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# Heterogeneity at Work: Implications of the 2012 Clinical Translational Science Award Evaluators Survey

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# Abstract

The Clinical and Translational Science Award (CTSA) program is an ambitious multibillion dollar initiative sponsored by the National Institutes of Health (NIH) organized around the mission of facilitating the improved quality, efficiency, and effectiveness of translational health sciences research across the country. Although the NIH explicitly requires internal evaluation, funded CTSA institutions are given wide latitude to choose the structure and methods for evaluating their local CTSA program. The National Evaluators Survey was developed by a peer-led group of local CTSA evaluators as a voluntary effort to understand emerging differences and commonalities in evaluation teams and techniques across the 61 CTSA institutions funded nationwide. This article presents the results of the 2012 National Evaluators Survey, finding significant heterogeneity in evaluation staffing, organization, and methods across the 58 CTSAs institutions responding. The variety reflected in these findings represents both a liability and strength. A lack of standardization may impair the ability to make use of common metrics, but variation is also a successful evolutionary response to complexity. Additionally, the peer-led approach and simple design demonstrated by the questionnaire itself has value as an example of an evaluation technique with potential for replication in other areas across the CTSA institutions or any large-scale investment where multiple related teams across a wide geographic area are given the latitude to develop specialized approaches to fulfilling a common mission.

# Keywords

clinical translational science awards; evaluation methods; translational science; peer led

The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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# Introduction

# The Clinical and Translational Science Awards (CTSAs)

The CTSAs are funded by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH). The mission of the CTSA is to accelerate the process of translating laboratory discoveries into treatments for patients, to engage communities in clinical research efforts, and to train a new generation of clinical and translational researchers. The program began in 2006 with funding for 12 medical research centers and has expanded yearly, representing a projected investment in excess of US \$2.2 billion (Department of Health and Human Services [DHHS], 2010). By December 2012, the CTSA had funded 61 leading teaching hospitals and medical research facilities to serve as a consortium of clinical and translational research centers. This article describes a peer-led effort to better understand the role of *internal evaluation* across the CTSA recipient institutions through a questionnaire distributed to all active CTSA evaluation directors.

### A Mandate to Evaluate

From the beginning of the CTSA program, NIH required evaluation and tracking as one of a set of suggested key functions (KFs)<sup>1</sup> within each CTSA-funded organization (Frechtling, Raue, Michie, Miyaoka, & Spiegelman, 2012). In the initial Request for Applications (RFA) in 2006, CTSA internal tracking and evaluation was described as a separate component within each CTSA recipient institutions, responsible for assessing the administrative and scientific functioning of the organization (DHHS, 2005). Under this original model, each CTSA-funded institution was expected to design and implement a traditional series of self-evaluation activities such as tracking the number of investigators, publications, grant proposals, and awards associated with the program as well as the career trajectory of junior researchers supported through CTSA-funded scholar and trainee career development awards.

# Localized Evaluation Designs

Since the outset of the CTSA program, the RFA language made it plain that CTSA program leaders should plan for and support "self-evaluation" at each CTSA institution. However, the NIH mandate stopped short of outlining specific policies or parameters on how each center would staff their evaluation teams, or what specific tools, methodologies, or evaluative approaches each team should adopt. Outside of required annual NIH reporting, internal evaluation efforts at individual CTSA institutions were left to evolve locally.

Having been commissioned by NIH and conducted by the independent consulting firm, Westsat, the first national external evaluation report was completed in 2012 (Frechtling et al., 2012). The report observed widespread variation across all KFs at each CTSA institution, stating:

(It is) important to recognize that evaluating the CTSA program is a challenge, not only because of its ambitious goals but also because of its many moving parts and the flexibility afforded the participating institutions.... (the CTSA institutions) are expected to undertake substantial change in their infrastructure and cultures;

<sup>&</sup>lt;sup>1</sup>The following 11 standard key functions (KFs) are based on the original Clinical and Translational Science Award (CTSA) Request for Application (RFA): administration and governance; biomedical informatics; community engagement and research; design, epidemiology, biostatistics and ethics; education, training, and career development; novel clinical and translational methodologies; participant and clinical interactions resources; pilot and collaborative; regulatory knowledge and support; translational technologies and resources; and evaluation and tracking. In practice, many CTSA institutions have developed variations on and deviations from the standard KF structures and titles.

recognizing the variation in the medical research centers and the communities they serve, the sites have been given license to do so in a variety of ways.

