


REMS...

It's Not Just About Sleep Anymore


Megan Anderson, Pharm.D.
PGY1 Pharmacy Practice Resident
Saint Vincent Health Center
Erie, Pennsylvania



The Heart Center for Great People!


What does REMS stand for?

- Routine Evaluation of Medication Side-effects
- Risk Evaluation and Mitigation Strategies
- Rescue and Emergency Medical Services
- Radiopharmaceutical Enforcement Management System



The Heart Center for Great People!


Residency Research Project: Evaluation of Hospital Pharmacist Knowledge of REMS



The Heart Center for Great People!

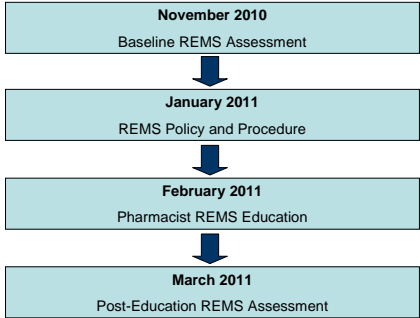
Purpose

- To evaluate hospital pharmacists' knowledge of REMS and then to assess the impact that REMS education had on their knowledge-base




The Heart Center for Great People!

Methods



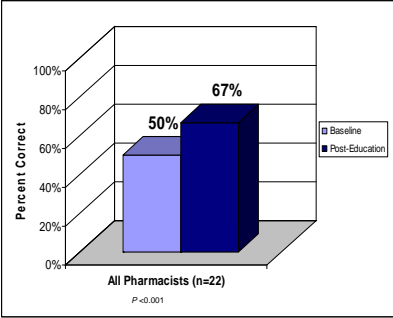
```

    graph TD
      A[November 2010  
Baseline REMS Assessment] --> B[January 2011  
REMS Policy and Procedure]
      B --> C[February 2011  
Pharmacist REMS Education]
      C --> D[March 2011  
Post-Education REMS Assessment]
  
```




The Heart Center for Great People!

Comparison of Pharmacist REMS Assessment Scores Baseline vs. Post-Education



Assessment	Percent Correct
Baseline	50%
Post-Education	67%

All Pharmacists (n=22)
P < 0.001

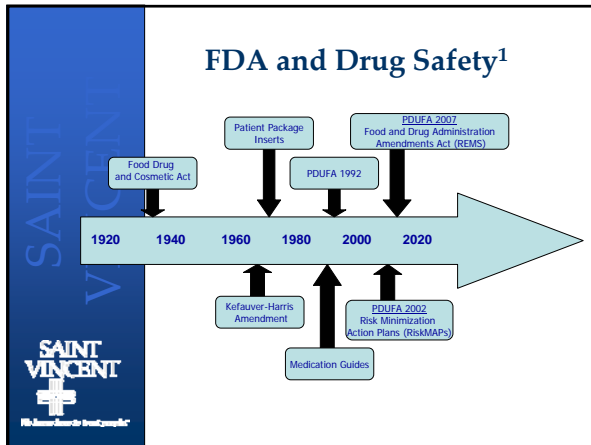


The Heart Center for Great People!

Study Conclusions

- Pharmacist baseline knowledge of REMS was poor
- An educational session did improve the pharmacists REMS knowledge
- Need for national education on REMS for all healthcare providers

Risk Evaluation and Mitigation Strategies (REMS)



Food and Drug Administration Amendments Act of 2007 (FDAAA)²⁻⁴

- Title IX, Subtitle A, section 901
 - Created new section 505-1 of Food, Drug and Cosmetic Act (FDCA)
 - Authorized FDA to require a proposed REMS to ensure that benefits of a drug outweighs the risks

Contents of a REMS^{4,6}


- Goals
- Timetable for Submission of Assessments
 - 18 months, 3 years, and 7 years
- Potential Elements
 - Medication Guide
 - Patient Package Insert
 - Communication Plan to Healthcare Providers
- Elements to Assure Safe Use (ETASU)

