Physicians' Experience of Ethical Dilemmas and Resource Allocation

Supporting Statement A

Project officer:

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Supporting Statement for Request for Approval from the Office of Management and Budget (OMB) for “Physicians’ Experience of Ethical Dilemmas and Resource Allocation”:

Abstract

This is a request for OMB to approve “Physicians’ Experience of Ethical Dilemmas and Resource Allocation.” This is a one time self-administered telephone survey consisting of a 20 minute questionnaire of a random sample of physicians in general internal medicine. The survey is intended to provide information about physicians’ experience with resource allocation in their practice. Data collected will help medical professionals across the country to better understand the current state of practice on the issue of the allocation of health care resources, and will assist respondents and policy makers in understanding the practice of resource allocation nationwide. In particular, the data will be valuable to other agencies within the Department of Health and Human Services (DHHS) in understanding the interaction between health policy decisions and allocation in clinical practice. Results of the survey will be reported confidentially, either in the aggregate or stripped of individual identifiers.

A Justification

A.1 Circumstances Making the Collection of Information Necessary

The role that physicians should play in health care rationing is a matter of debate. It has been argued on the one hand that cost should never enter into physician decision-making at the bedside as it leads to ethically problematic situations. It has been seen as being in contradiction with a professional role of patient advocacy. On the other hand it has also been pointed out that physicians' responsibility towards society does require

them to become stewards of scarce resources. This debate illustrates what is, in effect, a deep role conflict in the allocation of health care resources at the bedside by physicians.

Debates surrounding the role of physicians in allocating care at the bedside are also influenced by two different aspects of the physician's position as regarding the allocation of scarce resources. On the one hand, physicians are in a position to make difficult allocation decisions that are as respectful as possible of the context of individual lives. Knowledge of all alternatives and, more importantly perhaps, knowledge of patients' specific individual situation and needs give them tools that are not available to decision-makers who are more distant from the bedside. On the other hand, it can be problematic that any allocation decision on behalf of society should be made by individuals without being open to critique and wider input (Shaul RZ., Mendelssohn D.: Scarce resource allocation: issues of physician conflict and liability. Humane Health Care International.1997;13(1):25-8)

However, we do not know whether and how physicians in the US actually do make decisions to forgo beneficial interventions on the basis of cost. To what extent this kind of resource allocation is a reality in daily clinical practice is a question that has only been asked of physicians in Europe. The strong pressures to contain cost that pertain in most countries make it likely that some possibly marginally beneficial interventions are indeed withheld on the basis of cost. One survey has shown that there is support among physicians for guidelines discouraging the use of interventions with a small benefit and a high cost (Sulmasy D, Mitchell J: Physicians' ethical beliefs about cost-control arrangements. Arch Intern Med.2000;160:649-57). It has also been argued that such decisions are inevitable in clinical practice (Morreim E: Fiscal Scarcity and the

Inevitability of Bedside Budget Balancing. Arch Intern Med. 1989;149:1012-5). However, their extent is unknown, as well as the criteria that are used when such allocation decisions are made. This is an important point, as its implications may be greater than first meets the eye. Decisions made by physicians on the basis of individual situations become, in aggregate, a part of the health care environment. Whether or not this aspect of the health care system is a desirable one is a question that can only be answered if we know what the results of this aggregation of choices is likely to be.

The impact of macro-level allocation decisions on the ways in which physicians allocate care are also unexplored. The choices made by physicians in situations of scarce resources not only reflect their values, but also the constraints they must work with. Knowing more about the role of those factors could be an important contribution to an evidence base for health policy.

Preliminary data from our pilot, though very limited, shows a degree of agreement with bedside rationing, and a high prevalence of reported rationing at the bedside were shown in a small convenience sample of US internists.

The proposed survey is designed to improve understanding of the interaction of rationing at the provider and policy levels. This survey complements a similar survey which was run in Italy, Norway, Switzerland, and the UK, and will allow a better understanding of the impact of health care allocation at the policy level on allocation practices at the provider level. The need for comparative data from the US was underlined when data from our European study was published (Ubel PA: Tough questions, even harder answers. Journal of General Internal Medicine. 2006;21:1209-10). As the US health care system is very different from that of the other countries surveyed, this study will also

allow us to better understand the interaction between health policy decisions made at the macro-level and physicians' attitudes and practices of resource allocation at the micro-level.

We propose to address these questions by surveying a random sample of internists drawn from the American Medical Association Master List of Physicians and Medical Students for Mailing Purposes which provides a comprehensive list of physicians not limited to members of the American Medical Association. As general physicians, internists are in a position where they must face questions of resource allocation regarding a variety of services, including referral to other medical specialties. Thus, internists represent a logical place to begin to assess current resource allocation practices in the US.

