

POST-AWARD MANAGEMENT OF THE NATIONAL INSTITUTES OF HEALTH NANOMEDICINE INITIATIVE NANOMEDICINE DEVELOPMENT CENTERS

Executive Summary

Introduction

In spring 2008, the Science and Technology Policy Institute (STPI) at the Institute for Defense Analyses (IDA) began a study of the management of the National Institutes of Health (NIH) Nanomedicine Development Centers program. The management study was funded as an extension of a previous evaluation of the processes with which the program solicited and selected the eight current Nanomedicine Development Centers (NDCs).

During the course of this study, STPI conducted a series of interviews with NDC program participants, including Nanomedicine Implementation Project Team (NIPT) personnel, Extramural Consultant Group (ECG) members, and the principal investigators from each of the NDCs. Program documents were used as additional sources of information.

This study was envisioned as both a descriptive and evaluative effort. One goal was descriptive insofar that NDC program leadership has had some flexibility (relative to other programs at the NIH) in their management of the program's centers. Accordingly, this study describes the portfolio of "mechanisms" used by the NIPT (often with the help of the ECG) for program management:

- Annual meetings
- Site visits
- Progress reports
- Set-aside funds allocations

Another goal for the study was evaluative in that the perceptions and attitudes of program participants can help to identify the strengths and weakness of each mechanism. This "multiple perspectives" approach is common to management studies (e.g., across the fields of strategic management, industrial organization, and transaction cost economics) and can inform current practices. Importantly, this approach is not designed to evaluate specific outcomes (e.g., center productivity), but rather more broadly the "effectiveness" and "efficiency" (defined below), among other factors, of management and operations at the program level.

Method and approach

This study is qualitative, based on semi-structured interviews with NIPT chairs and personnel, ECG participants, and NDC directors. The interviews focused on the four mechanisms identified above used to manage the NDC program. Specifically, respondents were asked about the "effectiveness" and "efficiency." Mechanism effectiveness was not defined for the respondents. Rather, they were asked to identify the goals of the

mechanism, as they saw them, and then they were asked to report on the extent to which they perceived these goals to have been attained. Efficiency also was not defined for the respondents, but rather study participants were asked to identify specific activities for each of the management mechanisms that they felt facilitated or hindered the attainment of their goals.

It should be reiterated that the unit of analysis for this study is the *management of the NDC program as exercised by the NIPT*, with the assistance of the ECG, and not management of each of the individual NDCs. Therefore, characterizations in this study of particular management mechanisms as “effective” and/or “efficient” does not constitute an evaluation of the specific centers. This type of summative analysis is reserved for future outcome evaluations employing quantitative operationalizations of effectiveness and efficiency emphasizing the scientific productivity and progress toward clinical application of the centers.

During the interviews, respondents were also asked to identify what they perceive to be the most valuable aspect of the mechanism in question. For instance, many ECG participants suggested that the most valuable aspect of the annual meetings has been the poster sessions. Moreover, many NIPT personnel characterized as the most important aspect of site visits the opportunity to observe center leadership, faculty, and post-doctoral researchers and graduate students interact during question-and-answer sessions that follow the presentations.

The interviews concluded with questions about suggested changes for each mechanism and then more general questions about the NIPT. This component of the interviews was necessarily less structured (i.e., the questions were relatively open-ended) and took on the tone of an informal conversation.

In total, this study includes interview responses from 1 of 2 NIPT chairs, 12 of 15 NIPT personnel, 6 of 8 ECG participants, and 7 of 8 NDC directors. For full information regarding the method used for this study, see the appendices to this report.

Finally, it is important to note that in a qualitative case study, statistical inferences need not and cannot be made. For example, the perspective of one ECG member could be of greater insight and value to the program than a common (and perhaps contrary) perspective shared across all other external consultants. Accordingly, the findings in this report are presented as-is. When interpreted in this Executive Summary, weight is given to the study team’s perceived value of the perspective and not to the quantity of interviewees supporting that perspective. However, some highly “valued” perspectives may be shared across numerous or even all interviewees. Moreover, the quantity of quotations to support one perspective versus another is a function of the data, not of the perceived importance of a particular perspective on the part of the study team.

Findings in brief

This study was organized around assessment of the effectiveness and efficiency (as defined above) of three of the four mechanisms used by the NIPT to manage the eight

NDCs: annual meetings, site visits, and progress reports (hereafter collectively referred to as the “management mechanisms”). This study inquired as well about perceptions of the NIPT, ECG, and NDC directors of the set-aside funds allocations. These “base findings” are summarized here. Accordingly, the presentation here is a summary and brief.

In addition, a number of themes emerged from the interviews that speak across the management mechanisms that were the original foci of this study. These “collective findings” address the complementarity of the mechanisms as a management portfolio, the contingent basis upon which some of the mechanisms have been used, and the many informal management tasks performed by the NIPT that, from the perspective of many program participants, are as important as the formal management mechanisms.

