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Jornada Post Midyear 2009

"Apostando por el 2020"

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44th ASHP Midyear Clinical Meeting and Exhibition
Venetian Hotels & Sands Expo Center • Las Vegas, NV
December 6–10, 2009

http://www.ashp.org/Midyear2009

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Contribución Científica

E. Monte

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Contribución Científica

1. "Redefiniendo el modelo de práctica profesional: ¿de dónde venimos; hacia dónde vamos?"

    - De dónde venimos, hacia dónde vamos (70´s, 80´s, 90´s, 00´s)

    - Demostrando el impacto del farmacéutico

2. Contribución científica en forma de pósters

"Apostando por el 2020"

Contribución Científica

1. **"Redefiniendo el modelo de práctica profesional: ¿de dónde venimos; hacia dónde vamos?"**

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“Redefiniendo el modelo de práctica profesional: ¿de dónde venimos; hacia dónde vamos?”

2:00 p.m. – 5:00 p.m. Room 3104-Lido

Redefining the Practice Model: Where Have We Been; Where Do We Go?

ACPE Activity #204-000-09-241-L04P
3.0 Contact Hours / Knowledge-based
Educational Content: General Interest

Moderator: *Daniel Ashby, MS, FASHP*

LEARNING OBJECTIVES:

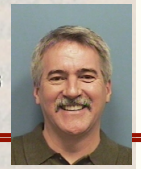
- Describe the key components of currently employed practice models.
- Describe the types of practice models that are most common in different types and sizes of hospitals.
- Describe the core essential patient-care services to which each patient should have access.

2:05 p.m. – 2:20 p.m.
Practice Model Initiative: Setting the Stage
Daniel M. Ashby, MS, FASHP

2:20 p.m. – 2:35 p.m.
Developing Practice Models in the 70’s
William E. Smith, PharmD, PhD, FASHP

2:35 p.m. – 2:50 p.m.
Developing Practice Models in the 80’s
Burnis Breland, MS, PharmD, FASHP

2:50 p.m. – 3:05 p.m.
Developing Practice Models in the 90’s
T. Mark Woods, PharmD, BCPS, FASHP



3:05 p.m. – 3:20 p.m.
Developing Practice Models in the 00’s
Steve Pickette, RPh, BCPS

3:20 p.m. – 4:00 p.m.
Demonstrating Pharmacists’ Impact
Marie A. Chisholm-Burns, PharmD, MPH, FASHP

4:00 p.m. – 4:55 p.m.
Roundtable Discussions and Reports

4:55 p.m. – 5:00 p.m.
Where Do We Go from Here?
Daniel Ashby, MS, FASHP

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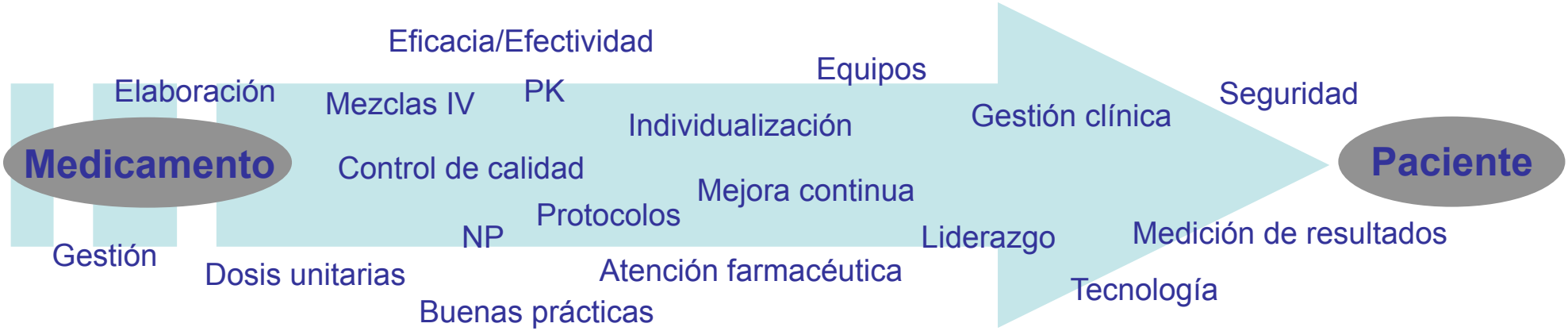
“¿De dónde venimos; hacia dónde vamos?”

- Breve repaso de la evolución de la farmacia hospitalaria en USA por décadas (desde los 70s hasta la actualidad)
- Desarrollo muy similar al vivido en España, quizás con un adelanto de una década respecto a nosotros



- Diferentes modelos y grados de desarrollo e implantación en diferentes estados y tipos de hospitales

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“¿De dónde venimos; hacia dónde vamos?”

LECCIONES APRENDIDAS DEL PASADO

- La filosofía de trabajo y el idealismo son atractivos

- Comenzar con el fin (objetivo) en la mente → tener clara la visión

- El cambio requiere la difusión de las innovaciones → los líderes de hoy deben descubrir la sabiduría del cambio y transmitir los valores a su gente

- La profesión necesita estar preparada para el cambio

“¿De dónde venimos; hacia dónde vamos?”

Pharmacy Practice Model Initiative

PPMI

PHARMACY PRACTICE MODEL INITIATIVE
Redefining. Reconstructing. Reinventing.
A joint project of ASHP and the ASHP Foundation

Redefining. Reconstructing. Reinventing.

At this pivotal time, there is an urgent need to create a forward thinking hospital and health-system pharmacy practice model. ASHP and the ASHP Research and Education Foundation will sponsor a Pharmacy Practice Model Initiative that will include a consensus summit, a robust social marketing campaign, and program evaluations.

http://www.ashp.org/ppmi

Vision

- The initiative and summit will create passion, commitment, and action among hospital and health-system pharmacy practice leaders to significantly advance the health and well being of patients by optimizing the role of pharmacists in providing direct patient care. By describing patient care services and activities that support the safe and effective use of medications, corresponding models can be adopted that optimize the full potential of pharmacist, technician, and technology resources.

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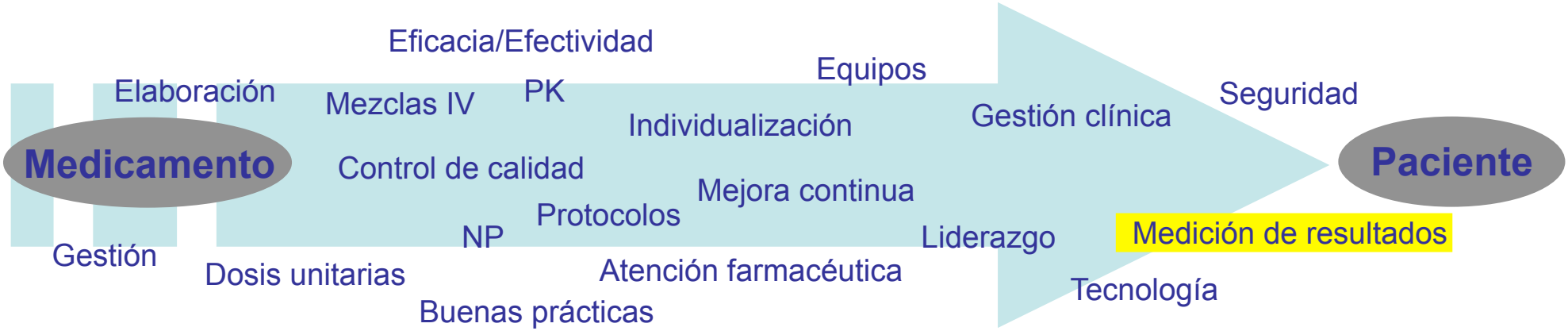

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“Demostrando el impacto del farmacéutico”