REMS Goals⁶

- Must include statement of one or more overall goals
 - If has ETASU, must include one or more goals for each ETASU
- Proposed REMS goal is the desired:
 - Safety-related outcome
 - Understanding by patients and/or healthcare providers of the safety risks
- Written in **absolute** terms


Medication Guides^{6,7}

- Written by the manufacturer
- Approved by the FDA to inform patient of serious risk(s) related to medication, adherence to directions for use, etc.
- Simplest form of REMS and the most common
- Recent guidance from FDA on distribution of Medication Guides related to REMS




Patient Package Insert⁶

- No changes to the components of PPIs from the initial regulation in 1968
- Goal:
 - Provides patient with easy-to-understand information regarding drug's indications, side effects, risks and benefits, etc.
- Unlikely that many new medications will have PPIs
 - Medication Guides will likely "replace" PPIs




Communication Plan^{6,7}

- Letters to healthcare providers
- Disseminating information to encourage implementation or explain safety protocols
- Disseminating information through professional societies about any serious risks of the drug and any protocol to assure safe use




Elements to Assure Safe Use (ETASU)^{6,7}

- Health care provider training or certification
- Certification of pharmacies dispensing drug
- Limit setting where drug can be dispensed (e.g., hospitals)
- Dispense only after evidence/documentation of safe-use conditions
- Patient monitoring
- Patient registry




Enforcement of REMS⁶

- Drug considered misbranded
- Civil monetary penalties
 - Up to \$250,000 per violation, not to exceed \$1 million in a single proceeding
- Manufacturer cannot introduce drug into interstate commerce
 - Prevent distribution/sale of drug



Saint Vincent Health System Policy for REMS



Physician Responsibilities

- Ensure that all requirements of REMS are met
- This may include:
 - Certification to prescribe medication
 - Distribute Medication Guide to the patient
 - Have risk/benefit discussion about the prescribed medication with the patient
 - Complete and sign informed consent/acknowledgement form with the patient
 - Fill out hospital order set, if applicable

Pharmacist Responsibilities

- If hospital order set required for a medication, contact physician to have order set completed
- Upon receipt of medication order, the following must be completed prior to dispensing medication:
 - Verify physician eligible to prescribe medication
 - Verify patient eligible to receive medication
 - Obtain copy of informed consent/acknowledgment form
- Send Medication Guide to floor to be dispensed to patient prior to the 1st dose of the medication

Examples of Medications Affected by REMS

Procrit® (epoetin alfa) & Aranesp® (darbepoetin alfa)

- Medication Guide
- Communication Plan
- Elements to Assure Safe Use
 - Certification of healthcare providers
 - Certification of hospitals/pharmacies dispensing Procrit® and Aranesp® to patients for chemotherapy-induced anemia
 - Documentation of safe use conditions
 - Acknowledgment Form
 - Hemoglobin levels

Order Sheet & Progress Record
USE BLACK BALLPOINT PEN INK ONLY Page 1 of 2

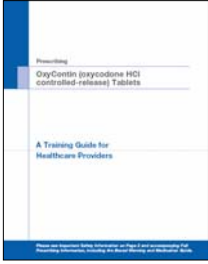
DATE	PROGRESS RECORD	DATE	MEDICATIONS-DIETS-TREATMENTS-LAB TESTS
HGB: _____	HCT: _____	PROCRI/EPGEN ORDER SET	
FOR ALL PATIENTS:			
Nursing to provide Procrit/Epogen Medication Guide to patient prior to first dose of epoetin alfa			
INDICATION: (check one box)			
<input type="checkbox"/> ESRD (end stage renal disease)			
<input type="checkbox"/> Non-ESRD, anemia, chemotherapy-induced			
<input type="checkbox"/> Anemia, no renal disease, chemotherapy-induced			
<input type="checkbox"/> Non-ESRD, anemia, radiation-induced			
<input type="checkbox"/> Anemia, no renal disease, radiation-induced			
<input type="checkbox"/> Non-ESRD, anemia, non-chemoradiation induced			
<input type="checkbox"/> Anemia, no renal disease, other			
FOR CHEMO-INDUCED ANEMIA: (must complete)			
Physician ESA APPRISE enrollment number: _____			
<input type="checkbox"/> Continuation of therapy			
Location of initiation: _____			
<input type="checkbox"/> New course of therapy (circle YES/NO)			
<input type="checkbox"/> Physician and patient signed the APPRISE Acknowledgment Form: YES NO			

