ACCP

Characterizing the American College of Clinical Pharmacy Practice-Based Research Network

Jacqueline S. Marinac, Pharm.D., and Grace M. Kuo, Pharm.D., M.P.H.

Study Objective. To present the member registry survey methods and characterize the first national clinical pharmacy practice-based research network (PBRN).

Design. Cross-sectional online survey.

Setting. A national clinical pharmacy association.

Participants. American College of Clinical Pharmacy (ACCP) full and associate members, integrated health system groups of pharmacists, and existing PBRNs were invited to participate in the registry and complete the survey.

Intervention. An association-wide invitation to join the ACCP PBRN was sent to ACCP members who were actively involved in direct patient care or who had access to a patient base for research purposes. Interested pharmacists completed a three-part online survey regarding professional background, practice site, and clinical pharmacy practice.

Measurements and Main Results. A total of 416 members completed the online registry. These pharmacists practice at 263 distinct clinical sites in 43 states. Forty-six percent of the sites were located within a university hospital, and 30% were within a community hospital setting. Of those working in these two hospital settings, 33% and 40%, respectively, practiced within an outpatient clinic. The ACCP PBRN member pharmacists spent an average of 5 half-days providing clinical pharmacy services and saw a median of 30 patients/week. The most common laboratory tests ordered by member pharmacists were metabolic panels, prothrombin times or international normalized ratios, liver function tests, and blood glucose levels. The most frequently managed conditions or disease states were pharmacotherapy and/or polypharmacy, anticoagulation, diabetes mellitus, and hypertension. Almost two thirds of the pharmacists used an electronic medical record system. Thirty-five percent operated with the use of collaborative practice documents within their sites, whereas 32% had scope of practice agreements. Ninety-five percent did not bill for clinical pharmacy services rendered.

Conclusion. The ACCP PBRN is the first national clinical pharmacy PBRN. Its membership has a distinctive profile of primary care and specialty clinical pharmacists who work both within inpatient and outpatient settings. Both internal and external stakeholders are expected to use these ACCP PBRN registry data to support the capabilities and capacity of the ACCP PBRN.

Key Words: practice-based research, registry, clinical pharmacy.

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The history and role of practice-based research networks (PBRNs) in physician-based primary care research settings have been well described.[1, 2] According to the Agency for Healthcare Research and Quality (AHRQ), PBRNs are groups of primary care clinicians and practices working together to answer community-based health care questions and translate research findings into practice. PBRNs engage clinicians in quality improvement activities and an

evidence-based culture in primary care practice to improve the health of all Americans.

In 1992, U.S. government legislation (Public Law 106-129) directed the AHRQ to link research to clinical practice by including the use of PBRNs in primary care. Growth in the number and type of PBRNs has continued, with more than 100 primary care research networks registered with AHRQ's PBRN Resource Center, currently located at the University of Minnesota.[3] Pharmacist networks are eligible to be registered as an affiliate network with the AHRQ Resource Center.

It is important to characterize the practices, sites, and clinicians in addition to the patient population when conducting PBRN research. PBRNs are formed by combining groups of clinicians around a set of shared characteristics. Many PBRNs are geographically defined (e.g., national, statewide, regional, rural), whereas others, such as the American College of Clinical Pharmacy PBRN (ACCP PBRN), are discipline related (e.g., primary care providers, nurses, dentists, pharmacists), and some are disease- or population-specific (e.g., human immunodeficiency virus [HIV], pediatrics). Irrespective of the type of network, all provide a community-based setting for research studies and ideas.

In mid-2008, the Board of Trustees and the Board of Regents at ACCP charged the Research Institute to create the first national clinical pharmacy PBRN. Several pharmacist-based PBRNs have sprung up in the United States in the past 10 years. At the time of writing, only the *Virginia Community Pharmacy Education and Research Network* is listed on the AHRQ Web site as an affiliate network.[3] Unlike the ACCP PBRN, that network is composed of community pharmacy practice sites. Thus, the ACCP PBRN represents the first large, national, multi-specialty clinical pharmacy based PBRN in the United States.

The described mission of the ACCP PBRN is "to facilitate collaborative research that promotes the safe, efficacious, and cost-effective use and delivery of medications and clinical pharmacy services." The vision for the ACCP PBRN is to be recognized as one of the premier PBRNs in the nation within its defined research focus. Furthermore, the ACCP PBRN research focus will align with the ACCP strategic plan and will be recognized as the premier facilitator of clinical pharmacy PBRN research. This facilitator role will include promoting collaborative efforts between other pharmacy organizations as well as between other national and local PBRNs.