# A Voluntary National Network of CTSA Evaluators

While each CTSA-funded institution developed specialized local evaluation strategies, a national network of CTSA programs was also developed with nominal guidance from the NCATS predecessor organization that originally funded the CTSA programs.<sup>2</sup> The CTSA national consortium includes participation with individuals associated with every major CTSA KF, including evaluation and tracking. Since the inception of the CTSA program, the National Evaluation KF Committee (KFC) has functioned as an active forum for existing and newly formed CTSA evaluation teams across the country. National participation is voluntary and is conducted primarily via conference calls and annual face-to-face meetings.

This decentralized approach to CTSA evaluation—specialized local CTSA management coupled with a voluntary and virtual national committee system—has attracted important critics. In 2013, the incoming NCATS Director Dr. Chris Austin acknowledged the lack of centralized organization saying that the CTSA programs have so far mostly operated "without particular encouragement or direction from the NIH, and thus in a disjointed and uncoordinated fashion" (Wadman, 2013).

# The Shared Resources Group Launches the National Evaluators Survey

Although appreciative of the ability to tailor their evaluation and tracking efforts to the relative award size, cohort (age), and unique characteristics of each local CTSA program, evaluators active in the national KFC and consortium had long recognized the problems associated with a lack of national continuity and transparency and had already begun examining some of the "disjointed and uncoordinated" aspects of CTSA program evaluation. One noteworthy approach from within the National Evaluation KFC consortium was the National Evaluators Survey from the Shared Resources Working Group (SRWG). The SRWG is an informal subgroup of the Evaluation KFC organized around the basic mission of providing a forum for discussing effective strategies and ongoing challenges relevant to the task of providing internal evaluation at CTSA-funded institutions. In 2008, the SRWG designed a short annual questionnaire to poll their evaluation across the country. The most recent iteration (2012) of this questionnaire is the subject of this article.

The primary goal of the National Evaluators Survey has been to provide simple summary descriptions for internal administrative use at each CTSA institution. As a result, the specific findings are likely to be of most interest o individual principal investigators at CTSA-funded institutions and to the respondents themselves. However, as a methodology, the low-burden utility of the questionnaire and the participatory nature of census level self-evaluation may be useful to other CTSA KFCs, NIH leadership, as well as other large federally funded projects of this scale.

The recent Institute of Medicine (IOM) review of the CTSA program (Leshner, Terry, Schultz, & Liverman, 2013) explicitly advocated increased coordination of CTSA evaluation efforts. One of only seven primary recommendations in the report specifically stated that the CTSA should: "Formalize and standardize evaluation processes for individual CTSAs and the CTSA Program" (Leshner, Terry, Schultz, & Liverman, 2013). Dr. Austin

<sup>&</sup>lt;sup>2</sup>Originally the Clinical and Translational Science Award (CTSA) was funded by the National Center for Research Resources (NCRR), at National Institutes of Health (NIH), but at the end of 2011, NCRR was dissolved; the National Center for Advancing Translational Sciences (NCATS) was established, and the CTSA program was moved to NCATS.

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(2013) echoed this recommendation in a subsequent public statement saying that, "Designation of clear, measurable goals and objectives that address critical issues across the full spectrum of clinical and translational research will be one of our first tasks."

Despite this mounting pressure to expand and coordinate CTSA evaluation efforts, at present there is very little widespread data available about the variety of individual evaluation teams and specific evaluation techniques already in place at the 61 existing CTSA institutions. In the Westat external evaluation report (Frechtling et al., 2012), only 9 (15%) out of the then 60 CTSA programs were targeted for the case study. The most recent SRWG Evaluators Survey is based on data from 58 (95%) of the 61 currently funded CTSA institutions.