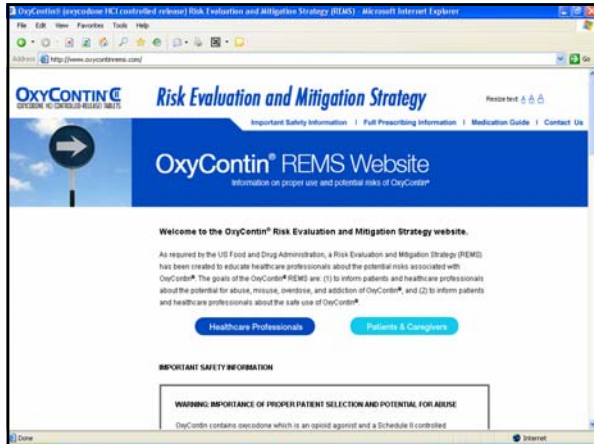
New order set contains an order for nursing to dispense Medication Guide to patient prior to first dose of Procrit

New section added to Procrit order set for chemotherapy-induced anemia. If prescriber chooses an indication with "anemia, chemotherapy-induced" this section MUST be completed.

OxyContin® (oxycodone CR)

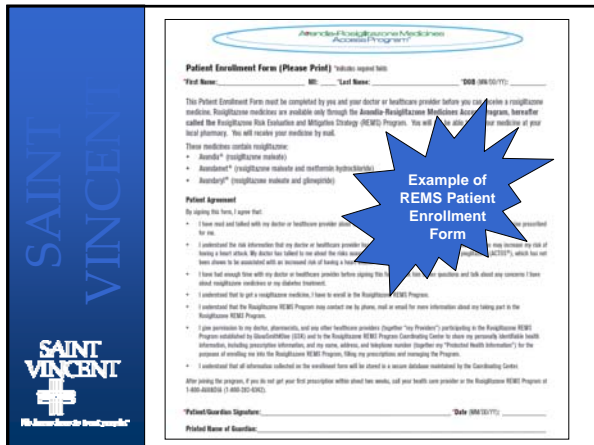
- Medication Guide
- Elements to Assure Safe Use
 - Healthcare provider training
 - Printed training packet
 - OR
 - Online training





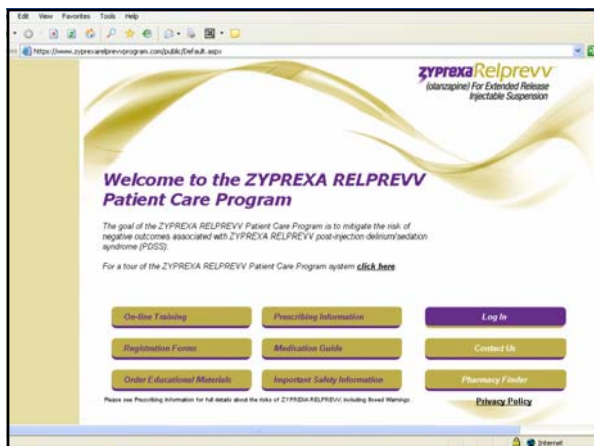
Avanida® (rosiglitazone) & other rosiglitazone-containing products

- Medication Guide
- Communication Plan
- Elements to Assure Safe Use
 - Certification of healthcare providers
 - Medication only dispensed from certified pharmacies
 - Documentation of safe use conditions
 - Patient Enrollment Form
- Implementation System
 - Includes withdrawal of rosiglitazone-containing products from uncertified pharmacies, maintain web-based database of enrolled parties



Zyprexa® Relprevv™ (olanzapine)

- Medication Guide
- Communication Plan
- Elements to Assure Safe Use
 - Certification of healthcare providers
 - Enrollment of pharmacies and healthcare settings where medication is dispensed
 - Evidence of safe use conditions
 - Patient enrollment in Zyprexa Relprevv Patient Care Program
 - Monitoring of patient following administration



