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## What Happened to Research in Clinical Microbiology in the United States?

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The title of this article is loaded with negative innuendo—the question is not “What is the state of research in clinical microbiology in the United States” but, rather, “What has happened to research in clinical microbiology in the United States.” We begin with the premise that there has been a decline in the amount of clinical microbiology research in the United States in recent years, present evidence supporting that premise, and offer some reasons why we believe that this has occurred. In addition to this, we also suggest some approaches that could be attempted to reverse this trend.

One metric that can be used to measure clinical microbiology research in the United States is the number of manuscripts published by authors employed by American institutions in the *Journal of Clinical Microbiology* (JCM), which is arguably the most prominent clinical microbiology journal in the United States. Figure 1 summarizes the relative number of manuscripts submitted and published from 1975 to 2010 by American and non-American authors. Clearly, there was a significant decline in the percentage of manuscripts submitted to and manuscripts published by JCM by authors from the United States from 1980 to 2005 compared with the number of manuscripts submitted to and manuscripts published by authors from outside of the United States. As shown in Fig. 2, the proportionate decline in manuscripts from American authors cannot be explained by an increase in manuscripts from non-American authors. Indeed, the number of manuscripts submitted and published by American authors has declined steadily over the past 30 years. When the number of manuscripts published by American authors is divided into 3 groups—hospital/university (H-U), government (national or state labs)/H-U collaboration, and industry/H-U collaboration—a decline is noted in each group. It is noteworthy that publications arising from collaborations with industry have become nearly nonexistent in recent years.

One explanation for the decline in the number of manuscripts published by American authors in JCM could be that authors are choosing to publish in journals that may be clinically germane to the data being presented, such as pediatric, infectious disease, or obstetric-gynecology journals. By publishing in these clinical journals, authors may believe that they are better targeting end users of their research with information that can help them make decisions in their clinical practice, as well as increasing the visibility of the profession of clinical microbiology to clinicians. By publishing in the journal

for our own profession, i.e., microbiology, we are “preaching to the choir,” with less opportunity to reach the end user and influence clinical practice. However, our group concluded that while some authors may be targeting these clinical discipline-specific journals, this alone does not account for the drop in publications by American authors in JCM.

It appears that the decline in American publications is not unique to clinical microbiology; there was an overall decline in U.S. representation in clinical research journals from 1977 to 1988, as reported by Stossel and Stossel (4). Specifically, this study looked at the *New England Journal of Medicine*, the *Journal of Clinical Investigation*, and the *Lancet* and in a specialty journal, *Blood*. During this period, the proportion of papers from outside the United States increased between 2- and 3-fold. Most non-U.S. research published originated in Western Europe or Japan. This decline coincided with the slowed growth of funding for clinical research from the NIH.

A specific example of the decline in the number of publications by clinical microbiologists was cited by Gary Doern at the 1998 General Meeting of the American Society for Microbiology (ASM). He randomly identified 10 clinical microbiologists from academic medical centers who presented lectures at the 1988 ASM meeting and compared their publication record for the 5 years prior to that meeting with the publication record of a similar group of 10 individuals from the 1998 meeting for the 5-year period prior to that meeting. In 1988, the 10 speakers had published a mean of 6.2 articles per year in peer-reviewed journals, while in 1998, the 10 speakers had published a mean of 1.1 articles per year in peer-reviewed journals (1). Although anecdotal, Doern's data are consistent with the experience and impressions of our group.

### FACTORS CONTRIBUTING TO THE DECLINE IN CLINICAL MICROBIOLOGY RESEARCH

What does account for the decline in clinical microbiology research in the United States? There would seem to be several not mutually exclusive explanations.

**Government oversight/regulation.** The regulatory environment for clinical laboratories and manufacturers of laboratory devices and instruments has become increasingly complex and cumbersome over the past 20 years or more. The cost for manufacturers to complete Food and Drug Administration (FDA) *in vitro* diagnostic product (IVD) submissions has increased significantly, with a general perception that the FDA has become much more restrictive. This environment has had the effect of stifling IVD submissions and the concurring validation studies. Conflict-of-interest policies, driven at least in part by government oversight, have made collaborations with