Marie Chisholm-Burns

PharmD, MPH, FCCP, FASHP, is Professor and Head of the Department of Pharmacy Practice and Science at The University of Arizona College of Pharmacy. She received her BS in Psychology and Biology from Georgia College, BS in Pharmacy and Doctor of Pharmacy degree from The University of Georgia, and Masters in Public Health from Emory University.
She completed her residency at Mercer University Southern School of Pharmacy and at Piedmont Hospital in Atlanta, Georgia. Dr. Chisholm-Burns is Founder and Executive Director of the Medication Access Program, which increases medication access to transplant patients. She has served in numerous leadership positions in several different professional organizations and worked in multiple pharmacy settings. With more than 200 publications and approximately $8 million in external funding as principal investigator from organizations such as the National Institutes of Health and several foundations, she is a prolific scholar. In 2008, a textbook co-edited by Dr. Chisholm-Burns, Pharmacotherapy Principles and Practice, received the Medical Book Award from the American Medical Writers Association. She has received numerous additional awards and honors including the Robert K. Chalmers Distinguished Pharmacy Educator Award from the American Association of Colleges of Pharmacy, the Clinical Pharmacy Education Award from the American College of Clinical Pharmacy, the Daniel B. Smith Practice Excellence Award from the American Pharmacists Association, and the Rufus A. Lyman Award for most outstanding publication in the American Journal of Pharmaceutical Education (both in 1996 and 2007). She lives in Tucson, Arizona with her husband and son.

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“Demostrando el impacto del farmacéutico”

- Presentación del proyecto “Demonstrating Pharmacists’ Impact on Therapeutic, Safety, Humanistic and Economic Health Outcomes: Systematic Review and Meta-analyses.”

- Financiado con una beca de la American Society of Health-System Pharmacists Foundation

- Equipo multidisciplinar: farmacéuticos, un especialista en economía de la salud, un médico, un abogado, un trabajador social, una enfermera y dos documentalistas

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"Demostrando el impacto del farmacéutico"

- Revisión sistemática de publicaciones que valoran el impacto del farmacéutico en resultados de salud en Estados Unidos

- Fuente de datos: bases de datos bibliográficas electrónicas (PubMed, Ovid, IPA, Cochrane, NGC, DARE, ClinicalTrials, Google Scholar…), búsquedas manuales de referencias y consultas con expertos

- Selección inicial de >56.000 artículos; revisión final de unos 3.500 artículos completos o abstracts → 335 artículos

- Evaluación artículos con criterios MBE

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“Demostrando el impacto del farmacéutico”

- Metanálisis a partir de los ensayos metodológicamente más robustos

- Mayoría de estudios en pacientes NO ingresados

- Resultados medidos:

  - Terapéuticos: efecto terapéutico (clínico) producido por una intervención
  - Seguridad: prevención de EM o daños producidos por un mdto
  - Humanísticos: adherencia, psicosociales
  - Económicos: costes (MC, CE, CU, CB)

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- Resultados terapéuticos: beneficio significativo
- Resultados en seguridad: beneficio significativo
- Resultados humanísticos
    - Adherencia: beneficio significativo
    - Satisfacción del paciente: beneficio no significativo
    - Conocimiento: beneficio significativo
    - QoL: beneficio significativo
- Resultados económicos: resultados positivos (no se hizo metanálisis por escaso número de estudios y variabilidad de endpoints)

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“Demostrando el impacto del farmacéutico”

“Overall, our findings were positive. The studies show that pharmacists have a favorable impact on patient outcomes (particularly therapeutic and safety) in different populations and settings.”

- La “utilización” del farmacéutico en la atención directa al paciente (direct patient care) es una estrategia factible para afrontar los desafíos de la atención sanitaria

- Existen oportunidades y desafíos para los farmacéuticos

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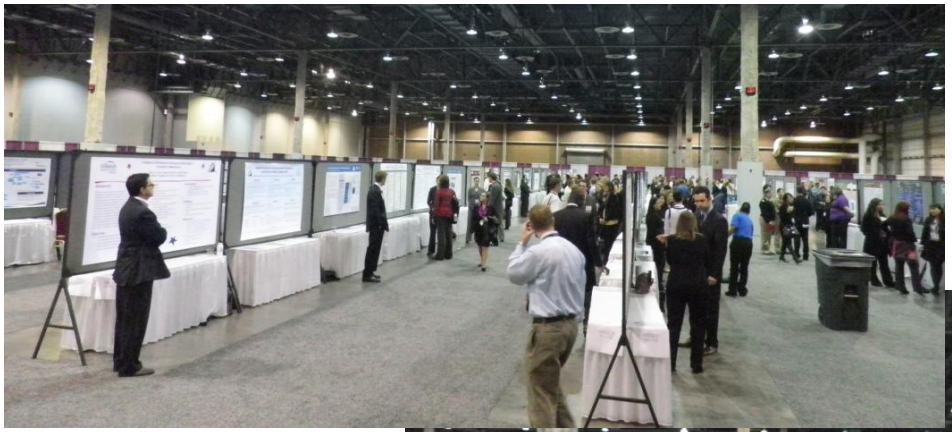
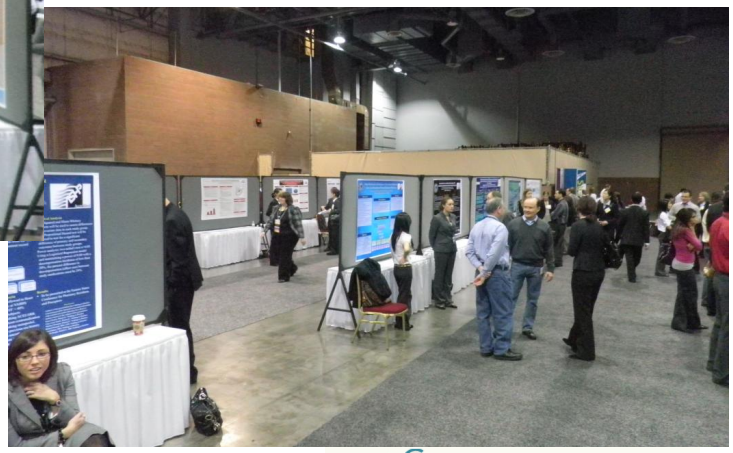
   - Demostrando el impacto del farmacéutico

2. **Contribución científica en forma de pósters**

Contribución científica en forma de pósters





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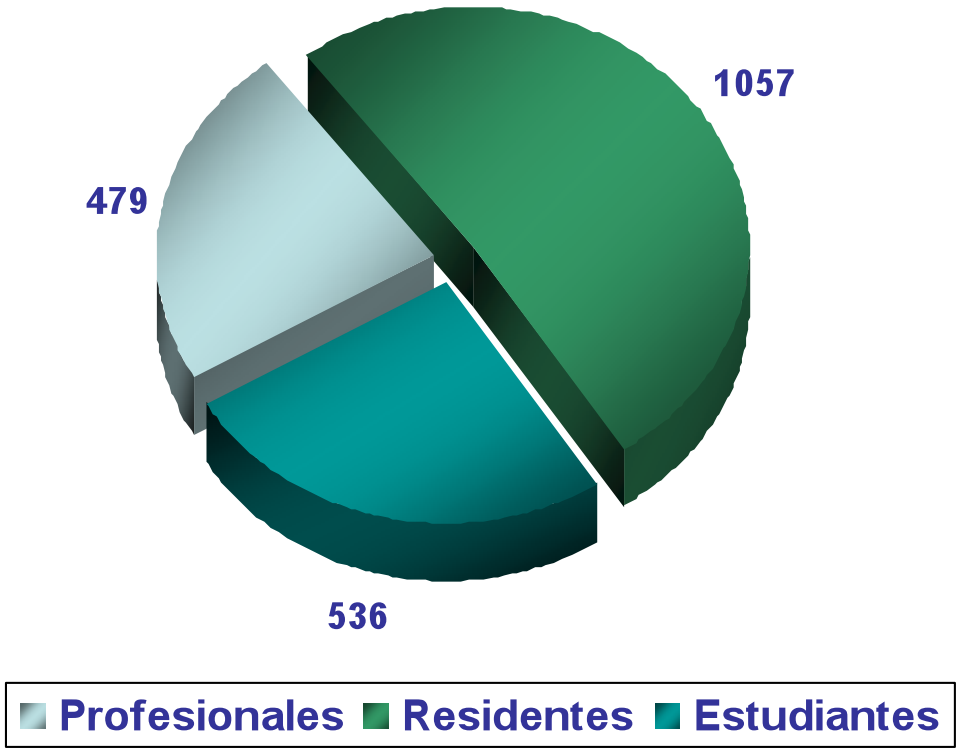
Contribución científica en forma de pósters

