

AACP REPORTS

Report of the AACP Educating Clinical Scientists Task Force II

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INTRODUCTION

Clinical/translational research can be separated into two components, T1 and T2. T1 research applies discoveries generated during preclinical laboratory research to the development of clinical efficacy trials in humans, leading up to the submission of a New Drug Application or an amended New Drug Application claiming new uses of an approved medication. The second component of translation research, T2, is aimed at developing and identifying actions, interventions, or practices that enhance the effectiveness of approved agents in the larger population. The delivery of effective treatments through the implementation and evaluation of best practice guidelines within practice settings is another component of T2 research, but some authors have broken this aspect of patient care and practice into a subcategory of T2 research or simply labeled it as T3 research.^{1,2} Clinical and/or translational research are not new areas of research, but their importance in improving the public's health was heightened with the introduction of the National Institutes of Health (NIH) Roadmap programs and by the Roadmap's Clinical and Translational Science Award (CTSA) program which aims to consolidate a number of NIH clinical research and training programs at the nation's Academic Health Centers (AHCs).^{3,4} A primary requirement for a successful CTSA program is the demonstration of involvement of several health professions colleges/schools that are either members of the submitting institution's AHCs or from a medical school and health professions programs at another institution. A number of the successful CTSA applications have significant involvement of colleges/schools of pharmacy.

In 2006-07, AACP President Marilyn Speedie appointed an Educating Clinical Scientists Task Force (ECSTF I) with a charge to explore how academic pharmacy can increase its capacity for training clinical scientists to expand pharmacy's involvement in clinical and translational research, particularly through the CTSA program. The ECSTF I focused its efforts primarily on how to best educate and train clinical/translational scientists to contribute effectively in the area of bench to bedside research (T1). The ECSTF I came to a consensus on a unique education and training model for a Pharmacist Clinical Scientist at the PhD level. This initial ECSTF presented their recommendation to the 2007 AACP House of Delegates (HOD) in the form of a Policy Statement which was approved by the HOD. The policy statement is as follows:

AACP encourages research intensive university pharmacy programs associated with academic health centers (AHCs) to accept as a necessary component of their research/graduate training mission, a significant interdisciplinary education/training program for clinical scientists in experimental pharmacotherapeutics at the PhD level.

The proposed interdisciplinary PhD program in experimental pharmacotherapy is discussed in detail in the ECSTF I report.⁵

Shortly after the release of the ECSTF I report, members of the Academy started to inquire about the role of pharmacy faculty in T2 education and research. Therefore, 2007-08 AACP President Cynthia Raehl appointed a second Educating Clinical Scientists Task Force (ECSTF II) to continue the exploration of how academic pharmacy can increase its capacity for education and

research with a particular focus on T2 research from bedside to patient care.

ECSTF II met November 8-9, 2007 in Chicago, IL to discuss the following charges from President Raehl:

1. Define all the potential research activities or disciplines in colleges/schools of pharmacy that deal with therapeutic agents that have received FDA approval for use in patients. Confine your considerations to T2 research as opposed to T1 research, the focus of ECSTF I.
2. After defining those areas of research that could be the focus of colleges/schools of pharmacy faculty, either as individual investigators or members of a larger multi-disciplinary team of researchers, assess the current state of the research capability in the Academy.
3. Make recommendations to the Academy as to the potential future of this type of research (T2) within colleges/schools of pharmacy, recruitment of faculty needed to accomplish the research missions, and recommendations for educating the next generation of these faculty scientists in colleges/schools of pharmacy, from current PharmD students to current pharmacy faculty.
4. Identify opportunities for pharmacy college/school faculty and students to engage in NIH Clinical and Translational Sciences Awards (CTSA) programs.

5. Identify existing Pharmacy Practice Based Research Networks within the Academy.

BACKGROUND

Translational Research

The components of clinical and/or translational research were discussed in detail in the ECSTF I report.⁵ Figure 1, adapted from Westfall, Mold, and Fagnan, illustrates the relationship of T1 to T2 research by expanding and modifying terminology into recognizable pharmaceutical science and pharmacy practice research focus areas.¹

There has been increasing recognition of the importance of BEDSIDE TO PRACTICE or BEDSIDE TO PATIENT(s) Clinical or Translational Research (T2). This is a large part due to the Institute of Medicine reports on adverse medical events, several high profile medication recalls due to unrecognized or unreported untoward effects during Phase III clinical studies, and the Rand studies which demonstrate that patients do not often receive appropriate medical care, primarily drug therapy, for correctly diagnosed illnesses.⁶⁻¹²

T2 research attempts to define and understand all the parameters for the effective use of an approved drug product in the entire population of patients that are candidates for that drug product or an alternative drug therapy. Most importantly T2 research explores health practitioner and patient behaviors that can lead to an increase in drug effectiveness, reduce adverse drug events, or alternatively, decrease or eliminate the need for drug therapy. These