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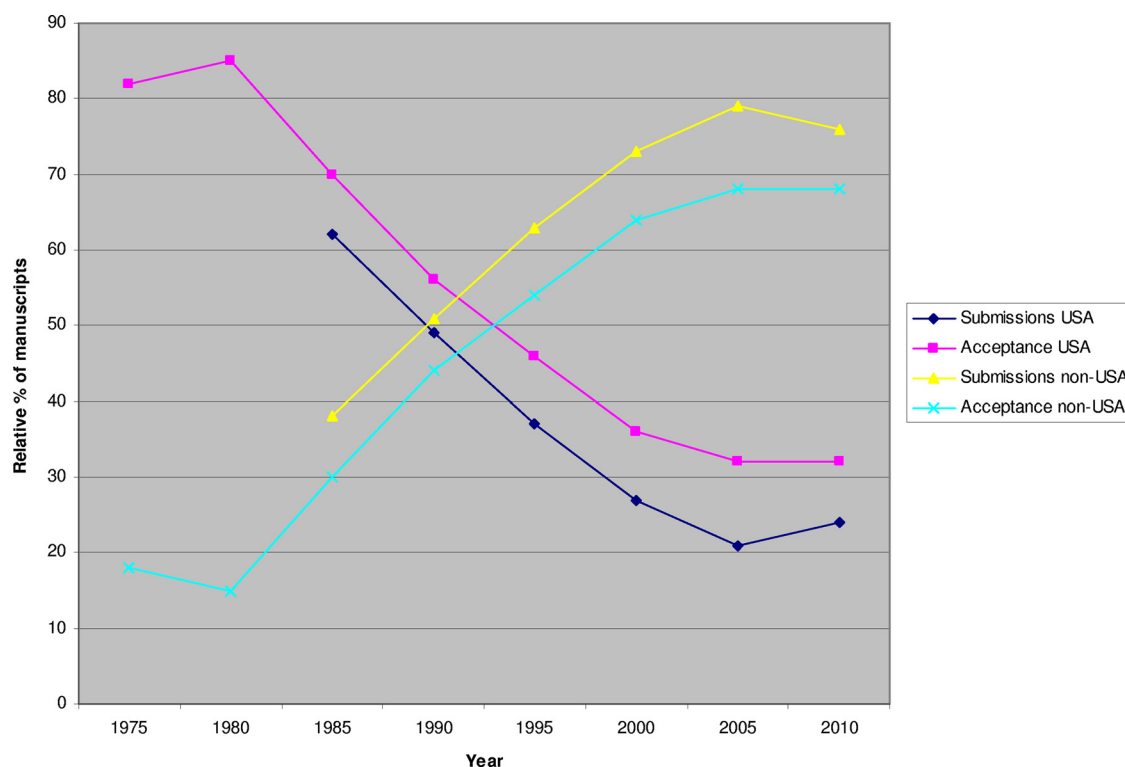


FIG. 1. Relative number of submissions to and publications in the *Journal of Clinical Microbiology* by American and non-American authors. Values from 1985 to 2010 (courtesy of Charles Brown, ASM) were based on the total number of articles submitted or published for the entire year in each of the 5-year intervals. Acceptance values for 1975 and 1980 were based on data tabulated from the January issue for each of those years.

industry increasingly burdensome. At one time, the presentation of the results of product validations at national meetings was a commonplace occurrence. Today, industry has tight restrictions on when, how, and if this can occur because of concerns related to illegal endorsements. It is our impression that some manufacturers have shied away from providing research support because of concerns that they may be perceived to be supporting or condoning an illegal relationship with the laboratory, even if that is not actually the case.

In many institutions, the institutional review board (IRB) process is viewed as a significant impediment to performing clinical research. It is our belief that the IRB process has become progressively more complex, and it is viewed by many laboratorians to be overly burdensome. Much attention has been devoted to approaches and controversies regarding informed consent and confidentiality when obtaining and using human specimens in research protocols (2). This can be an impediment to conducting research.

Some laboratory directors now find the IRB process at their institutions to be so onerous that they have chosen to reduce or eliminate research activities. Thus, some directors have found the returns from these activities not to be worth the effort expended and feel disincentivized to perform this work.

In addition, in some institutions, the actual members of the IRB may have limited knowledge of the discipline of clinical microbiology. An example of this is the failure of IRBs at some of our institutions to recognize the difference between a microbial isolate and the specimen from which the isolate was obtained when evaluating a research protocol. This has been

identified as an impediment to participating in scholarly activities; for example, some institutions are unable to submit clinical isolates to national collaborative antimicrobial susceptibility studies, studies that provide information of much potential benefit to the public health.

