INNOVATIONS in pharmacy Iip

Volume 3 | Number 2 Article 78

2012

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Financial Disclosure Statement: Dr. Snyder's effort was supported in part by KL2RR025760 (A. Shekhar, PI). The Center for Medication Safety Advancement and Rx-SafeNet were founded with funding from a Lilly Endowment Grant.

Conflict of Interest Disclosure Statement: The authors declare no conflicts of interests or financial interests in any product or service mentioned in this article, including grants, employments, gifts, stock, holdings, or honoraria.

Acknowledgments: We would like to thank Ms. Brenda Hudson for her critical review of earlier drafts of this paper and Dr. Matthew Hoch for his assistance in preparing this manuscript. We would also like to thank all members of Rx-SafeNet for their support of advancing community pharmacy practice through practice-based research.

Previous Presentations: Poster presentation at the 2012 Translational Science Meeting in Washington, DC.

Keywords: practice-based research networks, research, pharmacy practice, medication safety, community pharmacy

Abstract

In 2010, the Purdue University College of Pharmacy established the Medication Safety Research Network of Indiana (Rx-SafeNet), the first practice-based research network (PBRN) in Indiana comprised solely of community pharmacies. In the development of Rx-SafeNet and through our early project experiences, we identified several "lessons learned." We share our story and what we learned in an effort to further advance the work of the greater PBRN community. We have formed the infrastructure for Rx-SafeNet, including an Executive Committee, Advisory Board, member pharmacies/site coordinators, and Project Review Team. To date, 22 community pharmacies have joined and we have recently completed data collection for the network's first project. Lessons learned during the development of Rx-SafeNet may benefit PBRNs nationally. Although community pharmacy PBRNs are not yet commonplace in the U.S., we believe their development and subsequent research efforts serve as an important avenue for investigating medication use issues.

Introduction

In 2010, the Purdue University College of Pharmacy established the Medication Safety Research Network of Indiana (Rx-SafeNet), which is administered by the College's Center for Medication Safety Advancement (CMSA).[1] Rx-SafeNet is the first practice-based research network (PBRN) in Indiana comprised solely of community pharmacies.[2] To our knowledge, Rx-SafeNet is also one of only a very few PBRNs nationally to focus on community pharmacy practice,[3-5] and the only to focus specifically on medication safety.

Community pharmacy PBRNs, like Rx-SafeNet, offer unique benefits and research opportunities beyond those of traditional primary care PBRNs. These benefits have been previously described extensively and include: community pharmacists' access to and frequent contact with patients, unique involvement in the medication use process, and ability to observe self-care behaviors involving over-the-counter medications and supplements provide community pharmacy PBRNs with opportunities for insight into medication use issues from another perspective.[6]

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The launch of Rx-SafeNet is one of several initiatives on which the College is collaborating with the goal of advancing new community pharmacy practice models that improve medication safety in Indiana. Related efforts include collaboration with community pharmacies to provide community pharmacy residency/fellowship training and with our state pharmacy association to form a pharmacist practice network to support pharmacist provision of medication therapy management, collaborative drug therapy management, and other patient care services to community-based patients. Start-up financial support for these efforts was provided by a Lilly Endowment, Inc. grant received by the College in 2006. In the development of Rx-SafeNet and through our early project experiences, we identified several "lessons learned." In this paper, we share our story and what we learned in an effort to further advance the work of the greater PBRN community, particularly pharmacy PBRNs. We have emphasized specific issues that do not appear to have been discussed extensively in previous PBRN literature.

Summary of Steps Taken in Network Development

A timeline describing our development steps is provided in Figure 1. The decision to establish a community pharmacy PBRN was made in the fall of 2009. This decision was reached after several early conversations to determine stakeholder support. These included meetings with leaders in the pharmacy community, the College of Pharmacy, and the University. Specifically, we first met with the Medication Safety Partnership of Indiana, a group representing numerous pharmacy organizations in the state interested in medication safety, to assess initial interest in a PBRN endeavor and answer questions. Initial support at the College level was sought from the Head of the Department of Pharmacy Practice and the Managing Director of CMSA. We also reached out to our University Institutional Review Board (IRB) early on to begin to discuss the unique human subjects protections issues raised by the formation of a PBRN, pulling from the experience of other networks (such as human subjects protections training requirements for participating clinicians, etc.).