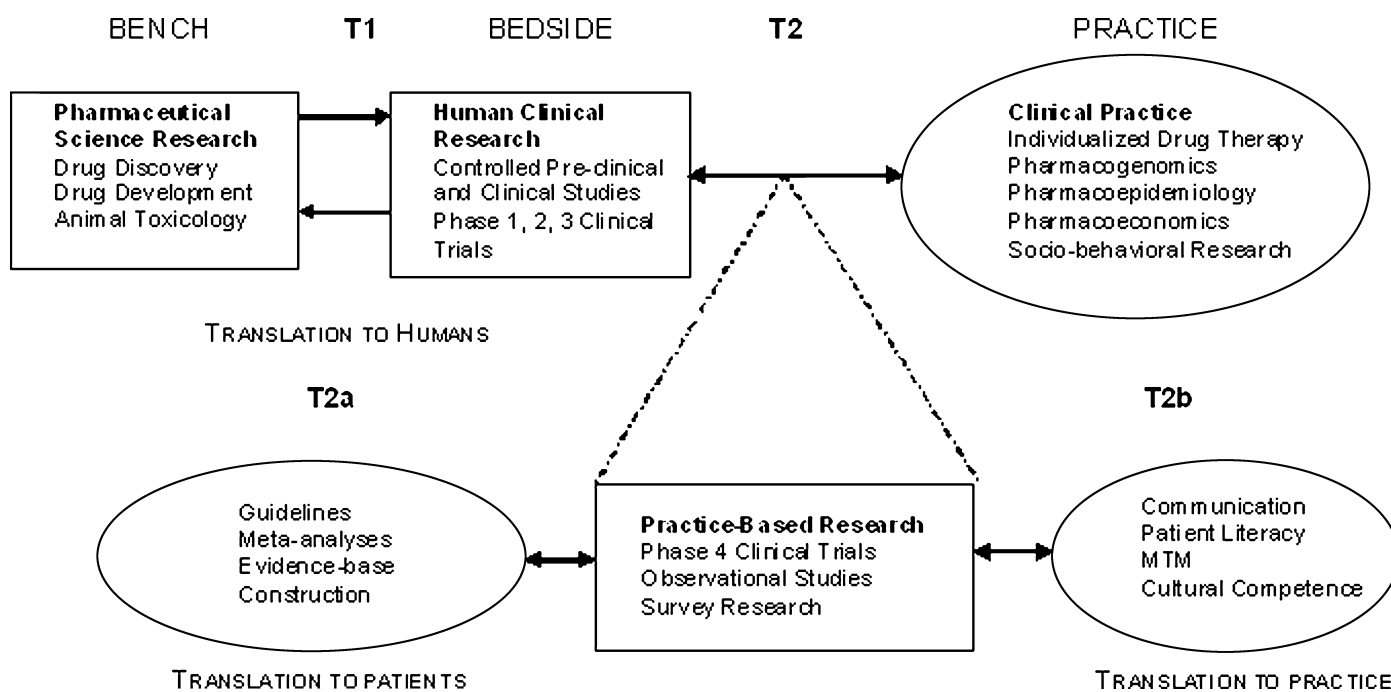


Figure 1. The components of translational research as applied to the pharmaceutical sciences.

goals of T2 research are not unfamiliar or unimportant to academic pharmacy and pharmacy practice and are consistent with the concept of pharmaceutical care. Examples of T2 research include comparative drug effectiveness trials, quality of life evaluations, drug-drug interactions, and refinement of dosage regimens based on genetics, organ function, age, and gender. Other examples include patient, prescriber, and pharmacist behaviors that might influence the choice of therapy (e.g., guidelines) or patient medication use (e.g., patient literacy, clinician-patient communication skills, self-management skills, cultural factors), and non-medical factors such as insurance payment policies (private or public) and the medical/pharmacy practice environment. T2 research encompasses all those factors that lead to an enhanced or diminished effectiveness in treating disease in the broader patient population after an intervention such as drug therapy has been shown to be efficacious in a selected study sample.

The Current Involvement of Academic Pharmacy in T2 Research

Examination of college/school of pharmacy websites reveals that a significant number of colleges/schools of pharmacy either offer advanced coursework and/or are engaged in T2 research. Graduate programs in the Social and Administrative Sciences (SAS) and/or Pharmacy Practice list the following research focus areas which lead to a graduate degree (M.S. or Ph.D.). The term Social and Administrative Sciences is not used by all colleges/schools of pharmacy, but the AACP Section containing the majority of faculty in this field is termed Social and Administrative Sciences and therefore is used throughout this paper.

- Organization Structure and Management
- Pharmaceutical/Health Economics or Pharmacoeconomics
- Pharmaceutical/Health Policy
- Pharmaceutical/Health Outcomes
- Pharmaceutical/Health Socioeconomics
- Pharmaceutical Health Services
- Pharmacoepidemiology
- Pharmaceutical/Medical Informatics
- Pharmacotherapy Outcomes
- Pharmacogenomics
- Socio-Behavioral sciences

Pharmacoeconomics and Outcomes Research (P/OR) are probably the most commonly mentioned focus areas for SAS graduate programs. In a follow-up survey of graduate programs in P/OR completed in 1998-99, Jackson and Draugalis found that an extensive growth had taken place in both the number of colleges/schools offering graduate programs in these areas over a five year period,

along with a growth in the students enrolled in these program areas.¹³ Of 41 colleges/schools offering graduate degrees (MS and PhD) in SAS, 35 responded that P/OR were part of their degree options. Examination of the responding institutions websites confirms that these disciplinary areas remain a focus of many SAS graduate programs. Jackson and Draugalis used the definitions of P/OR from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) lexicon.

Pharmacoeconomics has been defined as “the field of study that evaluates the behavior of individuals, firms, and markets relevant to the use of pharmaceutical products, services and programs, and which frequently focuses on the costs (inputs) and consequences (outcomes) of that use.