The goal of the ACCP PBRN registry was to develop a comprehensive descriptive database of participating clinical pharmacists, practices, and patient populations. Furthermore, the registry sought to comprehend the health information technology and institutional review board (IRB) support within these database systems. This information is critical for directing the selection and suitability of potential studies presented to the network as well as for defining the ACCP PBRN's capacity for such projects. The objectives of this study were to determine the characteristics of ACCP PBRN members, their practice sites, and the patients they serve in order to direct future projects and define capabilities for both internal and external stakeholders. This analysis describes the initial phase of the registry database.

Methods

Eligibility

The criteria for membership in the ACCP PBRN were (1) ACCP membership, (2) provision of direct patient care or access to patients for research purposes, and (3) voluntary entry of registration data online. For registry purposes, clinical services were defined as time spent in the provision of patient-focused care. Pharmacists were instructed not to include time spent in administrative, classroom, or dispensing functions. Existing PBRNs or large, integrated health systems were invited to join as groups of clinical pharmacists. More than 200 additional pharmacists belonged to these group registra-tions. However, because the data elements of the existing or integrated health systems registry varied considerably from the individual registry tool, only the individual pharmacist registry data were included in this analysis.

Survey Development

The registry survey was designed to meet four objectives: (1) describe the characteristics of the clinical pharmacists participating in the network, including the site and scope of their clinical practice; (2) identify the information technology use and research capacity of the sites; (3) identify the therapeutic categories or disease states related to the scope of clinical pharmacy services and subspecialties within the network; and (4) connect

From the American College of Clinical Pharmacy, Lenexa, KS (Dr. Marinac) and the Skaggs School of Pharmacy and Pharmaceutical Sciences and the School of Medicine, University of California, San Diego, CA (Dr. Kuo).

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For reprints or questions, contact Jacqueline S. Marinac, Pharm.D., Director, Research Institute, American College of Clinical Pharmacy, 13000 West 87th Street Parkway, Suite 100, Lenexa, KS 66215; e-mail: jmarinac@accp.com.

in a meaningful way with the clinical pharmacists, providing them perspective on how they compare within the overall network.

In constructing the survey instrument, the ACCP Research Institute conducted a literature and online review of the methods used to describe other networks (clinicians, practices, and patients) and found considerable variation, ranging from only a few items to those several pages in length. Other pharmacy PBRNs were contacted, the representatives of which provided feedback on this registry tool.[4] With input from ACCP members, ACCP PBRN investigators developed a registry instrument and divided it into three domains: clinical pharmacist demographic information, site-specific information, and clinical practice information.

The survey tool consisted of 35 items related to practice ownership, location, use of health information technology, use of collaborative practice agreements, billing for services, subspecialty area, practice description, scope of practice, site location, affiliation with academia, and insurance status of patients; demographics of the patients treated were also collected. Members who practiced at more than one site were encouraged to register with both sites and enter practice-specific information within the tool.

The survey tool was loaded onto the ACCP Research Institute Web site. Completion of the registry tool using the online data collection tool was a requirement for membership in the ACCP PBRN. Online completion was required because the ACCP PBRN envisioned functioning as a paperless PBRN, with all study documentation and data capture performed using an electronic Web-based format.

Data Collection

Initial testing of the survey tool was performed between December 2008 and February 2009 using factitious data with select ACCP members. Based on feedback from the test group of more than 30 clinical pharmacists, the tool was modified and reevaluated. This study was approved by the University of California–San Diego Human Research Protection Program. After notification of IRB approval, the registry was officially launched to the membership in late February 2009. Members who registered with the ACCP PBRN were given the opportunity to opt out of having their data included in this aggregate study.

ACCP members were invited to join the registry by e-mail list, the *ACCP Report* newsletter, direct communications at ACCP national meetings, and print media. Between February and December 2009, ACCP members were encouraged to join the registry and enter data online. PBRN research requires an effective means for two-way communication between the members and the leadership. Thus, a unique ACCP PBRN e-mail list was created for members to communicate with one another, and a group e-mail was created to ensure that communication from members was sent to all who were part of PBRN leadership. This provided an effective means by which the ACCP PBRN could respond to technical assistance questions, items needing clarification, and reminders. The registry and this communication structure will remain open.