Base findings

Effectiveness and efficiency

With few exceptions the participants in this study considered the goals for the awardee meetings, site visits, and progress reports to have been effectively attained. Moreover, the goals identified across the participant groups for each of the management mechanisms suggest that there is goal consensus across the NDC program. In none of the interviews was there evidence of divergent perspectives of the purposes or intentions of the interactions (between the NIPT, ECG, and NDC leadership and faculty) that occurred during the annual meetings, site visits, and progress report processes. This finding is notable given that the NDC program is still somewhat new.

The interview findings suggest that each of the management mechanisms is perceived across the participant groups as efficient. There were very few suggestions for revising or omitting existing activities; and few suggested adding new activities to the annual awardee meetings, site visits, and progress report processes. One exception was responses from a small number of ECG participants and NIPT personnel that sometimes the site visits can be “too formal” and therefore less conducive to the types of informal and focused discussions and interactions between the site visit team and center leadership that the visits are intended to facilitate.

Appropriateness of set-aside funds allocations

All of the respondents to this study characterized the use of set-aside funds thus far as appropriate. However, some did have recommendations for future use. A notable recommendation was to use some of the funds for “informatics infrastructure” whereby a common database tracking project data and results across the NDCs would be constructed for common access and use across the NDC program. Another recommendation was to use set-aside funds to broaden participation in the center’s activities by funding outside investigators. A last recommendation of note suggested a needs-based approach for determining set-aside funds amounts and recipients.

Perceptions of the NIPT and the ECG

This study was also designed to discern any “expertise gaps” on the NIPT and ECG rosters. NIPT personnel, ECG participants, and NDC directors were asked about their perceptions of the “span” of scientific and technical expertise represented by the NIPT and by the ECG. Interviewees were not asked about their same-group colleagues. For instance, ECG participants were asked about their perceptions of the NIPT, while NIPT personnel were asked about the ECG. NDC directors were also asked about their perceptions of the teams of ECG participants and NIPT personnel with whom they interact at the annual meetings, during site visits, and during the progress report review and feedback process. Generally, all respondents indicated that the NIPT and ECG are appropriately staffed in terms of scientific and technical expertise.

Collective findings

Complementarity of the management mechanisms

It became clear during this study that, collectively, the site visits, annual awardee meetings, progress reports, and set-aside funds allocations constitute a portfolio of management mechanisms that enables the NIPT to address both the research and management aspects of the NDC program. Generally, the mechanisms were characterized as providing different types of information that together aid in the evaluation of each NDC and the program as a whole.

The chapters below presenting the “base findings” on each management mechanism confirm this complementarity. It was often difficult for study participants to discuss the goals and value of one of the mechanisms without explaining how these complement the other mechanisms. A meta-analysis of the base findings suggests that the annual meetings provide information regarding a center’s broad-based goals and “fit” within the program vis-à-vis the other centers, the site visits provide information about the management and collaborative culture of each center in addition to more in-depth discussion of research, while the progress reports codify all of the center’s accomplishments, specifically those related to dissemination efforts such as publications and presentations.

Contingency management style

One of the challenges that the NDC program faces is limited resources, especially the time of NIPT personnel and ECG participants. One common management response to resource scarcity is to manage on a contingency basis, using resources strategically (Rainey 2003). This study reveals evidence that the NIPT is doing this with regard to the time commitments of its personnel and the time commitments of ECG participants. For example, though the site visits were initially a mechanism used for all centers, more recently they seem to have been reserved primarily for NDCs perceived to be “problematic” either in terms of the

direction of their research or center management, based on information from the annual meetings and progress reports.¹

Informal and accessible management style

Study participants also emphasized the accessibility of the NIPT, especially of the NDC program director, Richard Fisher. Dr. Fisher has been readily available to NIPT members, ECG participants, and NDC leadership throughout the program.

Challenges and recommendations

Based on the findings summarized above, the management of the NDC program has been effective, efficient, and has used funds appropriately. These successes seem to have been a function of the management style of the NIPT, which has used complementary mechanisms to gather information about the NDCs' progress and barriers, in some cases on a contingency basis, in addition to engaging in informal interactions with center leadership when required. However, with each of these successes come challenges. The most formidable of these challenges relates to the time constraints of NIPT and ECG personnel. This and other challenges are discussed below. Some challenges are accompanied by recommendations while others require further study.

Divergent perspectives of the centers

As the NDC program matures, the need for an outcomes-based evaluation of each of the centers is fast approaching. One observation from the interviews that was not directly related to the management focus of this study was that there exist divergent perceptions and expectations of the NDCs among the NIPT and ECG. Specifically, while some of the interviewees expressed satisfaction with the progress and direction that each of the centers have taken thus far, others were more critical, maintaining that as many as half of the centers seem to be lacking either in terms of the quality of the science being conducted therein or in terms of progressing towards programmatic goals.