Outcomes research has been defined as “the collection and analysis of data on the use of health care products, procedures, services, and programs, and the evaluation of clinical, economic, quality of life, and patient satisfaction outcomes of that care, to determine the value of the products, procedures, services, and programs.

The behaviors of patients and providers can significantly influence whether the goals of therapy, including drug therapy are realized. According to the NIH Office of Behavioral and Social Science Research (OBSSR), “the core areas of behavioral and social sciences research are those that have a major and explicit focus on the understanding of behavioral or social processes, or on the use of these processes to predict or influence health outcomes or health risk factors.”¹⁴ Areas considered “behavioral” by OBSSR include cognition, emotion, temperament, and motivation while the social sciences include socio-cultural, -economic, and -demographic status.

Lonie et al. examined published abstracts from 1989-1999 of SAS faculty members to determine the extent of behavioral science research by SAS faculty.¹⁵ The authors excluded research papers in a number of areas, including those dealing with pharmacoeconomics, management and pharmaceutical care outcomes. The authors found that the majority of selected behavioral science publications explored topics such as attitudes, beliefs, and perceptions of patients and pharmacists. Medication issues/problems in the elderly were also a major topic. Approximately half the publications focused on pharmacists’ feelings, beliefs, and attitudes toward the profession and potential expanded roles in counseling, job satisfaction, burnout, etc. Most studies were descriptive in nature and few explored the impact of pharmaceutical care interventions on patients, particularly the elderly. There was little or no attempt in any of the selected studies to examine the effect of an intervention on health outcomes

or health risk factors. In recent years, a small number of SAS faculty have received NIH and the Agency for Healthcare Research and Quality (AHRQ) research awards for examining the efficacy of various interventions, including pharmacists' interventions, on the outcomes of drug therapy.

Pharmacoepidemiology is a T2 research area often used to detect adverse reactions, determine adherence to prescribed regimens, and provide evidence as to the effectiveness of alternative therapies. Nwokeji et al. surveyed pharmacoepidemiology education in US colleges/schools of pharmacy, given that ACPE has included pharmacoepidemiology as a required component of the pharmacy professional degree curriculum.¹⁶ For the purposes of the study, pharmacoepidemiology was defined as the "application of epidemiologic reasoning, methods, and knowledge to the study of the uses and effects (beneficial and adverse) of drugs in human populations."¹⁶ Research in this area requires access to large medical databases containing drug prescribing behavior such as those available in some private Health Maintenance Organizations (HMOs) and government agencies such as the Veterans Administration (VA) or Medicaid. Of the 89 (100%) colleges/schools responding to the survey, 83 percent indicated they offered some level of pharmacoepidemiology instruction, and 35 schools indicated they provided pharmacoepidemiology to their MS or PhD students. Examination of 38 college/school websites for graduate programs in SAS or Pharmacy Practice revealed several programs listing pharmacoepidemiology as a focus area for faculty research.

While informatics is not exclusively a T2 research area, the use of digital information in electronic prescriptions, patient records, and drug use patterns complements pharmacoepidemiology research. The AACP Technology in Pharmacy Education and Learning (TiPEL) Special Interest Group (SIG) published an article on "Implementing Pharmacy Informatics in College Curricula," informatics within pharmacy being defined as using digital information to improve pharmaceutical outcomes and student learning.¹⁷ Data management, information acquisition and communication, research of both patient and population-specific outcomes overlap with the area of pharmacoepidemiology. The TiPEL SIG suggests that academic pharmacy strongly consider developing residency programs and graduate degree programs in informatics to insure that pharmacy does not abdicate its role to other health researchers in the emerging area of informatics. Presently, there appears to be one informatics graduate program that addresses clinical and translational research affiliated with a college/school of pharmacy.

Pharmacy Practice departments without SAS faculty members generally do not offer graduate degrees beyond the MS level, but there is considerable interest in education/training and research activity from faculty in this discipline that is classified as T2. Pharmacy Practice faculty engaged in research focused on methods to optimize or individualize therapy based on patient organ function or genetics are involved in T2 research, as are those exploring the impact of various pharmacist interventions in modifying drug therapy. The American College of Clinical Pharmacy's (ACCP) research agenda identified six high-priority research areas, all of which can be characterized as T2 research.¹⁸ These are:

1. Identify and evaluate patient, clinician, and system factors that contribute to the safe and effective use of drugs in clinical practice.
2. Evaluate the effects of drugs on patient clinical, humanistic, and economic outcomes in settings typical of routine clinical practice.
3. Develop and use data repositories and novel population-based methods to identify new indications or uses of drugs, and for identification and confirmation of new adverse events.
4. Characterize general patterns of drug use, and their use in populations not previously studied, to determine their effect on clinical, humanistic, and economic outcomes.
5. Identify and evaluate patient, clinician, and system factors that influence the provision and effectiveness of care provided by clinical pharmacists.
6. Evaluate the effect of pharmaceutical care delivery models and other pharmacy services on patient clinical, humanistic, and economic outcomes.

