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Lessons learned in the growth and maturation stages of a community pharmacy practice-based research network: Experiences of the Medication Safety Research Network of Indiana (Rx-SafeNet)

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Abstract

Community pharmacy practice-based research networks (CP PBRNs) are a relatively new arena for pharmacists. While some lessons may be gleaned from primary care PBRNs, the experiences of CP PBRNs have much to offer the profession in terms of organization and practice. In 2012, we reported on our early experiences developing the Medication Safety Research Network of Indiana (Rx-SafeNet) after establishing the Network in 2010. Over the past 3 years, our CP PBRN of approximately 180 members has managed further growth by revisiting policies and procedures, maintaining CP PBRN member relationships, and preparing for financial sustainability. We look forward to furthering our CP PBRN projects in the coming years and collaborating with other CP PBRNs to enhance medication safety in Indiana and beyond.

Introduction

Community pharmacy practice-based research networks (CP PBRNs) have the potential to enhance patient care, improve medication usage including adherence, and foster collaboration among pharmacists and other healthcare providers.¹ In 2010, a CP PBRN termed the Medication Safety Research Network of Indiana (Rx-SafeNet)² was launched by the Purdue College of Pharmacy to connect College faculty with practicing community pharmacists. Rx-SafeNet's mission is to improve medication safety and advance community pharmacy practice in Indiana through the conduct and dissemination of collaborative, patient-centered, practice-based research. Despite such efforts and those like it, development of new CP PBRNs has remained slow compared

to development of other healthcare PBRNs.³ Current literature to assist aspiring PBRNs focuses on progressive growth and network maturation may be thought of as occurring in a step-wise progression of four stages of development: 1) conceptualization;⁴ 2) implementation;⁵ 3) growth⁶ and finally, 4) maturation.⁴

Most PBRN literature has focused on conceptualization and implementation challenges; for example, Rx-SafeNet⁵ and Seston et al.⁷ previously shared early experiences about laying the groundwork for their CP PBRNs, drafting policies and procedures, and completing early projects with a small number of pharmacies. However, generalizability of these findings are limited by the projects' small sample size and few participating pharmacies.⁶ Further findings by Schommer provide suggestions for stimulating inter-network growth by boosting participating community pharmacies and sample size,⁸ but more research is warranted to explore the proposed strategies. To address the paucity of literature regarding the challenges facing CP PBRNs during later stages of development, we are sharing the experience of growing

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Rx-SafeNet with specific challenges related to managing growth and sustainability. In this context, growth refers to the addition of pharmacies and pharmacist members, implementation of increasingly complex projects, and the movement toward greater external grant funding for research projects. Specifically, we are sharing techniques we have developed and utilized to overcome several challenges experienced during the growth and early maturation stages, including: 1) Increasing membership, 2) Staffing needs, 3) Revisiting policies and procedures, 4) Relationship building, 5) Developing project ideas, and 6) Achieving maturation.

Network Overview

Rx-SafeNet was launched in 2010 by the Purdue University College of Pharmacy as part of a larger initiative designed to enhance the community pharmacist's role in promoting medication safety.^{5,9} The Network includes independent, chain, and hospital/health-system outpatient community pharmacies across the state of Indiana and is led by a 4-person Executive Committee comprised of a faculty member, fellow, and two staff members. The Network is also supported by a Project Review Team (PRT), comprised of Purdue faculty who review proposed study protocols for scientific quality and feasibility. Finally, Network leadership also includes an Advisory Board that meets quarterly and shares expertise from working with other PBRNs, assists with strategic planning, and provides guidance concerning Network policies.

See Table 1 for a compilation of all challenges and solutions presented.

Challenge: Increase Membership

To increase Network membership, as described previously,⁵ formal information sessions for pharmacy staff were initially held in the community to raise awareness and provide education regarding the benefits of Network membership. While these sessions were valuable and resulted in new members, we found they attracted less than 25 pharmacists and technicians total.

Solution: To stimulate additional interest in Rx-SafeNet and achieve greater attendance at information sessions, we worked with our College's continuing education (CE) department to develop a 1 hour CE credit course for pharmacists and pharmacy technicians. The cost of developing the CE included personnel time, limited marketing materials (e.g., post card mailers), and space rental in some cases. There was no cost to participants to attend the CE session and refreshments were served. The CE sessions included a history of PBRNs, their function and examples of successful PBRNs.

