Practice-Based Research: Lessons from Community Pharmacist Participants

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We designed this project to determine community pharmacists' opinions regarding the challenges and motivations of their recent participation in a pharmacy practice-based research study. At the conclusion of a randomized, multicenter study, 87 community pharmacist-investigators were sent a questionnaire that explored four areas: motivating factors to participate, barriers to participation, communication tools used by study coordinators, and design issues for future studies. Fifty-eight (67%) completed questionnaires were returned. Key factors motivating participation in the study were desire to improve the profession and opportunity to learn. Time was the greatest barrier to participation. Pharmacy practice-based research has two distinct advantages. First, it translates clinical knowledge into direct application in the community. Second, it provides needed data to demonstrate the value of enhanced pharmacy practice. Thorough understanding of pharmacists' opinions is necessary to optimize the design of future studies.
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More than a decade has passed since the introduction of the concept of pharmaceutical care[1] and the potential benefits of an enhanced level of practice by pharmacists. The past decade presented many new opportunities for pharmacists to increase the capacity of their practice. This expanding role resulted from considerable effort by pioneers in the profession. Tremendous opportunity remains to explore larger roles for pharmacists in contemporary health care systems. A secondary, albeit still important, hurdle to overcome is the reimbursement of pharmacists for nondispensing activities.[2, 3]

In an era of evidence-based decision making, the expansion of the professional role may be facilitated by strong evidence that an enhanced level of practice leads to improved health outcomes for patients. If we liken this situation to that of decisions regarding drug therapies, such evidence should be in the form of randomized controlled trials with rigorous design.[4, 5] Given the recognized importance of

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strong clinical and pharmacoeconomic evidence for pharmaceutical products before approval for formulary listing, it would be incongruous to expect policy decisions regarding the pharmacist's role and reimbursement to be made in the absence of equally robust evidence.

To that end, research focused on the expanding practice of pharmacy has increased over the past decade. A body of both theoretical and empirical research has examined the benefits of pharmaceutical care activities. Empirical data, however, were largely limited to retrospective reviews or uncontrolled, prospective studies of short duration or with limited numbers of patients on inpatient wards,[6–9] or to hospital-based ambulatory clinics.[10–15] Because few pharmacists practice in institutional settings and most people who benefit from pharmacy services are in the community, evidence of the impact of pharmacists' interventions in community pharmacy settings must be generated.[16]

Since 1993, several large-scale, multicenter studies in ambulatory clinics or community pharmacies have been conducted.[5, 17–23] One review examining the impact of pharmaceutical services in community and ambulatory care settings suggests that pharmacists can affect the health care system by means of patient counseling and physician education.[24] Another review suggests that pharmacists can improve detection and significantly reduce the impact of drug-related problems.[25] Although it is unclear whether patient health outcomes may be affected, evidence supports the assertion that these enhanced services likely can result in reduced health care use and substantial cost savings.[23, 26–30] Reviews of pharmacy practice evaluations suggest that well-designed studies with many subjects are necessary to clearly establish the impact of pharmaceutical services on patient outcome.[16, 24, 25] The application of methods developed for large multicenter clinical trials[4] could be applied to the naturalistic practice setting to generate stronger evidence for the efficacy, effectiveness, and efficiency of enhanced pharmacy practice interventions.[5]

Most pharmacists in community practice have had limited exposure to clinical research methodology. Academic researchers may go to great lengths to design rigorous experimental studies, but taking that research to the field requires active participation of pharmacy practitioners. For this interaction to benefit the profession, a clear and mutual understanding of the issues and expectations of both groups is needed. Lack of understanding about important methodologic components of study design by pharmacy practitioners may reduce internal validity of study results. Furthermore, when academic researchers lack awareness of issues and challenges facing practicing pharmacists, the result can be frustrating for both parties. In both cases, execution of the study may be jeopardized, resulting in less than optimal outcomes.