ACCP has also supported further education in P/OR by developing guidelines for fellowships in these areas of research. The organization and outcomes of these ACCP fellowships were evaluated and judged to be appropriate models to develop expertise in the areas of P/OR needed, particularly in the pharmaceutical industry.¹⁹⁻²¹

Thus, both SAS and Pharmacy Practice faculty at colleges/schools of pharmacy provide instruction or conduct research in areas relevant to T2 research, although some may not be aware that it is categorized under that rubric. The cited studies of pharmacy faculty involvement in research and graduate education in P/OR and social and behavioral research are somewhat dated,^{13,15} but the study results are consistent with the focus areas listed on contemporary pharmacy college/school websites describing graduate degree program focus areas. Practice-based research networks (PBRNs) that specifically utilize

an organized group of practice environments for T2 research is just starting to be undertaken in pharmacy.

The Impact of Social and Administrative Sciences and Pharmacy Practice on T2 Research

There have been and are now, a small cadre of SAS and Pharmacy Practice faculty who are recognized by their peers both inside and outside of academic pharmacy as excellent T2 researchers and contributors to the discovery, understanding, and evaluation of the multiple factors that contribute to patient outcomes from drug therapy. There is a second and somewhat larger group of SAS and Pharmacy Practice faculty known for their T2 research, much of it descriptive, within academic pharmacy and the local or regional practice community, but who are unknown outside of academic pharmacy. The third and largest group SAS and Pharmacy Practice faculty contribute little to the area of T2 research either because their research interests lie elsewhere, they are interested but not prepared to conduct T2 research, or they are not interested in research.

The members of the first two groups of faculty primarily differ in focus and funding of their research. Conducting intervention research requires much more funding than descriptive research. Funds are needed for recruiting patients and/or practitioner collaborators, salaries for personnel to conduct the intervention, and the data analysis. Intervention research may involve graduate students or fellows but cannot be carried out solely by these trainees. Federal agencies are the primary sources for the amount of money required for conducting intervention research. Pharmacy faculty members must convince study sections comprised of scientists from multiple disciplines that they have the expertise and ability to carry out the proposed interventional research study. Assuming the proposed research is addressing a significant health problem, the funding of the proposal will be graded on whether the investigator has the recognized expertise, both educational and experiential to carry it to successful completion. To obtain the requisite expertise, an investigator must focus on a research area that has significance to the public's health, not the profession of pharmacy.

Successfully funded research can and does involve pharmacy and pharmacists, but utilizes pharmacy/pharmacists as a treatment or intervention in an outcomes study, not as the *raison d'être* of the study. Successfully funded investigators are connected and can enlist colleagues as co-investigators or consultants from across their campus and others to significantly improve chances for funding their research proposal and ensure a successful outcome to the research project. Interestingly, many but not all SAS funded faculty received their graduate educa-

tion outside of SAS in one of the disciplines that forms the knowledge base for SAS.

The second group of SAS and Pharmacy Practice faculty are often academically prepared in SAS graduate programs or Pharmacy Practice fellowships, but a reluctance to apply for or an inability to obtain significant funding, specifically to conduct outcomes research, leads them to jump from research area to research area, never developing the requisite expertise needed to obtain significant federal agency funding. In Pharmacy Practice, projects, particularly those funded by the pharmaceutical industry are necessarily designed so that they can fit into the one or two year time frame or a residency or fellowship. As a result, much of the research of this faculty group is descriptive and focuses on aspects of pharmacy practice or pharmacists. These SAS and Pharmacy Practice faculty publish almost exclusively in pharmacy journals, and as a result, their research findings are primarily confined to pharmacy and their disciplinary peers. Their funding comes almost exclusively from pharmacy associations/foundations who are interested in obtaining data to prove the "value" of pharmacy services or pharmacists, or from the pharmaceutical industry which is looking for study results to provide a marketing advantage for one of their products. Some SAS and Pharmacy Practice faculty have obtained state agency funding, often through contract research designed to assist various state agencies improve drug utilization in programs such as Medicaid, and thus have developed expertise in T2 outcomes research.

Federal agencies which fund health-related research are not interested in pharmacists' perceptions/attitudes or the economic well being of pharmacy or pharmacists, as they view the medication use process as primarily controlled by physicians or other prescribers, not pharmacies or pharmacists. However, these agencies are interested in whether pharmacy services or pharmacists' interventions can improve patient outcomes and improve public health. While there are studies that document the value of pharmacy services in managing various chronic diseases and their medications, many of these studies lack control groups (they are simply pre-, post-designs), include numerous biases, do not control for critical potential confounding variables and do not have rigorous clinical trial designs.²²⁻²⁴

The third and perhaps largest cohort of both SAS and Pharmacy Practice faculty are not involved in T2 research. In SAS, many faculty are engaged in research other than T2 because of the breadth of topics that make up this field. Sorofman defined SAS as "... not pharmaceuticals, not medicinal chemistry, not pharmacology, and not clinical sciences—but everything else that makes up the practice of pharmacists, the system of pharmacy in

society (including education), human behavior, social interaction, and the consumption of drugs.”²⁵ Sorofman’s definition of what SAS is not has been oft-quoted, and is used to explain the wide variety of topics taught by SAS faculty in the professional degree curriculum. However, there is a statement from Sorofman’s same presentation that deserves more attention than the “not” definition, given at an AACP Conference on the Future of Graduate Education in the Pharmaceutical Sciences. His charge was to look to the future of graduate education and research in SAS. In discussing the changes occurring in the social/health care environment, science and science education, Sorofman spoke of the need for more interdisciplinary and multidisciplinary approaches in SAS research. To quote:

The analyses of outcomes, whether they are humanistic, economic, and even clinical, of pharmacist practices and pharmacotherapy, and the establishment and evaluation of the structure and function of a health care system including pharmacy are within our domain. There is no question of need for scientists in the Social and Administrative Sciences.²⁵

This would imply that the major focus of SAS in the future is outcomes research broadly defined. While many SAS faculty are involved in outcomes research and studies of the structure and function of the health care system as it relates to patient safety—pharmacy education, assessment of educational outcomes, professionalism, marketing and sales, regulatory/legal affairs, and management sciences remain a significant part of SAS. How SAS can increase its national profile in outcomes-related research, and teach and conduct research in all the other areas presently imbedded in SAS poses a challenge to the field, academic pharmacy, pharmacy practice, and its role in the larger health care system.