During this time, we also began to write our mission statement, draft network policies, and form an advisory board. We identified potential advisory board members with a variety of professional backgrounds, including practicing community pharmacists, pharmacy faculty, individuals with PBRN development and administration experience (including both pharmacy and other PBRNs), and a medication safety expert (CMSA Managing Director) who could help guide the mission of the network. Throughout this process we reviewed the PBRN literature and modeled our initial policy drafts after others, primarily physician networks (i.e., the American Academy of Family Physicians National Research Network),[7,8] as we found, not surprisingly, most information available was for primary care PBRNs. Additionally, we surveyed Indiana community pharmacy employees in order to gauge overall interest in joining a PBRN, the benefits and barriers to joining a network, potential research topics, as well as pertinent background and demographic information.[9,10] In total, 140 pharmacists and 40 support staff responded to the survey, and in doing so helped the network identify key areas in which to focus efforts and resources. For example, the survey identified an overwhelming desire to have more information about PBRNs in general, and specifically Rx-SafeNet. This informed a series of outreach events (described below), including live information sessions held in geographically diverse Indiana cities, as well as the development of Rx-SafeNet "FAQs" that were presented during the sessions. Perhaps, more important to the longevity of the network, was the fact that the barriers and benefits results were interpreted and used to guide the development of the policies and procedures of the network, allowing for preemptive diminishing and highlighting of the issues respectively.

Finalizing network policies included a review by the Department Head and also a conversation with the University contracting office. We were required to seek out the latter specifically for approval of the Memorandum of Understanding that each member pharmacy is asked to sign when joining Rx-SafeNet. The intent of this document was not to provide a binding legal contract, but to offer each prospective member a set of assurances that all members have agreed to abide by the same guidelines and that nothing would represent a breach of their standard duties to their patients or parent companies (as applicable). After the survey was completed, the network was named and registered with the Agency for Healthcare Research and Quality PBRN Resource Center as an Affiliate PBRN[11] and initial policies were finalized, we then began to formally conduct outreach activities and invite pharmacies to join Rx-SafeNet. We engaged in several outreach efforts, including contacting pharmacy leaders directly, hosting webinars, conducting live information sessions in four locations throughout the state, and purchasing exhibit booth space at state pharmacy association meetings. While our state has a centrally located capital, which is also our most populous city, we found it to be incredibly important to reach out to pharmacies in their own communities as a sign of making this a true statewide effort. Continued statewide outreach is ongoing.

Resulting Rx-SafeNet Infrastructure

Rx-SafeNet is led by a three member executive committee which consists of the Network Director (full-time Purdue Pharmacy Practice tenure-track faculty responsible for overseeing the College's community pharmacy/medication safety initiatives), Network Coordinator (0.45 pharmacist FTE with the PBRN, remaining effort devoted to the College's other community pharmacy/medication safety efforts), and a postdoctoral pharmacist research fellow mentored by the Director. In addition, the executive committee meets quarterly with an advisory board. As described above, advisory board members include both pharmacists and non-pharmacists and several individuals with PBRN experience, including those in leadership roles with the Indiana Clinical and Translational Sciences Institute (CTSI)[12] and other local networks.

We also formed a Project Review Team (PRT). The PRT is responsible for reviewing submitted project protocols to provide guidance not only on scientific issues, but also on feasibility and project implementation issues in a community pharmacy environment. The PRT currently consists of Purdue

Pharmacy Practice faculty, but the intent is to ultimately invite practicing clinicians to participate as well. The process for how projects are selected for completion within Rx-SafeNet is available on our website (http://www.pharmacy.purdue.edu/rx-safenet/).