Total: 2.072 pósters



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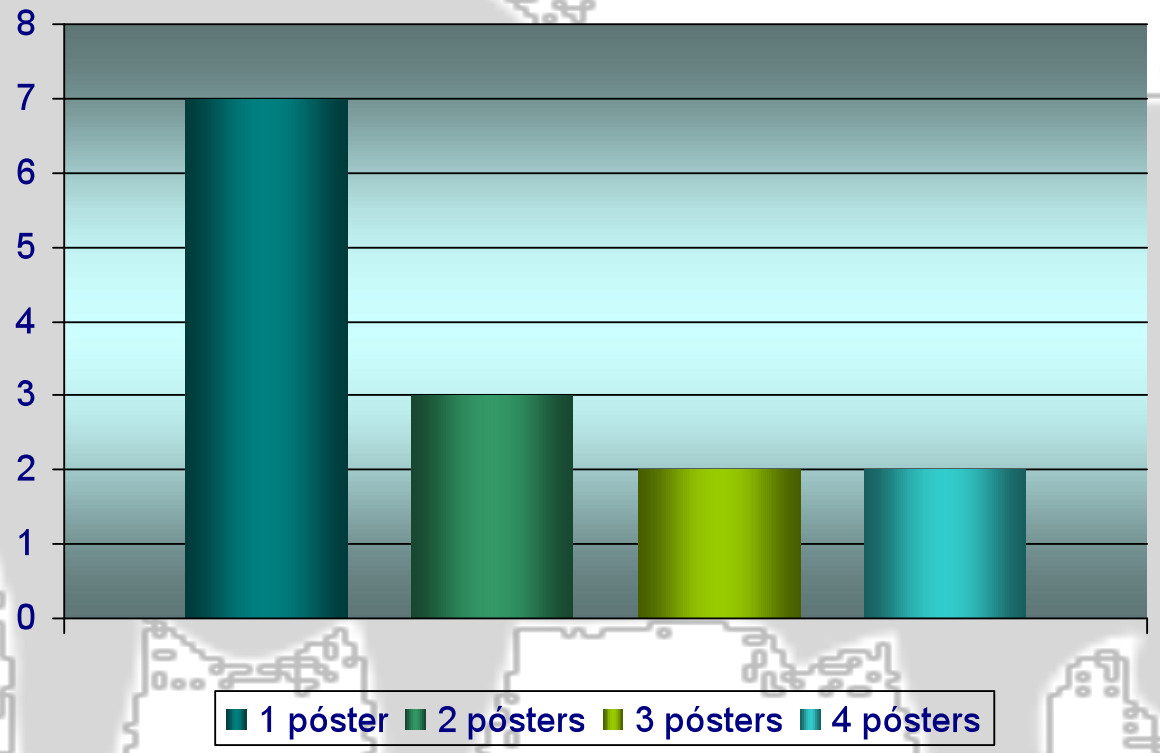
Contribución científica en forma de pósters

Contribución española: 14 centros / 27 pósters



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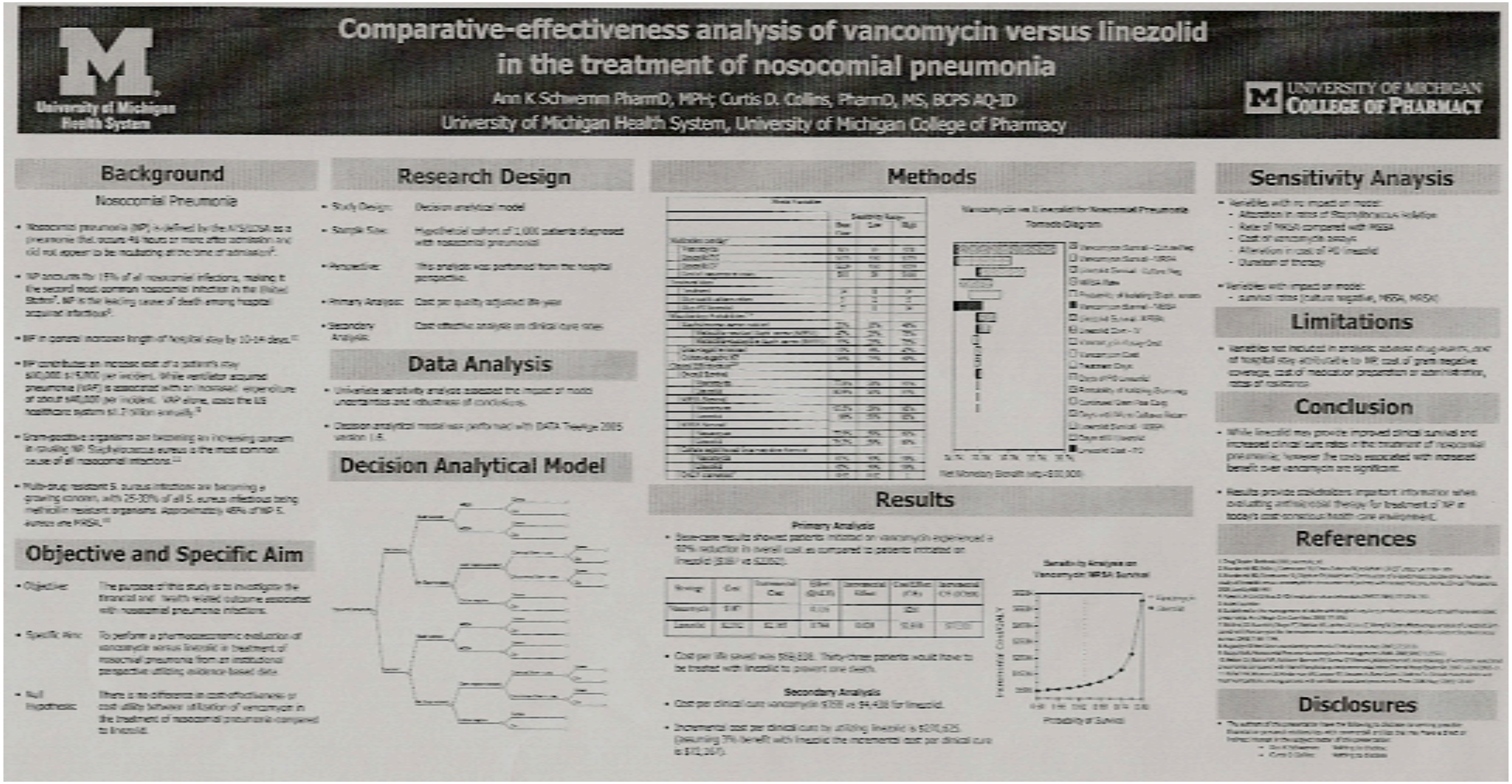
Contribución científica en forma de pósters