Data Management and Statistical Analysis

All submitted online data were reviewed for completeness. Only data from member pharmacists who consented to be in the registry study were included in this data analysis. StataSE version 10.0 (StataCorp LP, College Station, TX) was used to generate descriptive statistics for all data. Data are reported as the mean (± SD), where appropriate. When the mean values have a large standard deviation, the median and range are also presented. The percent total is indicated only for the mutually exclusive selections.

Results

Pharmacist Information

A total of 416 clinical pharmacists completed the registry, 95% of whom were current ACCP members. They averaged 9 ± 7 years (median 8 years [range 0–32]) years from the completion of their terminal degree. Sixty percent were currently involved in clinical research as an investigator, sub-investigator, or study coordinator. For those not currently conducting research, the mean number of years since the member had been involved in human research was 1.8 ± 2.

Fifty-one percent (n=214) had been principal investigators, and 67% (n=277) had been co- or sub-investigators at some time during their career, 19% operated as a study coordinator, and 73% reported they had research experience as a student or resident. Five percent had no research experience of any kind. With specific respect to human subjects' research experience, 60% of ACCP PBRN members reported having clinical research experience, and 60% reported prior practice-based research experience. Industry-sponsored research (phases I–IV) experience was reported by 30% of respondents, with 38% having been involved in behavioral/educational/ survey research at one time

in their career. Four percent had other research experience. Only 8% stated that they had no human subjects' research experience. Almost three of every four had completed human subjects' research training, with 64% reporting completion of their training in either 2008 or 2009.

Clinical Sites

ACCP PBRN members in this study practiced at 263 unique clinical sites in 43 states (see Figure 1). Ninety-five percent of the practice locations were in an urban setting. For this study, urban was defined as communities having 50,000 or more people and their adjacent and contiguous urbanized areas using the U.S. Census Bureau standard.

ACCP PBRN clinical pharmacists may provide services at more than one practice site; therefore, respondents were asked to register any site they wished to use as a future research site. For example, a pharmacist may provide clinical services during hospital rounds and work at an outpatient clinic within the same health system. Thus, the percentage of pharmacists who worked within any specific area (i.e., either inpatient or outpatient settings) may total more than 100%.

With respect to the 263 sites registered, 76% were located within a university hospital or community hospital setting or system. As previously noted, this does not mean that 76% of the ACCP PBRN members worked in an inpatient setting; rather, it means that roughly three of every four ACCP PBRN members practiced within a hospital-affiliated system (for example, an integrated delivery system) (see Figure 2). For those who reported working in a university-affiliated hospital setting, 74% worked at an inpatient site and 51% worked at an outpatient site. For those based in a community hospital setting, 81% worked in an inpatient setting and 38% in an outpatient setting.

Almost two-thirds (65%) reported using an EMR (electronic medical record system). Regarding patient charts, 7% used paper charts only; 23% described their site as "totally paperless" with respect to charting, billing, coding, and outside reports; and 70% stated that their site used a hybrid system of electronic media and paper. Specific