Current Status

To date, 22 community pharmacies have joined Rx-SafeNet. Data collection for the first project conducted in collaboration with the network has been completed. This initial project involved only one network pharmacy location as we describe further in our lessons learned. At this time, we have received project idea submissions from network leadership, other colleges in our University, outside technology vendors, and community pharmacy residents affiliated with Purdue.

Lessons Learned

Infrastructure/General Developmental Issues

1. Published guidance regarding "essential elements" of PBRN infrastructure has worked well for a new non-primary care (i.e., community pharmacy) PBRN.

Green et al. describe infrastructure elements necessary for all PBRNs, along with mission-specific elements that will vary.[13] Although their paper focuses on primary care PBRNs, we have found that their recommendations are applicable to a community pharmacy PBRN. Except for two-way communication among members and regular network meetings (which are being planned), Rx-SafeNet as a young PBRN has developed each of the "common infrastructure elements" (including a membership roster, a board, a director, a coordinator, a news-sharing function, and a means of addressing IRB and HIPAA issues) and to date, they appear to be reasonably effective.[13] Furthermore, we believe the recommendations regarding "mission-dependent" elements are also very relevant to pharmacy or pharmacist networks. Rx-SafeNet emphasizes practice staff (pharmacists, technicians, etc.) as active collaborators that may conduct the majority of data collection for some studies; therefore, we have placed less of an emphasis on using research assistants (RAs) to serve this role. For networks less focused on engaging practice staff directly in research activities, RAs may play a greater role. Additionally, Rx-SafeNet has not addressed some of the information technology infrastructure considerations presented by Green et al.[13] For example, because the same pharmacy management software programs are not used across all community pharmacies (i.e., the entire potential Rx-SafeNet membership pool of independent pharmacies, chains, etc.), common data elements (e.g., drug therapy problems detected through the provision of direct patient care services) are not always documented and therefore, potentially unavailable.

2. IRB decisions will vary widely across PBRNs; early conversations are important.

As we discussed, we took examples from the PBRN literature to initial meetings with our IRB to discuss human subjects protections issues. One of the issues we identified early on was a need for a "non-affiliated investigator" mechanism to cover Rx-SafeNet clinicians under our University's Federalwide Assurance, as community pharmacies do not routinely hold assurances or report to an IRB of their own. Although we shared information from Graham et al. who describe a non-affiliated investigator agreement (NIA) that appears to only be completed by the investigator once every three years,[8] our IRB crafted an agreement that is project-specific. Therefore, a new NIA is required by each non-affiliated investigator for each project they collaborate on that details the specific project-related activities that the non-affiliated investigator will engage in.

3. "Pre-launch" surveys can assist in ongoing network planning and development.

As mentioned above, a pre-launch survey was executed that queried Indiana community pharmacy employees about their interests, perceptions of benefits and barriers to joining a PBRN, and pertinent background (e.g. previous research experience) and demographic (e.g. pharmacy type) information.[9,10] One goal of the survey was to create network "ownership" among community pharmacy stakeholders in the state by inviting survey respondents to vote on the official name of the new PBRN and provide input that influenced network policies and procedures. The survey responses also serve as baseline data to which the results of future membership surveys can be compared, in order to identify long-term trends in interests, concerns and perceived value to being an Rx-SafeNet member.

4. Insight from practicing clinicians could prove enormously helpful in refining project protocols.

As previously described, the PRT currently consists of Purdue Pharmacy Practice faculty, but the intent is to invite practicing clinicians to participate as well in the future. Through the implementation of our first project, the protocol was reviewed by the PRT and Rx-SafeNet Executive Committee for appropriateness. However, upon visiting the Rx-SafeNet pharmacy to provide staff training on project implementation, the site coordinator quickly identified issues that required clarification and opportunities to make additional improvements. Having practice staff participating in initial PRT review of the proposed protocols will likely help to further streamline the process to ensure projects can be easily implemented in a community pharmacy setting with as few disruptions in workflow as possible. Despite this, we realize that every pharmacy will be unique and may require

small changes to work effectively in an individual site's existing workflow.

