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Clinical Services Provided by Inpatient Pharmacies in Alabama

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Background

Clinical pharmacy services are progressively becoming a mainstay of modern pharmacy in both inpatient and outpatient settings. There is evidence for the clinical and economic benefit of specialized pharmacy services. For example, in a study published in The Journal of the American Medical Association in 1999 it was established that pharmacist presence on rounds in the medical intensive care unit substantially lowered the rate of adverse drug events caused by prescribing errors.[1] In 2003 a meta-analysis was published in Pharmacotherapy reviewing the body of literature available from 1996-2000 concerning the economic benefit of clinical pharmacy services. Of the 16 studies reviewed in this meta-analysis, most studies identified a positive economic impact in relation to health care cost related to clinical pharmacy services.[2] A subsequent meta-analysis published in the American Journal of Health-System Pharmacy in 2008 revealed similar results with respect to the economic benefit of clinical pharmacy services.[3] Because innovative "non-traditional" clinical pharmacy services are quickly becoming an integral part of inpatient pharmacy nationwide, the Alabama Society of Health-System Pharmacists desired to identify clinical services being offered by inpatient pharmacies in the state of Alabama.

Methods

In order to identify the clinical services being offered at institutions throughout Alabama, ALSHP conducted a survey of health-system pharmacists throughout the state of Alabama. The survey was distributed via email to pharmacists that identified themselves with the Alabama State Board of Pharmacy as working at a hospital; follow-up emails were also distributed. Those who chose to participate in the survey were asked a series of demographic questions as well as questions regarding services provided in their respective institutions. With respect to demographic data, pharmacists were asked to indicate their hospital setting, the number of beds in their institution, and the number of full time pharmacists employed by their institution. Additionally, pharmacists responding were asked to choose the best description of the pharmacy model within their institution. Duplicate responses were not used in compiling the data; if multiple responses from the same institution were noted, the response from the pharmacy director or clinical coordinator was used. By obtaining this data it was the hope of the investigators to identify the most common services provided as well as the characteristics of hospitals with robust clinical service options and the characteristics of hospitals that lack/have limited clinical services. Auburn University's Institutional Review Board approved this study.

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Results

Overall, there were 27 respondents representing 22 institutions throughout the state of Alabama. Only 22 surveys were included in the compilation of results after excluding duplicates. Of these, 14 respondents indicated their role to be pharmacy director or manager (64%). The majority of hospitals (86%) represented in the study were identified as general acute care institutions. Half of the respondents practice in a rural setting and 41% in an urban setting; two respondents chose suburban as their setting. Over half of the respondents indicated the bed size of their institution to be 100-500 beds (68%) followed by <100 beds at 27% and 501-1000 beds at 5% (one respondent). Less than half of the respondents indicated that their institution employs a pharmacist that serves solely as clinical coordinator. Selected results with regards to services offered from the study are depicted in Figures 1 and 2 below. Suburban institutions and hospitals with a bed size of 501-1000 beds are not represented in Figures 1 or 2 due to the low number of responses

In general, urban institutions (represented by the orange blocks in Figure 1) tended to offer more clinical services than rural institutions. Specifically, urban institutions were more likely to have a dedicated clinical pharmacy specialist, to provide retrospective chart review, to attend various codes and to provide anticoagulation consults. In contrast, rural institutions were more likely to conduct non-physician led rounds, to provide patient assistance programs, and to perform medication reconciliation. Additionally, urban institutions offered patient education and nursing education more often than rural settings, while rural institutions offered physician education more frequently. Regardless of setting, the majority of institutions represented in this study offered renal dose adjustment (86%), pharmacokinetic consults (86%), and nursing education (73%).