Temática:

- Enorme variabilidad de temas
- Algunos temas más recurrentes:
  - Patologías crónicas (diabetes, hipertensión, hiperlipemia…)
  - Anticoagulantes
  - Interacción clopidogrel-IBP
  - Antimicrobianos (mucha vancomicina!!, bastante sobre IFI)
  - Conciliación
  - Urgencias
  - Información, counseling… influencia sobre adherencia
  - EUM, seguimiento/cumplimiento de protocolos
  - Tecnología (PEA)



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Evaluation of the Drug Interaction Between Clopidogrel and Proton Pump Inhibitors and the Impact on Rehospitalization for Patients with Acute Coronary Syndrome

Jonathan Imler, Pharm.D., Evelyn Hermes-DeSantis, Pharm.D., BCPS
Robert Wood Johnson University Hospital

Introduction

Coadministration of proton pump inhibitors (PPI) with clopidogrel may reduce the effectiveness of the medication in preventing future cardiovascular events, specifically in patients with acute coronary syndrome. Clopidogrel is a prodrug that is converted in the liver to an active thiol metabolite through a two-step process involving the cytochrome P450 system. Cytochrome P450 2C19 plays a major role in this process. This active metabolite irreversibly inhibits the $P2Y_{12}$ receptor on the platelet surface which prevents the activation of the GPIIb/IIIa receptor complex, thus inhibiting platelet aggregation.

Several published studies have suggested a possible interaction between PPI and clopidogrel. However, there is discussion questioning whether all agents in the PPI class demonstrate the same degree of inhibition of cytochrome P450 2C19. It is hypothesized that certain PPI, such as omeprazole, lansoprazole, and rabeprazole, inhibit P450 2C19 to a greater degree than do other agents, such as esomeprazole and pantoprazole.

Objective

- To compare the rate of rehospitalization due to acute coronary syndrome in patients originally discharged on clopidogrel and one of three PPI, esomeprazole, pantoprazole, or lansoprazole.

Methods

- A retrospective study was conducted at Robert Wood Johnson University Hospital (RWJUH) in New Brunswick, NJ. The hospital database was searched for patients who had been discharged on clopidogrel plus either esomeprazole, pantoprazole, or lansoprazole between 1 January 2009 to 31 May 2009.
- Patients were excluded if they had previously been taking clopidogrel prior to the study period based on electronic chart records or if the patient expired at any point after 1 January 2009.
- Patients were counted as being rehospitalized if they were readmitted to the hospital at anytime between 2 January 2009 and 1 November 2009. A documented diagnosis of acute coronary syndrome (ACS) had to also be documented in the chart (including ACS, myocardial infarction, or unstable angina).
- Baseline demographics collected included patient age during original admission, sex, other medical conditions, and concurrent medications prescribed upon discharge.

Results

- 1880 patients taking both clopidogrel and one of the study PPI were initially collected. Of these, 53 patients died during the study.
- 153 total patients met entry criteria and were evaluated for rehospitalization.
- Baseline characteristics were generally similar between groups.
- Of the study patients readmitted to the hospital for ACS after discharge, 25.7% were taking esomeprazole, 27.6% were taking lansoprazole, and 22.2% were taking pantoprazole.

Table 1. Baseline Characteristics†

	Esomeprazole (n=113)	Lansoprazole (n=29)	Pantoprazole (n=18)
Age, mean (SD)	66.7 (12.9)	68.1 (13.3)	69.6 (10.6)
Male sex	69 (61.1)	16 (55.1)	11 (61.1)
Concomitant medical conditions			
Diabetes mellitus	33 (29.2)	8 (27.6)	3 (16.7)
Congestive heart failure	12 (10.6)	3 (10.3)	3 (16.7)
Malignancy	18 (15.9)	7 (24.1)	2 (11.1)
Hypertension	78 (69.0)	16 (55.2)	9 (50.0)
Cardiovascular disease	10 (8.8)	2 (6.9)	2 (11.1)
Discharge Medications			
Aspirin	104 (92.0)	22 (75.8)	16 (88.9)
Beta-blocker	94 (83.2)	21 (72.4)	11 (61.1)
ACE inhibitor	43 (38.1)	9 (31.0)	4 (22.2)
Statin	102 (90.3)	24 (82.8)	16 (88.9)
Angiotensin receptor blocker	18 (15.9)	7 (24.1)	5 (27.8)

Abbreviations: ACE, angiotensin-converting enzyme.
†Values expressed as number (percentage) unless otherwise noted.

Table 2. Analysis of Rates of Readmission Between Study Agents

	Esomeprazole (n=113)	Lansoprazole (n=29)	Pantoprazole (n=18)
Total	113	29	18
Readmitted for ACS	29	8	4
P-value	P=0.92		

Abbreviations: ACS, acute coronary syndrome.

Figure 1. Number and percentage of patients readmitted for ACS

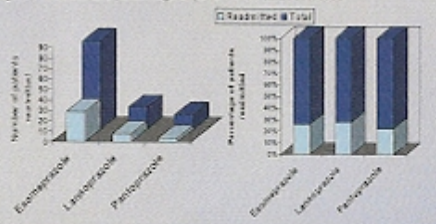

Table 3. Risk of Rehospitalization Following Discharge for ACS

Primary Outcome	Esomeprazole (n=113)	Lansoprazole or pantoprazole (n=47)	Odds Ratio (95% CI)
Rehospitalization for ACS	29	12	1.007 (0.48-2.20)

Abbreviations: CI, confidence interval; ACS, acute coronary syndrome.

Discussion

- Among patients discharged on both clopidogrel and a PPI, no significant difference in the rate or the risk of rehospitalization for ACS was found.
- Recent studies hypothesize that the interaction is not a class effect and might vary between agents. Omeprazole exhibits stereoselective metabolism via cytochrome P450 2C19. This feature is not apparent for other agents in the class, including esomeprazole, pantoprazole, and lansoprazole.
- The findings of the study help confirm that all three of the agents examined demonstrated similar percentages of rehospitalization.
- There appeared to be no increased risk of rehospitalization for ACS when comparing the formulary PPI at RWJUH to two other PPI that are still sparingly used when patients bring their own medications to be used while they are admitted.
- These findings suggest that no changes should be made to the formulary choice at this time.
- However, because the number of patients presenting to the hospital who use their home PPI while admitted is few, a far greater number of study individuals were analyzed while taking esomeprazole.
- It is also important to note the comparison of patient baseline demographics when interpreting the results. Patients in all three groups were similar in respect to concurrent comorbidities that could possibly put them at a greater risk of developing ACS.

Discussion (continued)

- In addition, medications prescribed on discharge were similar. The selected medications are important because appropriate use can decrease the risk of developing recurrent symptoms.
- Patients were not assessed or counseled on medication adherence during the study.
- While this study details strong evidence that there is not an increased risk of rehospitalization between patients taking several different proton pump inhibitors, further trials should be conducted with larger amounts of patients over longer periods of time to determine if the interaction is an entire class effect.

Limitations

- Chart review and subsequent follow-up was limited to RWJUH, with no tracking of admissions at other health care institutions.
- Although most patients received initial loading dose of clopidogrel, it was impossible to completely determine that the patient had not received clopidogrel before original admission at another institution.
- Esomeprazole is the only PPI on formulary at RWJUH, therefore, patients are more likely to be discharged on this medication.
- Study period and follow-up was shorter than the recommended one year of clopidogrel therapy.
- Compliance to study medications was assumed if patient profiles included both at original time of discharge and upon discharge during subsequent readmission.