Membership and Outreach Issues

1. In community pharmacy, where a large proportion of the market is encompassed by chains, both "top-down" and "bottom-up" outreach approaches seem to be warranted. As described above, we have utilized several approaches for getting the word out about Rx-SafeNet. These have included both "top-down" (e.g., contacting corporate pharmacy leadership directly) and "bottom-up" (e.g., inviting all community pharmacy employees to attend information sessions) approaches. Although Rx-SafeNet is still in its infancy, we believe this approach has value. The information sessions and attendance at state association meetings have been helpful in raising individual pharmacist interest and awareness. However, the decision-makers for most (i.e., chain) community pharmacies are not at the store level and may not be present at these sessions. Therefore, it has been important to identify who in an organization can provide approval (i.e., sign the membership MOU) for a pharmacy to join the network and to reach out to them to provide more information. Depending on the organization, the individual with the authority to give permission to join could be at different corporate levels. This is still ongoing for our network and has been one of the greatest challenges Rx-SafeNet has faced in growing its membership. Other community pharmacy PBRNs have excluded chain pharmacies from participation,[3,4] perhaps partially because of these issues, but we continue to pursue engaging chain pharmacies as we value representation from a variety of community pharmacies.

2. In defining roles within community pharmacy PBRNs, flexibility is key.
When each pharmacy joins the network, we ask them to name a site coordinator. We realized early on that for some pharmacies, particularly those with multiple locations, the pharmacy may prefer to name "co-site coordinators" with a single individual in a leadership role for the company named, along with an individual (e.g., pharmacy manager) at the particular pharmacy. This approach enables pharmacy leadership within an organization to "stay in the loop" on all network communications and seems to have worked well for Rx-SafeNet members choosing to employ this approach. This experience has emphasized for us a need to be flexible in adjusting our policies and procedures to reflect the reality of community practice.

3. Balancing the network's philosophy of ongoing collaboration on a variety of projects over time with the perception that some practitioners want to focus on a specific project is a challenge during initial outreach.
Recently, network leadership have been advised that practitioners would be more likely to join Rx-SafeNet if they were interested in a specific project. While we certainly recognize this and are able to share with interested practitioners examples of project ideas that have been submitted, pursued, or that network leadership are interested in, we have also attempted not to emphasize any one project. Our primary concern is creating a confirmation bias about the nature of the network or the type of involvement that is expected from the membership. This type of bias could lead to two issues: 1) pharmacies refrain from joining because they are not interested in early project opportunities and do not understand that future projects may be quite different, and 2) pharmacies join to participate in a specific project without a significant interest in participating in future projects. We continue to assess the balance between fostering early excitement for the network by offering specific targeted research projects and avoiding a confirmation bias that could be detrimental to the future of the organization.

Project Development and Implementation Issues

1. Starting small has been key in identifying potential project implementation issues and refining PBRN procedures.
We have recently completed data collection for the first small study on which the network is collaborating. Data for this study were in the form of questionnaires completed by the pharmacist during the course of normal counseling activities with a specific patient population. The participating pharmacist did not alter their counseling behavior for these patients, but made a note of the types of patient questions and medication-related problems identified. Data collection occurred at one pharmacy, as most of the pharmacies in Rx-SafeNet signed up after the network was approached with this project. We decided to include this as an official network project even with only one pharmacy participating as an opportunity to test our network processes and policies for future projects. While future projects will engage multiple pharmacies, we have found that starting very small has been extremely helpful in refining our policies and network workflow. For example, this project gave us experience in convening the project review team. In addition, as this project was submitted by non-network leadership or pharmacy members, it prompted us to develop a guidance document for non-member investigators wishing to collaborate with the network to ensure everyone is on the same page. Furthermore, we worked to develop a standardized approach to the style of training materials and data collection training activities and created a system for tracking Collaborative Institutional Training Initiative (CITI)

training completion, which is required of all practitioners (depending on their role in the research) participating in network projects. Finally, it has allowed us to reflect on our communication practices and training procedures, including methods for data transfer, and make adjustments. Working on our initial project with a pharmacy that is truly engaged and enthusiastic about this concept has been helpful. The pharmacy is very flexible and full of ideas to improve the process.