Figure 1: Clinical services provided with respect to setting

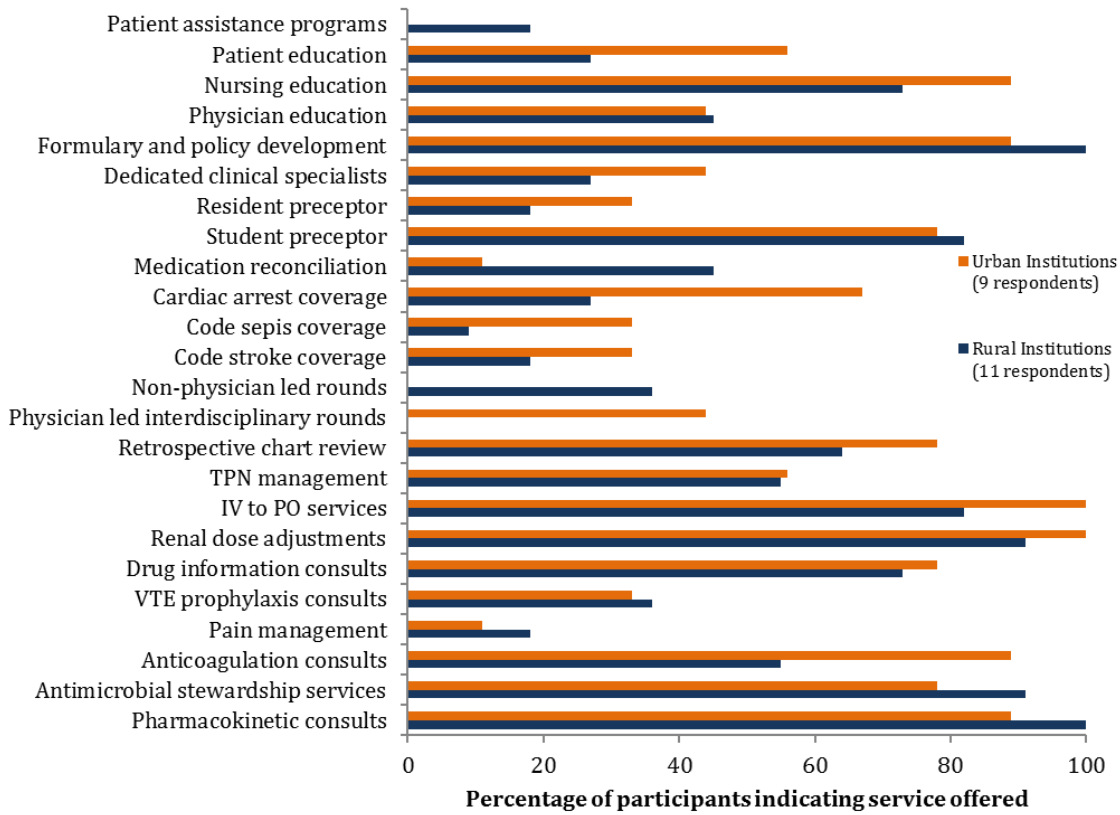
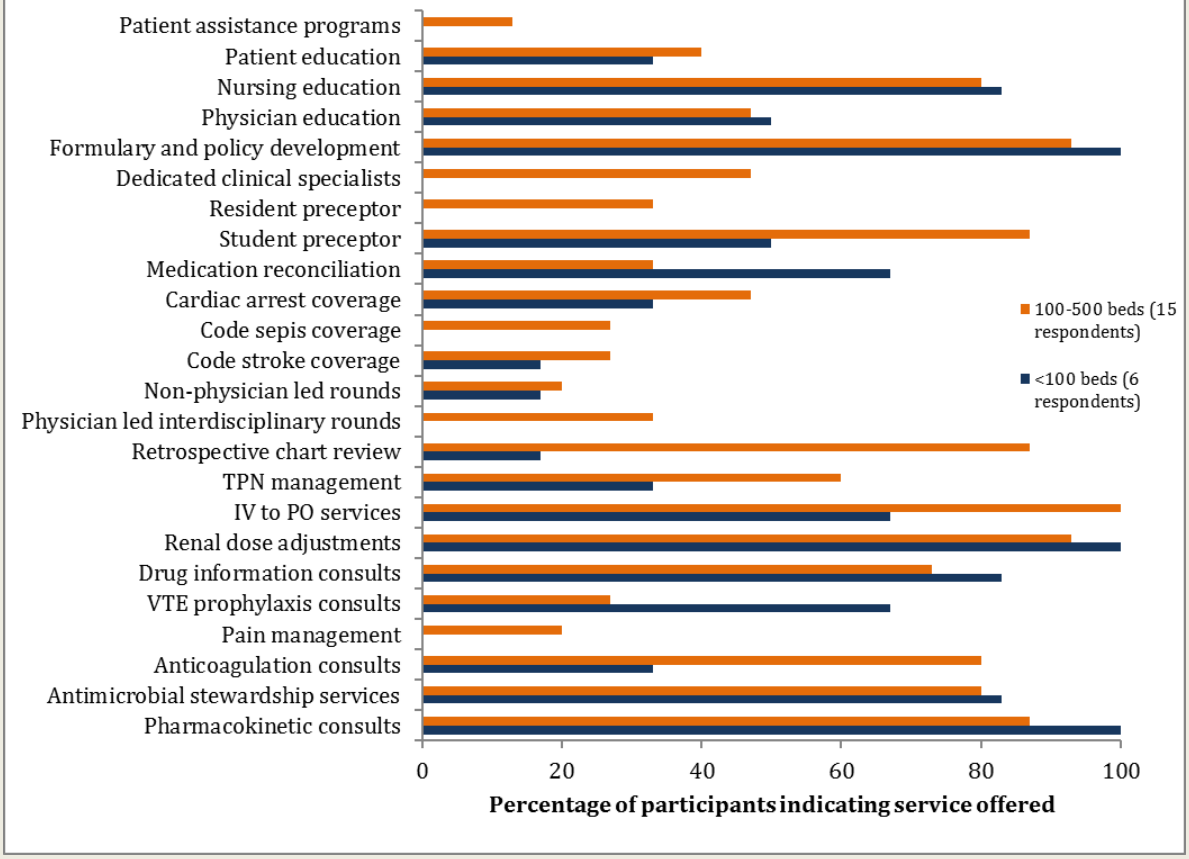


