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Original Research

Defining and implementing a model for pharmacy resident research projects

Travis B. DICK, Krystal L. MOORMAN, Elyse A. MACDONALD, Alissa A. RAINES, Kathryn D. MATHEWS COX.

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ABSTRACT[*]

Objective: To describe a standard approach to provide a support structure for pharmacy resident research that emphasizes self-identification of a residency research project.

Methods: A subcommittee of the residency advisory committee was formed at our institution. The committee was initially comprised of 2 clinical pharmacy specialists, 1 drug information pharmacist, and 2 pharmacy administrators. The committee developed research guidelines that are distributed to residents prior to the residency start that detail the research process, important deadlines, and available resources. Instructions for institutional review board (IRB) training and deadlines for various assignments and presentations throughout the residency year are clearly defined. Residents conceive their own research project and emphasis is placed on completing assignments early in the residency year.

Results: In the 4 years this research process has been in place, 15 of 16 (94%) residents successfully identified their own research question. All 15 residents submitted a complete research protocol to the IRB by the August deadline. Four residents have presented the results of their research at multi-disciplinary national professional meetings and 1 has published a manuscript. Feedback from outgoing residents has been positive overall and their perceptions of their research projects and the process are positive.

Conclusion: Pharmacy residents selecting their own research projects for their residency year is a feasible alternative to assigning or providing lists of research projects from which to select a project.

Keywords: Pharmacy Residencies; Research; Education, Pharmacy, Graduate; Specialization; United States

[*]**Travis B. DICK**. PharmD, MBA, BCPS. Solid Organ Transplant Clinical Pharmacy Specialist, Department of Pharmacy, Intermountain Medical Center. Murray, UT, (United States). travis.dick@imail.org

Krystal L. MOORMAN. PharmD, BCPS. Clinical Assistant Professor, Pharmacotherapy; University of Utah College of Pharmacy. Salt Lake City, UT, (United States). krystal.moorman@pharm.utah.edu

Elyse A. MACDONALD. PharmD, MS, BCPS. Drug Information Specialist, University of Utah Drug Information Service. Salt Lake City, UT, (United States). elyse.macdonald@hsc.utah.edu

Alissa A. RAINES. PharmD, BCPS. Hospital Pharmacy Operations Manager, Department of Pharmacy, Intermountain Healthcare. Murray, UT, (United States). alissa.raines@imail.org

Kathryn D. MATHEWS COX. PharmD, BCPS (AQ Cardiology). Cardiology Clinical Pharmacist, Department of Pharmacy, Baylor University Medical Center. Dallas, TX, (United States). Kathryn.Mathews@Baylorhealth.edu

INTRODUCTION

The future of our profession is evolving with the American Society of Health-System Pharmacists (ASHP) Pharmacy Practice Model Initiative (PPMI). There is an obvious shift in practice models by integrating the pharmacist into the multidisciplinary care team and providing the pharmacist with more clinically intensive responsibilities.[1] As pharmacist clinical services expand and the healthcare spectrum, from policy discussion to direct patient care, becomes more relevant to practicing pharmacists, our profession is adapting current skills to accommodate the needs of our institutions.[2] Participating in research may not only positively affect pharmacotherapeutic endpoints, but may also enhance the credibility of the profession to other healthcare professionals and patients.

The ASHP Postgraduate Year 1 (PGY1) residency objectives for goal R.4 of the old standard and R2.2 of the new standard state that graduates of an accredited residency program should demonstrate project management skills by completing a practice-related project.[3,4] This includes all aspects of the project, including identifying a topic, designing the study proposal, submitting an application to the Investigational Review Board (IRB), collecting and analyzing data, and completing a manuscript suitable for publication. While the project is required for accreditation, ASHP does not specify how the research process is designed.[3]

Resident project ideas are often generated by pharmacy practitioners several months before the residents start their training program.[5,6] Historically, our residency program maintained a list of potential projects and presented research ideas to incoming residents, commonly referred to as a “project pitch”. Importantly, the resident was not involved in generating research questions, and the actual IRB submission and research design began when the resident arrived on site. Residents chose one of the projects and completed it with the associated preceptor on the list. We identified that this process missed a crucial element of research - idea generation, which is necessary throughout the residents’ careers.

Our process is similar to other research processes, but focused on clearly defining deadlines and expanding the timeline of the resident project to begin in June. This allows the residents to identify and refine their own original research topic. The overall goal of the advanced timeline and research question generation is to ensure residents have a meaningful project that will impact patient care, clinical services, published literature, protocol

development, and maximizing responsible medication use. In addition, the independent nature of the research project should facilitate preparation to conduct successful research efforts after residency training.