At the end of the CE course, attendees were invited to stay for an information session (not part of the CE course) describing Rx-SafeNet. This portion of the session included details of how to join, benefits and expectations of membership, project examples, and a question and answer portion. Interest in CE has increased attendance at the information sessions, and consequently, interest in Rx-SafeNet. By promoting the CE course through post card mailers and state professional associations, we have delivered CE to more than 50 pharmacists and pharmacy technicians. In addition, some of our existing members have utilized the CE course to educate their own pharmacists and technicians to enhance their understanding of what it means to be an Rx-SafeNet member and participate in a CP PBRN. To date, the CE program has been offered 6 times throughout the state, and currently, we have plans to offer it as a face-to-face course with concurrent webinar streaming to reach more pharmacists and technicians and pharmacy managers.

Challenge: Staffing Needs

Moving from the implementation stage into the growth stage resulted in the addition of approximately 160 pharmacies over a three-year period. Today, approximately 180 pharmacies employing collectively about 322 pharmacists are members of the Network. This growth required more person hours to maintain Network productivity as the workload increased and thus, to handle day-to-day operations it was necessary to increase from a half-time Network Coordinator to a full-time Network Manager. Funding for initial projects completed during the first 2 years came from the overarching Lilly Endowment, Inc. grant that funded the new College community initiative. These early projects provided the opportunity to pilot Network operations. In terms of budgeting, an estimated \$100,000 would be needed to cover salary and benefits, for the approximately 2,288 person hours needed to maintain CP PBRN stability during the mid-growth stage (2,080 hours or 100% salary coverage for a Network Manager, and 208 hours or 10% salary coverage for a Network Director). This budget estimate is based on a goal of three small projects per year (e.g., a project involving 5-10 pharmacies with data collection time-limited to 6 months or less).

Solution: A full-time Network Manager position was created with the responsibility to: 1) develop project protocols, 2) garner project support, 3) organize and manage projects, 4) add new Network members, and 5) secure project funding. It was decided that these tasks would be well served by an individual with previous PBRN research, but not necessarily pharmacy practice experience. Consequently, Rx-SafeNet hired a full-time Network Manager with a Doctorate in Public Health and previous PBRN experience. In addition, we have

offset staffing needs by creating opportunities for learners including Doctor of Pharmacy (PharmD) students and the College's Community Practice Research Fellow (beginning in 2011). Further integration of the Fellow into Network activities was achieved in 2013 by having the Fellow conduct their primary research project in collaboration with Rx-SafeNet. This has enhanced the Fellow's familiarity with Network procedures as well as his/her relationships with our members. Starting in 2013, PharmD students have become more involved with the Network by completing a 1-month rotation (i.e., advanced pharmacy practice experience [APPE]) during their fourth year of pharmacy school under the mentorship of the Rx-SafeNet Director, who is a faculty member in the College of Pharmacy. Since then, a total of 8 students have completed this APPE. The objectives of this APPE are for students to actively participate in the College's community programs, including Rx-SafeNet; to gain experience in research; and to interact with other learners including the Community Practice Research Fellow. This has created a "win-win" situation, as the Network receives additional support and the learners gain important exposure to community pharmacy research. In terms of student learners, projects have been tailored that usually could be completed during their one-month rotation; although, planning is critical due to the wide variance in the workload of the Network in number of submitted grant applications, complexity of applications and manuscripts, and timing of student rotations.

Challenge: Revisiting Policies and Procedures

In tandem with Network growth, it became apparent that changes to the Network's policies and procedures were required. One example of a required policy change involved the Project Review Team (PRT). The PRT members, faculty in the Department of Pharmacy Practice, felt burdened with the number of studies progressing through the Network during each successive review period. Further, they felt that submitted project protocols were written in a manner that did not provide sufficient information for review. In addition, we observed confusion with existing policy regarding the PRT members' role and in particular, whether they needed to "approve" protocols or simply offer feedback. Another example of a required policy change involved working with investigator(s) that were not Rx-SafeNet members. Specifically, it was important to ensure appropriate acknowledgment was given to Rx-SafeNet for studies that resulted in publication. Finally, a policy that we added concerned pharmacy and pharmacist confidentiality with respect to Rx-SafeNet membership.

Solution: With respect to the PRT, streamlining the workload by updating the policy was needed for the PRT to function

efficiently. Thus, the PRT policy was updated to ensure that investigators submit a proposal in final form as well as an IRB application to ensure study clarity. This updated role created an avenue for PRT member compensation and provided clarity that a review, not approval, is the expectation for PRT members. To compensate the PRT members, we also developed a policy to fund attendance to one national conference per year for each member, dependent upon available funding.

With respect to investigators external to Rx-SafeNet, we have identified a need for better education. For example, early study investigators unaffiliated with the Network did not routinely adhere to our publication policy, which stipulates that investigators mention Rx-SafeNet in the methods section as well as the secondary title of a journal article, for example, "*Title of Study: a study of the Medication Safety Research Network of Indiana.*" While we had drafted a guidance document for collaborators previously, we have been working to further emphasize its content.