Figure 2: Clinical services provided with respect to bed-size



In general, as bed size increased the number of clinical services available increased. Institutions with larger bed size (100-500) were more likely to offer services such as a dedicated clinical pharmacy specialist, retrospective chart review, physician-led interdisciplinary rounds, and anticoagulation consults. Services offered more frequently in institutions with <100 beds were pharmacokinetic consults, drug information consults, venous thromboembolism prophylaxis consults, medication reconciliation and formulary and policy development.

Among the services available for selection, the most commonly offered were pharmacokinetic consults, renal dose adjustment, IV to PO services and formulary and policy development. Some of the least commonly offered services were enteral nutrition management, pain management, non-physician led rounds, transition of care services, and patient assistance programs. Only two rural respondents indicated that their institution provides patient assistance programs; no urban respondents selected patient assistance programs as an offered service.

Discussion

Although the data is largely difficult to interpret given the low response rate, there are general trends that can be seen. Urban institutions as well as those with larger bed size were more likely to offer robust clinical pharmacy services. It is important to note that regardless of setting or size, institutions frequently provide services integral to patient safety (i.e. renal dose adjustments, pharmacokinetic consults, and nursing education) as well as services with cost-saving implications (i.e. IV to PO conversions and formulary and policy development). Hopefully, these results will encourage the further development of pharmacy services throughout Alabama.

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Lessons Learned from Multiple, Extended Data System Failures in a Small Community Healthcare System

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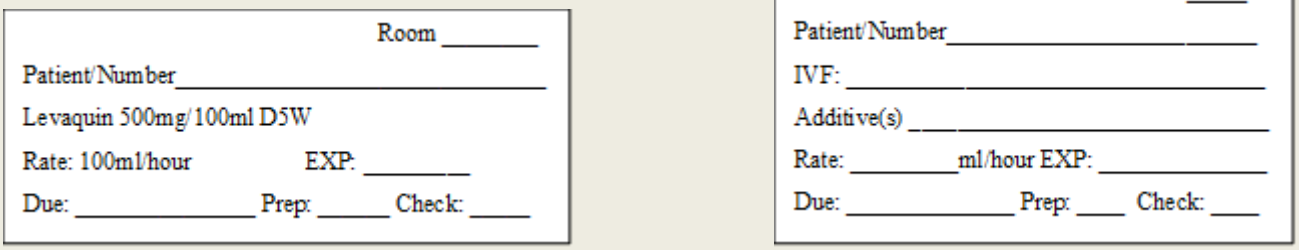
In a small healthcare system during the tornado outbreak of April 2011, the optical cable connecting two hospitals' computer system failed. For six days, a manual system was implemented in the facility that did not house the primary servers. Four years later, the entire healthcare system's Information System experienced a perfect storm, losing the backup mirror one day and the entire system mainframe the next. Over the next two weeks, the system experienced two extended failures of 5 days each and more lessons were learned. The information to follow is provided to help others prepare for similar disasters.