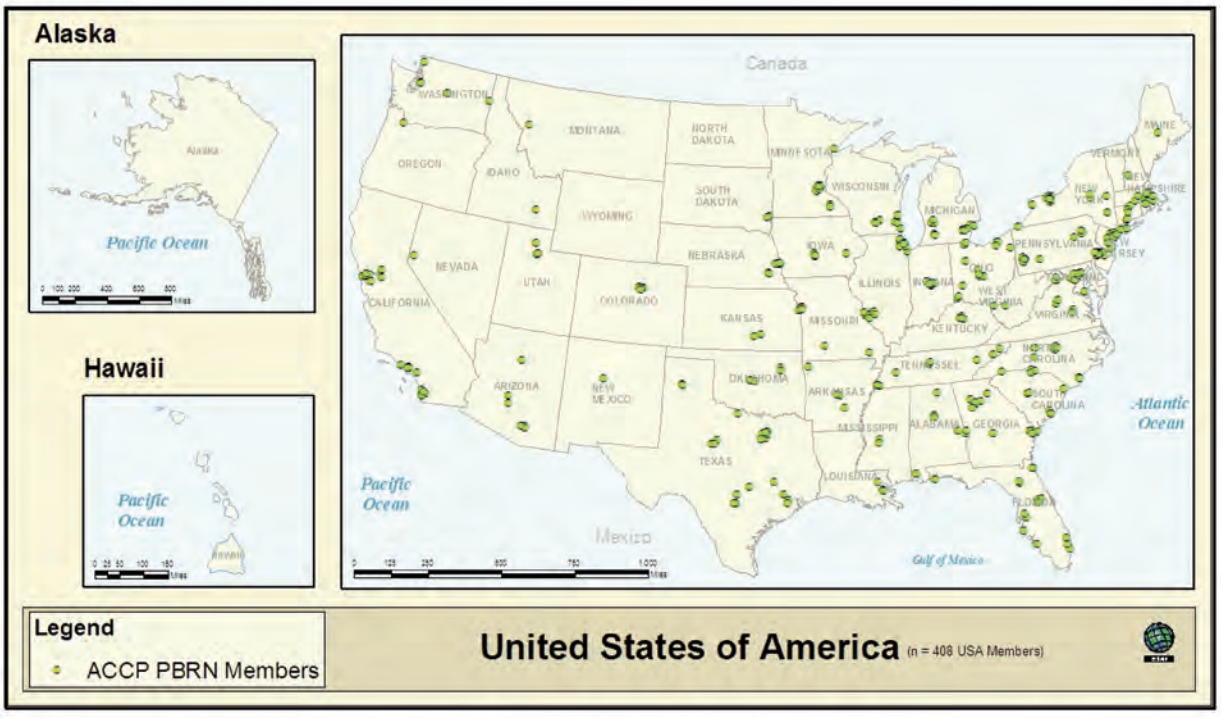

Figure 1. Geographic distribution of ACCP PBRN member locations (n=408). Source: Data produced using Tele Atlas North America, Inc., ESRI, Redlands, CA

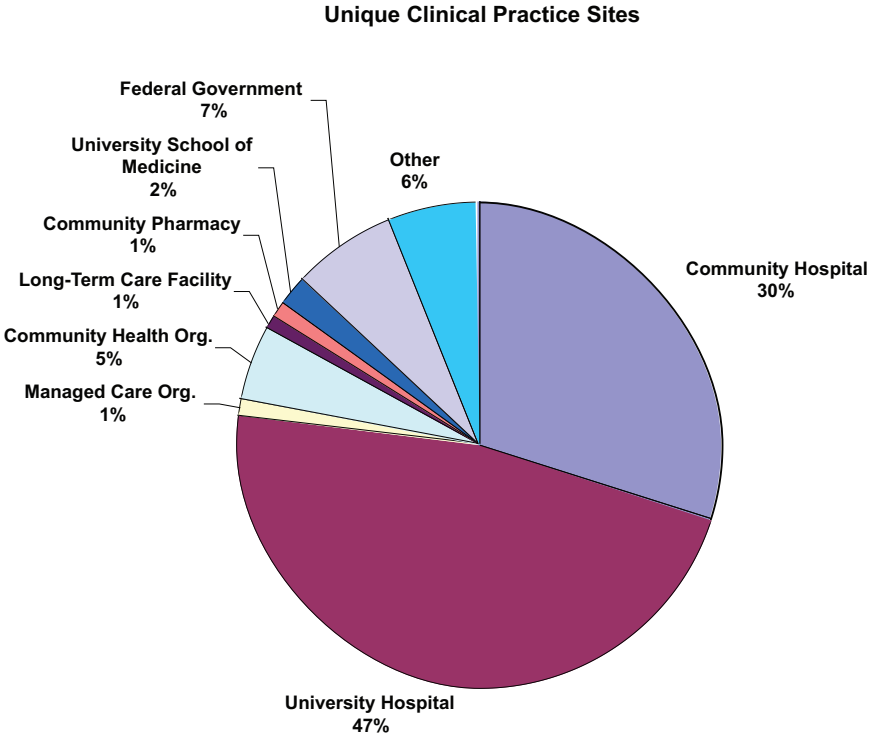

Figure 2. Percentage of ACCP PBRN members working at a practice site

computer and software capabilities accessible to the clinical pharmacist within the clinical setting included e-mail access (92%), word processing (90%), Internet access (92%), and fax capabilities (73%).