This collection of data represents an appropriate project for the Department of Clinical Bioethics at the Warren G. Magnuson Clinical Center at the NIH. First, the project falls within the authorized role of the NIH as a research institution within the Public Health Service, as expressed in 42 USC 241a.

Second, the project is not duplicative of any other research being conducted by other agencies within the DHHS. We have consulted with representatives from the Agency for Health Care Policy Research (AHCPR) and the Health Resources and Services Administration (HRSA), and have received confirmation that our project was not duplicative.

Third, the project represents an important follow-up to the survey conducted in Europe, and will allow us to better understand the practices of resource allocation in different health care systems.

Finally, the project falls within the more specific goals of the Department of Clinical Bioethics. The department exists both to serve the needs of the NIH staff and patient population and to conduct research on important ethical issues in medical practice and research. This project is consistent with these roles.

A.2 Purpose and Use of the Information

The survey instruments will gather data in the following categories:

- Extent to which internists forgo using different kinds of interventions for reasons of cost to the health care system.

-Extent to which internists agree that they should forgo using interventions for reasons of cost.

-Frequency with which internists encounter various types of ethical difficulties, including situations of scarce resources, in their practice.

-Extent to which internists feel pressured to deny expensive interventions

-Strategies used by physicians to allocate resources.

-Extent to which physicians feel that resource allocation interferes with the doctor-patient relationship, and extent to which they discuss considerations of cost with their patients.

-Extent to which internists find that resources they deem to be necessary for their patients are available to them.

-Extent to which internists find that their health care environment is fair and non-discriminative.

-Acceptability to internists of various methods of resource allocation.

-Demographics of respondents

The results of this survey will be used in several important ways. First, through publication, we hope that the data will be used by medical professionals to help them to better understand the current state of practice in resource allocation.

Second, we hope to provide a more accurate assessment of current practice so that the medical community and policy makers may be able to evaluate more effectively the role of macro-level allocation policies on clinical practice. In particular, the survey will be useful to the other agencies of the DHHS in their work.

Third, the data will contribute to the debate about whether physicians should have a role in allocating resources, and precisely what this role should be.

Finally, by providing vital empirical information as to how physicians allocate resources in different health care systems, the data will help inform cost containment policies in health care. Because of the lack of previous collections of information on the effect of resource allocation policies in health care on medical practice, the survey will be very useful.

A.3 Use of Information Technology and Burden Reduction

Respondent burden is already at a minimum, because respondents simply have to provide their answers and are not required to take any further action. In addition, there are no costs other than the short amount of time involved, an amount that is reduced to the smallest amount possible that will allow for an adequately comprehensive collection of information. We are not aware of any technological measures that could be employed to reduce respondent burden any further.

A.4 **Efforts to Identify Duplication and use of Similar information**

The literature has been extensively searched for empirical work on the allocation practices of physicians. While there is a significant amount of conceptual literature on the ethics of this issue and a significant amount of empirical work on specific interventions, there is very little empirical data. One evaluation of allocation strategies of physicians in the UK has been published in a peer-reviewed journal (Ayres PJ: Rationing Health Care: Views from General Practice. Soc Sci Med. 1996;42(7)1021-5). Our own data suggest that US physicians are faced with resource constraints (Hurst S., Chandros Hull S., DuVal G., Danis M.: Physicians' Responses to Resource Constraints. Archives of Internal Medicine. 2005;165(6):639-44). Both are exploratory qualitative studies which did not systematically examine the types of interventions that physicians forgo for reasons of cost, or the frequency with which they do so. Also, because each was conducted in a single region, they could not evaluate effects of health policy on the allocation practices of physicians. Data from our European study show that physicians in Norway, Italy, Switzerland and the UK report bedside rationing (Hurst S., Slowther A., Forde R., Pegoraro R., Reiter-Theil S., Perrier A., Garrett-Mayer E., Danis M.: Prevalence and Determinants of Physician Bedside Rationing: Data from Europe. Journal of General Internal Medicine. 2006;21(11):1138-1143) . Comparative data from the US are currently lacking. Finally, through conversations with professionals involved in health systems research (physicians and ethicists) in the US, it is clear that there is uncertainty about the practice of resource allocation in medical practice.

A.5 Impact on Small Businesses or Other Small Entities

As we will be surveying physicians in private practice, this project does involve small businesses. The burden involved in answering the survey is minimal, and the data gathered will be directly useful to them in a difficult area of their work.