After the computer downtime in 2011, the pharmacy added intranet space which included tools to aid both nursing and pharmacy if an extended downtime occurred. One of these tools was parenteral labels (medication-specific and generic). The medication-specific labels allowed the pharmacist or technician to quickly prepare an admixture preparation and label. Criteria to be added to the label manually was the patient's name, hospital number, room number and time scheduled for the medication. The labels included medication name, dose, fluid, volume, and administration rate. Generic labels were used for less common medications and solutions. Examples are noted below in Figure 1:

Figure 1: Downtime intranet medication-specific and generic labels



Another set of tools developed during downtime was a pharmacy medication administration record (MAR) and a nursing MAR. The final version of the pharmacy MAR was a 10-day document, designed to reduce rewrites and provide pharmacists with a more complete hand-written record. Example of the document is noted below in Figure 2. The nursing MAR was a 21-day style document to provide nursing with a more consistent documentation. The nursing MAR was designed to reduce the amount of writing and rewriting during the administration of medications during a downtime period (Figure 3).

Issues identified during a computer system failure in 2015 was the lack of preparation and education. Nursing education was insufficient which lead to poor consistency of documentation. The first issue noticed was inconsistent use of standard forms and confusion about documenting "as needed (prn)" medications on the forms. In addition, an issue of the lack of an up-to-date patient census was identified. Shortcomings lead to document expansion on the site, production of an intranet space to track census, and expanded education for staff. The census document was a live document that provided accurate, timely patient census. The live census document was located on the hospital intranet portal, allowing the staff easy access. It included a feature to allow simple preparation of physician/physician group-specific patient lists as noted in Figure 4:

Figure 2: Example of a pharmacy medication administration record (MAR) during downtime

Allergies				Name				Number/DOB			Room Number		
Start Date DC Date	Drug Regimen	Pharmacist Initials	Date Schedule										

Figure 3: Example of a nursing MAR during downtime

Nursing Downtime MAR Allergies			Name/DOB/Room Number								
Start Date/Time	Medication/Route/Schedule	Date Due Time									

Figure 4: Example of an intranet portal patient census document

Room Number	Last Name	First Name	Patient Account Number	Physician	Group	Consult MD	Diagnosis	Diet	Admit Date Time	Discharge Date Time
214										
215										
216										

Figure 5: Examples of "as needed" (prn) and pain management MARs

Prn Profile - Use as many columns each day as necessary Allergies			Name/DOB/Room Number								
Start D/T	PRN Medication	Date									
		Time									
		Initials									
		Time									
		Initials									
		Time									
		Initials									
		Time									
		Initials									

Pain Order Profile - Use as many columns each day as necessary Allergies			Name/DOB/Room Number								
Start D/T	PRN Medication	Date									
	Morphine _______mg IV/IM q3h prn pain for patients not tolerating po medications and patients that tolerate po medications, but have breakthrough pain or refuse po agents (use IV if IV access)	Time									
		Initials									
		Time									
		Initials									
		Time									
		Initials									
		Time									
		Initials									
	Norco _______ po q6h prn pain (mg - hydrocodone) For patients tolerating oral medications	Time									
		Initials									
		Time									
		Initials									
		Time									
		Initials									

As the process continued, more documents were added to the intranet portal such as MARs for use by pharmacy and nursing that were pre-populated with the more common {non-physician specific} standing orders and a new MAR specific to prn medications. Example of these documents are noted in Figure 5.

