

2013

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Recommended Citation

Holmes, Kristi L.; Lyon, Jennifer A.; Johnson, Layne M.; Sarli, Cathy C.; and Tennant, Michele R., "Library-based clinical and translational research support." *Journal of the Medical Library Association*. 101,4. 326-335. (2013).

https://digitalcommons.wustl.edu/open_access_pubs/1883

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Library-based clinical and translational research support*

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DOI: <http://dx.doi.org/10.3163/1536-5050.101.4.017>

BACKGROUND

There has been a shift in the workflow at academic biomedical research and clinical care centers to promote more efficient clinical and community implementation of bench discoveries. Strong financial support for this effort is provided by the Clinical and Translational Science Awards (CTSAs) from the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), awarded to about sixty biomedical research institutions constituting the C TSA Consortium [1]. CTSAs offer an opportunity to speed the translation of bench discoveries to improved human health by transforming the

* Research reported in this publication was supported by Clinical and Translational Science Awards UL1 TR000448, UL1 TR000064, and 8UL1TR000114-02 from the National Institutes of Health (NIH). This project has been funded in part with federal funds from the National Library of Medicine, National Institutes of Health, under contract #HHS-N-276-2011-00004-C.

research enterprise at the local, regional, and national levels. These efforts include large-scale infrastructure projects, institution-wide coordination and provision of services, incentives to facilitate collaboration and team-based science, and education programs designed to train the next generation of researchers.

In this age of translational science, biomedical libraries can provide critical support. In 2011, Tennant [2, 3] performed a survey to explore how libraries provided support to clinical and translational science researchers at CTSA-funded translational science institutes (TSIs). The majority of respondents indicated that they provided services to such researchers, and almost a third were officially affiliated with their institution's TSIs. Library-based translational research support programs are frequently built with a combination of specialized informationists (SIs), who often have advanced training in basic science or clinical areas, and librarians (Ls). By developing innovative services and providing access to a wide variety of information types and resources, libraries are in a key position to successfully respond to translational scientists' information needs.

This paper describes current and potential library-based support efforts for clinical and translational research and puts these activities into the context of key function areas (KFAs), following the national-level organizational scheme of the CTSA Key Function Committees [4] to support the goals of translational science.

ENVIRONMENTAL SCAN

The library-based TSI support activities reported in this paper were obtained through an environmental scan consisting of personal experiences, a literature search, an Internet review of conference presentations [3, 5–11], results of brainstorming activities conducted at continuing education (CE) courses [12, 13], and services provided by the authors at their respective institutions. The literature search was carried out in January 2013 to identify examples of service activities that was presented in tables and text and was not considered to be a comprehensive review. Searching was conducted using MEDLINE/PubMed, Web of Science, and SciVal Scopus databases. In addition, Google was used to locate additional conference abstracts and other gray literature. These searches included KFA-associated concepts and other related terms. Instructors of the cited Medical Library Association (MLA) CE classes contributed examples of library-based service concepts from class discussions that might align with the KFAs. Finally, the experiences of the authors, in terms of services either provided or envisioned for their institutions, were included. The authors' individual contributions to this report reflect their diverse environments: public and private institutions with different reporting structures (in the health sciences or the university library system) and levels of involvement with their respec-

tive TSIs. The examples gathered from these various sources were then organized into KFAs.

CTSA Consortium-level activities are focused on five strategic goals facilitated across fourteen KFAs by specific committees [4]. The fourteen KFAs encompass a number of activities that are actively supported by libraries (e.g., research, clinical care, community outreach, and education). By considering the role of the library in the context of the fourteen KFAs, it was possible to identify existing and proposed service areas and understand how current services can be effectively presented to campus stakeholders. Table 1 presents the results of the scan. References denote published sources; other examples were derived as described above.

KEY FINDINGS BY FUNCTION AREA

Administration

Library support of TSI administrative efforts is a natural fit and helps guide the work of the library in supporting other translational initiatives. Working directly with administrators facilitates library understanding of TSI priorities and positioning to respond to these needs in an efficient manner, enhancing the visibility of the library as a partner to support other TSI activities. While the majority of these efforts tend to play to traditional library strengths (e.g., literature searching, use of bibliographic resources, and reference management software), new opportunities arise in which libraries act as direct collaborators in strategic institute-level events. Additionally, libraries can inform administrators of trends and prospects in translational research and scholarly communications [14].