Despite this and the rapid growth in pharmacy practice-based research, surprisingly little literature addressed the attitudes and opinions of pharmacists regarding involvement in practice research; a literature search identified only three articles on the topic.[31–33] Whereas certain barriers to participation might be predictable, such as confidence, motivation, and logistic issues of workload,[34, 35] little evidence indicates the degree to which these factors affect participation in practice-based research.

The Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP), a large-scale, multicenter, randomized trial of community pharmacist intervention in cholesterol risk management, provided an opportunity to evaluate pharmacy practice research from the perspective of the community-based practitioner. Study design and description of services provided in SCRIP are published elsewhere.[5] Briefly, SCRIP was a randomized, multicenter trial designed to evaluate the efficacy of a community pharmacist program of cholesterol risk intervention in patients who are at high risk for cardiovascular disease. Eligible patients were randomly assigned to receive either intervention or usual pharmacy care. Intervention consisted of a pharmacist-led interview to identify modifiable and nonmodifiable cardiovascular disease risk factors, a point-of-care cholesterol assessment, education on heart disease and risk factors, and instructions to visit their family physician for further risk-factor assessment. A single-page form containing the patient's risk factors, as well as total cholesterol and blood pressure levels, was faxed to the patient's family physician. Usual pharmacy care was defined as provision of a heart-disease brochure and usual pharmacy services from each center.

Fifty-four community pharmacies from Alberta and Saskatchewan, Canada, participated in SCRIP: 37 in large urban centers (Edmonton, Calgary, and Regina), 8 in smaller urban centers, and 9 in rural areas. Of the 54 pharmacies, 34 belonged to a chain and 20 were operated independently. The planned enrollment for

SCRIP was 1000 patients, with 500 in each treatment group.[5] Participating pharmacies were asked to recruit 25 patients each; suggested recruitment rate was one patient/week. At this rate, the recruitment goal was anticipated to be achieved approximately 6 months after the pharmacy entered the study. The first patient was enrolled during spring 1998.

During winter 1999 an external data and safety monitoring committee reviewed the data and recommended early termination of SCRIP because of striking benefit of the intervention program. At the conclusion of recruitment, 675 patients had been enrolled, with 7 (13%) pharmacies reaching the recruitment goal of 25 patients (Figure 1). Overall, an average of 12.5 patients were recruited by each of the 54 SCRIP centers; however, this figure ranged from 1–40 patients/center. Although not all centers started at the same time, the 2 years required to recruit 675 patients was longer than anticipated.

Discussions with other researchers leading large, multicenter, pharmacy practice-based research studies suggested that our experience in SCRIP was not unusual. Therefore, our purpose was to determine community pharmacists' opinions regarding the challenges and motivations regarding their recent participation in a pharmacy practice-based research study.

Methods

A survey of participating pharmacists was conducted during the closeout phase of the main study. During spring 2000, approximately 1 month after the final investigator meeting, questionnaires were mailed to the 87 pharmacists who participated in SCRIP by enrolling and following at least one patient according to the study protocol. To facilitate candid answers, responses were anonymous, and consent to participate was indicated by the returned questionnaire. Monthly newsletters and a local study representative reminded pharmacist-investigators to complete and return the survey.

Items for the questionnaire were generated through a literature search and from issues raised by pharmacist-investigators during the study. Previous surveys exploring pharmacists' attitudes toward practice-based research[33] and pharmacy practice[36–38] were reviewed for relevant survey questions. Review articles on pharmacy practice research were also examined for applicable information.[39–41] The questions were grouped into four key areas: motivating factors to participate as an investigator, barriers to participation, communication tools used by the study coordinators, and design issues for future studies. Pharmacist-investigators' opinions in these areas were explored by a combination of closed and open-ended questions.

A five-point Likert scale was used for response options to the closed questions; responses were evaluated with descriptive statistics, using SPSS software (SPSS Inc., Chicago, IL). Responses to the open questions were grouped thematically.[42]

Results

Fifty-eight (67%) completed questionnaires were returned from the 87 pharmacist-investigators. To maintain anonymity, respondents' demographic data and site information were not collected. Therefore, we could not compare data from nonrespondents or between centers with different levels of recruitment.