With few exceptions, SAS faculty of the 1970s were not interested in assessing the outcomes of the developing practice model of clinical pharmacy. Marketing and management was still a primary focus of SAS graduate programs throughout the 1970s and early 1980s. The discipline that emerged to provide an evidence base to assist pharmacy graduates succeed as small business owners was slow to change its focus as the profession changed from individual to corporate ownership and from its product to patient orientation. The interdisciplinary and multidisciplinary (SAS and Pharmacy Practice) approach to research called for by Sorofman was not and still is not practiced in many colleges/schools of pharmacy today, even when the two disciplines have been combined under the same administrative umbrella, although that now appears to be changing.

ACCP, the association recognized for supporting research in clinical pharmacy issued a research agenda in 2006, “Ensuring Medication Effectiveness and Patient Safety” which is congruent with the focus areas of T2 research.¹⁸ Pharmacy Practice faculty teach and interact with patients at the bedside in acute care facilities, with patients or caregivers in chronic care facilities, and in a variety of ambulatory care clinical environments, including the community pharmacy. The goal of the pharmacist in all these environments is to optimize or individualize patient drug therapy to maximize desired clinical outcomes including quality of life and minimize toxicity or undesirable adverse events. Practicing pharmacists, whether they have an academic appointment or not, could be and should be conducting outcomes research on each and every patient they encounter. However, many Pharmacy Practice faculty do not view “practice” as an environment for outcomes research, nor do they view treating individual patient’s problems as scholarly activity. The result of this separation of practice and the practice site from research or scholarly activity within the Academy has been that pharmacy lacks a large body of rigorous data demonstrating the “value” of various pharmacist interventions on patient outcomes of drug therapy, particularly in ambulatory care. Certainly, pharmacists and academic pharmacy have convinced themselves of the pharmacist’s value, and the profession has made inroads with some states, federal agencies, and private insurers of the value of pharmacist medication management, but pharmacy has not convinced the broader public or organized medicine of the importance of the pharmacist’s role in patient care.

One reason a “gap” exists in the perceived value of patient-oriented pharmacy practice amongst the public and the funders of health care is that the Academy has not done rigorous and appropriate research to demonstrate the pharmacist’s value outside of the profession itself. Why not? In the early 1970s, when clinical pharmacy was emerging, the post-BS PharmD programs of that era focused much of their effort in establishing practice sites and on improving pharmacist-physician interaction, often through the tools of biopharmaceutics and pharmacokinetics, not on pharmacist-patient interactions. The value of pharmacists’ improving drug dosing utilizing the tool of pharmacokinetics had impact on individual patients, but the interventions were often with the prescribing physicians, not the patient.^{26,27} There was little pharmacist-patient outcomes research done on these many studies because the new clinical faculty were not educated and trained to evaluate their then new interventions. The new Pharmacy Practice faculty members required the assistance and collaboration of colleagues who

were interested in the new practice model and had the expertise to evaluate the new and evolving clinical role of pharmacists, but collaborations were infrequent.

A significant factor contributing to the paucity of T2 research by Pharmacy Practice faculty with a PharmD degree is a lack of education, training, and experience to carry out this type of research.²⁸ Students in the PharmD degree program receive limited exposure to research methodology. ECPTF I recommended a change in the accreditation guidelines to address this deficiency in the PharmD program. This deficiency is not remedied by a residency, as most residency programs have either dropped or diminished the research component in lieu of more patient care responsibilities. Faculty with a PharmD degree and residency training could perform research, but most do not. There are examples of SAS and Pharmacy Practice faculty, including those in non-tenure track positions, who have published important T2 research.²⁹⁻⁴⁷ Some of these studies have become some of the most highly cited in the medical literature in recent years.^{30,34} This small cadre of excellent T2 researchers in Pharmacy Practice are the exception, not the rule.^{48,49}

The Future and Importance of Social and Administrative Sciences in T2 Research

Given the importance of T2 research in improving drug therapy outcomes, a primary mission of pharmacy and pharmacy education, why have a significant number of colleges/schools of pharmacy, particularly those with active graduate programs in the pharmaceutical sciences, chosen not to support graduate education and the necessary accompanying T2 research programs in SAS? Compared to the number of institutions that offer graduate degrees in the pharmaceutical sciences, SAS has the least number of PhD-granting programs, the smallest graduate school enrollment and smallest number of PhD graduates of any other pharmaceutical sciences discipline and the smallest amount of research funding.⁵⁰ During the 1990s, the number of PhD degrees granted in either SAS and/or Pharmacy Practice was relatively small, averaging approximately 30 per year.⁵¹ The number of PhD degrees granted from 2000-2006 has averaged 45 per year, only enough to replace those SAS positions presently vacant, those opening up because of retirement and those needed to staff new colleges/schools of pharmacy. That assumes that most SAS PhD graduates would accept an academic position. The majority will probably accept a non-academic position or an academic position in a non-U.S. college/school of pharmacy as approximately 50 percent of recent SAS PhD graduates are foreign students, so some will return to their home countries to faculty or private sector positions.