With regard to our confidentiality policy, we have found that some members would rather not disclose their participation in the Network to other members, while other members are very open about their participation. Thus, we have made a blanket policy to keep all membership confidential. As such, all mass communications to Rx-SafeNet members are emailed under blinded copy, and membership status is not disclosed to anyone outside of Network/College leadership without member permission. We are currently in the process of revisiting the policy to determine if another revision is warranted to formalize members' ability to waive their confidentiality in specific circumstances, and to encourage dialogue among members for the purpose of identifying potential pitfalls upon introducing study protocols.

Challenge: Relationship Building

One of the challenges that we discovered was to find the time required for pharmacists to complete human subject protection training for studies in which a pharmacist is a co-investigator or participating in data collection. In carrying out projects during the growth stage, we noted the importance of incentivizing members for projects requiring human subject protection training to ensure participation. Also, with regard to our Institutional Review Board (IRB), we discovered that this relationship was a challenge common to PBRNs that had to be addressed.¹⁰⁻¹⁵ In some cases, we received differing advice from the IRB when a question emerged. For example, in several studies, the question arose as to whether pharmacists and technicians were key personnel or non-key personnel on several particular projects. This issue was important because it dictated human subject protection

training requirements. We had received differing opinions from IRB representatives regarding this issue based upon the individual's involvement in the study. Another challenge was in building relationships with other CP PBRNs in our region and nationally. It became apparent during the growth phase that the Network could substantially benefit from establishing relationships with other CP PBRNs. Finally, another challenge has been to engage the Department of Pharmacy Practice faculty within our College for the purpose of promoting introduction of Network project ideas, and to develop relationships with faculty at other universities for this purpose.

Solution: To offset the burden to pharmacists and technicians who may be involved in projects for time spent on human subjects training, we implemented a process for compensating both pharmacist and technician time. Member pharmacies receive \$150 for each pharmacist and \$75 for each pharmacy technician who completes training. In addition, 6 CE credits are available for training completion as designated by the Indiana Board of Pharmacy for pharmacists and pharmacy technicians. To date, thirteen member pharmacists have completed human subject protection training to engage in data collection for Network projects. No pharmacy technicians have completed the training to date. With regard to the IRB, we established a positive relationship with the IRB Director and commonly contact her directly for advice. In more than one instance, it was necessary to discuss the situation with the IRB Director to reach clarity. Previously, we shared our experiences about working with our IRB to create non-affiliated investigator agreements⁵ and the experiences we have shared have solidified the need to maintain a positive working relationship and open communication with the IRB.

In terms of engaging other CP PBRNs to promote Network projects, we have been successful in establishing a relationship with a CP PBRN in our region and were able to jointly participate in a project idea introduced by an outside organization. The project was conducted in both PBRNs and we plan to work on joint projects in the future. In addition, AHRQ offers a PBRN conference each year, also promoting the opportunity to meet and potentially work with other CP PBRNs and other PBRNs that may be interested in our work. As a result of attending the PBRN conference in 2014, we established a working relationship with a PBRN focused on studies to prevent drug abuse. Ultimately, our Network was written into their grant proposal which was funded, including funding for a study within our Network. In addition, an investigator from another College of Pharmacy expressed interest in utilizing Rx-SafeNet for a pilot project that was successful. Plans are currently underway to use the pilot

project as preliminary work for a larger, federal application that will benefit the Network and the outside investigator.

Challenge: Member Engagement

As mentioned previously, project ideas are received from academic investigators both within and outside of the College of Pharmacy, and also from Network members. Ideas from members are communicated by Site Coordinators; they are the designated contact for the participating community pharmacy in discussions with the Network, primarily the Network Manager. All of the ideas offered by the different groups propelled us into Network growth as we found that we needed to increase the number of member pharmacies to share the activities required of an increasing number of projects. In addition, it is important for Site Coordinators to remain engaged with the Network when they are not involved in a specific project.

Solution: To ensure that projects are of interest to Site Coordinators, we established a "project idea form" for investigators and members early in our history to assess the viability of the project ideas. Individual investigators or pharmacist members are able to propose a research idea by filling out a brief 1-page project idea form located on the Rx-SafeNet website.⁹ Examples of projects proposed have related to medication disposal, medication therapy management, health promotion, and pharmacist-provided education.