Initial Interest

Pharmacist-investigators in SCRIP were asked to indicate the extent to which various recruitment strategies influenced their decision to participate in the study. Factors that were anticipated to play a role are shown in Table 1, with summarized responses. The most important factors were desire to improve the profession, opportunity to learn more about disease management, and ability to provide enhanced service to patients. Reputation of the academic researchers who organized the study and curiosity were less important than interest in clinical research or recommendations of a colleague.

Comments from the open-ended questions on motivating factors mirrored responses to the

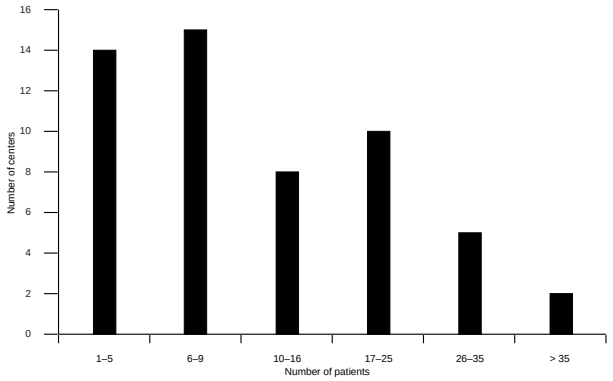

Figure 1. Recruitment rates.

Table 1. Factors That Motivated Participation

	Responses (%)				
	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
Interest in clinical research	2	10	24	52[a]	12
Researcher reputation	19	9	38[a]	19	16
Colleague's recommendation	19	12	16	43[a]	9
Learn more about disease management	0	2	5	48[a]	45
Provide another service to patients	0	3	10	40[a]	47
Curiosity	9	9	45[a]	22	16
Desire to improve the profession	0	0	7	40	53[a]

[a]Median response.

Table 2. Barriers to Participation

	Responses (%)				
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Hard to find eligible patients	9	49	28	14	0
Promotional items not helpful	9	46	21	25	0
Study activities took too much time	0	50	27	23	0
Too many internal issues (e.g., staff holidays, pharmacy renovations)	2	23	23	43	9
Other responsibilities cut into time for study	0	16	21	50	14
Lack of reimbursement	2	36	34	23	5
Poor physician attitudes	7	48	23	18	5
Low level of confidence	21	55	21	5	0
Initial responses were discouraging	28	54	14	5	0

closed questions. Ten respondents indicated that their desire to participate in practice-based research came from a need to change the nature of pharmacy practice. A recurring theme was the desire to broaden the pharmacist's role to involve more clinical programs and move away from dispensing. Fourteen respondents reported that participation gave them a chance to enhance their knowledge and improve patient-care skills. Participation in SCRIP was viewed as an exciting opportunity that added to daily practice.

Barriers to Participation

Time was identified as the greatest barrier to participation and patient recruitment (Table 2). Approximately two-thirds of respondents agreed or strongly agreed that time devoted to other duties at work diminished the time available to participate in the study. However, only 23% felt the study-related activities took too much time. Responses also indicated that internal issues such as staff holidays limited ability to participate in SCRIP. On the other hand, low level of confidence and poor initial responses were not considered barriers to participation. Other possible barriers, such as lack of reimbursement and poor physician attitudes, were considered less important.

Comments regarding barriers to participation focused on support from other pharmacy staff and time. Most SCRIP centers had one or two pharmacists participating as investigators. Several respondents reported that lack of support from other pharmacy staff made it difficult to identify patients and perform study-related activities. This lack of support, combined with few pharmacists working on each shift, made it hard to complete other expected activities to allow time for the study. Study activities were imposed on an already busy day in the dispensary. Despite these challenges, respondents indicated that the study activities were well organized and easy to follow.