The large percentage of foreign students comprising graduate program enrollment in PhD programs in all the pharmaceutical sciences is not a recent phenomenon, but the increase in foreign student enrolment is more recent and dramatic in SAS. In 1990, less than 20 percent of the total enrollment in SAS PhD programs consisted of foreign students. Foreign students became a majority in 2002, and in 2006 was 54 percent of total fulltime PhD enrollment, second only to that of pharmaceuticals. The absolute number of US pharmacy graduates enrolled full time in PhD programs in SAS has remained relatively low (approximately 75) but constant from 1990-2005.⁵¹ Thus foreign students have provided most of the enrollment growth in SAS PhD programs over the same time period.

Why are not more US PharmD graduates attracted to SAS, the pharmaceutical sciences discipline whose main goals are the study of all those factors which can influence patient drug therapy outcomes? Certainly, the financial incentives to enter practice upon graduation, coupled with the increasing debt loads of the contemporary student and the relatively low wages of a teaching or research assistantship act as a potential deterrent to entering a graduate program. However, financial considerations alone do not deter thousands of pharmacy graduates each year from entering into residency programs. Is there a perception on the part of PharmD students that graduate programs in SAS are not patient oriented but more focused on database analyses, survey methodology, and policy analyses, making them less attractive to the contemporary professional student? Or alternatively, are the four or more years required for a degree too unattractive in the current environment with high pharmacist salaries?

Unique and critical areas of research which focus on drug therapy outcomes broadly defined are not strongly supported in academic pharmacy, through sufficient faculty numbers and graduate education programs at many of our research intensive colleges/schools of pharmacy. In turn, the lack of a strong research focus and impact in this important area throughout the Academy contributes to a lack of interest in graduate education by US PharmD students. One obvious solution would be to hire more SAS faculty with the hope that this would increase scholarly productivity in the discipline. A common reason given for why SAS has not been more productive in research is too much teaching responsibility and lack of a "critical mass" of faculty. With regards the size of the SAS faculty, the numbers of full-time faculty in SAS who are not deans is approximately 60 percent of the other pharmaceutical sciences such as pharmaceuticals, medicinal chemistry, and pharmacology/toxicology.⁵² The counter argument to increasing the size of the SAS faculty is that the discipline is not effective in attracting research funding, particularly

funding from federal agencies that also provide indirect costs to the institution. External funding is necessary to fund both research and graduate student stipends, as fewer institutional funds are available for those purposes. Therefore, unless the discipline can demonstrate the ability to obtain in more external funding, it will be difficult to support new graduate programs.

The SAS faculty have a legitimate argument that the discipline does not receive the same “support” from the Academy as the other pharmaceutical sciences. For example, start-up funds for a new SAS faculty pale in comparison to the other pharmaceutical sciences, where equipment and lab support now reach a million dollars and \$250,000-\$500,000 is not uncommon. However, a return on investment of start up funds of this magnitude is expected in the form of NIH research dollars. Would larger start-up support of SAS faculty for research assistants result in the same return on investment as is achieved in other pharmaceutical science disciplines? Additionally, financial support for other new pharmaceutical scientists is usually predicated on building up a focus area of the discipline or adding a new research area that is being supported by federal funding. Available federal funding for a research area is now considered in the hiring of new SAS faculty, but given the fact that past funding has generally come from the pharmaceutical industry or state agencies, this was not a common practice. Additionally, other pharmaceutical sciences faculty are often hired after demonstrating the ability to do scholarly work, particularly through multiple years of postdoctoral training. Most SAS faculty move directly from graduate school into an academic position, and unless they have had the ability to publish before completing their thesis, they may spend the first several years in an academic position publishing their thesis project. They often do not experience the chance to practice writing a grant proposal, unless that is a requirement of the graduate degree program. Therefore, in addition to not receiving an equivalent start up package, the new SAS faculty member does not have the research and publishing experience that their colleagues in the other pharmaceutical sciences have accrued through their postdoctoral experience. Combine this with teaching assignments across several years of the curriculum and it is not surprising that scholarly activity gets off to a slow start.

With regards to research/scholarship, SAS faculty research interests have considerable diversity. While this is true in the other pharmaceutical sciences, increasingly these other disciplines have recognized that focusing the department or division in an area of research, with individual faculty bringing in unique expertise and technical skill is highly desirable, particularly for obtaining larger program project grants and common equipment or form-

ing institutes or centers on the university campus with other related disciplines. This does not suggest that every SAS graduate program have a single or identical research focus, but some area of T2 research should be a major focus, particularly as it relates to drug therapy outcomes. This is particularly important as research becomes more multi- and interdisciplinary across the university. If drug therapy outcomes, broadly defined, is **not** a major focus of SAS research, and SAS departments/divisions are **not** viewed as the experts in this most important area of public health, other disciplines in the health sciences such as public health, economics, and medicine will continue to have highest profile in drug therapy outcomes research and pharmacy will continue to have little impact and may not be invited to become part of university or Academic Health Center programs.