Biostatistics/epidemiology/research design (BERD)

Library-based support activities for biostatistics/epidemiology/research design (BERD) vary widely and can present libraries with a clear path toward more in-depth SI services, as BERD impacts TSIs on many levels, including research design and awareness and training on data sources and software. While a number of libraries have subject matter experts on staff to provide in-depth consultations and training, other libraries find that they can also offer support through coordinating software site licenses and organizing training opportunities from vendors or local topic experts [15, 16].

Clinical research ethics

Many libraries actively support the clinical research ethics KFA through collaborative partnerships and support services and gathering of resources for training programs. Libraries also work with research subject advocates to teach investigators and clinicians about scholarly publishing issues and developing curricula on the responsible conduct of research [17, 18].

Table 1
Current and potential library-based support efforts for clinical and translational research*

Clinical and Translational Science Awards (CTSA) key function area	Key function committee (KFC) description [4]	Library support activities
Administration	The Administration KFC is composed of a lead administrator from each institution and provides direction for program execution by sharing best practices and methods, facilitating grants management, collaborating, and managing programs. This KFC also undertakes special projects for consortium leadership.	Assist with events such as retreats and seminar series; provide consultation and training services on library tools and services (searching bibliographic databases, utilizing bibliographic management software, etc.); create a translational science institute (TSI) collection in the campus institutional repository containing peer-reviewed journal articles and other materials; participate in planning retreats and goal development workgroups; assist administrative core with large-scale institutional grant proposals (conduct literature searches, organize and format references); provide consultation services for productivity and performance data sources; assist with facilitating current and retrospective compliance of public access mandates; advise administration of new trends or efforts in the field such as researcher identifiers (e.g., ORCID [66]) or new compliance requirements.
Biostatistics/epidemiology/research design (BERD)	The Biostatistics/Epidemiology/Research Design KFC focuses on the integration of biostatistics, epidemiology, and research design into clinical and translational science research programs across CTSA institutions. This KFC encourages the use of best practices, identifies barriers to research, and develops strategic approaches to overcome these barriers, including new methodologies and novel educational approaches.	Coordinate library-based or vendor training on biostatistics topics and tools; provide basic biostatistics consultation support and training for statistical analysis best practices, tools, and data sources; collaborate with departments or cores on initiatives and software purchases; create research resources catalogue or toolkit (e.g., eagle-i [67]) to assist researchers in navigating research processes; identify relevant resources and information for all stages of translational research; locate national resources within the CTSA consortium.
Clinical research ethics	The Clinical Research Ethics KFC is focused on supporting collaborative clinical ethics research through the use of clinical research ethics best practices and education. The committee also addresses other ethical issues germane to clinical and translational research, as necessary.	Collaborate with conflict of interest (COI) officer and TSI research support staff to survey faculty perceptions of COI and identify training needs; assist research subject advocate to find information to support development of a training certificate program for clinical trial coordinators; support and develop training efforts related to human research subjects, COI, scholarly communications (e.g., responsible conduct of research, scholarly publication issues, public access mandates, copyright).
Clinical research management	The Clinical Research Management (CRM) KFC supports efforts to improve efficiency, reduce cost, and support research participant safety in areas such as protocol development; regulatory reviews including institutional review board (IRB) or institutional animal care and use committee (IACUC) review; study recruitment and retention; and data management tools, processes, and quality standards; among others.	Participate on the TSI's regulatory knowledge and research support committee (RKRS) and contribute to the development of standard operating procedures for investigative new drugs (INDs) and other RKRS research support activities; serve on committee that validates and creates validated survey instruments and questionnaires for researchers to use in their studies; support IRB, including assisting with protocols, performing or training researchers to perform searches related to IRB protocols, and integrating a librarian into the IRB; train in Clinicaltrials.gov compliance; provide customized literature search services.
Clinical services core	The Clinical Service Core (CSC) KFC shares best practices, resources, and business models on topics related to technological, nursing, and other expertise that may not be generally available in a clinic setting but that are required for translational science.	Participate on the TSI RKRS; develop resource guides (e.g., research participant confidentiality resources and policies); serve on a campus-wide dissemination and implementation workgroup; provide advice and training on topics related to enhancing the dissemination of research [19].
Communications	The Communications KFC includes CTSA and National Institutes of Health (NIH) staff who share local and national communications best practices, activities, and experiences; and identify communications opportunities and challenges. The Communications KFC works to increase awareness of program value, improve dissemination of National Center for Advancing Translational Sciences (NCATS) and CTSA-related news and information, and supports collaborations.	Provide consultations to enhance awareness of research efforts; collaborate with TSI on materials and messaging from the local institute to stakeholders on the website [20], in newsletters, and emails; facilitate social media activities (e.g., Twitter, blogs, Facebook) for efforts within the local institute [21]; support open access initiatives.
Community engagement	The mission of the Community Engagement KFC is to implement community and practice engagement plans by sharing knowledge, expertise, and resources. The goal of the Community Engagement KFC is to engage communities and practices in translational research through community and practice outreach with the translational research process via bidirectional dialogues. The KFC helps establish partnerships for collaborative development of curricula, evaluation outcomes, and metrics for research.	Provide outreach and health literacy resources to assist in reducing health disparities; participate on community engagement leadership teams and provide information resources and strategic guidance; serve as grant reviewer for community engagement pilot grant initiatives; serve on campus-wide dissemination and implementation workgroups; provide information literacy training and health information to patients in clinical or other settings; consult on appropriate literacy practices for community-based materials; identify resources in languages and appropriate reading levels for community-based materials; assist with enrolling participants into trials; provide local support for ResearchMatch [68]; identify community partners; promote research networking systems; review community engagement grant proposals; leverage existing outreach relationships; provide current information to meet the needs of community engagement stakeholders.
Comparative effectiveness research (CER)	The Comparative Effectiveness Research KFC focuses on CER and patient-centered outcomes research through methods development, training and education, community engagement, and dissemination of findings.	Provide guidance and training on resources that can inform CER; develop resource guides [69] on comparative effectiveness policy issues and legislation and disseminate critical CER research news [70]; develop a resource guide on available CER data sources and tools; provide consultation support on CER guidelines, policy issues, data sources and tools, and field resources; maintain a list of key CER journals, conferences, and organizations; participate on a local CER committee.