Communication

Ongoing communication with the community pharmacist-investigators was a priority for SCRIP coordinators. Various methods were used to monitor recruitment progress, solve problems as they arose, and keep the pharmacist-investigators motivated. Almost three-fourths of respondents indicated that monthly newsletters, investigator

meetings, and site visits by area monitors were quite helpful or extremely helpful for maintaining interest in SCRIP. Many respondents remarked that the investigator meetings were invaluable tools for discussing issues with other pharmacist-investigators and learning more about the study. Two respondents suggested holding regular conference calls because this format was perceived to be more convenient, especially in rural centers.

During the study, recruitment was the primary message to the pharmacist-investigators; several incentives were used to stimulate and encourage recruitment. For example, four recruitment challenges were held during SCRIP, with rewards given to the group who recruited the most patients. Individual recruitment milestones were celebrated with recognition at investigator meetings and lapel pins (silver for 10–16 patients, gold for 17–25 patients, platinum for 26–34 patients, and diamond for more than 35 patients recruited). Respondents indicated they enjoyed having their achievements recognized and felt this was a major factor in motivating their continued participation.

During the latter phases of recruitment, the project office faxed weekly word puzzles as reminders to encourage recruitment. These were less enthusiastically received than other forms of communication. Some respondents indicated that the puzzles were irritating and recommended that efforts be redirected toward in-person meetings or center visits.

SCRIP Study Design Issues

To obtain feedback for future practice-based research studies, pharmacist-investigators were asked the open-ended question, "If you could change any one part of SCRIP, what would you do?" The responses fell into three themes: investigator training, case report forms, and study procedures.

Training

Eighteen (31%) respondents commented on training provided for the study. Comments centered mostly around training more than one pharmacist at each site. For example, one respondent stated, "All pharmacists must be trained in each pharmacy—answers questions and motivates! Difficult to do, but essential to encourage full participation."

Training included discussion of background and study procedures, as well as management issues for hypercholesterolemia and clinical evidence to support administration of cholesterol-lowering drugs; it began several months before the start of the study. Also, the study coordinator visited each site to review study procedures in detail and provide tips on patient identification and recruitment. Several pharmacist-investigators who entered the study after it had begun commented that they would have liked more training. As new staff joined the pharmacy and other pharmacists became involved with SCRIP, it became apparent that repeated training visits would have been helpful.

Case Report Forms

Eighteen (31%) respondents commented on the case report forms: five thought there were too many, and four objected to the transmission of forms by fax machine to the study coordinating office. Despite these comments, respondents recognized the need for the forms and found them logical and easy to follow. Respondents suggested that future studies use a computer-based system with online or e-mail transmissions.

Study Procedures

A few respondents commented on study procedures. Two thought the first two follow-up visits (at weeks 2 and 4) were too close together; another felt the device used for cholesterol testing (Accutrend GC) was unreliable.

Advice for Future Studies

Pharmacist-investigators were asked if they would participate in a future study and for their opinions regarding reimbursement and recruitment expectations. Enthusiasm for participation in future research projects was high; 48 (83%) respondents stated they would absolutely or most likely participate in another unpaid study with our research group. Only one indicated refusal to participate in another research study.

When respondents were asked what they considered reasonable reimbursement for future SCRIP-like studies, 21% suggested $25–40, 52% suggested $50–75, and 21% suggested more than $75 for each patient. Six respondents felt they should be reimbursed for cognitive services provided as part of the study. One respondent commented that other pharmacists felt reimbursement was a necessary part of any study: "While I don't need reimbursement…Several

other pharmacists who work for the same organization had asked me often if I was getting paid for this work. When I told them 'no,' they told me that we were wrong to do it."

When respondents were asked what they considered a reasonable recruitment goal (SCRIP goal was 25 patients), 63% indicated 10–20 and 37% indicated 25 patients. Fifty-two (90%) respondents commented on recruitment, covering several themes. Work environment conducive to patient contact (time commitment, staffing, and managerial support) was cited frequently as a major factor in recruitment. Size of patient base (i.e., prescription volume) and proportion of eligible patients also were cited often. Many respondents indicated that because of the prevalence of cardiovascular disease and diabetes, this was not a legitimate reason for poor recruitment. Several respondents indicated that 20–25 patients would be optimal because it would allow them to gain experience and "get good at it."