To improve pharmacy’s research excellence in the area of T2 research and graduate education, actions will be necessary to increase SAS’s integration into the T2 research community on campus. SAS departments/divisions must view the research expertise sought in new faculty hires from the larger needs of the university T2 research community, not from the immediate teaching needs of the PharmD program. A new SAS faculty member who brings research expertise to the university or academic health center or public health community not just the college/school of pharmacy, can result in joint appointments and the contribution of other university units to salary and start up costs. The impact of this type of hire is increased research collaboration across university units. AHRQ programs such as the Centers for Education and Research in Therapeutics (CERTs) and Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Networks not only require collaboration across the university, but often among different university units and health care facilities.^{53,54} Involving SAS faculty and graduate students in large collaborative research projects is important if academic pharmacy desires to increase its impact in health care research and practice.⁵⁵

With the transformation of the profession away from the pharmaceutical product to the patient, the ultimate goal of providing a body of knowledge to assist pharmacists be more effective and efficient in carrying out their responsibilities to society remain paramount. SAS graduate programs must change to address the new realities of drug therapy and health care.

The Importance and Future of Pharmacy Practice in T2 Research

Pharmacy Practice’s future research goals as identified by ACCP are all essentially T2 in focus and scope, but

the problem facing most Pharmacy Practice faculty is not what type of research to conduct, but how to conduct research. The problems facing outcomes researchers are qualitatively different from those conducting other types of research, but the education and training required for conducting this type of research are no less rigorous. Masters level education and training such as available through the NIH's K23 program will provide some Pharmacy Practice faculty with a larger set of skills to conduct T2 research. For the current PharmD student, in addition to increasing the exposure to research methodology in the professional degree program, Masters degree programs could be offered as part of a concurrent dual degree program within the college/school of pharmacy in SAS or alternatively in a school of public health or public policy if T2 research expertise is not available within the SAS faculty. A full or part-time Masters-level degree program with or without a residency/fellowship following graduation could also provide needed research tools. However, if the pharmacy Academy is going to be a major contributor in the area of T2 research on a national level, there must be a larger number of PharmD graduates educated and trained at the PhD level, either in a PhD program in the SAS or the disciplines found in schools of public health. That means that more PharmD students must be attracted to PhD graduate programs in the SAS.

Given that over one-half of full-time pharmacy faculty are Pharmacy Practice faculty, the most expeditious way to expanding T2 research in academic pharmacy is through increasing the involvement of Pharmacy Practice faculty in research. All full-time Pharmacy Practice faculty should contribute to scholarly T2 research, not just those on tenure track. While many of these faculty will not necessarily be independent researchers, all members of the Academy should be collaborating on such research. This is not simply a matter of adding more requirements for promotion and/or tenure. The future of pharmacy depends on expanding our knowledge base of what works and what does not work in pharmacists' attempts to improve patient drug therapy outcomes. The approach must be multi-pronged given the large number of pharmacy practice faculty, the majority of whom are at the assistant professor level with little or no research or research training experience.⁵⁰ Some new Pharmacy Practice faculty should be encouraged or required to apply for an NIH K23 award, while others can take advantage of courses offered through an institution's CTSA award.⁵⁶ All Pharmacy Practice faculty members should identify faculty either within the college/school's SAS faculty, the school of public health, the college of medicine, or at their practice site to develop a collaborative research program. As noted below, the American Academy of Family Physicians has

been a leader in promoting practice-based research for all Family Physicians, including non-academic practitioners. We believe that all academic pharmacy faculty should be held to similar expectations regarding T2 research. For those Pharmacy Practice faculty who have the academic preparation to conduct outcomes research, the provision of adequate startup funding and reasonable teaching responsibilities in the first several years of their appointment is as important to them as to pharmaceutical sciences faculty. Investment in bridging research support for those Pharmacy Practice faculty who complete a K23, K08, or CTSA-sponsored Master's degree program would also insure that the investment in faculty development through these programs is not wasted.

Educating and Training the Next Generation of Academic Pharmacy T2 Researchers

The source of graduate students for T2 research programs needs to be expanded. Practitioners of T2 research should have an understanding of the drug therapy and disease processes under investigation, and should be aware of the standard tools used for measuring clinical outcomes, or alternatively develop and validate new tools. Studies must be theoretically grounded, rigorously designed and methodologically sound. A pharmacy background would be highly advantageous to an individual interested in conducting T2 research, but graduate programs in colleges/schools of pharmacy which focus on developing T2 researchers should also actively recruit other health professions graduates including physicians, nurses, physician assistants, allied health professionals, and students with backgrounds such as sociology, psychology, and economics.

In hiring new SAS faculty, while the teaching requirement of the PharmD degree program cannot be ignored, an individual with a strong background in T2 research and having an interest in factors which can influence drug therapy outcomes should be competent to address required professional degree competencies. Programs also must look beyond graduates of SAS PhD graduate programs for their new faculty. While an argument can be made that a contemporary professional degree pharmacy graduate who obtains a SAS PhD offers a unique perspective on T2 research, there are few such graduates each year. The other pharmaceutical sciences have always strengthened their research programs by hiring scientists educated outside of colleges/schools of pharmacy. Given that SAS is such a broad field of study with many applied areas of research, it is important that individuals who are educated to conduct research in disciplines such as social science, educational psychology, economics, public health, and epidemiology are incorporated into SAS

graduate faculties to bring new ideas and perspectives to the problems facing health care and pharmacy practice.