Conclusions

- There was no significant difference in renospitalization for acute coronary syndrome for patients originally discharged on clopidogrel and one of three PPI (esomeprazole, lansoprazole, and pantoprazole).
- There was no significant increase in risk between patients discharged on the formulary PPI (esomeprazole) and the other two study agents.
- Further research should be conducted comparing the risk of morbidity and mortality for patients taking various PPI concomitantly with clopidogrel, instead of generalizing the interaction as a class effect.
- At this time, it is suggested that esomeprazole remain the agent of choice for patients at Robert Wood Johnson University Hospital.

Disclosures & Acknowledgements

All authors of this study are paid employees of Robert Wood Johnson University Hospital and/or Rutgers, the State University of New Jersey and have nothing to disclose.

Acknowledgements: Steve Kravetz, PharmD and Fred Pace, RPh.

SAINT BARNABAS MEDICAL CENTER

An affiliate of the Saint Barnabas Health Care System

Epidemiology, risk factors, treatment, and outcomes of candidemia in a 600-bed teaching hospital

Ruth Kurland, Pharm.D., Daryl Schiller, Pharm.D.

SAINT BARNABAS HEALTH CARE SYSTEM

Clinical Pharmacy Collaborative Network

Background

- Candidemia is the fourth most common cause of blood stream infections in the United States.
- Mortality has been reported as 15-25% for adults and 10-15% for neonates and children.
- The prevalence of the *Candida* species has been changing. While *C. albicans* remains a large cause of candidemia, there has been an increase in the occurrence of non-*C. albicans* candidemia, particularly *C. glabrata*.
- As with other microorganisms, different species of *Candida* are susceptible to different antifungal medications.
- Historically, fluconazole has been the treatment of choice for candidemia. However, with the advent of the echinocandins and the change in *Candida* species seen, there has been a shift in the treatment of candidemia.

Objective

The objective of this study was to evaluate the epidemiology, risk factors, treatment, and outcomes of candidemia and to assess whether they differ for the different species seen at our institution.

Methods

- The study was approved by the Institutional Review Board.
- Blood culture reports from the microbiology lab were used to identify inpatients with candidemia between January 2008 and December 2008.
- For those patients with multiple blood cultures reported, only the first blood culture was used for data collection.
- A corresponding chart review of those patients with candidemia was performed.
- Epidemiological data and data pertaining to risk factors of candidemia and its treatment were collected.
  - Chi-square test was used for discrete data with $\alpha<0.05$ as a cutoff for significance.
  - Odds Ratio was calculated for developing a *non-C. albicans* infection.

Results

- 5.1% (n=112) of all blood cultures grew *Candida* in 2008. This represents a total of 42 patients who were included in the study.
- The average age of patients was 62 years and 47.6% (n=20) were male.
- 75.6% (n=31) of patients acquired candidemia in the hospital.
- The overall mortality rate was 23.8% (n=10).
  - 10.5% in *C. albicans* vs. 34.8% in non-*C. albicans* (p=0.066)

Figure 1 – Percentage of Risk Factors for *C. albicans* versus non-*C. albicans* Species

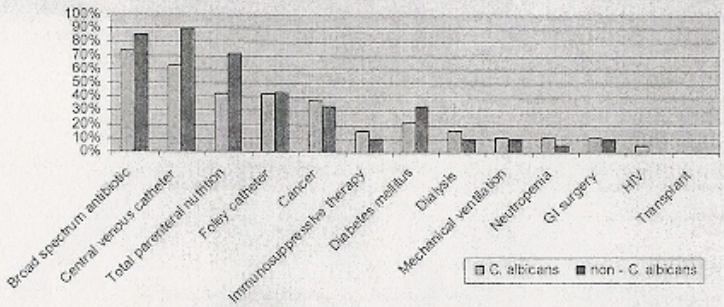

Figure 2 – Percentage of *Candida* Species Seen

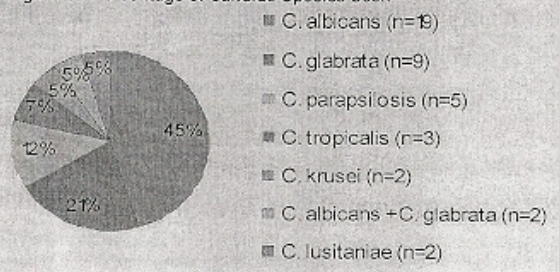

Figure 3 – Incidence of Escalation or De-escalation

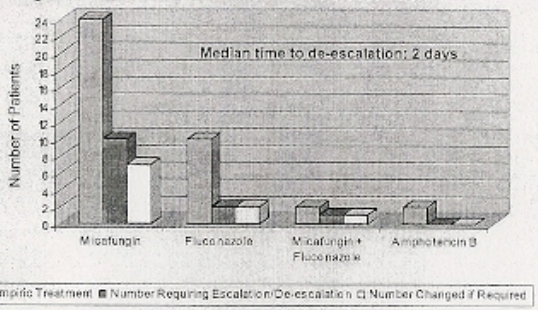

Table 1 – Statistically Significant Differences Between Risk Factors for *C. albicans* versus non-*C. albicans* Species

Risk Factors	*C. albicans*	Non – *C. albicans*	Odds Ratio (non-albicans)	P-value
Central venous catheter	68.4%	95.6%	2.864	0.027
Immunosuppressive therapy	15.8%	47.8%	1.83	0.028
Broad spectrum antibiotics	73.7%	87.0%	1.569	0.276
Total parenteral nutrition	42.1%	65.2%	1.549	0.134

Disclosure

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:
Ruth Kurland: Nothing to disclose
Daryl Schiller: Nothing to disclose

Conclusions

- Incidence of candidemia at our institution is similar to the current general trends.
- Majority of candidemia were due to non – *C. albicans* with *C. glabrata* being the most prevalent. This validates the greater use of micafungin for empiric treatment.
- Trend towards greater mortality with non-*C. albicans* fungemia.
- The most significant risk factors for causing non-*C. albicans* candidemia were central venous catheters and immunosuppressive therapy.

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Therapeutic drug monitoring with posaconazole therapy in a patient with invasive mucormycosis: a patient case report

Rachana P. Patel PharmD Candidate 2010[1], Diana Mercado MD[2], William Pace MD[2] , Brandon J. Palermo MD, MPH[2], Radhika S. Polisetty PharmD, BCPS[3]
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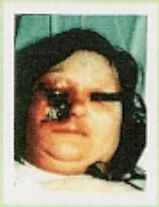
Background

Rhinocerebral Mucormycosis (Zygomycosis)

- Is a fungal infection of the sinuses, brain, or lungs that occur primarily in immunocompromised patients.
  - Poorly controlled diabetes
  - HIV/AIDS
  - Chronic steroid use
  - Chemotherapy
  - Organ transplant
- Symptoms include:
  - Acute sinusitis
  - Eye swelling
  - Dark nasal eschar
  - Fever
  - Redness of skin overlying sinuses



- Treatment includes:
  - Surgical debridement of dead and infected tissues
  - Antifungal therapy particularly high dose Amphotericin B
- Mucormycosis has a high mortality rate even with aggressive treatment

Patient Case

- The patient is a 32 year old female with a past medical history of pre-B cell acute lymphoblastic leukemia, vitamin B12 deficiency, beta thalassemia, and sinusitis.
- She received her last round of chemotherapy with methotrexate, leucovorin, and pegaspargase in June 2009 and four weeks later presented with complaints of right jaw pain. She also had right face swelling, eye swelling, and a maxillary abscess.
- Invasive fungal infection was suspected, and surgery was consulted for the debridement of the right orbital maxillary cavity. Meanwhile, the patient was started empirically on voriconazole 200mg twice daily and amphotericin B lipid complex 450 mg intravenously.
- Culture came back positive for mucor species. At this time, voriconazole was discontinued and caspofungin 70mg (loading dose) and then 50 mg once daily was added to the amphotericin B lipid complex for synergy.
- After extensive surgical debridement and being treated with high dose amphotericin B and caspofungin for three weeks a magnetic resonance imaging (MRI) report revealed new areas of infection. At that time, posaconazole 200 mg four times a day was initiated for salvage therapy.
- Since the patient was receiving her nutrition through a nasogastric tube, therapeutic drug monitoring was recommended and her dose adjusted to 400 mg four time a day based on her levels to ensure adequate posaconazole levels.

