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From Free to Free Market: Cost Recovery in Federally Funded Clinical Research

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Abstract

In a climate of increased expectation for the translation of research, academic clinical research units are looking at new ways to streamline their operation and maintain effective translational support services. Clinical research, although undeniably expensive, is an essential step in the translation of any medical breakthrough, and as a result, many academic clinical research units are actively looking to expand their clinical services despite financial pressures. We examine some of the hybrid academic-business models in 19 clinical research centers within the Clinical and Translational Science Award consortium that are emerging to address the issue of cost recovery of clinical research that is supported by the United States federal government. We identify initiatives that have succeeded or failed, essential supporting and regulatory components, and lessons learned from experience to design an optimal cost recovery model and a timeline for its implementation.

ACADEMIC-BUSINESS MODELS IN CLINICAL RESEARCH

There is nothing new about the concept; academia must demonstrate tangible results in return for the substantial tax dollars it attracts for research. One clear way for universities to validate their return on investment (ROI) is by the translation of basic biomedical research out of the lab and to the patient's bedside (1, 2). Despite the enviable pool of talent that U.S.

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SUPPLEMENTARY MATERIALS

Methods

Fig. S1. Overview of the current CTSA cost recovery landscape and the associated impact.

Table S1. CTSA cost recovery interview guide.

Table S2. Current CTSA approaches to the main cost recovery focus areas.

Table S3. Current CTSA policies for cost recovery subsidies.

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universities can draw from, our research enterprise has yet to overcome major challenges in this process (3, 4). The U.S. National Institutes of Health (NIH) Director Francis Collins has called for more focused efforts “devoted to the translational process itself as a scientific problem amenable to innovation” (5). We embraced this directive to investigate how Clinical and Translational Science Award consortia (CTSAs) are addressing one challenge to translation: that of cost. This Commentary thus represents a stepwise, scientific approach toward an optimal mechanism for the recovery of costs from federally funded clinical research.

The flagship initiative driving the translation of NIH-funded research is the CTSA consortium (6, 7), a collaboration of 60 leading U.S. academic research institutions with a combined NIH investment of \$500 million per year. Patient-oriented clinical research is essential to the success of this program (8, 9), and within the individual CTSA organizations, the expertise and infrastructure is provided by Clinical Service Cores (CSCs). Previously, General Clinical Research Centers (GCRCs) were supported by the National Center for Research Resources, allowing them to provide their services free of cost for federally funded research. Under the CTSA mechanism, however, the expected scope of the program has been broadened, and cost recovery from research studies using CSC resources is now allowed. Streaming the funding directly to the principle investigator (PI) empowers them to take their clinical research to the most efficient service provider and introduces a “free market” element that could reduce waste and encourage cost-sharing of institutional resources (10). Such a move presents major challenges to institutional CSCs, the most notable of which is the need to restructure and share the associated costs and risks of the research instead of simply providing a zero-cost service. As a result, new stresses have been introduced to the CSC system regarding the need to evaluate research “worth” and cost by a dollar amount and, ultimately, to charge investigators directly to recover some of these costs.

Valuing academic research and scientific success is not a straightforward matter. Although a conventional business model uses the primary metric of dollar profit, competitive excellence in academia is measured by elements that quantify outstanding research, such as impact factors, *h* indices, and citation numbers (11). Furthermore, making a profit is at odds with the tax-free status of academic research. To begin to discover how a cost recovery mechanism (CRM) can operate in the academic environment, we examined cost recovery in 19 CTSAs across the United States, representing approximately one-third of the consortium.

CTSA COST RECOVERY MODELS

The language of CRMs is still evolving (12). The definition of a CRM here is the introduction of “any new charging mechanism” since the inception of the CTSA. For industry-sponsored studies, GCRCs historically operated a charging mechanism, and CTSAs have conventionally maintained this practice. What was not known is how widespread cost recovery for federally funded research had become within the consortium. Data were collected through iterative one-on-one interviews with the leadership of each participating CSC to cross-check the data as they were acquired (Supplementary Methods; table S1). An overview is given in fig. S1 of the current landscape for cost recovery in federally funded clinical research identified from our study. Each institution reported that their individual model is still developing, indicating a rapidly evolving CTSA environment. Of the 19 CTSAs examined here, 13 currently have an operational cost recovery mechanism in place.