METHODS

This project was reviewed by the institutional review board and was deemed exempt (IRB#1040168). Our residency program is at a tertiary medical center that employs approximately 60 pharmacists and enrolls 3 to 4 residents annually. The typical start date of the residency program is the last Monday in June, which allows for residents to secure benefits early in their residency. Over half of the pharmacy staff precept residents either on rotation, longitudinally for staffing purposes, or for research projects.

At our institution, a subgroup of the Residency Advisory Committee was formed to define a process for pharmacy resident research. Representatives of the original resident research committee (RRC) included two clinical pharmacy specialists, one drug information pharmacist, and two pharmacy administrators. The RRC was developed to provide oversight and assistance to the residents in order to achieve research goals and completion of the projects by the end of the residency. This committee was charged with developing research guidelines to be distributed to the residents prior to the residency start date. Also, the RRC was responsible for delivering a formal presentation of research deadlines and expectations during resident orientation. This process was intended to facilitate residents to initiate, design, and complete a research project. The residents were encouraged to submit the manuscript with results for publication.

Residents were required to complete human subjects training determined by the local IRB prior to residency orientation. They were notified of this prior to starting the residency in a letter that introduces the research project. In addition, residents were encouraged to start thinking about areas they may be interested in researching. A formal overview of the research process was provided by the RRC during the residents' first week on site. Examples of previous resident projects were presented, and clear direction was provided for upcoming deadlines. Significant time was spent discussing how to generate research ideas during this presentation. After initial instruction, the residents were given one week to formulate a research question. Residents were encouraged to formulate multiple questions, and those questions were then proposed to the RRC. Following the presentation to the RRC, the research questions could be refined by the RRC. Reasons a question may need refining include not aligning with system initiatives, the research question is already answered, data are not able to be collected, or the project is not feasible to complete in one year. The residents were then directed to content experts in the hospital to discuss their research idea in further detail. One member of the RRC was also assigned as a preceptor for the year to collaborate with the content experts to ensure the resident could maneuver around any unexpected barriers for completion and ensure that deadlines were met. One week was given to expand the research question to generate a research concept including an estimate of patient numbers, primary and secondary endpoints, and feasibility was submitted to the RRC for review. Upon provisional approval from the committee, the residents had one month to formalize a research protocol with their preceptors. Meetings with a statistician were encouraged, and the completed protocol was due by the end of July.

The RRC then gave final protocol approval, and the resident finalized the research protocol with their preceptors in order to submit their project to the IRB for approval by the third week of August. The following criteria were used to determine whether approval would be granted: feasibility of project completion in one year, financial impact for hospital, benefit for the resident, department, and organization, impact on patient care, innovation in practice, and impact on patient safety. At this point in the year, if a resident was unable to identify a research question, a research project was assigned by members of the RRC.

During the last week of August, each resident presented a 10-minute overview of his/her proposed research project to the pharmacy department. ACPE-accredited continuing education was provided to attendees, which provided additional encouragement for members of the pharmacy department to attend. Data collection and analysis were then performed in the coming months after receiving IRB approval. Interim results are presented at ASHP's Midyear Clinical Meeting in poster format. An interim report was due to the RRC in December to ensure the residents were on track for successful completion of their research projects. All data were analyzed by the end of April. Next, the residents presented their research methodology and results to the RRC and their preceptors and feedback was provided. Two weeks later, the revised presentation with complete results was given to the pharmacy department. Finally, their residency conference presentation was given in May, and a complete manuscript was submitted to the RRC prior to residency completion. Residents were again encouraged to submit this manuscript for publication.

The deadlines were intentionally set prior to actual meeting or organizational deadlines so that residents were given an opportunity to make edits prior to actual deadlines. For example, the IRB submission deadline for residents was one week prior to actual hospital submission deadline. The goal of the aggressive deadlines was to ensure the residents were not distracted from clinical rotations or delay their research for more natural tasks.

As previously mentioned, residents were assigned at least two project preceptors with one preceptor who was a content expert in the field of study and another member of the RRC interested in participating with research for the entire year. There was no requirement for content preceptors to have significant research experience since a member of

the RRC helped co-precept the project. The preceptors participated in the evaluation of the protocol design, research completion, and reporting of results. It was expected that the co-preceptors collaborated in order to provide direction for the resident and guide the resident toward clinically meaningful endpoints.

Preceptors provided support to the resident to meet residency program objectives and advised the resident throughout the year. The preceptors assisted in the development of the project goal and research hypotheses, facilitated resources and relationships necessary for project completion, and contributed to meeting deadlines for reviewed reports, presentations, and manuscripts. The RRC ensured that projects were feasible for completion in one year, and navigated the health system to facilitate necessary resources to ensure resident success. Preceptors were also responsible for maintaining appropriate IRB training and recertification, being available to assist with resident questions, notifying the RRC of research-related problems, and meeting with residents to ensure successful project completion. Furthermore, preceptors were required to provide regular feedback and document the feedback in Resitrak™ at least quarterly.