Over 150 medications have REMS... And the list is growing

For information regarding other medications with REMS

- FDA Website
 - <http://www.fda.gov/Drugs/DrugSafety/PosmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm>

The Impact of Education on Nurses' Knowledge and Attitudes Towards Pain

Melinda Wingard, PharmD
PGY1 Pharmacy Practice Resident
Saint Vincent Health Center



Objectives

- List nurse characteristics identified in the literature that can influence nurse's perception of patient's pain.
- Recognize barriers to appropriate pain assessment and management.
- Discuss the impact of educational sessions on nurses scores on a validated pain survey.
- Review the implications on physician's care of patients with pain.



Pain Definition

“An unpleasant sensory and emotional experience associated with actual or potential tissue damage”

- International Association for the Study of Pain



Inadequate Pain Control⁴⁻¹¹

- Needless suffering, complications, lifestyle modifications for patients
- Greater patient dissatisfaction
- Added healthcare costs



Barriers to Adequate Pain Control¹⁰

- Patient and families
 - Inability to communicate
 - Reluctance to report pain
 - Low expectations for relief
 - Fear of what the pain means
 - Fear of adverse effects
 - Fear of addiction
 - Financial barriers
 - Inability to locate a physician to adequately control their pain



Barriers to Adequate Pain Control¹⁰

- Healthcare system
 - Failure to make pain relief a priority
 - Failure to provide clinicians with tools and training
 - Lack of accountability for pain management
 - Fragmented patient care
 - Limited access to pain specialists and therapy
 - Inconsistent reimbursement



Barriers to Adequate Pain Control¹⁰

- Healthcare professional
 - Clinicians attitude, beliefs, behaviors
 - Inappropriate or exaggerated concerns
 - Regulatory scrutiny, adverse effects, addiction
 - Inadequate or inaccurate clinical knowledge
 - Understanding of pharmacology, misconceptions about pain

Barriers to Adequate Pain Control⁴⁻¹¹

- Nursing
 - Length of nursing experience
 - Education and knowledge
 - Perception of a patient's pain
 - Perceiver's personal beliefs of pain

Barriers to Adequate Pain Control¹¹

- An Examination of Critical Care Nurses' Knowledge and Attitudes Regarding Pain Management in Hospitalized Patients.
 - 30 medical/surgical ICU nurses
 - Nurses Knowledge and Attitudes Survey Regarding Pain
 - Significant increase in scores after the educational intervention ($p = 0.0005$)
 - Nurses with greater years of experience scored the lowest on the pre-test and had the most improvement in scores on the post-test ($p = 0.047$)

Barriers to Adequate Pain Control⁶

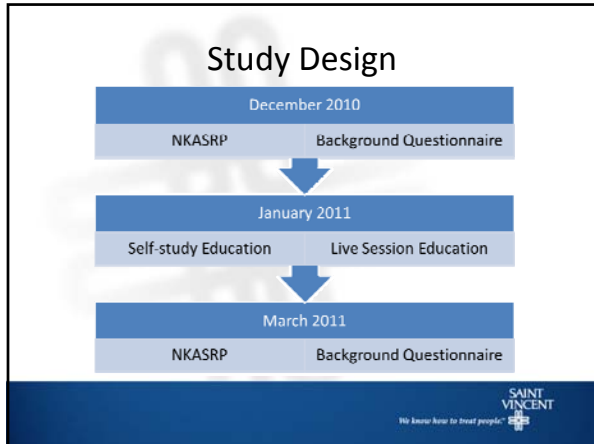
- A randomized controlled trial of an educational intervention on Hellenic nursing staff's knowledge and attitudes on cancer pain management.
 - 112 nurses: randomized
 - Validated Hellenic version of the Nurses Knowledge and Attitudes Survey Regarding Pain (GV-NKASRP)
 - Pre-intervention scores differed significantly with educational backgrounds ($p < 0.0001$)
 - Significant increase in scores after the educational intervention ($p < 0.0001$)