While it was not a goal of this study to consider center performance, these divergent perspectives of current center performance are suggestive of future program management and implementation barriers, especially regarding the eventual summative evaluation of each of the NDCs. Accordingly, the NIPT should start the center evaluation planning process sooner rather than later.

Specifically, because of the newness of the field and because of the breadth of scientific and technical foci across the centers, we recommend the development of a strategic plan for the eventual evaluation processes. The plan should have input from all relevant participants and be used to generate consensus across participants as to the expected outcomes and performance criteria for each of the NDCs. Based on the divergence of perspectives expressed in this study, at this point in time (pending further inquiry) we

¹ It should be noted that there is not always consensus amongst the NIPT and ECG that a particular NDC is "problematic."

suggest that the program take a contingency approach, considering expected outcomes and criteria that speak to programmatic goals on a center-by-center basis.²

Lack of expertise in organizational design and behavior

The NIPT personnel and ECG members who participated in this study consistently emphasized the importance of observing the interactions among each center's leadership, faculty, and other personnel (e.g., post-doctoral researchers), especially during site visits. Observing interactions was intended to identify the extent to which the center is "behaving like a center" – i.e., engaging and collaborating as a research unit with a unified purpose rather than as a loosely-conjoined group of individual investigators. Yet, the NIPT and ECG personnel interviewed have applied only loose heuristics for making this type of observation. For instance, one respondent reported that "one knows a functional center when one sees it."

The centers visited perhaps have incentive to steer attention away from any dysfunction that may exist. Therefore, the NIPT and ECG should become more systematic and unified in addressing the organizational and management aspects of each of the NDCs. There exists a growing field of practice using propositions from the management sciences and from theories of organizational behavior and leadership to assess organizations like university research centers. Though the interviewees for this study were unanimous in agreeing that the NIPT and ECG rosters contain no gaps in scientific and technical expertise, one recommendation along this line is that the ECG be expanded to include a management specialist to aid in the evaluation of those centers perceived as having management or leadership problems.

Communication of expectations for the site visits

The ability of the NIPT to make appropriate decisions regarding each of the NDCs is a direct function of the information gathered about each NDC, per the management mechanisms considered in this study. The information gathered at site visits was not perceived as satisfactory by some of the NIPT and ECG personnel who participated in this study. Some considered the site visits as too formal and therefore as less conducive to observing centers' workaday management and operations, which was a primary site visit goal for many interviewees (see above). Specifically, information gathered on some of the site visits was viewed as having too much overlap with that gathered at the annual awardee meetings.

This complaint seems to have been in part related to the fact that some site visits coincided with centers' internal annual meetings. However, for geographically dispersed NDCs, these internal meetings provide a rare opportunity to observe center participants interact. Given

² The RFA goals appear to be such that a contingency approach is feasible. The RFA from the second group of NDCs (RFA-RM-06-005), for example, lays out one overarching goal and three sub-goals for the centers. Though each NDC likely will approach these programmatic goals in a different fashion (since the capabilities, engineering principles, and interventions may vary), the program and individual centers can still be assessed relative to whether progress toward them has been achieved.

that site visits in the future will likely be reserved for centers viewed as “problematic” in one regard or another (see above), it is imperative that the organization and structure of the visits are such that the site visit teams can easily gather the information required to make sound decisions and to provide sound advice. Moving forward, the NIPT should ensure that centers to be visited are informed of the site visit team’s expectations prior to the visit. Specifically, the site visit team should communicate whether they want to spend the visit in a structured manner – e.g., listening to presentations and touring facilities – or whether the site visit should be less formal – e.g., without a strict agenda, formal presentations, and the like.

Time constraints

Practically all of the NIPT and ECG participants in this study mentioned at some point during the interviews that they do not have enough time to fulfill (to their satisfaction) their responsibilities to the NDC program. One NIPT member succinctly observed that “all of [program management and leadership] have day jobs.” Of course, this is common for professional scientists and engineers and there is no ready solution. Insofar that Flexible Research Authority requires more active management than passive administration, there are a number of considerations to make. First, ECG members perhaps should be recruited based on their ability to participate. For instance, a couple of the external consultants interviewed reported that they have not yet participated in site visits due to time constraints. The other consideration is of course to allocate more NIPT personnel time to the program, though the benefits and costs of this should be considered more formally than in this report.

Further study

The findings of this assessment of the post-award management of the NDC program demonstrate that program participants perceive the NIPT to be managing the program both effectively and efficiently. Therefore, although recommendations are made for improved program management, further inquiry into program management is unnecessary at this time. The next assessment should be an outcomes-based evaluation of center performance, though we recommend (see above) that the NIPT and ECG engage in an evaluation planning process to ensure that this evaluation focuses on the appropriate outcomes and will directly inform future decision making.