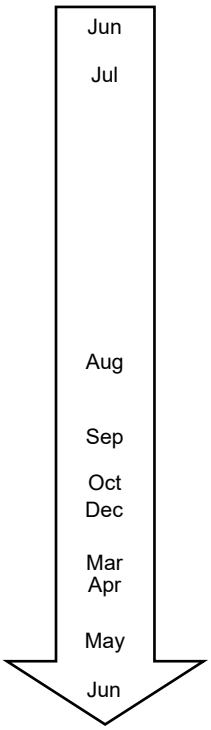
RESULTS

The timeline and important deadlines that were developed by the RRC are illustrated in Figure 1. In the 4 years this research process has been in place, all of the residents completed IRB training online through institution-approved programs by their first day of residency training. Importantly, 15 of 16 (94%) residents successfully identified their own research question. No preceptors have declined an opportunity to precept a resident research project. The one resident who was unable to independently identify a research question was assigned a research project. All of the other deadlines set forth by the RRC were met by all residents.

All residents submitted a complete research protocol to the IRB by the August deadline and protocols required minimal revisions and secured IRB approval by October. Residents met with a statistician during project development in the Fall and again for data analysis in the Spring. Furthermore, all residents presented methodology at poster sessions at the ASHP Midyear Clinical Meeting. Finally, all residents presented results at the regional residency conference and to the pharmacy department. Four of 16 residents have presented the results of their research at multi-disciplinary national professional meetings. One resident had their research manuscript published in a peer-reviewed journal. Four residents recently completed residency training and may seek presentation at a multi-disciplinary and/or seek publication of their research results.

DISCUSSION

Many programs struggle with the research project process.[5,7,8] Irwin and colleagues[7] surveyed residency program directors and residents who were likely to participate in the Western States Residency Conference to identify barriers to successful completion and publication of research projects. A total of 32 residency program directors and 97 residents participated in the survey. Barriers identified by program directors included identifying a research topic (33.3%), developing a realistic timeline for completion of the project during the residency year (40%), obtaining IRB or



- IRB training completed
- Research process presented
- Residents identify research question
  - Committee guidance
  - Project assigned if necessary
- Concept sheet
  - Provisional approval
- Two preceptors assigned
  - Content expert
  - Committee member
  - Others if necessary
- Completed protocol
  - Final committee approval
- Statistical consultation
- Protocol revision
- IRB submission
- Department presentation for ACPE continuing education credit
- Data collection upon IRB approval
- Interim report due
- Data collection
- Data analysis
- Conference presentation rehearsal
- Manuscript preparation
- Department presentation
- Residency conference
- Manuscript due

Figure 1. Pharmacy resident research timeline.

departmental approval (46.7%), and navigating the publication process (73.3%). Barriers identified by residents included identifying a topic (31.2%), developing a timeline (45.2%), collecting data (34.4%), analyzing data (39.8%), and navigating the publication process (43%). Program directors were statistically more likely to identify obtaining approval and navigating the publication process as barriers (p=0.02 and <0.01, respectively). Residents were more likely to perceive collecting data and analyzing data as barriers (p=0.02 and 0.04, respectively). Additionally, 43.3% of residents reported that a lack of mentorship or structure hindered the completion and publishing of their project.[7,9] This perception is supported by the fact that about 25% of abstracts presented at the 2008 Western States Residency Conference only had 1 author.[10]

Additionally, the barrier of publishing results has been supported in several studies.[8,10,11] Publication rates for resident research projects range from 4.3% to 21%.[8,10-12] Abstracts that report results, those with a physician co-author, and observational studies are associated with higher publishing rates.[10,11] Among abstracts presented at the 2008 Western States Conference, 30.8% of PGY2 and 10.5% of PGY1 resident abstracts presented results.[10] While some residents may have presented results at the conference, this indicates that many residency projects are incomplete late in the year. Irwin *et al*.[7] found that the majority of resident research projects are initiated in the second or third month of residency.

We have found that with strategic planning, residents are able to identify a research question independently and design a project from start to finish. Instructing residents to start thinking of interest areas and come prepared with ideas for research has helped the process. Those ideas could then be refined and shaped into manageable research projects. In contrast with the report from O'Dell and colleagues, all of the residents who have participated in research after implementation of this process have had results to present at the regional residency conference. Beginning earlier facilitates earlier completion of the project. Additionally, thorough review and guidance from preceptors and the RRC in the Spring is essential to mentor the residents in converting their data collection efforts into meaningful results. Besides initial project conception, the spring feedback from project preceptors and the RRC is the most important step in the resident research process. The majority of projects have been refined and molded at this Spring meeting to be more impactful regarding patient care outcomes and practice improvement efforts for the institution.