Discussion with the CSCs revealed that on the whole, each developed their respective CRM independently; indeed, examination of the individual models reveals wide variation in approach. Even with a CRM, the majority of CSCs continue to subsidize services, aiming to

recover only an average of 40 to 50% (range, 0 to 70%) of costs depending on the institution and the study specifics. Because the CTSAs are not using common metrics to determine their base costs of operation, these figures have an inherent variability that we cannot define. Eleven of the 19 CSCs offer additional targeted subsidies to certain investigators, research fields, or study types, averaging ~50% but reaching up to 100% of total costs. Four of the 11 retain a set of “standard” services for which they operate no CRM, although the field is trending away from this approach; for example, two CSCs that initially incorporated free standard services later removed them, and a third is following suit.

The interviews also revealed an interesting trend towards calculating study costs using a bundled rate as opposed to pricing each service individually. Currently, seven of the CSCs here price services individually, four operate a bundled rate, one operates a mix of both, and one charges only for select services. However, two CTSAs that had started with individual pricing later changed to bundled rates, and others are now considering the same move, choosing to sacrifice a small amount of cost recovery for the cost-benefits of a simple CRM.

THE IMPACT OF A CRM

One of the most intense areas of interest for the CTSAs examined here is the impact of CRM on both the university and the science. This is typically measured by using metrics important to both the university and the CTSA, including the volume of research carried out within the CSC and the diversity of PIs using the services. As a nascent field, an objective, quantifiable analysis of the impact of a CRM has so far been lacking. Of the 19 CTSAs interviewed, nine had collected impact data of 12 months or more (fig. S1). Of these, eight maintained all of their pre-CRM services, and one considered that the costs recovered were not enough to offset funding cuts, ultimately reducing the number of services offered to preserve quality. In terms of billing mechanisms, the trend is toward automation of both billing and payment, owing to decreased costs and lag times. Several who started with manual systems have already moved toward automation. Because the income of the CRU is now partially dependent on the successful funding of the PI, the majority of CSCs have introduced a support service to help PIs write the new costs into their grants. The trend is toward providing this service.

The primary concern in introducing a CRM is the potential loss of the scientific user base to the private sector (PIs as “customers”), along with the negative effect this could have on the promotion of translational science. Of the CTSAs who currently have an operational CRM in place ($n = 9$), three saw a loss in market share, but the remainder reported no permanent fall (although two of these experienced a temporary decrease). Importantly, several CTSAs also reported a decrease in workload post-CRM because the PIs had made an effort to finish their studies under the original no-cost system. Some CSCs observed no overall decrease in customers at the time of CRM introduction but have seen falls more recently. These data from nine CTSAs, although only a portion of the whole, suggest that the observed downturns in CSC activity which are sometimes attributed to new CRMs, may be partially owing to CSC portfolio advancement combined with increased competition in federal funding.

THE OPTIMAL CRM

Once an overview of the current CTSA cost recovery landscape had been established, we then examined the interview responses to identify successful and failed initiatives and to highlight lessons learned. This information was applied to the design of an “optimal” CRM, incorporating the features that were identified as effective and efficient. The components that provide a framework on which to build a CRM are illustrated in Fig. 1, and a “menu” of

varied approaches participating CTSAs are currently taking to populate this framework are provided in fig. S1, the main aspects of which are discussed here.

Determine level of cost recovery

Determining the level of costs to be recovered through the CRM relies on identifying the cost of each service to the CSC and the percentage of these costs for which a charge could be compliantly levied. Identifying allowable costs requires the cataloging of every service offered combined with identifying the destination of all CRU income, to avoid charging for services for which the grant has already paid (“double-dipping”) and other regulatory compliance issues. When these have been fully understood, the CSCs can determine whether it is possible to retain a set of free standard services. Although the current trend is away from free services, there are several good reasons to consider them; for instance, in some cases, the administrative burden required to bill for a service may outweigh the cost of the service itself.

The cost recovery target is driven by the need to develop a sustainable business model, and some CTSAs are striving to recover the full CSC costs for individual research studies. A 100% recovery rate may be beneficial if it is required to maintain the range and quality of services offered, but this target must be tempered with a market analysis of external providers. An understanding of rates charged by other clinical service providers, such as industry, or typical service payers, such as Medicare, can offer a benchmark for the CSC to justify their CRM and highlight the level of institutional support that benefits the PI. This is important because PIs have been known to move their studies to private competitors who can offer a better deal or to establish their own clinical research operation independently from the CSC. The demise of CSCs in favor of independent operations is not desirable for cost efficiency, resources, or regulatory compliance. To minimize such issues, both the level of funding and prices charged by other providers of similar services must be fully analyzed when refining the target level of recovery.