A.6 Consequences of Collecting the Information Less Frequently

All information will be collected in a single questionnaire with each respondent.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This project fully complies with the guidelines of 5 CFR 1320.5

A.8 Comment in Response to the Federal Register Notice and Efforts to Consult outside Agency

The 60 day **Federal Register** notice was published in the **Federal Register** on May 17, 2007 in the Federal Register, pages 27817-18. We have received one comment questioning the value of the study and one inquiry about the questionnaire to date from the public on this project.

In order to develop a survey that is a valuable contribution and which does not duplicate existing work, we have consulted with a number of individuals in several different fields.

Within the DHHS, we have consulted the following agencies. They have assured us that this project is not duplicative of any work in their agencies.

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From the field of bioethics, we have consulted the following individuals as advisors in developing the instrument. They have all written extensively and are experts in the ethical issues in resource allocation.

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A.9 Explanation of Any Payment or Gift to Respondents

No incentive will be provided to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

We will ensure the confidentiality of all responses by unlinking all identifiers as soon as each individual survey is entered into the database. The identities of responders will be kept in a list, which will serve to identify responders and non-responders while data collection is open. After data collection is finished, the list will be destroyed. At that point, it will be impossible to connect an individual, or an individual organization, to a particular set of answers. Thus, no personal information will be maintained and retrieved by personal identifiers. For these reasons, the NIH Privacy Act Officer (Timothy Wheeles) has determined that the Privacy Act does not apply to this submission. As required by 45 CFR 46, this project has also been reviewed by an Institutional Review Board (IRB) at the NIH. The IRB of the National Institute of Child Health and Development has found the project to be in full compliance with the requirements of 45 CFR 46 and has approved it (Appendix number 3).

A.11 Justification for Sensitive Questions

No sensitive questions will be asked as a part of this project. All questions are asked of individuals in their professional roles. There will be no personal identifiable information collected.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

We estimate the respondent burden to be 20 minutes per respondent. This estimate is based upon preliminary testing of the draft survey instrument. Because this draft contained several questions that were included in the European survey, but will not be included in the US survey, it is possible that the respondent burden will be less.

A.12-1 Estimates of Hour Burden				
Type of Responden ts	**Number of Responden ts**	**Frequency of Response**	**Average Time per Response**	**Annual Hour Burden**
Physicians (internists)	500	1	0.3674	183.7
Total	500			183.7

The annualized cost to respondents is based upon our estimate of the hourly wages of the professionals from whom we are collecting the information. This was obtained by calculating from the median net income of internists after expenses, before taxes, and the median number of patient care hours per week, both published by the American College of Physicians. Our calculation was based on the assumption that internists are only occupied with patient care, which is often not the case. So it is possible that our calculation overestimates the hourly wage rate. In this case, the annualized cost to respondents would be overestimated also. There are no other costs that might be incurred by any respondents in this collection of information.

A.12-2 Annualized Cost to Respondents				
Type of	**Number of**	**Frequency**	**Hourly**	**Responden**

Responden ts	Responden ts	of Response	Wage Rate	t Cost
Physicians (internists)	500	1	$56.8181	$28,405
Total……….				$28,405

A.13 <u>Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers</u>

There are no additional costs to the respondents.

A.14 <u>Annualized Cost to the Federal Government</u>

The annualized cost to the Federal government is estimated to be $12,164. This estimate includes the following: $1000 for Department of Clinical Bioethics staff to supervise the project, $1022 to obtain the mailing information of 500 internists from the American Medical Association Master List of Physicians and Medical Students for Mailing Purposes, $10,142 for data entry by the survey firm.

A.15 <u>Explanation for Program Changes or Adjustments</u>

We had initially intended to conduct this survey through mailed questionnaires but have subsequently decided that the response rate would be better if a telephone survey is done.

A.16 <u>Plans for Tabulation and Publication and Project Time Schedule</u>

The data will be analyzed statistically. Analysis of variance will be used to identify associations between the types and frequencies of ethical dilemmas and independent variables. Multiple linear regression will be used to identify the independent variables associated with perceived health care system equity and with

reported rationing, separately. Should our results permit such an analysis, will look for an association between perceived equity of the health care system and reported rationing. Descriptive statistics will be used to characterize attitudes towards different possible methods of health care resource allocation. The time schedule for the project is contained in A.16-1.

A.16-1 Project Time Schedule	
Activity	**Time Schedule**
Administration of questionnaire	2 months after OMB approval
Analyses of questionnaire	8 months after OMB approval
Publication of results	12 months after OMB approval

A.17 Reason Display of OMB Expiration Date is Inappropriate

None

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

None