Table 1
Continued

Clinical and Translational Science Awards (CTSA) key function area	Key function committee (KFC) description [4]	Library support activities
Education and career development	The mission of the Education and Career Development KFC is to advance clinical and translational science through interdisciplinary education, training, and career development.	Provide workshops to TSI scholars and researchers (e.g., NIH public access policy, literature searching, expert searching and critical appraisal of the literature, systematic reviews, best practices in data management and data management plans [DMPs], institutional repositories, use of bioinformatics tools, assessment and/or enhancement of research impact, preparation for publication, optimization of the dissemination of research, and responsible conduct of research) and collaborate with training center on training events and seminar series; record training and publish video files and ancillary support materials to the web; develop resource guides (e.g., grant-writing); provide consultation services on copyright; serve on campus-wide responsible conduct of research workgroups; serve as a course master, instructor, or small group consultant in credit-based courses; inform trainees of educational and development opportunities (e.g., NIH webinars and videocasts [71], CTSA Consortium events, and other online training such as opportunities available through massive open online courses [MOOCs] and vendor webinars); provide information on institutional resources, support, and expertise (e.g., where on campus to find writing support, data storage, and other services and infrastructure).
Evaluation	The Evaluation KFC is focused on issues related to evaluation of local CTSA and issues related to the national program, through sharing information about evaluation approaches, challenges, and progress.	Serve on tracking and evaluation team for an institutional TSI; contribute reports, analyses, and effort for institutional TSI needs (e.g., productivity reports, publication reports, social network analysis [SNA] [72], bibliometric analysis, citation analyses); develop strategies for capture and validation of publication data; reconcile author name variants; provide consultation services (e.g., longitudinal evaluation, research impact analysis, guidance on productivity tracking and performance metrics); track NIH public access policy compliance; create frameworks for evaluation of research impact; serve on consortium-wide workgroups (e.g., bibliometric, SNA, or shared resources workgroups under the Evaluation KFC); create content for TSI website; create or perform quality control on unique author ID profiles (e.g., ORCID, Scopus Author ID, ResearcherID); help investigators identify indicators of impact to understand subsequent clinical applications resulting in meaningful health outcomes [30].
Informatics	The Informatics KFC (IKFC) assists in informatics support for all CTSA functions by sharing knowledge, expertise, and resources, and ensuring collaboration among researchers and their partners. The IKFC recommends standards and best practices for interoperability and ensures privacy and confidentiality protections for human participants.	Develop and/or support the education component of local informatics efforts, including library-based training and hosted vendor training; provide research consultations by bioinformaticists or other subject specialists; provide computers with research software for data analysis [73]; serve on campus informatics advisory groups; implement, support, and/or disseminate researcher profiling platforms (e.g., VIVO [74], based in the library or in tandem with other groups on campus); support semantic web initiatives on campus and educate about related topics (i.e., ontologies, linked open data, and semantic web standards and technologies); serve on consortium-wide workgroups (e.g., the research networking affinity workgroup or the ontology workgroup under the IKFC); offer clinical data repository support and clinical trials management systems support; support and train in the use of CTSA Consortium tools (REDCap [75]); license bioinformatics tools; create researcher networking visualizations [72]; develop bioinformatics or other resource portals; serve as archive for data; support the institutional repository.