Members were asked to provide the names and addresses of their local IRB. Furthermore, they were queried whether their site would defer IRB approval to a central IRB. Fourteen percent reported that their site would accept central IRB approval; however, 54% did not know whether their site would accept central IRB approval. The tool did not offer respondents the option of "conditional acceptance" of a central IRB. That is, in certain situations, some IRBs will defer to another IRB, and at other times, they will not. This may account for the unusually high "did not know" response.

The most common patient payment methods at the 263 sites were private health insurance 21%, Medicare 19%, uninsured 18%, Medicaid 16%, and "other" 38%.

Clinical Practice Information

The registry was open to all current ACCP members providing direct clinical pharmacy services or having access to patients for research purposes. A total of 344 unique practices were identified. Because members may practice at the same institution (i.e., hospital site) but work in two different clinics or locations within that site, the number of clinical practices did not equal the number of sites. Furthermore, the types of patients and thus patient-related services they provided within each setting could differ. When queried, 83% reported having direct patient care responsibilities within that practice site; 15% had no direct patient care responsibilities.

ACCP members are invited to belong to PRNs (practice and research networks) when they become members of the professional organization; these groups are similar to the special interest groups that might be present within other organizations.

Participation in a PRN is voluntary, and ACCP members may belong to more than one PRN. Figure 3 lists the PRN membership of ACCP PBRN members. The most common areas of specialty associated with ACCP PBRN members in the survey were ambulatory medicine, critical care, infectious disease, cardiology, and adult medicine.

On average, the ACCP PBRN pharmacist spent 5 ± 2 half-days each week (median 5 half-days [range 0–14] providing clinical pharmacy services. Seventy-six percent saw adult patients, whereas 9% worked with pediatric patients. ACCP PBRN members saw an average of 42 ± 42 (median 30 [range 0–300]) patients each week. The ACCP PBRN clinical pharmacist spent an average of 16 ± 22 hours (median 10 [range 0–120] each week in collaborative care with a physician, 13 ± 16 hours (median 10 [range 0–100] precepting students, 5 ± 11 hours (median 2 [range 0–100]) in curbside consultation with a physician, and 6 ± 16 hours (median 0 [range 0–100]) in independent patient management. On average, these clinical pharmacists spent 6 ± 9 hours (median 4 hours [range 0–50]) each week performing administrative duties and 4 ± 7 (median 2 hours [range 0–50]) hours conducting research within their practice settings. Only 40 pharmacists (less than 10%) reported having any medication dispensing duties. Of those, the average number of hours spent dispensing each week was 1 ± 5 (median 0 hours [range 0–40]).

When asked to estimate the ethnicity of the patients under their direct care, ACCP PBRN members reported that 79% were non-Hispanic or non-Latino and 21% were Hispanic or Latino. Regarding the race of these patients, 59% were white, 29% African American, 9% Asian, 2% Native American, and 2% Hawaiian or Pacific Islander.

ACCP PBRN members were asked to identify laboratory tests they routinely performed or ordered. They were asked to exclude tests in which their role was interpretation of results only. Most often cited were metabolic panel 45%, PT/INR (prothrombin time/international normalized ratio) 38%, liver function tests 38%, and blood glucose 33%. Other less commonly cited tests included lipid profile (28%), hemoglobin A1c 27%, other 26%, urinalysis 23%, and HIV testing 4%. The most frequently managed medical condition or disease states treated by these ACCP PBRN pharmacists were pharmacotherapy/polypharmacy, anticoagulation, diabetes mellitus, and hypertension (see Figure 4).

Thirty-five percent operated with the use of collaborative practice documents within their sites, whereas 32% had scope of practice agreements. Ninety-five percent did not bill for the clinical pharmacy services rendered. Of the 5% who did bill for their clinical services, six billed for less than $10,000 in 2008, seven billed for between $10,000 and $30,000, and three billed for amounts above $30,000.