Most residents admitted feeling overwhelmed with the process at the beginning of the residency year, but support from the RRC helped decrease this anxiety per their report. Overall feedback at the end of the year from outgoing residents has been positive, and their perceptions of their research projects and the process has been acknowledged as a positive learning experience. In addition, Department of Pharmacy staff members have appreciated attending the resident presentations both in the Fall and learning the results in the Spring at departmental staff meetings. Increased interest in learning about research at the end of the residency year was also described by Ellis and colleagues.[13]

While this process has been positive, areas for improvement exist. For one, not all residents had a longitudinal mentor from the RRC due to attrition from the facility. As one might expect, we found that even with a defined process and timeline, residents without mentors from the RRC struggled to keep up with the defined deadlines. A resident without RRC mentorship often fell behind deadlines likely because the RRC met monthly to address challenges or barriers to project completion. Going forward, residents will be reassigned to a new RRC member for mentorship in the event that their initial mentor is no longer available.

Despite our efforts to provide enhanced support from project preceptors and the RRC, many residents still have difficulty collecting data with the deadlines originally set by the resident and preceptors. Often times we have found it is because the resident's efforts to work independently discourage them from asking preceptors for help when challenges arise. More frequent meetings between residents and preceptors are often established in the Spring, which provides the resident the opportunity to detail their successes and challenges in person and allows the preceptors to provide immediate guidance and schedule additional meetings and deadlines when applicable.

ASHP mandates that residents execute project management skills during the course of their residency curriculum. By incorporating residency requirements into projects and research, we can achieve outcomes to support the PPMI and advance our profession. Although publication of research is not mandatory, it should be encouraged as the final component necessary to communicate knowledge and experience gained. Publication of residency project results may help justify additional pharmacist positions, generate additional research ideas for peers, and quantify the impacts of interventions. Furthermore, better outcomes from resident projects may help justify future resident positions and alleviate some of the mismatch in the number of resident candidates and available residency positions. The results may also be beneficial to other institutions that face similar challenges.

CONCLUSIONS

Our center has developed a research structure with a model that incorporates practitioners with a variety of skill levels as it pertains to research experience. By encouraging residents to identify their own research questions to initiate their research, we are training them to contribute to professional development and pharmaceutical outcomes through meaningful, independent, pharmacist-driven research. Furthermore, this process will prepare residents to continue to participate in research long after the completion of residency training. Allowing

pharmacy residents to identify their own research project ideas at the beginning of residency training is an alternative to having projects proposed or assigned by preceptors as it allows residents to develop and demonstrate their skills throughout the entire research process from project conception to completion.

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CONFLICT OF INTEREST

None declared.

DEFINICIÓN E IMPLANTACIÓN DE UN MODELO DE PROYECTOS DE INVESTIGACIÓN PARA RESIDENTES EN FARMACIA

RESUMEN

Objetivo: Describir un abordaje estándar para proporcionar una estructura de apoyo a los residentes de investigación en farmacia que enfatice la auto-identificación de un proyecto de investigación en la residencia.
Métodos: En nuestra institución se creó un subcomité del comité asesor de la residencia. Inicialmente el comité se componía de 2 especialistas en farmacia clínica, un farmacéutico de información sobre medicamentos, y dos administradores de farmacia. El comité desarrolló guías que detallaban el proceso de investigación, fechas límite importantes, y recursos disponibles, y que se distribuyeron entre los residentes antes de comenzase la residencia. Se definieron claramente instrucciones para la junta de investigación de la institución (IRB) con entrenamiento y fechas límite para varias tareas y presentaciones a lo largo del año de residencia. Los residentes concebían su propio proyecto de investigación y se colocaba énfasis en completar las tareas de la parte inicial del año de residencia.
Resultados: En los 4 años que este procedimiento de investigación lleva en vigor, 15 de los 16 (94%) residentes identificaron con éxito sus propias preguntas de investigación. Todos los 15 residentes enviaron un protocolo de investigación completo al IRB en la fecha límite de agosto. Cuatro residentes presentaron resultados de su investigación en reuniones profesionales nacionales multidisciplinarias y uno publicó un artículo. El retorno de los residentes salientes ha sido en general positivo y sus percepciones sobre sus proyectos de investigación y el proceso son positivas.
Conclusión: Residentes de farmacia seleccionando su propio proyecto de investigación es una alternativa factible a asignar o proporcionar listas de proyectos para que elijan uno.

Palabras clave: Residencias en Farmacia; Investigación; Educación de Posgrado en Farmacia; Especialización; Estados Unidos

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