Public-private partnerships	The Public-Private Partnerships KFC aims to identify and facilitate partnerships and collaborations with a variety of stakeholders, including industry and trade groups, other institutions and academic groups, and advocacy groups through a variety of methods.	Perform literature searches for the technology transfer office; develop educational programming on topics such as filing a patent application and retaining investigators' rights; manage research networking tools or provide instruction on their use; host researcher networking events (e.g., "speed dating," CoLAB planning series [76]) to facilitate interdisciplinary collaborations.
Regulatory knowledge	The Regulatory Knowledge KFC is focused on supporting consortium efforts in human subjects research and compliance. This work includes education and training efforts and communication about best practices on topics such as informed consent, adverse event reporting, safety, and regulatory management and compliance, among others.	Serve on TSI's responsible conduct of research committee; collaborate with TSI's office of compliance and office of sponsored research to promote compliance with NIH public access policy through developing educational sessions and resources, developing guidance, researching publisher policies, reviewing references to determine compliance status, obtaining documentation of compliance, and submitting papers to PubMed Central; register clinical trials; perform data entry into ClinicalTrials.gov; support responsible conduct of research through development of educational sessions and resources [18]; work with campus IRB and IACUC regulatory units, both in helping investigators with protocols and integrating a specialized informationist or librarian into the committee activities [77, 78].
Translational	The Translational KFC works to develop the necessary infrastructure to foster advances in translational research and technologies throughout the CTSA Consortium. This is accomplished by informing TSI researchers about relevant resources and by funding inter-TSI collaborative efforts.	Provide instruction on team science activities, resources, and strategies; provide library services to support grant writing and clinical trial development.

* The fourteen CTSA key function areas are listed in the far left column, and the mission of the corresponding key function committee [4] within the CTSA structure is indicated in the middle column. Reported or potential library service activities that support key function areas are listed in the third column; activities listed include survey results [2, 3], results of discussions and brainstorming activities from continuing education courses [12, 13], personal communications, and services provided by the authors at their respective institutions.

Clinical research management

Facilitating the management and processes of clinical research is a key goal for a TSI. Each institution approaches this goal uniquely, but enhancing and formalizing communication among the intra-institutional clinical research support or regulation services is a common approach for library integration. While the names and structures differ across TSI sites, most contain an administrative coordinating group that serves as the connection point for units such as institutional review boards (IRBs), research offices, research support advocacy, clinical research centers, and technology transfer offices.

Clinical services core

The clinical services core KFA works to improve the efficiency of clinical research units (CRUs). To date, SIs and Ls have reported little or no involvement in these units, except for providing basic literature searching and standard library services to the staff. It is the opinion of the authors that opportunities to develop closer relationships with CRUs are most likely to develop from SI integration into the broader efforts of the TSI, such as service on their institutions' research support coordinating committee or through dissemination and impact work [19].

Communications

Communication about local and consortium-level activities is a vital component to the success of the overall CTSA program, and dissemination of research products and knowledge to stakeholders is critical. Communication activities and modes of dissemination represent an area where the library can leverage its campus relationships, understanding of the scholarly ecosystem, and expertise in targeted use of social media (e.g., wikis, dashboards, and research networking systems [RNS]) to help communicate the efforts of the TSI [20, 21] and facilitate communication and collaboration, thereby strengthening the cohesiveness of the national CTSA Consortium [22].