Posaconazole

- Is an oral broad spectrum triazole antifungal agent which is currently indicated for prophylaxis of invasive *Aspergillus* and *Candida* infections as well as treatment of refractory oropharyngeal candidiasis
- Posaconazole is also used for treatment of mucormycosis as salvage therapy. The standard dose for the treatment is 800 mg/day in 2 or 4 divided doses
- In the study by Greenberg et al., posaconazole has shown to be effective in mucormycosis as salvage therapy. Of 24 patients with mucormycosis in the study, rates of successful treatment were 79% in 19 patients with zygomycosis refractory to standard treatment and 80% in 5 subjects with intolerance to standard therapy. Patients that failed therapy was due to worsening of underlying illnesses or withdrawal from therapy.
- Posaconazole has sporadic absorption. Adequate posaconazole absorption and subsequent plasma levels are dependent on food. It is recommended that posaconazole be given within 20 minutes following a high fat meal or with an acidic carbonated beverage to enhance its absorption.
- There is limited data on posaconazole plasma concentration monitoring. However, in a review article by Andes et al., patients with lower plasma levels (less that 500 ng/mL), experienced the lowest rate of clinical response for the treatment of invasive aspergillosis. Patients with higher levels between 500 and 700 ng/mL were treated successfully 53% of the time

Discussion

- Therapeutic drug monitoring is typically not indicated with posaconazole therapy and there are no clear guidelines available on the subject. However, posaconazole is only available orally and is known to have variable absorption especially in patients who do not have a normally functioning GI tract, are receiving proton pump inhibitors or have diarrhea.
- Since our patient was receiving nutrition through a nasogastric feeding tube and her condition was not improving despite aggressive treatment, the decision to obtain posaconazole levels was made. After 7 days of therapy after the drug achieved steady state, a trough level was obtained and revealed a posaconazole level of 200ng/mL.
- Therapeutic ranges for posaconazole levels have not been established, but in some studies, levels between 700ng/mL to 1200ng/mL have been associated with better outcomes. Therefore, the posaconazole dose was increased to 400mg four times a day and the subsequent trough level was 880ng/mL.
- After approximately 6 weeks of aggressive antifungal therapy, the patient became clinically stable and transferred to a nursing home

Conclusion

- This case report illustrates the challenges of treating invasive mucormycosis and a situation which may warrant the use of therapeutic drug monitoring with posaconazole therapy. It also shows that standard dosing regimens may not be sufficient to obtain adequate posaconazole levels.
- There may be several reasons for the lack of response to antifungal therapy including the severity of disease and location of infection, but studies have shown that plasma levels of <700 ng/ml are associated with higher incidence of treatment failure. There are no clear guidelines on this subject and further studies are needed.
- If posaconazole is used, clinicians should consider monitoring levels to ensure adequate serum levels. This may be especially important in patients receiving active treatment for invasive fungal infections such as aspergillosis or mucormycosis, as well as in patients who are receiving nutrition through tube feedings, as this may result in erratic absorption of posaconazole and inadequate serum levels.

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Disclosure - Authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Rachana P. Patel, Diana Mercado, William Pace, Brandon Palermo, Radhika Polisetty

Assessing patient adherence and adverse events with oral chemotherapeutic agents

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ABSTRACT

Purpose: Cancer is becoming a chronic disease state, and patients are being treated in the outpatient setting with the use of oral chemotherapeutic agents. Most would assume that medication adherence to chemotherapy would not be a problem due to the severity of cancer. However, studies have shown that compliance is relatively similar to that seen with other chronic diseases. The objective of this pilot study is to evaluate the need for pharmacists' intervention based on adherence and adverse events in patients using oral chemotherapeutic agents.

Methods: This is a retrospective, non-interventional, pilot study that has been approved by the Institutional Review Board at the WJB Dorn Veteran Affairs Medical Center. Patients will be included in this study if they are at least 18 years of age, are treated at the VA hospital, and are actively using at least one oral chemotherapeutic agent. Patients on anti-estrogens and aromatase inhibitors will also be included. Patients will be excluded if they have taken oral chemotherapeutic agents previously but are not actively taking them now, or if they do not receive their medications through the VA. Medical records will be reviewed and refill records collected for patients meeting inclusion criteria. Refill records will include if the prescription was filled early, late, or on time. Early refilling will include at least 3 days early from the previous prescription, while late refilling will include at least 3 days late from the previous prescription. Data collected from the medical records will include age, gender, comorbidities, current medications, duration of chemotherapy, and any noted adverse events. The primary outcome of this study is to determine the adherence rate. Secondary outcomes include adverse events and drug interactions.

BACKGROUND

- Cancer is becoming a chronic disease state, and patients are being treated in the outpatient setting with the use of oral chemotherapeutic agents instead of the old standard use of intravenous delivery.
- Most would generally assume that medication adherence to chemotherapy would not be a problem due to the severity of cancer as a disease. However, some studies have shown that compliance is relatively similar to that seen with other chronic diseases.
- Nonadherence leads to significantly reduced therapeutic outcomes, as well as increased visits to the physician, increased hospitalizations, and increased hospital stay.
- Adverse events and drug interactions are found to be higher with oral chemotherapy use:
  - Elderly with comorbidities necessitating more medications
  - The use of complementary and alternative medications
  - New mechanisms of action that are not fully understood
- Potentially pharmacists can significantly improve patient compliance and overall outcomes for those using oral chemotherapeutic agents.

OBJECTIVE

- The objective of this study is to evaluate the need for pharmacists' intervention based on adherence and adverse events in patients using oral chemotherapeutic agents.

METHODS

Study Design:
- Retrospective, non-interventional, pilot study
- Medical records were reviewed and refill records collected for patients meeting inclusion criteria.
- Refill records included if the prescription was filled early, late, or on time

Inclusion Criteria:
- At least 18 years of age
- Patients treated at the VA hospital
- Actively using at least one oral chemotherapeutic agent.
- Patients on anti-estrogens and aromatase inhibitors were also included.

Exclusion Criteria:
- Patients who were not on active oral chemotherapy
- Patients who received oral chemotherapy outside of the VA system

Primary Endpoint:
- Adherence rate

Secondary Endpoints:
- Adverse events
- Drug interactions

RESULTS

- Forty five patients were screened for study inclusion.
- Thirty six patients met the criteria.