# Method

The SRWG designed the questionnaire with widespread participation across the national consortium of internal evaluators in the Evaluation KFC. The process has been peer led from the start and was neither proposed by nor led by NCATS. The SRWG distributes and analyzes this survey as an independent activity. The questionnaire was originally developed in 2008, first distributed in 2009, and has been administered annually. The survey is voluntary and confidential, and results are not reported at the level of specific CTSA institutions. After the questionnaire is closed, the results are deidentified, summarized, and made widely available in the CTSA national consortium. In the 3 years it has been distributed, the questionnaire has enjoyed a high response rate (95% in 2012).

#### Survey Instrument

The survey was originally developed using an extensive participatory process (Yarbrough, Shulha, Hopson, & Caruthers, 2011) via break-out group sessions at the 2008 Evaluation KFC face-to-face meeting and is annually refined by the SRWG chairs. The questionnaire includes only 15 items. It is brief in order to keep response burden low. The questions were designed to collect high-level generalizable information, so while a few key open-text questions are used, the majority of the questionnaire is comprised of fixed response questions. The first section of the questionnaire focuses on evaluation team composition and management and includes questions regarding the relationship between the evaluation team and internal administration, the level of substantive support from staff outside the evaluation team, the total number of evaluation staff and their full-time equivalent (FTE), the types of professional experience and advanced degrees currently held by evaluation team members, issues around data collection and storage, and the frequency of evaluation team meetings with internal leadership and committees. The remainder of the questionnaire focuses on the wide variety of techniques used to conduct internal evaluation at CTSA institutions, explicitly the use of surveys, case studies, interviews, focus groups, data extraction from existing records, grants analysis, financial analysis, bibliometric analysis, social network analysis, experimental or quasi-experimental designs, multivariate or regression analysis, process mapping, milestones, logic modeling, formal work plans, and various business process management methods.

#### **Survey Sample**

The questionnaire is administered by the SRWG chairs, with the questionnaire sent directly to the e-mail address of the evaluation director named on the KFC voting members list. Responses are limited to one questionnaire per CTSA institution. Because of this sampling technique and the high response rate, the sample amounts to a census of all CTSA-supported academic institutions.

# Analysis

Results presented in this article have been limited to data from the 2012 survey in order to present the most current and accurate overview of evaluation resources at participating CTSA institutions. Descriptive statistics and frequencies were generated for each question on the questionnaire. Responses to open-ended questions were coded by themes where appropriate and reviewed alongside comparable quantitative data. For the open-ended text boxes associated with the questions about best practices in evaluation, two individuals blind coded and ranked themes by frequency mentioned (Creswell et al., 2011; Patton, 2002). Additionally, the relationship between two specific types of evaluation methods included in the questionnaire (regression analysis and experimental or quasi-experimental design) were examined relative to several other survey variables, such as cohort, total amount of funding, number of staff, number of FTEs, using both Excel correlation functions and frequency procedures in SAS. Univariate regression analysis was used to examine the relationship between team size (as measured by either FTE or number of staff members) and each of three variables: amount of total funding (millions) for each CTSA program, number of tools, and number of methods; and a p value of less than 0.05 was considered as evidence that the two variables in the model were related.

# Results

# **CTSA Evaluator Expertise**

CTSA internal evaluators represent a wide range of training and experience in terms of disciplines, orientation, degrees, and academic status. Although some of the open-text responses mentioned only degrees (PhD, MD, master's) others added academic fields including education, sociology, business, public health, psychology (clinical, community, industrial/organizational, social), public policy, epidemiology, mathematics, anthropology, experimental medicine, biostatistics, industrial engineering, molecular biology, computer science, evaluation, and law.