Based on the experiences during various downtimes, a system guideline was developed for extended computer downtimes. The guidelines developed included the following categories:

1. Laboratory / Respiratory / Physical Therapy / Diagnostic Imaging orders
    - Laboratory Rounding and stat/now orders
    - Consecutive day orders
2. Census
    - Admissions / Discharges / Transfers, Midnight census, and Physician Rounding Lists
3. Patient Labels
4. Use of the Call Center to maintain patient flow
5. Nursing Documentation
    - Day Surgery and Surgery Processes
    - Emergency Department Process for T-systems failure
    - Other Nursing Unit Documentation and Processes
        - Activating manual system for downtime at 3 hours
        - Initial 24 hours, prolonged downtime, and standard format/forms
        - Complete documentation and Legibility
6. Medication Administration
7. Supplies / Charges
8. PC Backup of system for use in unexpected computer downtime
9. Education

Through each occurrence of downtime, lessons were learned which lead to improvements and better preparation for future events. After the initial downtime, people thought that a similar disaster would never happen, so preparation, debrief, and education were less than optimal. As one would expect, when tested by a recurrence four years later, all were found lacking. The second lesson learned was; if you see something that can be improved during a disaster or shortly thereafter - improve it, don't wait. The modifications made during the 3-days between the serial computer failures greatly benefitted the pharmacy and all areas that received education concerning the improvements. Following the third failure, everyone involved was much more receptive to computer emergency preparation. A more heightened sense of urgency lead to the approval of system guidelines for downtime, expanded education, and more serious consideration of process beta-testing.

Please do not take disaster preparedness lightly. It can happen to any facility and can happen again and again. Despite preparation you will probably find weaknesses in the system. Plan, prepare, and test your downtime processes. A disaster of this type may never happen in your facility, but if it does, everyone will be thankful for the preparation.

The Role of PCSK9 Inhibitors for Treatment of Hyperlipidemia

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The Proprotein Convertase Subtilisin/kexin Type 9 (PCSK9) inhibitors are a novel class of antihyperlipidemic agents that recently received US market approval. In July and August of 2015, alirocumab (Praluent®) and evolocumab (Repatha ®), respectively, were granted FDA approval to serve as adjunctive therapy to maximally tolerated statins for additional lowering of low-density lipoprotein (LDL). PCSK9 inhibitors exert their lipid lowering activity by helping to preserve LDL receptors (LDL-R).[1-2]

LDL-R, which are primarily found on the surface of the liver, bind with circulating LDL. The resulting complex is transported into the cell via endocytosis, at which point the complex disassociates. The LDL-R is transported back to the surface of the cell to repeat this cycle, and the LDL is broken down. This accounts for 75% of circulating LDL removal.[3-4]

PCSK9 inhibitors help to preserve LDL-R by irreversibly binding to PCSK9. PCSK9 also binds to LDL-R and results in endocytosis but prevents the complex from disassociating. PCSK9 therefore leads to loss of available LDL-R. PCSK9 production can be upregulated in response to low intracellular cholesterol stores, i.e. when a patient is on a statin. Inhibiting PCSK9, then, can increase LDL-R availability thereby decreasing circulating LDL.[1-2]

A table comparing alirocumab and evolocumab is listed below. Both alirocumab and evolocumab are indicated for use in addition to a maximally tolerated statin to lower LDL in adult patients with heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease (ASCVD).[1-2] Evolocumab has an additional indication for use in patients with homozygous familial hypercholesterolemia (HoFH), including adolescents. This distinction in indications is primarily due to the use of evolocumab in the TESLA Part-B study, which is the only PCSK9 inhibitor trial to enroll HoFH patients.[5] Both HeFH and HoFH are associated with marked LDL-R dysfunction, with untreated LDL typically reaching over 300mg/dL in those with HeFH and over 500mg/dL in those with HoFH.