Figure 1: Demographics	(N = 36)
Mean age (years)	60.5
Gender	
Males	17
Females	19
Race	
African American	16
Non-African American	17
Unknown	3
Mean height (cm)	170.2
Mean weight (kg)	87.9
Mean body mass index (kg/m^2)	33.8

RESULTS

Figure 2: Prevalence of Comorbidities

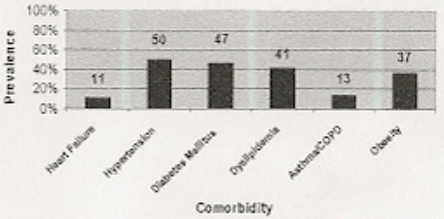
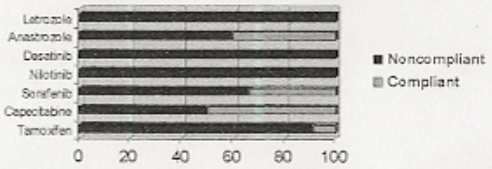


Figure 3: Type of Malignancy

Figure 4: Compliance



Primary Endpoint:
- Adherence rate: 50% (18 of 36 patients)

Secondary Endpoints:
- Adverse event rate: 75% (27 of 36 patients)
- Drug Interactions: 2
  - Average 13 medications per patient
  - Interactions:
    - Tamoxifen and warfarin
    - Dasatinib and omeprazole

CONCLUSIONS

- There is a need for a pharmacists' intervention based on adherence and adverse events in patients using oral chemotherapeutic agents.
- Future research includes:
  - Evaluating the effectiveness of a pharmacist's intervention, which may include the following:
    - Monthly assessment of each patient
    - Calling patients monthly to remind them to take their medications
    - Counseling patients starting new oral chemotherapeutic agents before they initiate the therapy
      - Compliance
      - Side Effects
      - Drug interactions
  - Cost effectiveness of a pharmacist's intervention

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44th ASHP Midyear Clinical Meeting and Exhibition – Las Vegas, NV – December 6-10, 2009

Disclosure
Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:
Nothing to disclose

Safety of Highly Active Anti-Retroviral Therapy (HAART) in the Setting of Acute Hepatitis B: A Case Report

Jason Babby, Pharm.D., Joseph L. Gugliotta, M.D., Ashmi A. Philips, Pharm.D., Rani Patel, Pharm.D.
Hunterdon Medical Center, Flemington, New Jersey
Pharmacy Department

INTRODUCTION

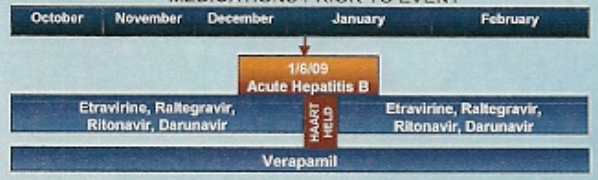
- The optimal management for those coinfected with HIV and acute HBV is not clear, specifically if HAART regimens would cause additive hepatic toxicity.
- Limited studies address the safety of HAART regimens in the face of acute HBV co-infection.
- To date, no published studies have examined the use of HAART in patients with acute HBV.
- We report the safety of reinitiating HAART in the setting of acute hepatitis B.

CASE REPORT

- A 46-year-old black male was admitted to the hospital due to jaundice secondary to acute hepatitis B.
- The patient had no known drug allergies.
- Past medical history was significant for:
  - HIV
  - Hypertension
  - Lymphadenopathy
  - Herpes zoster
  - Perianal warts
  - Cluster headaches
  - Hypogonadism
- Medications prior to admission:

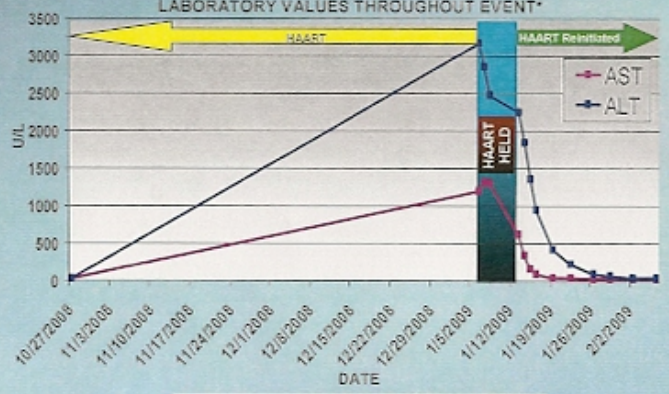
	HAART REGIMEN
•Famciclovir 250mg PO PRN	•Etravirine 200mg PO BID
•Verapamil 120 mg PO daily	•Raltegravir 400 mg PO BID
•Tadalafil 10mg PO PRN	•Ritonavir 100 mg PO BID
•Testosterone patch 5mg TD daily	•Darunavir 600 mg PO BID

MEDICATIONS PRIOR TO EVENT

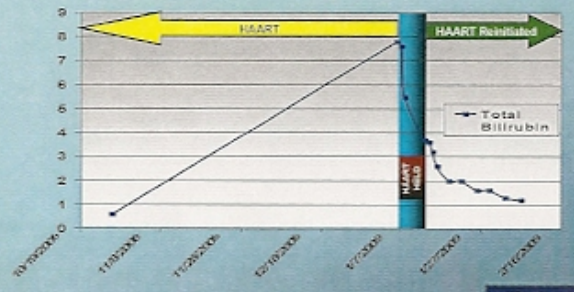


CASE REPORT *(continued)*

LABORATORY VALUES THROUGHOUT EVENT*



Date	TEST
1/7/2009	•HBSAG Confirmatory (+) •Hepatitis C Antibody (-) •RPR Non-Reactive
1/8/2009	• Hepatitis B Core IGM (+)
1/20/2009	• Hepatitis B DNA (+): 42600 IU/mL
2/17/2009	• Hepatitis B E AG Reactive



*Charts not drawn to scale

DISCUSSION

- While hospitalized:
  - Intravenous fluids and lactulose were administered
  - All hepatic markers started to resolve
- On day 4, the patient was discharged only on verapamil.
- Restarted on his previous HAART regimen 4 days later.
- The hepatic function panel was closely monitored for four consecutive days.
- Despite restarting HAART, continued improvement in the hepatic function was noted.
- By week 3, the patient's hepatic function panel was within normal range and has remained stable for the last seven months.
- In this case, the given HAART regimen was safely reinitiated with little or no hepatic toxicity.

CONCLUSION

- The initiation of HAART in the setting of acute hepatitis B has not yet been studied.
- In this case, vigilant laboratory monitoring of hepatic function demonstrated that this HAART regimen appeared to be "hepatically safe."

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The authors have nothing to disclose

8-101

Identification of the Sources of Medication Errors in Inpatients Infected with the Human Immunodeficiency Virus (HIV)

Jessica Adams, PharmD[1], Mark Sawkin, PharmD Candidate[1,2], Megan Winegardner, PharmD[1], Susan Davis, PharmD[1,2], Rachel Chambers, PharmD[1]

[1]Henry Ford Hospital and [2]Wayne State University, Detroit, MI

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Abstract

Purpose: High levels of medication adherence are imperative to the ability of antiretrovirals to suppress the human immunodeficiency virus, to prevent viral mutations that could lead to drug resistance and for preserving the immune system of patients infected with HIV. Previous studies have proven that HIV infected patients are at a great risk for medication errors in regards to their antiretroviral regimens when they are hospitalized. The objectives of this study are to identify the sources of medication errors involving antiretrovirals, evaluate where in the medication use process the errors are occurring and identify contributing factors in order to implement corrections to the medication use system.

Methods: Prior to commencement, this retrospective study will be submitted to the Institutional Review Board at Henry Ford Hospital for approval. Patients will be identified using the pharmacy department medication order entry system. Any patient taking at least one antiretroviral medication as an inpatient between July 1, 2008 and July 1, 2009 will be identified and assessed for inclusion, with the first 50 patients meeting criteria to be included. In order to be included in the study, patients will have had to be at least 18 years, with a confirmed HIV diagnosis, and have been admitted for at least 24 hours. Patients will be excluded if they were pregnant at the time of their inpatient stay. Data collected will include patient demographics, patient care unit (including transfers), and length of stay. The National Coordinating Council on Medication Error Reporting (NCCMERP) taxonomy will be used to record types of errors incurred, in addition to medications involved, node in the medication use process where the error occurred (prescribing, transcribing, dispensing or administration), contributing factors and whether the errors were resolved during hospital admission. All data will be recorded without patient identifiers and maintained confidentially. Data will be analyzed using descriptive statistics. Endpoints will include the percentage of patients in which an error occurred, and the frequency of each type of error. The percentages of errors due to prescribing, transcribing, dispensing and administration and the frequency of contributing factors associated with each (based on the NCCMERP taxonomy) will be reported. These results will be used to identify fixes to the medication use process that could prevent the errors from occuring in future admissions of HIV infected inpatients.