Community engagement

Community engagement in TSIs is of paramount importance because translational science cannot yield health outcomes that matter unless health disparities are addressed [23]. Many SIs and Ls have been actively engaged in outreach programs, understanding health literacy and the importance of including underserved populations in the design, and implementation of health information and services [24, 25].

Comparative effectiveness research

Libraries are poised to provide information, guidance, and training on resources that can support comparative effectiveness research (CER) competencies [26] and inform CER efforts such as clinical trials or

research project databases. The National Library of Medicine has developed excellent resources to support CER activities [27], providing a good starting point for libraries offering much-needed support to researchers working to understand how and why one intervention works better than another [28].

Education and career development

Education of the next generation of clinician-scientists is a major priority for the CTSA Consortium [29] and for institutions. There have been significant efforts at all levels to provide education and training for a multitude of topics related to research, clinical care, career development, team science, and others—offering the library the opportunity to support these activities.

Evaluation

Evaluation of scholarly output and assessment of research impact—particularly meaningful health outcomes resulting from translational research—is a growing trend and is important across all strategic goals of the consortium. Evaluation of biomedical research is typically conducted by traditional bibliometric measures and leverages skill sets that are well suited to the librarian. Some libraries extend evaluation by also using non-publication data, offering the opportunity for powerful analyses to demonstrate a more robust overview of the impact of research [30].

Informatics

Bioinformatics support services have been entrenched within libraries for almost twenty years [31]. These services largely focus on training and database or tool support for researchers but more recently have morphed into broad support across bioinformatics, medical informatics, clinical informatics, and information technology (IT) infrastructures. Other activities include support of the RNS either by offering the tool directly through the library or by providing guidance on data sources or training to help facilitate local adoption and promote profile completeness. The authors find that support in this area often involves working with semantic web standards and technologies [32], offering another area where SI expertise may be applied.

Public-private partnerships

The CTSA Consortium institutions are encouraged to foster partnerships with each other, as well as with industry and other government-funded programs [33]. Advancing public-private collaborations involves challenges and barriers [34], including intellectual property issues, proprietary challenges, communications, clinical trial recruitment, and other sensitive issues that require openness and transparency. SIs and Ls can best support partnerships through familiarity with the resources that TSIs

Table 2**10 strategies for building a successful clinical and translational science support program**

1. Visit the Clinical and Translational Science Awards website [1] and become familiar with goals and key function areas of the consortium. Understand the program and the national infrastructure in place to facilitate this work.
2. Understand your institution's proposal and consider ways that the library can help meet the stated goals.
3. Understand national-level competencies [79]; how can the library help meet these competencies?
4. Rebrand or reorganize a library division to align with major initiatives or areas of emphasis on campus and consider renaming it so that this emphasis is clear to campus stakeholders [80].
5. Reassign existing staff, provide training if necessary, and change working job title to indicate translational support. Encourage some specialization among existing staff; some areas to consider include research database searching, evaluation activities, community outreach, ontology support, and semantic web standards and technologies. Hire subject specialists such as statisticians or basic or social scientists to support specialized needs; build a service program around their expertise and forge new partnerships.
6. Send library staff to nonlibrary conferences and workshops for training on team-based science, informatics, or research networking systems. Some examples include the American Medical Informatics Association joint summits on translational informatics and the annual VIVO conference.
7. Be familiar with trends and policy issues and how they can be opportunities for the library (e.g., National Institutes of Health [NIH] public access policy and data sharing mandates).
8. Attend a variety of campus events, including seminars and classes from the translational science institute (TSI).
9. Seek out interdisciplinary collaborations and look for funding. This helps to validate the library's contribution and move the project and partnership forward. (See National Library of Medicine administrative supplements [81], for example.)
10. Focus target populations for library projects to those emphasized by the local TSI.

leverage to identify possible partnerships and foster these relationships [35, 36].