Alirocumab and evolocumab are injected subcutaneously biweekly.[1-2] Evolocumab can also be given monthly. Labelling does not recommend renal or hepatic function adjustment for either agent, although chronic kidney disease (CKD) stage 4 and hepatically impaired patients were excluded in clinical trials. Monoclonal antibodies are not typically eliminated renally due to their large molecular weight. In terms of potential hepatic clearance, however, IgG are cleared to an extent by the liver.[1-2]

	Alirocumab (Praluent®)		Evolocumab (Repatha®)	
Indication	Adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL		Adjunct to diet and maximally tolerated statin therapy for the treatment of adults with HeFH hypercholesterolemia or clinical ASCVD, who require additional lowering of LDL Adjunct to diet and other LDL-lowering therapies (eg, statins, ezetimibe, LDL apheresis) for the treatment of patients with HoFH who require additional lowering of LDL	
Dose	75mg SQ once every 2 weeks. May increase to 150mg SQ once every 2 weeks if an adequate response is not achieved within 4 to 8 weeks		Hyperlipidemia: 140mg SQ once every 2 weeks or 420mg SQ once monthly HoFH: 420mg SQ once monthly	
Dosage form/AWP	Pen-injector: 75mg/mL ($672) 150mg/mL ($672)	Prefilled syringe: 75mg/mL ($672) 150mg/mL ($672)	Auto-injector: 140mg/mL ($650.77)	Prefilled syringe: 140mg/mL ($650.77)

A meta-analysis of over 10,000 patients included in phase 2 and 3 clinical trials for both alirocumab and evolocumab found that, compared to high intensity statin therapy or ezetimibe alone, PCSK9 inhibitors as either monotherapy or adjunct therapy produced additional LDL lowering of 50-60%.[6] Long-term cardiovascular endpoints as well as long-term neurocognitive endpoints are currently being studied in the FOURIER and ODYSSEY OUTCOMES trials which are projected to be finished in 2018.

Adverse effects between the two agents were found to be clinically similar. Compared to statins or ezetimibe, PCSK9 inhibitors are associated with similar rates of myalgias, muscle enzyme elevations, and liver enzyme elevations. Injection site reactions were more common with PCSK9 inhibitors, occurring in 4.1% of all patients assessed.[6] While it is difficult to accurately assess neurocognitive adverse effects given the available evidence, this adverse effect was more common with PCSK9 inhibitors vs. standard therapy in the OSLER[7] and ODYSSEY LONG TERM[8] trials. As monoclonal antibodies are generally too large to pass the blood brain barrier, it is proposed that PCSK9 inhibitors may produce neurocognitive effects via their severe lowering of LDL. Of note, the FDA released a warning regarding memory impairment and the use of statins in 2012.[9]

The role of PCSK9 inhibitors for treatment of hyperlipidemia remains somewhat unclear. While the 2011 European Society of Cardiology/European Atherosclerosis Society (ESC/EASC) guidelines[10] do not make recommendations regarding the place of PCSK9 inhibitors in therapy, the recently published American College of Cardiology (ACC) consensus statement[11] offers guidance on the role of non-statin therapies for LDL lowering. Authors recommend PCSK9 inhibitors in combination with maximally tolerated statin therapy as a reasonable option in patients with clinical ASCVD or LDL $\geq$ 190 mg/dL if additional LDL lowering is desired. While significant LDL lowering of these agents has been proven, trials assessing cardiovascular benefits have yet to be published. Differences in cardiovascular outcomes in favor of PCSK9 inhibitors were found in the OSLER[7] and ODYSSEY LONG TERM[8] trials, although neither of these trials were designed to assess long-term cardiovascular endpoints. The grey area for PCSK9 inhibitors will likely not be "will these agents reduce cardiovascular events" but rather "how much will these reduce cardiovascular events, and will they be worth the cost?". As PCSK9 inhibitors are often assigned higher tiers or non-preferred status for third party payers, it may be hard for patients and healthcare systems to justify the high price of these agents. Until additional cardiovascular outcome data is available, the cost-effectiveness of PCSK9 inhibitors may be difficult to assess.

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Is Pursuing a Pharmacy Residency for Me?

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As you can see the finish line, you wonder what to do once you graduate. Some people may already have career plans lined up while others have an idea if they want to go into a retail or an institutional setting. When I was in my last year of pharmacy school, I would hear from teachers, alumni, and classmates that finding an inpatient job these days would be difficult without a residency. I wasn't sure if pursuing residency was right for me, but I went along since my other classmates were either applying for residencies or fellowships. Here are some tips to help you determine if residency is right for you:

1. Be a leader!

Taking the initiative in determining what you want in the future is beneficial and important. Having a list of your goals, pros and cons of pursuing a residency, and your level of commitment will definitely help with your decision. Even if all of your friends are applying for residencies, don't feel pressured to follow, but rather be committed to your decision.

