder (18.4%) divided among other professional schools, independent hospitals, nonprofit research institutions, and forprofit organizations. Most have PhD degrees (62.3%); the rest (37.6%) are comprised of MD's (29.1%) and PhD/MD's (8.5%). Academic ranks vary from professor (65%) to assistant professor (4.1%). A representative list of Study Sections is shown in Table 1.

The range of expertise on any particular study section is varied. For example, General Medicine B Study Section reviews water and electrolyte metabolism as well as mineral metabolism, renal hormones, and vitamin D, indicating that its expertise ranges from nephrology to biochemistry. The IRGs consideration and discussion of a research grant application are guided by six criteria set forth in the Public Health Service Scientific Peer

 Table 1. DRG Study Sections

Study section	Code
Allergy and Immunology	(ALY)
Bacteriology and Mycology*	(BM)
Behavioral and Neurosciences-Fellowships*	(BNS)
Behavioral Medicine	(BEM)
Biochemical Endocrinology	(BCE)
Biochemistry*	(BIO)
Biomedical Sciences-Fellowships*	(BI)
Bio-Organic and Natural Products Chemis-	(BNP)
try	(77.77)
Biophysical Chemistry	(BBCB)
Bio-Psychology	(BPO)
Cardiovascular and Pulmonary	(CVA)
Callular Diology and Physiology*	(CVD)
Chemical Pathology	(CB1)
Clinical Sciences-Fellowships*	(CLN)
Diagnostic Radiology	(RNM)
Endocrinology	(END)
Epidemiology and Disease Control*	(EDC)
Experimental Cardiovascular Sciences	(ECS)
Experimental Immunology	(EI)
Experimental Therapeutics	(ET)
Experimmental Virology	(EVR)
General Medicine A*	(GMA)
General Medicine B	(GMB)
Genetics	(GEN)
Hearing Research	(HAR)
Hematology*	(HEM)
Human Development and Aging*	(HUD)
Human Embryology and Development	(HED)
Immunobiology	(IMB)
Immunological Sciences Memmelian Constian	(IMS) (MGN)
Maininanan Ochetics Medicinal Chemistry	(MCHA)
Metabolism	(MET)
Metallohiochemistry	(BMT)
Microbial Physiology and Genetics*	(MBC)
Molecular and Cellular Biophysics	(BBCA)
Molecular Biology	(MBY)
Molecular Cytology	(CTY)
Neurological Sciences*	(NLS)
Neurology A	(NEUA)
Neurology B	(NEUB)
Neurology C	(NEUC)
Nutrition	(NTN)
Oral Biology and Medicine*	(OBM)
Orthopedics and Musculoskeletal	(OKTH)
Pathology A	
Pathology A Pathology B	(FTHA) (PTHB)
Pharmacology D	(PHRA)
Physical Biochemistry	(PB)
Physiological Chemistry	(PC)
Physiology	(PHY)
Radiation	(RAD)
Reproductive Biology	(REB)
Respiratory and Applied Physiology	(RAP)
Sensory Disorders and Language	(CMS)
Social Sciences and Population	(SSP)
Special Programs	(SSS)
Surgery and Bioengineering	(SB)
Surgery Anesthesiology, and Trauma	(SAT)
Toxicology	(TOX)
I ropical Medicine and Parasitology	(TMP)
virology Visual Sciences **	(VK)
visual Sciences P	(VISA) (VISD)
visual ociences D	(VISD)

* Flexible study sections consisting of two or more subcommittees.

Review Regulations (1). These include: 1) the significance of the research problem, 2) the experimental approach/methodology, 3) the investigator's qualifications and experience in the area of the application, 4) resources, 5) the adequacy of the budget, and 6) research (humans, animals, and the environment) risk protection.

After discussion of the application has been completed and a motion for a recommendation has been made, each IRG member participates in a formal vote to recommend to the relevant Bureaus, Institutes, and Divisions National Advisory Council either approval or disapproval of the application. Approved proposals are assigned a priority score (1.0-5.0). The application priority score is the mean of the sum of all scores for a competing application, not an individual IRG member's score. A recommendation may be deferred by the IRG pending the receipt of further information either by mail or through a project site visit.