**Changing mission of public health laboratories.** There has been a shift in the mission of the Centers for Disease Control and Prevention (CDC) and the state public health labs over the last number of years. While much clinical microbiology research continues to be performed and published by microbiologists at the CDC, the mission of the CDC has changed, with the result that the breadth of that research has narrowed. Furthermore, many state public health laboratories have undergone significant downsizing, often driven by fiscal constraints and fewer resources for pursuit of research activities. The implications of this downsizing on the public health of the United States unfortunately go far beyond a lack of support for research activities.

**Consolidation of manufacturers.** The consolidation of manufacturers, whether by merger/acquisitions or manufacturers leaving the market, has also negatively impacted clinical microbiology research. This has occurred with medium manufacturers as well as with device and equipment manufacturers. With fewer competitors in the market, there may be less incentive for industry to initiate studies to demonstrate the superior performance of a company's product versus a competitor's. Fewer new products are being developed and submitted for IVD clearance, in part due to the regulatory atmosphere that we have previously mentioned but also because there is

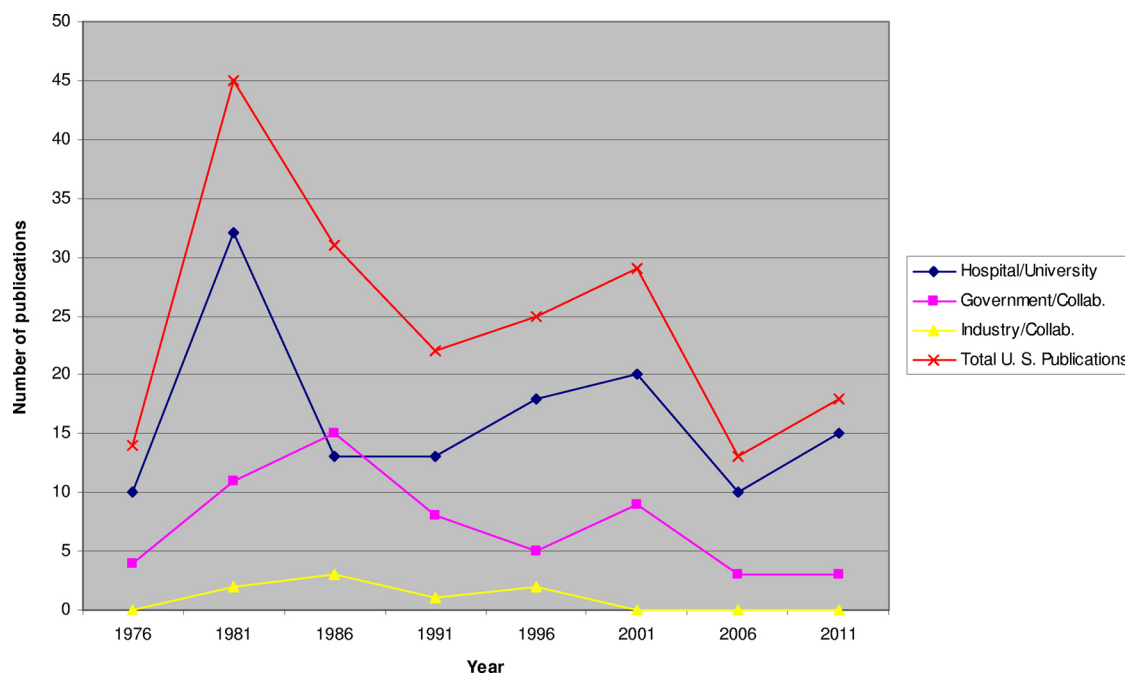


FIG. 2. Number of publications by American authors in the *Journal of Clinical Microbiology* for January issues at 5-year intervals from January 1976 until January 2011. In addition to the total number of publications, separate numbers are provided for publications with authors from hospitals or universities, national or state public health laboratories with collaboration from hospitals or universities, and industry with collaboration from hospitals or universities.

little impetus or incentive for companies to devote funds to performing studies or promote products that are considered to be already established and proven, especially if these are already commanding market share.