2. One year of your life

You may think a year is not a lot of time, but it really is! Especially if you end up moving for your residency, it may take some time to adjust to the new environment. However, if you take the time to find a residency program that is a good fit for you and in a location you like, you'll find that year going by much faster. Here are some suggestions that can help you determine the best location for you:

- Touring the hospital can help you get a feel of how the interdisciplinary team interacts
- Ask good questions of the faculty, preceptors, and residents to determine if their residency is a good fit for you
- Don't forget to consider the location, so try and pick a place that you'll enjoy spending your downtime.

3. Money, money, money

This can be a determining factor in pursuing a residency. A resident makes less than half the salary of a pharmacist. Ask yourself if money is going to be an issue due to loans, rent, and etc. Keep in mind that if you pursue a residency, you can defer loan payments during that time, but interest will still be accumulating. This goes back to the pros and cons list of pursuing a residency; money comes and goes, but gaining experience from doing a residency will not happen more than once. Doing a residency for a year is like buying a new car; both are considered to be an investment for the rest of your life. When applying for jobs, you will have an advantage over new graduates due to your residency training. Many places, especially competitive areas in institutional settings, require or prefer residency trained applicants.

4. Recognize the road ahead

Residency will be a challenging opportunity, but in the end the rewards are significant. Residency training may help increase your job prospects, help you gain confidence and experience in your chosen profession, and allow you an opportunity to experience new and exciting places. As a health care practitioner, we should always strive to keep learning even after graduation as well as keeping up to date with the most current medical information; pursuing a residency will help with that.

Graduation is both an exciting and nervous time. Even if you do not have a job secured by the time you graduate, there are many pharmacy career paths. Hopefully this article can help guide you with your decision. I wish you the best of luck!

Submission Guidelines for ALSHP's *InPharmative Quarterly* Clinical e-Journal Publication

The InPharmative Quarterly Clinical e-Journal publication provides a forum for communication of relevant information for the practice of pharmacy. The publication encourages manuscripts from pharmacists, non-pharmacist in a pharmacy setting or academia, residents, and students. Types of contributions including original research papers, reviews, program descriptions, and short descriptions of clinical controversies or patient cases. The journal encourages new authors to submit manuscripts, and foster engagement in sharing of expertise.

To ensure that only accurate and substantive articles are included, all manuscripts require an editorial approval prior to acceptance. Submission of a paper to InPharmative Quarterly clinical e-Journal publication will be taken to imply that it represents original work not previously published, that it is not being considered elsewhere for publication, and that if accepted for publication it will not be published elsewhere in the same form without the consent of the editors.

Types of Contributions

The journal will publish the following types of communications:

Research papers

Research articles describe experimental or observational investigations that used formal methods for data collection and reporting of results of studies related to pharmacy practice (maximum 2000 words).

Reviews

Reviews are comprehensive, well-referenced descriptive papers on topics directly related to the practice of pharmacy such as new drug updates, disease state reviews or change in practice (maximum 2000 words).

Program descriptions and legislative updates

Program descriptions are descriptive papers outlining specific programs or service descriptions, upgrades and software changes, administrative items, and medication safety issues. To help promote practice development and progress, practice site descriptions and successful strategies implemented are very valuable as the role of pharmacy continues to grow in our state. Legislative updates are also welcomed to help keep members informed of changes affecting pharmacy practice. (maximum 1000 words).

Short descriptions of clinical controversies or patient cases

Short descriptions of controversies or clinical pearls related to pharmacy practice. In addition, authors may submit patient cases with a review section about the problem and solution. (maximum 500 words)

Manuscript Organization

Manuscripts should include title of the article, name of author or authors with credentials, title and institution followed by the body of the manuscript, references, tables and/or figures. References should be cited according to the AMA 10th edition. The telephone and valid e-mail of all authors should be included with an indication of the corresponding author who will check proofs and receive correspondence.

Submission

Manuscripts should be submitted electronically to Allison Meyer or an editorial board member as noted below.

The Editorial Board looks forward to reading and publishing the innovative programs, review articles, clinical controversies, and research that is happening across the state!

Editorial Board

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