Discussion

To our knowledge, SCRIP is the largest, randomized, multicenter study evaluating efficacy of community pharmacist intervention in cardiovascular disease management. This study demonstrated the beneficial effect of community pharmacists working in collaboration with patients and their family physicians to improve health care delivery.[43]

During the study, over 80 community pharmacists from 54 pharmacies in urban and rural centers joined the network and became practice-based investigators. These pharmacist-investigators provided valuable information for the design and execution of future research in community pharmacies.

Enlistment of interested pharmacist-investigators is a major concern for researchers. Our findings are similar to those of others[33] in that many pharmacists participated in practice-based research because of interest in research. More important, respondents to our survey indicated that a strong desire to expand their level of care (to provide more services) and to help demonstrate the value of the profession were motivating factors. Personal knowledge of academic researchers would suggest confidence in the design and purpose of the study; however, respondents did not consider this an important motivating factor.

Respondents provided more comments regarding barriers to participation than any other topic, perhaps reflecting the importance of recruitment barriers in this study. In general, most comments focused on a work environment conducive to provision of advanced services. As a profession, pharmacists (and pharmacy managers) must move toward a clear commitment to, and definition of, patient care. Participants of future practice-based research projects should consider coordinating staff and resources to facilitate patient care and implemen-tation of study procedures. Academic researchers should be sensitive to time constraints and responsibilities of community-based investigators when they develop study procedures. When pharmacists are not reimbursed for participation, 10–20 patients/pharmacy may be a reasonable expectation.

Despite careful attention to design of a practice-based research study, implementation in community pharmacies may be limited without adequate training. The SCRIP was the first major project in which many of our pharmacist-investigators had participated. Although pharmacists routinely communicate with their patients and are comfortable providing health care advice, approaching patients for recruitment into a study was a new experience for many. This inexperience and initial hesitation with informed consent and enrollment procedures may have kept some pharmacists from recruiting patients. Furthermore, pharmacist-investigator feedback indicated that patients were sometimes surprised when approached by their pharmacist for participation in a "research study." Working on the notion that this terminology may have conjured images of investigational drugs or invasive procedures, we found patients responded more favorably when words such as "program" were used instead of "research study." The pharmacist-investigators in SCRIP frequently commented on the need for continued training and contact with study support staff to ensure greater participation and recruitment.

Our training program for new investigators consisted of a meeting, a detailed study operations manual, and an on-site visit. Support was provided to investigators through monthly newsletters, investigator meetings (every 3–4 months), and a toll-free telephone help line. Many investigators wanted several pharmacy staff members to be trained at each site. Although we suggested this at the beginning of the study, it was often difficult to achieve because other pharmacists at the site lacked interest, the site was inaccessible, and/or many investigators were

unable to attend training sessions. In general, study coordinating staff observed that sites with several trained investigators seemed to have the greatest and most consistent recruitment. Therefore, we recommend that written commitment for training and participation be obtained from most of the pharmacy staff (including manager and/or owner) before a site is accepted for study participation.

Training issues may be alleviated by Internet technology, which provides delivery of interactive, problem-based, and accessible training whereby pharmacists can learn at their own speed. To this end, some members of our group developed a training program (modeled after SCRIP procedures) for management of a patient with elevated cholesterol: PHARMA*Learn*-CHOLESTEROL (available from www.pharmalearn.com). Proper training provides investigators with the incentive to not only learn, but also act.