Changes in the pharmaceutical industry have also impacted clinical microbiology research. There has been a decline in the introduction of new antibiotics, a trend that likely will continue in the near future, with almost no new antimicrobial agents in the pipeline. A paucity of new antibiotics impacts FDA submission studies, marketing studies to test collections of isolates to determine the efficacy of these agents against different microbes, and validation of antimicrobial testing methods and devices. Another downstream effect of the introduction of fewer new antibiotics is a decline in the number of studies sponsored by pharmaceutical and device manufacturers to support CLSI guideline development for these new antibiotics.

**Purchasing groups.** In an effort to reduce reagent and equipment costs, most laboratories belong to one or more purchasing groups. Membership in these groups usually mandates purchase of specific laboratory diagnostic reagents and equipment. In addition to potentially forcing a laboratory to use a less optimal product for its specific needs, this has the effect of limiting the opportunity for validation studies (and, ultimately, publication) of alternate products that are not included in the purchasing group contracts. Similar situations exist with large reference laboratories, where use of noncontract products may be precluded. The growth of the influence of purchasing groups may also have had an unintended consequence of making it more difficult for start-up companies to get into the market, despite the potential innovativeness of their products. The ultimate effect is to make it more costly and

time-consuming for new products to make it into the lab, thereby limiting the opportunity for published validation studies that were much more common some years ago.

**Industry collaborations.** Historically, industry contributed a certain number of publications, either independently or in collaboration with microbiologists in the field. More recently, publications from industry have become nearly nonexistent in JCM. The reticence of industry to participate in such activities is at least in part due to conflict-of-interest constraints, a barrier to these types of publications in recent times. It is apparent to us that perceived or real conflicts of interest have negatively impacted research support, particularly for things like travel support for presentation of validation studies. Just like medical directors, industry may feel disincentivized to initiate or participate in studies.

Moreover, the contract negotiation process has become increasingly more complex and time-consuming (due to both industry and hospital/university constraints) for the principal investigator (PI). The increasing outlay of time often yields marginal benefits to the career of the PI. Furthermore, with increasing overhead, IRB, and publication costs, it may be impossible to get sufficient funds from such studies for them to be considered to be of significant value.

**Hospital laboratory constraints.** Multiple constraints contribute to reduced research being performed in hospital laboratories. Hospital laboratories are increasingly focused almost exclusively on patient testing, with less and less time and resources available for research. Laboratories are usually looked upon as revenue-generating centers by hospital administrators, who often are struggling to keep their institutions fiscally solvent. As noted by Sintchenko and Gilbert, laboratory medicine

professionals have been increasingly burdened in recent years by a somewhat relentless increase in requirements to improve the efficiency and effectiveness of laboratory practice. Cost-reduction strategies have had a negative impact on research and development in clinical microbiology (3).

In the hospital environment, it is not always clear who should pay for test development. New lab tests are typically developed by or under the direction of the lab director, who may or may not be an employee of the hospital. The lab director may have to use his or her own resources/discretionary funds to pay a technologist to develop such tests. However, once the tests are introduced into clinical use, it is the hospital that will benefit from this development, both with revenues and with improved patient care. It is important for the laboratory director to communicate these development activities back to the hospital and the administration so that they understand the impact of this work and are motivated to devote resources to research activities with direct patient impact. However, with all of the other demands now placed upon the director, developing this presence is time-consuming and can take time away from other activities.

Space for performing studies has become a significant issue in many laboratories. Even if monetary resources can be procured for equipment, there may physically be no space to do this work in the laboratory. Laboratories compete with other areas of the hospital for what is often diminishing capital pools. Even though test menus and test volumes are growing, the growth of space in many laboratories has not kept pace.

The individual(s) actually performing the research has also become a significant issue. Previously, the "regular" med tech in the laboratory would be able to work on studies following completion of his or her daily clinical duties. However, with staffing vacancies and increasing workloads, this has become next to impossible for many laboratories. Being able to adequately staff the lab for even essential clinical functions has become an issue. Even if the monetary resources are available, qualified individuals to perform the work may not exist. If the lab is short staffed and folks are already working overtime, it is very unlikely that these individuals will want to prolong their working hours for research activities. Moreover, individuals in the laboratory workforce are aging and arguably working harder than they did earlier in their careers. These demands result in reduced motivation for contributing to research projects and/or participating in continuing education activities.

Separate funds are now typically required to pay a person dedicated to work on studies, if funds and space can even be secured for such work.