# **CTSA Evaluation Team Structure**

Evaluation teams at the responding CTSA institutions reported a median of three employees with an average of 1.3 FTEs. When asked how their evaluation team was structured relative to the local KF system, the majority of respondents reported their teams functioned as separate KF (62%), while 26% said their evaluation team was housed within the administration and governance KF, and the remaining 12% reported "other" and explained their team structure in the open-text section. A closer reading of this open text allowed for a recoding and a retrospective forced choice between two predominant responses (either evaluation KF or administration KF). This recategorization revealed a 3:1 ratio with a little under two thirds (66%) of responses in the evaluation KF category. Additionally, 76% of all respondents reported receiving significant assistance from outside KFs (such as administration and/or biomedical informatics).

#### **Evaluation Data Collection and Management**

More than two thirds of the responding evaluation teams (69%) reported that their data collection, record keeping, and management were conducted at the KF level (a noncentralized system). Nineteen percent reported using a centralized data collection and management system. Twelve percent reported "both/other" and added explanations in the open-text section describing a period of transition to more centralized systems. In terms of centralized relational databases, 54% of respondents reported using a centralized relational database for tracking evaluation data, while 22% did not. The remaining 24% were in the process of developing a centralized relational database.

In summary, of the 58 responding CTSA institutions, two thirds reported freestanding evaluation KF and a third reported evaluation programs nested within the administration KF. However, over three quarters of the responding institutions also relied on substantive contributions from other KFs (including but not exclusive to the Administration KFs). And for the time being, the majority of evaluation data is collected and stored at the KF level. In short, many evaluation activities (and therefore staffing) extend far beyond the 1.3 FTE and average of three employees formally reported as specific to part of the evaluation KF.

#### **Internal Evaluation Techniques**

"Evaluation technique" is used throughout this article as an umbrella term describing the wide array of evaluation approaches studied in the last half of the questionnaire. Evaluation planning methods, data collection, and storage approaches, various forms of evaluative analysis, and study design all fall under this broad categorization, with examples as diverse as logic modeling, surveys, interviews, social network analysis, and quasi-experimental evaluation designs discussed under the broadly inclusive term, evaluation techniques.

Figure 1 represents a summary of evaluation techniques by percentage of use at the 58 responding CTSA institutions in 2012. Traditional evaluation techniques played a central role for most respondents, with the majority using a mix of surveys (92%), routine meetings (with senior leadership 92%), interviews (88%), data extraction from existing records (75%), grants analysis (75%), bibliometrics (59%), and focus groups (51%). Milestones and logic models were used more often than not both for individual KFs and at the institute level. Three techniques from business and industry appeared in less than half of the reported cases: process mapping (38%), business process management methods (35%), and project management software (34%). The least frequently used evaluation techniques were experimental or quasi-experimental design and multivariate or regression analysis.

# Regression/Multivariate Analysis and Experimental/Quasi-Experimental Designs

Additional analysis showed that the smaller set of respondents conducting two of the more sophisticated evaluation methods, regression/multivariate analysis (n = 11) or experimental/ quasi-experimental models (n = 13), was more likely to be from earlier CTSA cohorts and to have received more NIH funding. They also reported having more evaluation staff, although again, interestingly not necessarily more FTEs, and were engaged in a wider array of evaluation techniques overall. Qualitative Feedback on "Best Practices" and "Challenges"

In the last section of the questionnaire, respondents listed evaluation best practices and challenges in an open-text box format (Creswell et al., 2011). Of the entire sample, 42 of 58 responded regarding best practices, and 52 of 58 responded regarding challenges. In general, the responses regarding best practices underscored the previously identified diversity of the evaluation teams and wide range of evaluation techniques and mixed methods currently in use. The primary themes that emerged included "The promotion of evaluative understanding/appreciation within our CTSA program"; "A comprehensive system for internal data reporting"; and "Aligning (our work) with the evolution of the national CTSA consortium." Additional best practices mentioned included the use of formal process improvement methods (e.g. Six-Sigma); social network analysis; bibliometric analysis; and data dashboards; and "a focus on evaluation research, not just program evaluation." Common themes regarding challenges included the need for additional resources, staff, time, data quality, and standardization, as well as a lack of guidance from funding agencies (Bamberger, Rugh, & Mabry, 2012). Respondents also listed "lack of information technology (IT) resources and informatics support"; "lack of attention to the importance of data for evaluation"; and problems with "making data useful to decision-makers." Several respondents referenced challenges with overall evaluation design within their individual

CTSA programs as well as major changes to direction and priorities in the most recent NCATS application guidelines. Respondents also specifically mentioned an overall "lack of standardization in metrics and definitions" relevant to internal evaluation at CTSA institutions.