NKASRP⁷

- Nurses' Knowledge and Attitudes Survey Regarding Pain (NKASRP)
- Developed by Ferrell et al in the 1980s
- Available in numerous languages
- 40 questions:
 - 22 true/false
 - 13 multiple choice
 - 2 case scenarios with 2 questions each

Study Goals

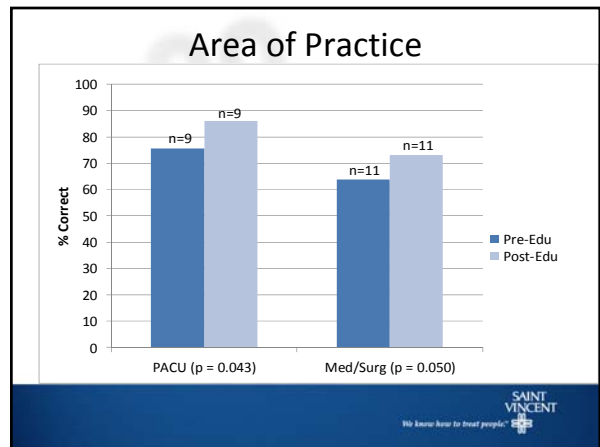
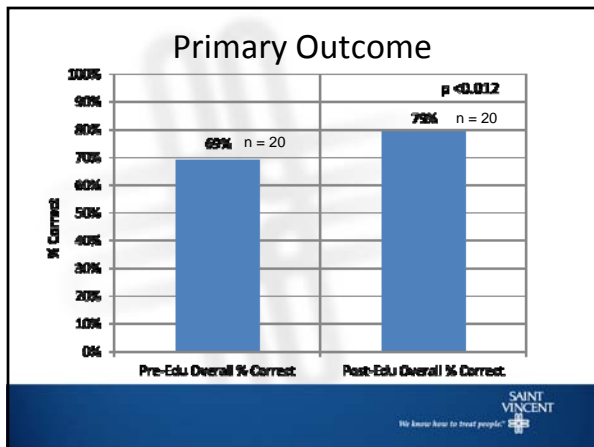
1. Assess nurses' baseline knowledge of and attitudes towards pain management using the NKASRP
2. Provide nurses with education on pain topics
3. Reassess nurses' knowledge of and attitudes towards pain management using the NKASRP

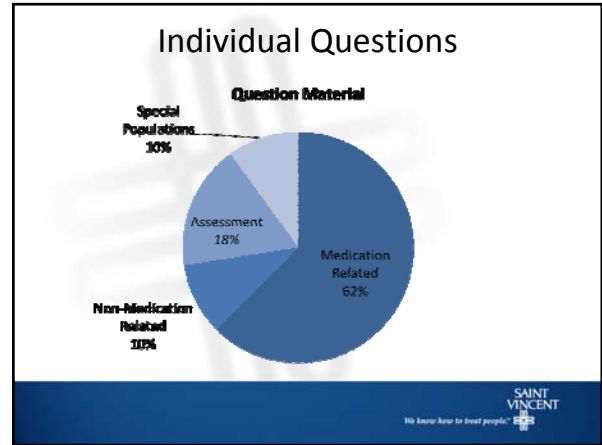
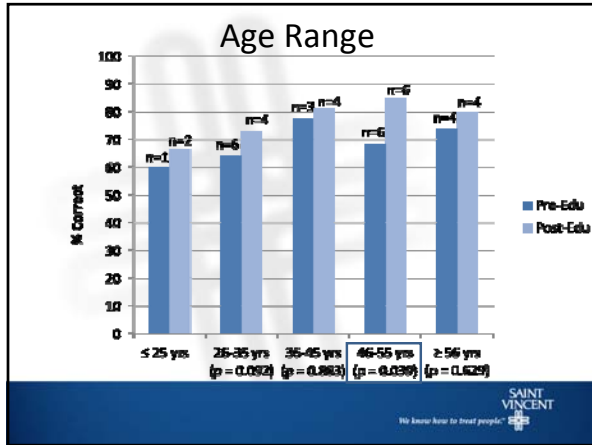
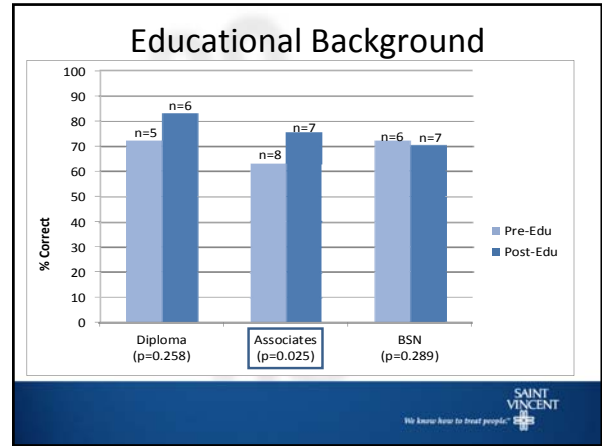
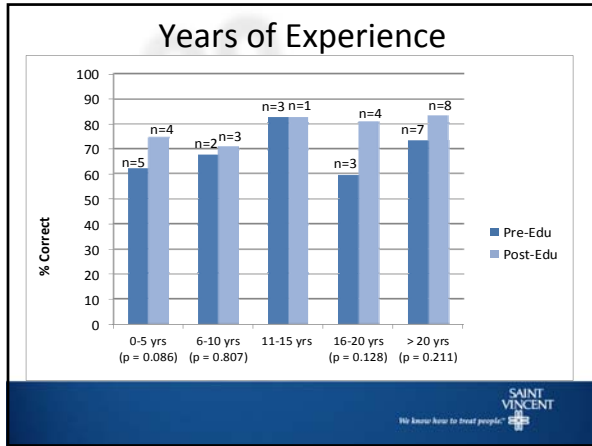