Documentation of the study data should be simple and a natural extension of the pharmacist's interaction with the patient. Case report forms (and data clarification forms that often follow from the study coordinating center) are a much-maligned part of any clinical trial. The SCRIP used concepts of a large, simple trial,[4] whereby only minimal information was collected from each patient. In addition, the case report forms were used as a means to implement clinical guidelines for cholesterol management. This resulted in having a single place for documentation of patient information, study procedures, and patient progress. A patient in the intervention group required 10 pages of forms during the study; a patient in the usual-care group required only 6 pages. Case report forms were faxed to the study coordinating center, where they were entered into the database manually. Nevertheless, several investigators indicated some dissatisfaction with the case report forms (volume of information required, pickiness of data quality procedures). Perhaps this is reflective of the fact that most investigators in SCRIP had not previously participated in research. In addition, as with any fax system of data transfer, some faxes are lost, frustrating investigators (and study coordinating center staff). Researchers could improve communication of case report form expectations and provide more timely feedback on data quality issues so as to prevent mistakes. By trying to ensure that documentation is considered as important for study purposes as for patient care, researchers may improve pharmacist-investigators' perceptions about required study documentation.

Although the survey questions were worded to elicit constructive criticism on study procedures, overall feedback on study design and conduct was very positive. One area involved communication from the study coordinating office. The SCRIP coordinators used a system of local study facilitators (similar to that used in the Digitalis Investigation Group trial[44] and Heart Outcomes Prevention Evaluation study) in addition to study newsletters and local meetings.[45] The five local study facilitators (two of whom were also investigators) provided local support and were crucial to the success of the project. These individuals acted as agents of the study coordinating center and visited the sites regularly to address recruitment and data quality issues.

Although SCRIP did not provide reimbursement for patient enrollment or follow-up, guidance was sought from the investigators regarding this issue for future trials. Average contact time between investigator and patient in the intervention group was 100 minutes, versus 60 minutes for patients in the usual-care group.[46] Three-fourths of the investigators felt that $25–$75/patient would represent fair reimbursement. Survey comments indicate that some respondents confuse issues of reimbursement for activities relating to practice-based research to prove the value of pharmacists' services with that of fees for cognitive services (i.e., income-generating activities). This is not to say that pharmacists should not be reimbursed for time spent in research endeavors (especially if it helps to gain pharmacy managers' support) but that they should appreciate that these are separate issues. Benefit of pharmacy services, as addressed by practice-based research, must be proven before government, insurers, and the public will be willing to reimburse for them.

Perhaps the best test of investigators' attitudes toward practice-based research is whether they would "do it again." It is encouraging that most investigators indicated willingness to participate in future research projects, although we do not know to what degree these opinions were influenced by the positive outcome of the study.

Limitations

Results of this survey of pharmacists' opinions toward participation in practice-based research may not be generalized to all community

pharmacists. We recognize that the respondent sample is inherently biased for two reasons. First, these participants had already demonstrated willingness to participate in such research. Second, the survey was administered shortly after investigators learned of the positive results of their efforts in SCRIP. Furthermore, issues related to pharmacy practice in general, such as the shortage of pharmacists for available positions, were not explored in detail in this survey. Still, these issues could affect the decision to participate in practice-based research. Despite these limitations, we felt that obtaining information from these motivated pharmacists would be valuable in planning future pharmacy practice-based research.

Summary

Pharmacist-investigators who responded to this survey indicated eagerness and willingness to participate in practice-based research in order to improve the pharmacy profession and take the opportunity to expand services to patients. For successful participation, pharmacists should secure support of other pharmacy staff, including managers and owners, and work as a team to support study-related activities. Academic researchers must ensure that practice-based research protocols can be integrated into existing time commitments and responsibilities of the community pharmacist. Comprehensive and ongoing training on the disease state under study is essential to give investigators confidence to perform study procedures. Finally, during execution of practice-based research, an ongoing support network should be in place for contact and support of the pharmacist-investigators.

Pharmacy practice-based research, particularly in community pharmacies, has two significant advantages. First, it uses an existing infrastructure to provide primary care services to patients at the community level and therefore serves as an excellent public health approach. Second, these projects have the potential to provide much needed data to demonstrate the value of pharmacists' clinical activities. These are compelling reasons to continue efforts to understand how best to conduct such research. We hope this article stimulates further discussion among pharmacy practitioners and researchers, so that research methods improve and the strength of evidence of the value of enhanced pharmacy services in the community increases.

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