# Discussion

#### Limitations

The National Evaluators Survey instrument is short and the questions are designed to collect general information, so our analysis is necessarily limited. The confined sample size of one response per CTSA institution keeps the data evenly weighted but makes for a relatively small N in any data subset. Additionally, the predominance of fluid or "fuzzy" boundaries for evaluation teams at the responding CTSA institutions poses a serious caveat for any correlation between the management of evaluation (evaluation team demographics) and the resulting evaluation tools and methods (evaluation activities). For instance, because it is a commonly used and easily understood metric, we continue to ask for evaluation staff FTE. However, if 76% of evaluation teams reported receiving significant assistance from other KFs, the efforts of these additional staff surely fell outside of the narrowly defined evaluation FTE. Similarly, "size of award" was based on publically available data. Many centers also have matching institutional funds and an array of complex funding sources that make award size equally difficult to measure. Finally, the evaluation techniques summarized in Figure 1 were generated as part of a participatory process with input solicited from all of the then-funded CSTA institutions. In the interest of keeping the length manageable, the menu of questionnaire options was kept intentionally broad. Therefore, affirmative responses to general choices such as the use of "surveys" and "interviews" reflect use patterns overall but do not reveal precisely who is being polled, about what, and why. Instead, these broad categories allow a rare generalizable look at prevailing evaluation norms across CTSA-funded programs, in what has emerged as an extremely varied environment.

Despite the stated limitations, important entities outside of the CTSA consortium such as the authors of the recent CTSA IOM report (Leshner et al., 2013) ultimately found the survey findings useful. While readily acknowledging the constraints of the SRWG survey inferences, in the section of the IOM report entitled "Self-Evaluations of the Individual CTSAs," the authors referenced the SRWG survey findings and reported the median number of evaluation staff and FTEs on average. Our evaluation staffing findings were not reported in isolation, and the IOM report also included information on the fluid boundaries of evaluation teams and the high levels of assistance from nonevaluation KFs as well as the preponderance of mixed methods approaches, and the wide variety of internal evaluation approaches across the CTSA programs.

#### Internal Evaluation at CTSA Programs: Heterogeneity at Work

Our most basic yet perhaps most important finding is that the internal evaluation at CTSAfunded programs is extremely heterogeneous in terms of the sheer variety of evaluation expertise, team composition, data management, as well as number and type of evaluation techniques currently being used. This finding constitutes both strength and a liability.

On one hand, the heterogeneity has strength in its diversity. The range of management approaches and evaluation techniques observed in the survey may well reflect a series of successful adaptations to real variations across the 61 CSTA institutions. Not all CTSA programs are created equal, and it is easy to postulate that evaluation teams and techniques were initially designed for, and have subsequently evolved to fit very specific niches within

each funded "academic home." To the extent that this is the case, it would be unfortunate to see funding pressures, the findings of the recent IOM report, or even the effects of the dissemination of this survey result in an overreach toward too much national evaluation homogeneity at the expense of local variety and vigor.

On the other hand, when asked for feedback on evaluation challenges, survey respondents were quite clear in articulating their desire for more standardization of metrics and key definitions and more overall evaluation guidance from the funding agency. This desire will only sharpen as evaluators observe the national trends toward the collection of metrics focusing on efficiency and costs (Collins, 2011; CTSA, 2013; DHHS, 2013). In that same vein, the diversity across evaluation teams and tools is also a liability. If faced with the question "how many person hours are devoted to evaluation at each CTSA program?" given the blended roles and responsibilities represented in the survey data, at present it would be nearly impossible to accurately assess the true cost (and therefore value) of evaluation at each CTSA institution.