- ### Study Population
- Inclusion
 - Nurses on two post-surgical nursing units
 - Registered nurses or licensed practical nurses
 - Exclusion
 - Float nurses not assigned to these units
 - Nurses not completing the pre-educational NKASRP
- SAINT VINCENT
We know how to treat people.

- ### Primary Outcome
- Overall average percentage of correct NKASRP answers (pre-educational vs. post-educational)
- SAINT VINCENT
We know how to treat people.

- ### Secondary Outcomes
- Overall average NKASRP scores (pre-educational vs. post-educational) based on:
 - Area of practice
 - Years of experience
 - Educational background
 - Age range
 - Average NKASRP scores for each question (pre-educational vs. post-educational)
- SAINT VINCENT
We know how to treat people.





Individual Questions

Question #	% Change (Post-Pre)	P Value	Question #	% Change (Post-Pre)	P Value
5	70	< 0.001	22	15	0.231
6	45	0.001	23	20	0.333
7	0	1.000	24	10	0.605
8	-10	0.695	25	15	0.407
9	5	1.000	26	20	0.320
10	5	1.000	27	10	0.751
11	35	0.048	28	20	0.341
16	-10	0.487	30	5	1.000
18	20	0.343	34	-10	0.752
19	10	0.741	35	20	0.320
20	25	0.091	36	10	0.716
21	5	1.000	37-B	20	0.341
			38-B	10	0.748

SAINT VINCENT
We know how to treat people.

Individual Questions

Question #	% Change (Post-Pre)	P Value
Non-Medication Related		
3	5	1.000
13	0	1.000
15	0	1.000
32	5	1.000
Assessment		
1	5	1.000
4	15	0.342
17	-10	0.661
29	10	0.487
31	0	1.000
37-A	20	0.106
38-A	10	0.487
Special Populations		
2	0	1.000
12	-10	0.487
14	5	1.000
33	-25	0.176

SAINT VINCENT
We know how to treat people.