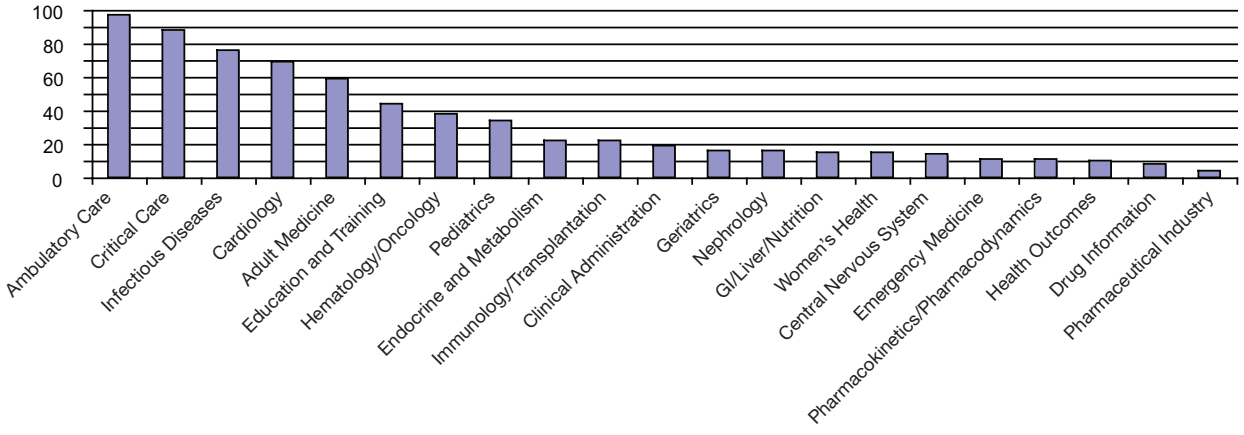

Figure 3. ACCP PBRN membership by Practice and Research Network (PRN)

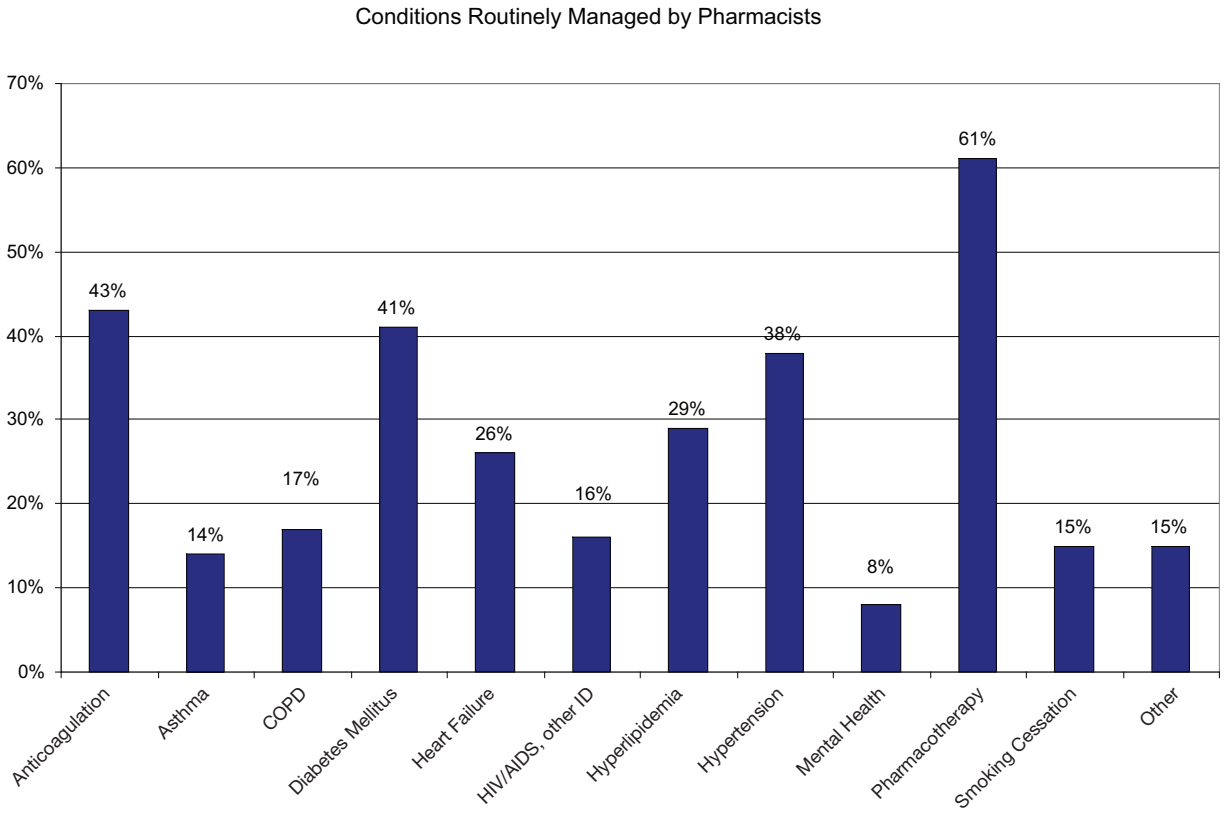

Figure 4. Percentage of ACCP PBRN members who routinely manage common medical conditions.