#### A Uniquely Comprehensive Summary

Despite its simple design and basic objectives, the 2012 National Evaluators Survey constitutes the most inclusive summary of evaluation teams and techniques across the CTSA programs to date. There is no other survey with this level of comprehensive participation across the Evaluation KFC. Indeed, the profound absence of centralized evaluation data in this area is another primary reason this survey is thought to be of interest to readers outside of the CTSA Evaluation KFC.

Several factors contribute to the lack of centralized information about internal evaluation across the CTSA consortium. The most obvious is the sheer complexity of the CTSA mission (Frechtling et al., 2012; CTSA, 2013). Also, as mentioned earlier, local evaluation within each CTSA program is mandatory, whereas participation in the national evaluation consortium is entirely voluntary. Given limited time and resources, it stands to reason that the unsubsidized and discretionary national evaluation projects would receive lower prioritization than the compulsory local evaluation deliverables for each CTSA program. Lastly, a fairly simple but profound piece of federal legislation makes the kind of broad evaluation represented in the National Evaluators Survey extremely difficult for all federal funders to conduct. The Paperwork Reduction Act of 1980/1995 (Federal Register, n.d.) states that federal government agencies must receive approval from the Office of Management and Budget (OMB) before promulgating a form that will impose an information collection burden on the general public. In practice, this effectively means that the NIH (or any other federal agency) cannot make a thorough assessment of any aspect of the CTSA programs without first going through the OMB. In many cases, peer-led approaches such as the SRWG survey are the most feasible approach for gathering this kind of data.

#### Recommendations

Our recommendations follow the same lines as our discussion results and would be applicable to evaluation efforts in any endeavor of this scale.

First, the heterogeneity of internal evaluation teams and techniques across the CTSA institutions should be recognized as the national consortium moves to adopt common metrics. These differences should certainly not be used as an argument against consolidation of national evaluation data or processes; however, any attempts to forge "sameness" in an environment with this degree of diversity should be well considered. NIH leadership should

expect an iterative process and not be surprised if the resulting data raise more questions than provide answers (Patton, 2011).

Second, as much as we need better data to inform critical funding and programming decisions, it will be crucial to keep the burden of census-level national evaluation efforts low. If additional surveys similar in scope to the SRWG are distributed, they should remain simple and brief. The national Evaluation KFC (or any large federally funded project) would do well to consider the use of modest peer-led projects such as this, or even more spartan "real-time" micro-polls at conferences and on webinars.

Third, provide transparent and utilitarian feedback (Patton, 2008). One primary lesson learned from 3 years of administering the SRWG survey is that program staff (and perhaps evaluators especially) will be extremely generous with their time and energy if they see that the data being collected will be used and ultimately available to help them improve their work at their institutions.

Fourth, because of the limited local resources and the practical concerns of the Paperwork Reduction Act, we also recommend that national leadership rely on existing data in addition to modest peer-led projects such as this survey. Examples include mining the historic data from annual progress reports and further formal discussion of the Evaluation Guidelines white paper generated in 2012 (CTSA Evaluation KFC, 2012).

# Conclusion

Any nationally funded initiative as important and complex the CTSA program requires rigorous evaluation. For readers outside of the CTSA consortium, our hope is that this article will function as an example of the kind of data that can be gathered using this type of lowburden participatory approach. As difficult as it will be to navigate the limitations and complexities of the heterogeneity illustrated in our findings, we believe that these differences will provide far more benefits than barriers to evaluation. Ultimately the peer-led approach and evolutionary richness demonstrated by the National Evaluators Survey can be a valuable model for use within the CTSA, or any large-scale investment where multiple teams are spread across a wide geographic area and given wide latitude to develop diverse approaches to fulfill a common mission.

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#### **Figure 1.** Reported evaluation techniques (N = 58).