Individual Questions

True/False

- Aspirin and other non-steroidal anti-inflammatory agents are NOT effective analgesics for painful bone metastases. ($p < 0.001$)
- Respiratory depression rarely occurs in patients who have been receiving stable doses of opioids over a period of months. ($p = 0.001$)

Individual Questions

True/False

- Morphine has a dose ceiling (i.e., a dose above which no greater pain relief can be obtained). ($p = 0.048$)
- Anticonvulsant drugs such as gabapentin (Neurontin) produce optimal pain relief after a single dose. ($p = 0.091$)

Individual Questions

True/False

- The usual duration of analgesia of 1-2 mg morphine IV is 4-5 hours.
- Elderly patients cannot tolerate opioids for pain relief.
- After an initial dose of opioid analgesic is given, subsequent doses should be adjusted in accordance with the individual patient's response.
- Giving patients sterile water by injection (placebo) is a useful test to determine if the pain is real.

Individual Questions

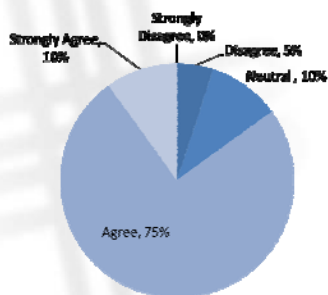
33. How likely is it that patients who develop pain already have an alcohol and/or drug abuse problem?

- < 1%
- 5 - 15%
- 25 - 50%
- 75 - 100%

34. The time to peak effect for morphine given IV is

- 15 min.
- 45 min.
- 1 hour
- 2 hours

Utility of Education



Study Limitations

- Variance between pre- and post-educational participants
- Small overall sample size
- Hospital changes to pain order sets during study
- Did not measure change in pain assessment, treatments, or patient satisfaction

Study Conclusions

- The education was effective at increasing scores on the NKASRP.
- Nurses from various units/areas of practice can benefit from pain education.
- The types of questions that changed the most were pharmacology questions.

Future Plans

- The live portion of the educational session will be included in mandatory nursing education house-wide.
- Results were presented to the health system at Nursing Grand Rounds.

References

1. IASP Pain Terminology. International Association for the Study of Pain. Accessed 09/02/10 <http://www.iasp-pain.org/AM/Template.cfm?Section=General_Resource_Links&Template=/CM/HTMLDisplay.cfm&ContentID=3058#Pain>.
2. Phillips DM. JCAHO Pain management Standards Are Unvelled. *JAMA*. 284 (4): 428-429. 2000.
3. *Health Care Issues: Pain Management*. The Joint commission on Accreditation of Healthcare Organizations (JCAHO). Accessed 09/02/10. http://www.jointcommission.org/jointCommission/Templates/GeneralInformation.aspx?NRMODE=Published&NRNODEGUID={A08FCD4F-CB99-4B32-8309-1FF1F51CC6C6}&NRORIGINALURL=%2FNewsRoom%2Fhealth_care_issues.htm&NRCACHEHINT=Guest#9.
4. Charap AD. The knowledge, attitudes and experience of medical personnel treating pain in the terminally ill. *Mt Sinai J Med* 45: 563-580; 1978.
5. Marks RM, Sachar EJ. Undertreatment of medical inpatients with narcotic analgesics. *Ann Intern Med*. 78: 173-181; 1973.
6. Patraki EI, Papatianassoglou ED, Tofas C, et al. A randomized controlled trial of an educational intervention on Hellenic nursing staff's knowledge and attitudes on cancer pain management. *Eur J Oncol Nurs*. 10(5): 337-352; 2006.
7. Heye ML, Goddard L. Teaching pain management: how to make it work. *J Nurses Staff Dev*. 15(1): 27-36; 1999.
8. Coulling S. Nurses' and doctors' knowledge of pain after surgery. *Nursing Standard*. 19 (34): 41-49; 2005.
9. Linkewich B, Sevean P, Habjan S, et al. Educating for tomorrow: enhancing nurses' pain management knowledge. *Can Nurse*. 103(4): 24-28; 2007.
10. American Pain Society. Pain: Current Understanding of Assessment, Management, and Treatments.
11. Erkes, EB, Parker VG, Carr RL, et al. An Examination of Critical Care Nurses' Knowledge and Attitudes Regarding Pain Management in Hospitalized Patients. *Pain Management Nursing*. 2(2): 47-53; 2001.

Impact of Pain Education on Nurses

Melinda Wingard, PharmD
PGY1 Pharmacy Practice Resident
Saint Vincent Health Center, Erie, PA