The particular manner in which the priority score is considered depends upon the individual Institute at NIH. Generally, Institutes rely heavily on initial review results, ranking applications by priority score, and awarding grants, beginning with the best priority score and continuing down to the last one for which funds are available. The priority score that separates funded applications from unfunded applications has become known informally as the "payline." However, priority score is only one factor; program considerations also are pertinent in funding decisions.

METHODS

To address the questions of pediatric nephrology review, the 10 Study Sections most frequently involved in the review of nephrology and related subjects were chosen. No special Study Section was included nor were applications reviewed by the Bureaus, Institutes, and Divisions considered. Similarly, only R01 (Traditional Research Projects), K series (K04-Research Center Development Award and K08-Clinical Investigator Award), and R23 (New Investigator Research Award) proposals were evaluated. No T32 (Institutional National Research Service Award), F32 (Postdoctoral Individual National Research Service Award), or P01 (Research Program Projects) applications were considered. The Study Sections selected for this analysis were: General Medicine B, Physiology, Experimental Cardiovascular Sciences, Cardiovascular and Renal, Bacteriology and Mycology, Surgery, Anesthesiology and Trauma, Pathology A, Nutrition, Human Embryology and Development, and Metabolism. The number of expert pediatricians on these Study Sections was approximately 16 during the period studied. The largest number was found in the Nutrition and the Human Embryology and **Development Study Sections.**

The time frame selected was 1980 through 1983, and included Council meetings from May 1980 through January 1984. Data on the applications were available from the open-pending files of the DRG Statistics and Analysis Branch and its Reports, Analysis and Presentation Section. These data were verified using descriptions from the Computer Retrieval of Information on Scientific Projects system. In addition, each application from each Study Section was manually checked to ensure strict accuracy in the study. All applications assigned to the 10 Study Sections were evaluated according to the total number of applications assigned, the number of nephrology and related subjects applications, the number of pediatric nephrology applications as a subdivision of the total nephrology applications, their approval and funding rates, and their priority scores.

RESULTS

As depicted in Table 2, the number of nephrology research grant applications has remained relatively stable over the 4-yr period with a larger than usual number (269 applications) in FY 1982. While the number of pediatric nephrology applications

Table 2. Pediatric Nephrology Grant Applications	NephrologyPediatricNephrologyNephrologyAll NIHapplicationsapplications	Recommended Funded		Funded, average Funded, average	SS) n %* n %† n % n %‡ priority score priority score	229 9 22 0.9 15 68 6 40 187 176	236 10 24 1.0 19 79 5 26 158 169	269 12 31 1.0 28 90 12 43 162 160	221 10 37 1.7 32 86 8 25 167 158	s reviewed by the 10 DRG Study Sections.	iewed as a percent of all applications reviewed by 10 DRG Study Sections.	shroloov annlieations recommended for annroval.
	Nephrology applications				ч <i>%</i>	229 9	236 10	269 12	221 10	ed by the 10 DRG St	a percent of all appl	annlications recomm
			No. of	applications	(10 DRG SS)	2449	2371	2259	2127	er of applications review	applications reviewed as	" of redioteic nerhrology
					FY	1980	1981	1982	1983	* Based on total numb	† Pediatric nephrology	+ Docod on the number

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was quite a small fraction of the applications reviewed by 10 DRG Study Sections, a steady growth both in number and percent of applications was observed, from 22 applications (0.9%) in 1980 to 37 applications (1.7%) in 1983. The proportion of pediatric nephrology applications recommended for approval increased from 68% in 1980 to an average 88% in the latest 2 yr. The number of applications funded also increased in the latter half of the period studied, from a mean of 5.5 the first 2 yr to an average of 10 in the latest 2 yr. This increase occurred while NIH award rates for all competing research project applications were declining.

Although the number of pediatric nephrology applications is not large enough to arrive at any significant statistical inferences about their treatment in the review and funding processes, the average priority scores of projects that were funded were not greatly different from those for all NIH funded projects.

At the 1982 Business Meeting of the American Society of Pediatric Nephrology the FY 1980–1981 NIH data were presented in greater detail than shown herein, with the suggestion that funding of pediatric nephrology research was at a low ebb, not because of peer review, but because of the low grant application submission rate. A similar assessment of the field for FY 1982–1983 was presented at the Annual Meeting of the Society for Pediatric Research in May 1984; this latest assessment did show a higher application submission rate and a higher level of funding of competing pediatric nephrology applications.