Construct the mechanism for cost recovery

Once the level of recovery has been determined, the practical mechanism (or mechanisms) by which the costs are to be accounted for and recovered can be constructed. Cost accounting here refers to whether the CRM calculates costs by service, by hour, or by a mixture of both. Each of these approaches was observed to be operating well within the CTSAs, and no trend away from or towards a specific approach was noticeable. The recovery mechanics refer to calculating the individual study budget and communicating that cost to the PI. In the 19 CTSAs interviewed, mechanisms ranged from simple budget calculation tools on a website to mandatory face-to-face meetings with the PI during budget preparation. From the PI’s perspective, identifying costs for their study may be a new and potentially time-consuming endeavor, and because the success of the CRM relies on retaining the customer base, it is important that communication between the CSC and the PI be efficient and streamlined.

Identify study policies

The rise of the CRM has introduced a difficult concept for CSCs in regard to approving new studies. CSCs now face the dilemma of assessing ROI by a dollar amount and potentially turning down some projects on the basis of being too costly or having insufficient impact on CTA priorities. Funding bodies such as the NIH have long operated with this model, but choosing not to support otherwise sound research in this way is new for CSCs. Existing studies also pose a challenge, putting CSC leadership in the tough position of weighing the risk of compromising the integrity of long-term studies against the expense of ongoing clinical research that was designed in a cost-insensitive climate. During the CRM process,

the decision may be taken to “de-resource” studies that have lost direction or priority to the CTSA. Such decisions will be controversial, possibly requiring particular institutional consideration and specialist counsel.

To help CTSAAs adapt to these decision requirements, new committee structures are evolving within CSCs. We analyzed these for function and contribution to the CRM, and the most impactful were incorporated into our optimal CRM design (Fig. 1). The Cost Recovery Committee, for example, is the flagship body of senior leadership, and their role can be as simple as providing signatures on communications to publicly demonstrate support during implementation of the CRM. The importance of this body was stressed by many CTSAAs; implementing a new CRM can meet strong resistance, and visible leadership engagement may substantially smooth the process. The Scientific and Subsidies Committees can operate as one entity, although associating scientific quality too closely with finances may lead to controversy, and for this reason, several CTSAAs separate them. Under the separate model, the Subsidies Committee evaluates subsidy requests, including those for studies not automatically eligible under the CSC policies but which are experiencing exceptional financial circumstances, such as budget cuts after extramural funding. The Scientific Committee evaluates the scientific value of the study and weighs its potential impact on the field against costs the CSC is asked to meet. This committee assesses both new studies that lack supporting peer review and grandfathered studies that are selected for reevaluation on a regular basis. In providing a mechanism for making the tough decisions, the Scientific Committee needs members from multiple disciplines with the scientific standing and targeted expertise to credibly de-resource studies.

Select subsidy policies

Subsidies are costs that are paid by someone other than the PI and could be resources provided for by the institution or grant that are not included in the cost basis for services. For external services, the trend is away from offering subsidies, as the expectation is that the PIs will now budget for this work in their funding proposals. The application of subsidies to CSC studies is one of the most difficult challenges to address because it is where the definition of research “value” is most contentious and the gap between business and academia most broad. Here, to make a decision is to make a divide because introducing a subsidy inherently involves supporting one kind of investigation by excluding another. Because that decision is based on the value of the research, according to multiple institutional priorities and metrics, the implication is that nonsubsidized research is of a lesser value. Approximately 80% of the CSCs interviewed limit subsidies to targeted groups along local CTSA priority lines, which has led to a range of innovative approaches for cost recovery models (table S2) and their supporting subsidy policies (table S3).

CRM implementation

A detailed timeline for CRM implementation is provided later, but some advice from the CSCs is highlighted here. The definition of the CRM implementation date must be clear, whether it applies to submission of a funding application to the NIH or submission of a study to the CSC. Most CSCs set a fixed date to implement their CRM in one step, and those who attempted staged implementation felt that it only increased the workload. Communication was identified as an essential component, and the primary advice was to preempt “selective hearing” by being very clear, via the Cost Recovery Committee, about the subsidy amount, the scope of eligible services, and where they do not apply. On implementation of the CRM, some CTSAAs also recommend being prepared to provide bridge funding for grandfathered studies because, whatever the policy, some studies of institutional priority will fall through the cracks. Last, it is recommended that grants officers

for each department be kept “in the loop”; they can be strong and unexpected allies of the CSCs and an important source of support for the PIs.