The Role of Pharmacy Practice-based Research Networks (PBRNs) in T2 Research

What about the large numbers of Pharmacy Practice faculty who have been practicing in an institutional, ambulatory care, or community pharmacy setting for a number of years? How can academic pharmacy involve these individuals in more research without disrupting their practice sites or add to their heavy teaching loads? One way is to recruit them into participating in the emerging Pharmacy Practice-based Research Networks (PBRNs). Pharmacy PBRNs are organized groups of practitioners which meet a certain threshold in term of practice sites, clinicians, mission, administration/management, community involvement, and communication.⁵⁶ Initially started by American Academy of Family Practice, PBRNs have been recognized for their significant role in improving patient care through their conduct of research on practice in practice.^{1,58} These physicians face the same pressures to see patients, and sometime teach, as do non-tenure track Pharmacy Practice faculty. Private physicians and non-tenure track pharmacy faculty will usually not be expected to be independent principal investigators on T2 research. However, their participation is critical to the success of T2 research. All Pharmacy Practice faculty should be expected to collaborate on T2 research and one outstanding opportunity is through PBRNs.

Practice-based research carried out through organized PBRNs can play an extremely important role in filling the knowledge gap of what happens after a patient receives a diagnosis and is given a prescription. What role do pharmacy-patient, pharmacy environment, patient-insurer, patient-disease, patient-literacy, etc., factors play in the acute and long-term outcomes of patient care? Research on practice factors conducted in practice settings by pharmacists, whether they be full or part-time pharmacy faculty, or practitioners serving as adjunct faculty preceptors will give academic pharmacy an important tool in understanding what practice works best when it comes to obtaining optimal patient outcomes from drug therapy. PBRN involvement is just not for Pharmacy Practice faculty. PBRNs are an excellent venue to form collaborations of SAS and Pharmacy Practice faculty with the larger practice community.

There has been much research on pharmacy practice, but not through organized PBRNs. However, the year 2007 was significant for Pharmacy PBRNs with an AACP-sponsored conference, "Embracing the PBRN Model to Improve the Medication Use Process," and a publication describing the first primary care pharmacist

(PBRN)^{57,58} At the 2008 Annual Meeting of the American Pharmacists Association (APhA), significant programming was devoted to Pharmacy PBRNs, with a number of papers presented at that conference published in the journal of the Association.⁶¹⁻⁶³ Pharmacy faculty have served as Directors of PBRNs and one PBRN has been formed in a national network of primary care clinics throughout the U.S. also directed by a pharmacy faculty member. These are outstanding opportunities for Pharmacy Practice faculty to assist with T2 research. It is not within the scope of this paper to review the PBRN model or explain how these organizations provide opportunities for collaboration between SAS and Pharmacy Practice faculty. The AACP and APhA conferences provide sufficient material to assist those interested in exploring the PBRN model.

RECOMMENDATIONS FROM THE TASK FORCE

1. Research that explores the social, economic, organizational, and clinical factors that influence the outcomes of drug therapy of disease should be a central mission of all colleges/schools of pharmacy.
Note: The AACP 2008 House of Delegates passed the following policy statement recommended by the AACP Board of Directors: *Research that explores the social, economic, organizational and clinical factors that influence the outcomes of drug therapy in prevention or treatment of disease should be central to the mission of all colleges/schools of pharmacy.*
2. Colleges/schools of pharmacy and their SAS faculty should develop strategic partnerships and alliances with Schools of Public Health to enhance graduate program training and research collaborations to enhance their capacity and competitiveness.
3. Colleges/schools of pharmacy should foster strong interdisciplinary research teams that include Pharmacy Practice, SAS faculty and qualified and complementary faculty investigators from medicine, nursing, public health, and other disciplines. The primary focus of these teams should be to obtain federal funding to conduct research in an area of expertise of the team and to provide funding for graduate students.
4. SAS and Pharmacy Practice faculty should develop the expertise in an area of T2 research such that they can lead interdisciplinary research teams and submit competitive applications for federal funding.

5. Pharmacy Practice PharmD full time faculty must take advantage of NIH K08 or K23 Career Development Awards (or VA Health Services Research & Development (HSR&D) mentored awards).
6. SAS Faculty at colleges/schools of pharmacy with graduate programs should be expected to pursue individual investigator awards either as a PI or co-PI from AHRQ or the NIH.
7. Every college/school of pharmacy at an institution that has, or is planning for a CTSA must be integrated into the training and research components of these awards.
8. Colleges/schools of pharmacy should identify junior clinical faculty who can enter research training programs (e.g. CTSA or K23) and require them to apply for an award within the first three years of their appointment. If possible, the tenure clock, if it applies, should be suspended during the award period.
9. Colleges/schools of pharmacy must increase professional student competencies in T2 research. ECSTFII reaffirms the recommendation of the ECSTF I that all students must receive appropriate training in T2 research and supports a new ACPE standard in this regard.
10. All Pharmacy Practice faculty, including non-tenure track, should be involved in T2 research either as a co-investigator or participating practitioner in a practice-based research network. Note: The AACP 2008 House of Delegates passed the following two policy statements recommended by the AACP Board of Directors:

AACP and colleges/schools of pharmacy should promote pathways of faculty development that enable pharmacy faculty members, including non-tenure track faculty, to lead and/or participate in practice-based translational research.

AACP and colleges/schools of pharmacy should promote pathways of faculty development and the requisite infrastructure for research that enable faculty members to lead or participate in practice-based research networks.

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