DISCUSSION

The foregoing represents an analysis of research grant applications in the area of Pediatric Nephrology. However, an evaluation of this type clearly has relevance for other subspecialty areas in pediatric research. To be funded an investigator needs to submit a competitive research grant application. In the pressurized environment of clinical academic medicine, all too frequently an investigator ignores the instructions for writing a research grant proposal or fails to be precise in describing his or her proposed research design. The following suggestions for the preparation of applications are provided to facilitate the writing of more competitive and more focused research applications (2).

1) Pay attention to detail in the instructions. 2) Never assume the reviewers will "know what you mean." The reviewer has no obligation to "read between the lines." 3) Refer to the literature thoroughly and thoughtfully. A relevant literature review is essential. 4) Represent investigator abilities and interests honestly. 5) State the goals and address the central hypothesis of the proposal. 6) Include well-designed and well-explained tables and figures. 7) Present an organized, easy-to-comprehend set of protocols. 8) Include an accurate abstract that outlines the objectives and methods of the proposed research. 9) Use experimental systems familiar to the investigator and describe the experiments, methodology and techniques, literature, and experience. 10) Describe clearly and thoroughly plans to analyze and interpret data.

Other items to consider when writing a proposal:

DO's

DON'TS

PERSONNEL

describe all personnel whether professional or nonprofessional, by name, position, and proposed time and effort—even if no salary is involved;

justify job descriptions; list dollar amounts separately for each individual; request only consultants who have agreed to participate. exceed 100% for the collective sum of percentages of time and effort proposed for each individual; request consultants that cannot be justified—either by lack of expertise or level of effort—for the proposed research.

DO's

EQUIPMENT AND SUPPLIES

request and justify all equipment necessary for the completion and performance of the proposed research; request and itemize supplies needed for completion of the proposed research; justify species, numbers, and cost of all animals; request cost for patient care, where appropriate; add subtotals

DO's

OTHER SUPPORT

describe for each professional, including the investigator listed on page 2 of the application, by time and effort all other

active support; applications and proposals pending review or funding; applications and proposals planned or being prepared for submission. DO's

TRAVEL

request travel monies and describe the purpose of the travel.

DON'Ts

request to purchase equipment that appears to be duplicative (*e.g.* investigator in previous proposal would have had to have such equipment to conduct the research);

add supplies indiscriminately; propose to use animal species that cannot be correlated to human data; or are not appropriate for the proposed area of research; request funds for coverage of laboratory tests which are routinely provided as part of a patient's basic tests; forget to check budget for

errors.

DON'Ts

forget to propose how priorities will be rearranged so as not to exceed 100% time and effort;

forget to address in detail potential overlap in scientific content between current proposal and others submitted.

DON'Ts

request travel for meetings not appropriate for the proposed area of research.

The investigator can submit, up to 4 wk before the Study Section meeting, any new data or manuscript that will aid the Study Section membership accomplish a thorough comprehensive review of the proposal. Similarly the investigator must be sure that all letters from proposed collaborators and letters of recommendation are in the hands of the Executive Secretary by the same 4-wk deadline.

In conclusion, an analysis of research grant submissions in the area of Pediatric Nephrology indicates that an increase in the number of approved applications has occurred since 1980. Although the number of investigators is not large enough to derive highly significant conclusions, these investigators seem nearly as successful being funded as those in other disciplines (Internal Medicine Nephrology Departments, Renal Physiology, and Biochemistry) when they submit a comprehensive proposal to the NIH. The problem appears to reside not in the review process but in the rate of submission of applications by pediatric nephrologists. In addition there is some indication that awards consist mostly of R01's, showing that the pediatric nephrology investigators have not utilized the broader spectrum of support mechanisms. In the past, the number of applications per Study Section meeting and their scientific content have been extremely varied. Thus, before reorganizing existing Study Sections, especially in view of the limited resources available, it is necessary to provide evidence that a change is warranted. The present review shows that this is not yet the case.

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REFERENCES

- Cuca JM 1983 NIH grant applications for clinical research: reasons for poor ratings or disapproval. Clin Res 31:453–461
- Novello AC 1985 The peer review process: how to prepare research grant applications to the NIH. Min Electro Metab (in press)