Even a strong CRM, incorporating the features identified here, needs a solid foundation to make it robust. We combined our “optimal” CRM design with post-CRM feedback from the interview process so as to develop a comprehensive, sustainable model (Fig. 1). An important foundational element of a CRM is that it be compliant with the A21 guidelines, which govern the eligibility and calculation of costs for federally funded research. Failure to comply has resulted in multi-million-dollar fines. An A21 tracking system can be as simple as a well thought-out Excel worksheet supporting the billing mechanism, but the bottom line is that being compliant is not enough: The CSC must be able to deconstruct every transaction and demonstrate compliance. Operation of the subsidies mechanism also falls within the A21 authority because subsidies must be demonstrably transferred between relevant accounts.

Foremost among initiatives to protect the customer base is the provision of support to help PIs write the new costs into their grants. Reminding and educating the PI about the level of institutional support that they receive, primarily by illustrating the total cost of services received on the bill and then highlighting the subsidies which offset or reduce those costs, is helpful for PI relations. Maintaining a CRM requires careful tracking of metrics, particularly in relation to impact areas such as research quality and PI diversity, as a means to keep the CSC responsive to associated changes in their portfolio of research studies. Monitoring impact is not restricted to PIs and their research. It is important to also bear in mind the impact on staff during the transition, identifying stressors and providing remedies in a timely fashion. Further, a marketing strategy is recommended as an effective way to help maintain a healthy customer base. Several CSCs reported that marketing their new CRM increased new studies simply by raising awareness of CSC resources.

PROPOSED IMPLEMENTATION PLAN

How the implementation steps of the CRM could be initiated and tested is illustrated in Fig. 2, including a 3-month period to issue mock bills to “stress-test” the system against real studies while still operating in a low-stakes environment and to acclimatize the customer base to the scale and source of costs involved in clinical research. Communication is vital. Thus, the flagship Cost Recovery Committee should be established early on to be the liaison to existing PIs. Establishing the Scientific and Subsidies Committees before or in parallel with the initial communication to PIs is an important step in allaying fears that their research will be valued by nonexperts before any de-resourcing decisions are made. CSC office hours and town hall meetings are scheduled to follow the organization-wide communications in order to maximize informed PI feedback. Similarly, making draft CRM documents available before the one-on-one office hours and group meetings will enable stakeholders to confidently engage in developing the optimal model. Staff support processes should result from the internal analysis and may simply require the development of guidelines or scheduling of regular feedback sessions. After a defined notice period, the primary output from each timeline stream becomes operational.

CONCLUSIONS

This work provides a snapshot of the cost recovery landscape in clinical research cores across the United States, illustrating both the nascent and the dynamic nature of the field within an evolving CTSA environment. Although the sample set is limited only to approximately one-third of the consortium, several common features and trends have been identified. The CSCs are testing new ground with the introduction of cost recovery, and

although remarkable progress has been made by the pioneering organizations, important concerns remain about the long-term implications. Many CTSA are reluctant to introduce charges that they believe may not be in line with their academic mission, and questions remain about the effect of a CRM on the quality and accessibility of research services. Nevertheless, several positive impacts of CRMs were identified from this work. In particular, some CSCs reported that new studies are generally more structured because PIs may be avoiding unnecessary costs, and in order to retain their customer base, CSCs may be increasingly motivated to provide quality, cost-effective services. An unexpected impact of the CRM is the observation of a new PI altruism, in which senior PIs have declined financial support on the basis that their more junior colleagues need it more. The cautious consensus is that these efforts appear to be strengthening the underlying science and, in turn, increasing CSC access relative to the pre-CRM environment.

Although clinical research is costly, it is an essential step in the translational process. Developing robust business models to underpin clinical research is a vital step in the evolution of the CTSA (13, 14), and an undeniable part of that evolution is now cost recovery. In the face of challenged industry pipelines (15, 16), radical new business models are being established to drive translation in drug development (17–19), and with the synergies of collaboration (20–22), the CTSA consortium is well placed to contribute to this new translational climate.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1. The path to CRM implementation
Features common to successful models within the CTSA consortium can be broadly categorized into five integral components involving decision-making steps that are based on due diligence and expert counsel. Making that model robust requires additional components that form an effective A21 compliance system. From experience, CTSA institutions have also developed a range of supporting systems to ameliorate their individual model.

Figure 2. A CRM implementation plan
On the basis of feedback from CSCs, we designed a “how-to” timeline that details CRM implementation over an 8-month period. Although some components can be initiated concomitantly, others build on the results of previous steps. The primary timeline includes components from Figure 1, with an additional step to present the draft CRM to stakeholders to obtain valuable feedback and/or identify bottlenecks before the model is finalized.