After a project idea form has been submitted to Rx-SafeNet by fax or email, Site Coordinators are polled to determine their interest in the project via email. These emails are ballots that have embedded links; the Site Coordinator can click on the embedded link to cast their vote on whether they are interested in pursuing the project. Projects are then tracked to inform Site Coordinators and the College of Pharmacy about progress on project idea generation. To date, 24 projects have been presented to Site Coordinators since inception and they voted to pursue 19 (approximately a 79% approval rate). Ten projects have been completed, 1 is in the data collection phase, and 7 have been approved for further development. Of the 7 approved for development, 1 proposal has been funded (the previously mentioned project with the drug abuse PBRN) and 6 proposals did not receive federal or foundation funding. To keep Site Coordinators engaged when they are not participating in specific projects, we include information on Network projects in our quarterly newsletter. These newsletters are emailed to each Site Coordinator, including polling results and progression of Network projects to completion. We also distribute a Project Summary report to all members upon project completion so they are aware of the project outcome.

Challenge: Achieving Maturation

When a PBRN reaches its maturation stage, members are engaged, large studies are being conducted and all studies are fully funded. While we continue to be successful in introducing studies, we still face challenges moving into maturation, largely as a result of sustainability concerns. Specifically, obtaining external funding is competitive and ideally, every proposed study utilizing the Network should have extramural funding.

Solution: To gain experience among our members and continue to full maturation, we utilized our start-up Lilly Endowment, Inc. funding to facilitate several smaller projects since 2012. These projects have been kept purposefully small, with few study sites (5-10 or less pharmacies) and a short data collection period (typically 6 months or less). This has provided an opportunity to test Network infrastructure without requiring a large budget. However, in an effort to maintain the Network's financial sustainability, we must now decline most investigator-initiated studies that are unable to obtain funding. In other words, it is a priority to seek federal or foundation funding for all Rx-SafeNet projects. We have sought several strategies to acquire funding. For example, after competing successfully for an internal University equipment grant, we were able to purchase several tablets for use in data collection in 2014.

Finally, to better understand member needs and enhance grant writing, we briefly surveyed Network Site Coordinators in 2014 regarding preferred monetary and non-monetary compensation for project participation. The majority of Site Coordinators indicated that gift cards are the preferred method of payment on both small and larger studies. In general, we compensate \$50-\$75/hour (typically to the member pharmacy) for pharmacist time spent on projects. However, there are some pharmacies that cannot accept remuneration for pharmacists' and/or technicians' time on specific projects due to their own policy which prevents this. In addition, hospitality in the form of staff lunches is not allowed per specific policies at some pharmacies. This has made it difficult to incentivize pharmacies for their project participation.

Conclusion

Clearly, issues emerge with the progression of PBRN development, with each step requiring reflection to promote ongoing success and sustainability. At the same time, adjustments to Network policies and procedures may be required. As described, Rx-SafeNet has progressed through PBRN growth and is in the process of attaining early maturation on its way to full maturation. We have discovered new challenges and lessons learned. Notably, we have been

successful in adding 162 pharmacies to the Network and thus are confident in our outreach strategies. As such, we continue to clarify policies for collaborators as early as possible, anticipating this is an area for continued vigilance as the network grows.

Promoting sustainability will require a continued focus on clinician involvement in research and further emphasis on the importance of identifying appropriate compensation for clinician members. This challenge has been noted by other PBRN researchers.¹⁶ As we continue to make strides toward full maturation, more complex studies and larger investigative teams, receiving large, federally funded studies will be critical. As Green⁴ notes about where primary care PBRNs were in 2006, it appears this is where CP PBRNs are at the present time: "These networks are now both a place and a concept. As a place, they are laboratories for surveillance and research. As a concept, they express the still unmet need for practicing clinicians to accept responsibility to improve clinical care by understanding what is happening in their practices." Full maturation is an ongoing challenge, however one that will certainly ensure the practice of pharmacy a richer experience for patients, pharmacists, and researchers.

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Table 1. Lessons learned in the growth and early maturation stages

Challenge	Solution
Increase pharmacist membership	Work with Continuing Education (CE) Department to develop a 1-hour course with CE credit for pharmacists and pharmacy technicians
Consider staffing needs as workload increases	Hire full-time Network Manager; use learners (PharmD students) and Fellows to assist with projects
Revisit policies and procedures: Examples include Project Review Team (PRT) and collaborator education	Compensate PRT members who review proposed projects with conference attendance or other incentive; ensure that collaborators adhere to a publication policy
Build relationships with members regarding human subject protection training and with the Institutional Review Board (IRB); build relationships with other faculty and PBRNs	Incentivize pharmacists and technicians by reimbursing them for time spent on human subject protection training; attend annual PBRN conference in Bethesda held in June.
Engage members in project ideas and the timeline for project progress	Ensure that projects are of interest to members by polling them, tracking progress and keeping members informed
Achieve maturation by becoming sustainable	At first, conduct projects with a small number of sites; at the same time, establish goals for attaining federal/foundation projects