**Increasing demands placed upon microbiology laboratory directors.** In our opinion, one of the major hurdles to microbiology research is the increased demands that are placed on the laboratory director on a daily basis and upon the clinical laboratory in general. We note that, compared with their responsibilities 10 or 20 years ago, most microbiology lab directors are now responsible for a larger diversity of testing areas, as well as more tests and more people. Indeed, many directors are now responsible for testing of specimens from more than one hospital, if not for the actual direction of more than one hospital microbiology laboratory. The demands of keeping scientifically up to date in all of the areas for which we are responsible is extremely time-consuming. As an example, one

of us (P.P.B.) directs a lab that in 1993 performed about 100,000 total microbiology tests, including no molecular microbiology tests. This year, the same laboratory will perform 400,000-plus tests, including 100,000-plus molecular microbiology tests for 19 analytes on 5 platforms. The current scientific and administrative responsibilities placed upon directors often leave little if any time for research.

As reported by Check, a number of prominent laboratory directors reported increasing demands on their time and indicated by consensus that the result is the creation of an environment that is not conducive to clinical research and development (1). One reason noted for this is that the lab director has less time for research and test validation but has an increasing burden of responsibility for financial management and implementation of cost-containment strategies (1). That is, lab directors are forced to spend more time on the business aspects of the laboratory, with less time for scientific endeavors such as test development and/or basic research (1).

**Reduced "value" placed on research by hospital/university administration.** At one time, the university-based clinical microbiologist was expected to perform research and publish in order to obtain tenure and advance in rank. Today, many universities have established "clinical tracks" which have the effect of deemphasizing the importance of research. On a monetary level, directors are often encouraged to devote most of their time to clinical service. "Relative value units" of clinical service may determine salary. Thus, what are the incentives to do research? It may not enhance one's salary or track for promotion, dissuading many folks from devoting significant time and energy to this.

## SOLUTIONS

We can summarize the information that we have provided in this article by simply stating that the current state of research in clinical microbiology is in decline and threatened.

It is not clear to us that the decline in clinical microbiology research can be reversed, but we offer the following suggestions as possible solutions to at least some of the problems that we have identified.

**IRB involvement.** We as microbiologists need to participate on IRB committees to represent the needs of the laboratory in research. We can educate our IRB colleagues to make reasonable, informed decisions about approaches to regulations and research protocols.

**Collaboration with clinical colleagues.** We need to collaborate more than we have in the past with other clinical colleagues on studies. We need to ask them what studies or issues they are interested in and provide microbiology expertise and laboratory support to get these done. This approach helps the field by bridging the collaborations and increasing the visibility of the lab, helps give the collaborators information that they may find helpful, and also spreads some of the burden caused by IRBs, contracts, etc. This is particularly possible in the medical school environment, where we can engage our trainees (fellows, residents, and medical students) to participate. Nonetheless, we recognize that overhead, as represented by indirect costs, can be a major barrier to research in the medical school/university setting. Many laboratorians have found that high overhead charges have contributed to "pricing themselves out



of the market.” This is a challenge in the academic environment.

**Collaboration with other microbiologists.** It was recognized that microbiologists need to collaborate among themselves to be more effective researchers. Collaborative efforts both reduce the individual effort required and add robustness to studies. Collaboration may make it possible to acquire more clinical outcome data, as well as circumvent issues such as clonality that may be encountered by performing a study in only a very small patient population or subset of organisms. There are also different skill sets, equipment, etc., in different centers, so this approach can capitalize on the best of everyone’s assets.

**Data mining.** We should try to do studies with information that we already have available to us, and this does not have to cost a lot of money. We can do data mining from our laboratory information systems or electronic medical records, providing data to our health care administrators to help them understand what we do and the impact that this can have on patient care, etc. The lab director should be encouraged to build a good relationship with the health care administration team, take the data that he or she generates to the health care

administration team, and help to optimize practices and hospital procedures. By highlighting these studies to the end users, we can hope to enact change. We need to promote ourselves and what we do. This gives us credibility not only within our profession but also in the hospital setting with both administrative and clinical colleagues.

While the prevailing tone of this article is somewhat grim, we urge and challenge our colleagues to continue to pursue quality research in clinical microbiology. It is essential to the advancement of our profession and for improved care for patients.

**Session discussants:** Kim Chapin, Stacey Klutts, Nathan Ledeboer, Mike Saubolle, Gongyi Shi, Michael Towns, and Ben Turng.

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