Discussion

As evidenced above, the development of Rx-SafeNet was primarily modeled after the work of our primary care PBRN colleagues and, at least early in the network's lifecycle, this approach has worked well. In Indiana, this has resulted in the first PBRN in our state to focus on community pharmacy, which we believe serves as an important complement to the other PBRNs that exist, including networks focused on primary care, pediatrics, family medicine, oncology, and adolescent medicine.[14-18] Rx-SafeNet leadership have had the opportunity to interact with these networks through meetings sponsored by the Indiana Clinical and Translational Sciences Institute (CTSI).[12] Although cross-network collaborative projects between Rx-SafeNet and the physician networks have not yet been pursued, we believe this is an excellent opportunity for future collaborative efforts. We are aware of other networks that appear to be considering this type of collaboration as well.[19] Primary care PBRNs with an existing connection to colleges of pharmacy through their sponsoring university or local Clinical and Translational Science Award (CTSA) institution[20] may benefit from pursuing this type of collaboration. Research exploring the medication use process, medication safety concerns, or medication-taking behaviors may be especially appropriate for cross-network engagement with primary care PBRNs, as primary care physicians are active in the prescribing, administration, and monitoring stages and community pharmacists are routinely more active in the dispensing and monitoring stages which, together, offers a more complete picture of patients' medication use and taking behaviors.

Although we found many similarities among Rx-SafeNet and the experiences of other networks, we discovered unique challenges and "lessons learned" that we offer up. As mentioned, we believe Rx-SafeNet is unique among existing and previous community pharmacy PBRNs for two main reasons: 1) Unlike Rx-SafeNet, many of the PBRNs that we are aware of are composed of pharmacists (not necessarily practicing in community) rather than pharmacies,[4,21,22] and 2) some of the other community pharmacy PBRNs we are aware of do not invite chain community pharmacies to participate.[3,4] The decision to focus on community pharmacy in Rx-SafeNet was made based on an increased overall focus on community pharmacy practice within the College of Pharmacy. Since its creation, Rx-SafeNet leadership have been approached by physician office or clinic-based pharmacists interested in participating, but the decision was made to limit participation to community pharmacies because of the need to focus on developing and advancing practice in this setting. Some of the workflow and procedural challenges that may make research more challenging in the community pharmacy setting, including chains, represent the same reasons that a focus is needed to help advance practice in these settings.

Rx-SafeNet recognizes the important role of technicians and other support staff in community pharmacy practice and the impact they could have on implementing projects. Because of this, the network attempts to engage pharmacy technicians and other support staff in the research process. The pre-launch survey administered to community pharmacy employees statewide during the development of Rx-SafeNet to assess interest and perceived barriers to participating in a PBRN included technicians and other support staff.[9,10] The membership registry survey collecting data on member pharmacies upon joining Rx-SafeNet specifically asks for information regarding technicians' education and special training.

Conclusions

Developing a community pharmacy network has provided network leadership the opportunity to reflect on many "lessons learned" that we believe have not yet been extensively described in U.S. PBRN literature. Although community pharmacy PBRNs are not yet commonplace in the U.S., we believe their development and subsequent research efforts, including those conducted in collaboration with primary care PBRNs, serve as an important avenue for investigating medication use issues.

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Figure 1. Rx-SafeNet Development Timeline

Fall 2009	Met with stakeholders
Spring 2010	Completed pre-launch survey
Summer 2010	PBRN named and registered with AHRQ PBRN Resource Center as an Affiliate Network
Fall 2010	Drafted policies Formed advisory board Met with University leaders
Spring 2011	Held state-wide information sessions Began member sign-up Finalized policies
Fall 2011	Continued outreach and member sign-up
Spring 2012	Hired 0.45 FTE pharmacist network coordinator Launched first project