Discussion

PBRNs play an integral role in providing health and wellness information, influencing patient care management, and providing practice norms within PBRN member communities. PBRNs are recognized by the National Institutes of Health (NIH) Roadmap Initiative as an effective tool to overcome the roadblock of translating efficacy and effectiveness studies into action at the community practice level.[5] The NIH Roadmap Initiative has provided financial support to Clinical and Translational Science Awards (CTSAs), and some CTSAs have effectively integrated PBRNs into their models.[6] The goal is that, with the increased collaboration between PBRNs and CTSAs, research findings will rapidly move into clinical and community practice settings. In a recent survey published by Fagnan and colleagues,[7] it is reported that CTSA and PBRN directors view the potential to build lasting and rewarding relationships in a favorable light. However, the authors note that whether these relationships will meet the expectations of both partners remains to be seen.

Working in conjunction with stakeholders, the ACCP PBRN's purpose is to advance the long-range strategic imperatives and mission of the ACCP College and Research Institutes, which will enhance the visibility and recognition of clinical pharmacists as vital practitioners and researchers. A robust description of the practices and clinicians in a PBRN provides several important benefits:

1. It offers a fundamental descriptive analysis of the network for granting agencies and internal and external stakeholders, including academic and government partners, research partners, other PBRN communities, and patients.
2. It provides an understanding of the structure and capacity of member practices for research.
3. It develops a connection with member practices and clinicians and the network infrastructure.

The goal of this registry description is to fulfill the capabilities necessary for the ACCP PBRN to

respond to a future task order of the AHRQ. In the past, the necessary capabilities were as follows:

1. There was a core of *at least 30 ambulatory practices and/or 50 clinicians* devoted to the primary care of patients.
2. Most practices were located in the United States, and the network had to have its headquarters in the United States.
3. The network had an accepted written statement of its purpose and research *mission*, which included an ongoing commitment to undertake research endeavors that transcended a single study.
4. A *director* was identified who was responsible for most administrative, financial, and planning functions.
5. The director was, or would be, supported by a *staff* of at least one person.
6. The network was required to have *immediate access to consultants* with expertise in areas such as biostatistics, research methodology, and clinical quality improvement.
7. The PBRN had in place *multiple systems of communication* with and among participating practices in the form of regularly produced newsletters, e-mail lists, conference calls, and/or face-to-face meetings of various combinations of network members.
8. The PBRN could document the completion of *at least one publishable research study* that involved primary data collection within the network. With this manuscript, the ACCP PBRN has successfully demonstrated its capabilities to work within the PBRN marketplace.

The makeup of the ACCP PBRN registry represents a unique niche within the PBRN enterprise as the only national clinical pharmacy PBRN in the United States with more than 400 individual members nationwide practicing at more than 200 sites and 43 states. There is no central registry to list all the pharmacist-led PBRNs in the United States. A 2007 article by Dickerson and colleagues[8] describes the formation of a primary care pharmacist PBRN. Pharmacists in that PBRN spent their time performing direct patient management and had collaborative practice agreements with physicians, like the ACCP PBRN. The authors report recruiting 81 pharmacists from 48 primary care practice sites in 11 states to join the PBRN. To our knowledge, their work is the only other published description of a clinical pharmacist PBRN.

The registry is the first large-scale documentation of what ACCP PBRN clinical pharmacists do on a daily basis around the country. As a group, ACCP PBRN pharmacists are experienced clinicians and researchers. Virtually all have had some research experience, with about half having held principal investigator status. They are typically 9 years out from their terminal degree. Around two-thirds of them practice within a hospital setting (either academically affiliated or non-academic), with a slight majority working within an inpatient clinical site. Furthermore, unlike most of the PBRNs listed on the AHRQ site, the ACCP PBRN is not limited to primary care providers. This PBRN thus represents a unique niche within the PBRN community. The ACCP PBRN has the diversity of membership and numbers of investigators to address questions of both inpatient and outpatient relevance. To our knowledge, this is the only large-scale PBRN with a national base of both inpatient and outpatient pharmacist members.