Background

- High levels of medication adherence are imperative to the ability of antiretrovirals to suppress the human immunodeficiency virus, to prevent viral mutations that could lead to drug resistance and for preserving the immune system of patients infected with HIV.[1]
- Errors made to an antiretroviral regimen when a patient is in the hospital have the potential to lead to decreased antiretroviral efficacy which in turn amounts to inadequate control of the human immunodeficiency virus and mutations leading to drug resistance
- Previous studies have confirmed that errors occur in up to 84% of HIV infected inpatients and have identified the types of errors that have occurred including dosing errors.[2]
- These studies, however, each only looked at one node of the medication use process (ie. prescribing, or dispensing)
- This study will not only identify the errors that have occurred in regards to antiretroviral medications, but it will also identify where in the medication use system these errors occurred and what the contributing factors were so that fixes can be implemented to prevent future errors.

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2. Pastakia SD, et al. Ann Pharmacother. 2008;42:461-7.

Methods

Objective

- The objective of this study is to identify the sources of medication errors involving antiretrovirals, to evaluate where in the medication use process these errors have occurred and to identify the factors contributing to these errors.

Study Design

- The study is a retrospective chart review

Setting and Population

- The project was conducted at Henry Ford Hospital, a 800-bed tertiary care facility and Level 1 trauma center located in downtown Detroit, MI. The study was approved by the HFH Institutional Review Board.
- Fifty adult patients who received antiretrovirals as an inpatient prior to July 1, 2009 were included
- Inclusion Criteria:
  - Age >18 years
  - Received at least one antiretroviral as an inpatient
  - Admitted for at least 24 hours
- Exclusion Criteria
  - Pregnancy
  - Antiretroviral treatment for a disease other than HIV (i.e. Hepatitis B)

Data Collection

- Data was extracted from medical records using a standardized instrument
- Data collected included the following
  - Demographics: Age, sex, race, height, weight, status as a Henry Ford Infectious Disease Clinic patient, unit(s), date/time of admission and length of stay
  - Comorbid conditions: renal or hepatic insufficiency
  - Medication error data: NCCPMERP taxonomy was used to identify types of errors that occurred, node of the medication use process where the errors occurred, contributing factors leading to the errors

Analytical Plan

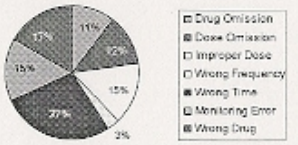
- Descriptive statistics will be used to analyze data, present results and draw conclusions

Preliminary Results

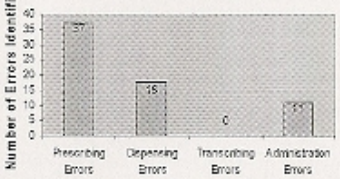
- Patient demographics for all 50 patients are presented below and error data for 25 of the 50 is presented

Baseline Characteristics	n (%) N=50
Male	37 (74)
Female	13 (26)
HFHS ID Clinic Patients	25 (50)
Race	
Caucasian	5 (10)
Black	42 (84)
Other	3 (6)

Errors Found by Category



Process Node Where Errors Occurred



Factors Contributing to the Errors Found	% of errors N= 66
Knowledge Deficit	78.8
Performance Deficit	42.4
Miscalculation of dose	4.5
Computer Error	10.6
Order Misinterpretation	1.5
Verbal miscommunication	1.5

Future Directions

- Upon completion of data analysis, interventions will be determined based on the most common errors, where in the medication use process they occurred and what factors contributed to the occurrences
- Following intervention implementation, the goal is for an overall quasi-experimental study to be undertaken for an additional fifty patients to be analyzed post intervention
- Results as of April 2010 will be presented at the Great Lakes Pharmacy Resident Conference.

Disclosure

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:
Jessica Adams: Nothing to disclose
Mark Sawkin: Nothing to disclose
Megan Winegardner: Nothing to disclose
Susan Davis: Research Support and Consultant: Pfizer, Cubist, Ortho McNeil
Rachel Chambers: Nothing to disclose

Contribución científica en forma de pósters

Calidad:

- …había de todo

- Curioso: muchísimos pósters (residentes, estudiantes) sin resultados, algunos con resultados preliminares

Pediatric Discharge Counseling by Hospital Pharmacists and Pharmacy Students Improves Medication Compliance

Emily J. Lancaster, Pharm.D. Candidate, Jennifer L. Tuttle, Pharm.D. Candidate, Abby A. Kahaleh, Pharm.D., MS, MPH, PhD

Lake Erie College of Osteopathic Medicine, School of Pharmacy, Erie, PA

Introduction

Managing medications after hospital discharged may be challenging for pediatric patients. Counseling is currently done by nurses with little physician or pharmacy involvement. Although this service is appreciated, medication discrepancies are commonly seen and could result in preventable adverse drug reactions.

The FDA defines adverse drug reaction (ADR) as "All noxious and unintended responses to a medicinal product related to any dose."[1] ADR's are one of the top ten leading causes of death in the United States, estimating $30-130 billion direct medical costs each year. Children are among the greatest risk of ADR's due to inability to communicate their drug therapy experience, giving them the title of "therapeutic orphans". Approximately 17% of pe
and 26,500 children deaths result each year fron

Purpose

To determine whether involvement of hospital pr
pharmacy students during pediatric discharge be
medication compliance and/or improves overall

Methods

Study design: Double-Blind, Randomized Cont

Pilot Study:
- 50 pediatric patients
- Three selected hospitals, not yet determined
- 5 months, June 1, 2010 – October 30, 2010
- Federal grants will be used to fund the study

Actual Study:
- 2000 patients
- The actual study will be determined based on p
available funding for research

Study Design

Patients randomized to control group or study group (1:1)
- Control – DCD counseling by nursing staff
- Study – DCD counseling by hospital pharmacist and pharmacy student

Inclusion Criteria:
- 24 months – 18 years
- Hospitalized >24hrs
- Discharged on at least 1 medication

Plan
1. Children and their parents will be counseled on all medications at time of discharge by hospital pharmacist and pharmacy students. The counseling secession will

Results/Conclusions*

Figure 1: Primary and Secondary Data

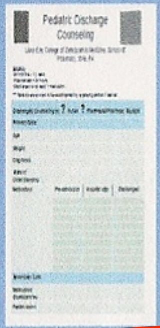
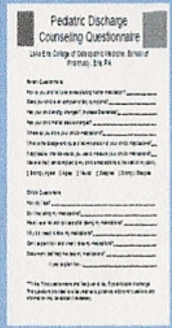


Figure 2: Open-ended Questionnaire



*Results/Conclusion will be completed upon trial completion.

Results of Literature Review

- There is a gap in literature due to limited studies on safety and tolerability for the pediatric population.
- Fatal ADR's are the 4th-6th leading cause of death in U.S.[2]
- 26,500 children (<18yo) in the U.S die each year due to ADR's.[3]
- 89% of ADR's are reported by the pharmacist.[2]
- According to FDA, 90% of ADR's are never

narcotic analgesics, anticonvulsants,
c agents, are top drug classes
with frequent ADR's.[2]

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Disclosure

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le – Nothing to disclose
alah, Pharm.D. – Nothing to disclose

*Results/Conclusion will be completed upon trial completion.

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GUIDING change

Contribución científica en forma de pósters

Calidad:

- …había de todo

- Curioso: muchísimos pósters (residentes, estudiantes) sin resultados, algunos con resultados preliminares

- Eso sí….. disponibilidad total de los ponentes para explicar el contenido y aclarar dudas


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