Regulatory knowledge

Many libraries have adopted formal support programs in partnership with university administrative units to support NIH-funded authors on issues related to compliance with public access mandates or compliance with federal research regulations such as clinical trial registration, data entry into ClinicalTrials.gov, and responsible conduct of research. Formal training in responsible conduct of research practices is required by some funding agencies such as the National Science Foundation [37] and NIH [38], and such support demonstrates how libraries are evolving to address the complexity of research in the twenty-first century [39–43].

Translational

Ultimately, the library's expertise as a campus conduit, helping researchers and administrators find resources and collaborators, is a key way to serve the translational KFA whose goal is facilitating inter-institutional collaborations. Furthermore, libraries have a long history of helping researchers find resources and expertise by searching bibliographic databases [44], and adopting institutional RNS and associated data standards [31] to ensure richly structured data provides new opportunities for libraries to leverage their expertise in information management. Institutional repositories also serve to highlight research outputs that demonstrate cross-disciplinary and collaborative authorship patterns in translational science research [45].

DISCUSSION

Until recently, library support for clinical and translational research has generally included only basic reference and instructional services; however, more

specialized services continue to develop, expanding the concept of the "informationist" [46]. In 2008, the NIH Library reported expanded informationist-integration activities—many of which align with KFAs—including attending clinical rounds; providing protocol searching; providing data support services; providing critical appraisal of the literature; searching chemical, patent, and competitive intelligence; partnering in manuscript writing and coauthoring; and providing onsite training [47]. Informationist collaboration with translational science researchers across the country has flourished in these areas and is expanding into new spheres, including integration of library, biomedical informatics, and scholarly communications into official TSI course work [8, 14]; knowledge management [48]; support for e-science [49]; data curation [50]; research networking [51–54]; health information management for quality improvement [55]; research impact [56]; bioinformatics and genomics [6, 8, 10, 57–60]; community outreach support; and team science [61].

Assessing library-based translational support services

To date, there has been no formal analysis of library-based support of TSIs, although this is essential to help libraries develop effective and efficient services. Evaluation research protocols should be codeveloped with new and expanding services. Indicators can provide anecdotal evidence that library-based support programs are succeeding. Perhaps the most obvious is the integration of library personnel into the TSI [62]. Invitations to participate in TSI events, workgroups, and renewal efforts exemplify integration and provide evidence of deep TSI partnerships. Some SIs and Ls serve as official members of local KFA teams with their local TSIs, opening the door for participation on national CTSA-level KFCs and interest groups [63, 64] and assignment to CTSA-related projects such as the Research Electronic Data Capture (REDCap) Shared Digital Instrument Library Committee (REDLOC) [65]. Perhaps the most

significant indicator of success of a library-based program is financial support, through paid effort on the CTSA, commitment of funds for shared resources, and/or funds for library personnel to travel to conferences and training.

Moving forward with library-based translational science institute (TSI) services

Various barriers can make it difficult for libraries to successfully deliver services and resources to the local TSI. It can be difficult to understand what opportunities allow libraries to move forward in this arena and how the roles of library-based personnel are changing. Other significant barriers have confronted libraries for years, including a lack of understanding of library services and personnel by campus communities, and budget constraints to fund equipment, specialized tools, subscriptions or licenses, databases, and staff. Specialized service areas require expertise that does not always exist in the library. Inadequate training of existing library staff or a budget that does not allow new hires in specialty areas can present significant challenges when trying to develop support services for a TSI. The paucity of peer-reviewed manuscripts on the topic of libraries and TSI support, combined with an increasing number of conference reports on the topic, suggests to the authors that libraries engaged in TSI efforts should consider reporting their work in the peer-reviewed literature for the benefit of all.

Perhaps the biggest barrier for libraries is a lack of understanding of TSI goals and requirements, including national-level priority areas. Table 2 lists ways that libraries can gain such understanding. It is essential for libraries to be agile and creative in their TSI support efforts and outreach strategies. As libraries become better integrated across key areas, they become better poised to bridge silos and support the research, clinical, and community-based efforts of the TSI, ultimately ensuring a vibrant future for the library as a key partner in significant institutional efforts.

ACKNOWLEDGMENTS

The authors acknowledge attendees of the MLA CE classes noted in the paper and Paul Schoening, Cecilia E. Botero, Robert Engeszer, AHIP, Hannah F. Norton, and Rolando Garcia-Milian, AHIP, for helpful discussions.

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Received March 2013; accepted May 2013