Perhaps of more interest than the practice site location of ACCP PBRN members is the area of specialty or interest. Although not all ACCP PBRN members report belonging to a practice subspecialty, the results shown in Figure 3 deserve additional comment. The ACCP PBRN has members who practice in traditional primary care areas such as ambulatory care, pediatrics, and adult medicine; however, it also has a large cohort of specialists within areas such as infectious disease, cardiology, and critical care. Thus, the ACCP PBRN has the additional capability of addressing disease-specific as well as site-specific types of questions.

ACCP PBRN clinical pharmacists perform a variety of duties in various practice settings. They spend about 20 hours/week providing direct patient care, 6 hours/week in administrative duties, and about 4 hours/week in research pursuits. ACCP PBRN members are also involved in precepting students, with about 1.5 days/week devoted to educating future health care providers.

On average, ACCP PBRN clinical pharmacists treat 42 patients (median 30 patients [range 0–300]) per week. Thus, ACCP PBRN registrants provide clinical pharmacy services to more than 17,000 patients every week. ACCP PBRN members provide clinical pharmacy services in more than 800,000 patient encounters each year.

According to the 2000 Census, Latinos comprise 12.5% of the population. With respect to race, it was estimated that whites comprise 75.1% of the U.S. population; blacks or African Americans, 12.3%; Asians and Pacific Islanders, 3.7%; and Native Americans, 0.9%.[9] The demographic distribution of the patients served by ACCP PBRN members roughly reflects U.S. racial and ethnic norms, and most practices are within urban areas.

Very few ACCP PBRN clinical pharmacists spend time in the dispensing arena: less than 10% have any dispensing duties. Of the 40 ACCP PBRN pharmacists who do dispense drugs, each spends less than 2 days a week dispensing prescriptions. By contrast, about 60% of new U.S. Pharm.D. graduates go directly into primary dispensing jobs at community pharmacies—from big chains to small independent stores.[10] ACCP PBRN clinical pharmacists typically do not work in community pharmacy settings. ACCP PBRN pharmacists are more likely to be in affiliation with a university or community hospital than in a community pharmacy setting.

Within the clinical arena, more often than not, clinical pharmacists work in collaboration with a physician or perform curbside consultations. About one-third of ACCP PBRN member pharmacists work under the umbrella of collaborative care agreements; very few pharmacists are directly reimbursed for the clinical services they provide.

Limitations

Although the registry data provide the largest single snapshot of the professional life of a U.S. clinical pharmacist, the findings have limitations. One limitation of using self-reported survey tools such as the ACCP PBRN registry tool is that no mechanism exists to independently verify the validity of the data entered. Networks consist of self-selected members, and not all clinical pharmacists agree to participate. This has implications for selection bias, particularly in studies such as this in which the clinical pharmacist or the practice is the subject of study. The recruitment of ACCP members into the ACCP PBRN, as well as into subsequent research studies, depends on members' interest and willingness to contribute to research.

Conclusion and Future Direction

Working in conjunction with stakeholders, the purpose of the ACCP PBRN is to advance the long-range strategic imperatives and mission of the ACCP College and Research Institutes. The ACCP PBRN registry survey method provides a clinical pharmacist context as well as a practice context for describing the settings of ACCP PBRN members within the first nationwide clinical pharmacy PBRN. This registry description is an important step for the ACCP PBRN, the membership of which represents a unique laboratory for research within the PBRN community. The ACCP PBRN has the diversity of membership and numbers of investigators to address questions of both inpatient and outpatient relevance within clinical pharmacy. In addition, the ACCP PBRN possesses a cohort of both primary care and specialty clinical pharmacists across the country.

The vision for the ACCP PBRN is that it will be recognized as the premier facilitator of clinical pharmacy PBRN research. This will include promoting collaborative efforts between other pharmacy organizations and between other national and local PBRNs, industry, foundations, and federal granting agencies. The survey instruments of the ACCP PBRN will be offered for use by other pharmacy networks to facilitate cross-network comparisons. Ultimately, the goal of the ACCP PBRN is to enhance the visibility and recognition of clinical pharmacists as vital practitioners and researchers while promoting the safe, efficacious, and cost-effective use and delivery of medications and clinical pharmacy services.

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