National Partnership to Improve Dementia Care in Nursing Homes & Quality Assurance and Performance Improvement (QAPI)

December 1, 2015

Disclaimer:

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Agenda:

- Welcome & QAPI Update   Deb Lyons, CMS
- Effective Management of High Dr. Susan Levy, AMDA
  Rick Medications
- Importance of Drug Regimen   Dr. Nicole Brandt, ASCP
  Review & Medication Reconciliation
- National Partnership Update   Michele Laughman, CMS
  & Closing
- Question & Answer Session   Moderator

Welcome & QAPI Update:

Effective Management of High Risk Medications: A Medical Director's Perspective

Susan M. Levy, MD

Learning Objectives:

- Understand roles and responsibilities of the medical director and prescribers in medication management.
- Identify areas to focus QAPI efforts and what to monitor.
- Discuss issues related to anticoagulants and anti-psychotics, as examples of high risk medications.
- Describe medication issues and transitions of care.

F501: Medical Director Regulations

§483.75(i) Medical Director
(1) The facility must designate a physician to serve as medical director.
(2) The medical director is responsible for –
  (i) Implementation of resident care policies; and
  (ii) The coordination of medical care in the facility.

F501: Surveyor Guidance

Intent:

The facility has a licensed physician who serves as the medical director to coordinate medical care in the facility and provide clinical guidance and oversight regarding the implementation of resident care policies.

F501: Separate Roles

While many medical directors also serve as attending physicians, the roles and functions of a medical director are separate from those of an attending physician.

The medical director's role involves the coordination of facility-wide medical care while the attending physician's role involves primary responsibility for the medical care of individual residents.

AMDA - The Society for Post-Acute and Long-Term Care Medicine:

MEDICAL DIRECTOR: ROLE AND RESPONSIBILITIES AS LEADER AND MANAGER

Function 1 - Administrative
- The medical director participates in administrative decision making and recommends and approves policies and procedures.

Function 2 - Quality Assurance (QA)
- The medical director participates in the process to ensure the appropriateness and quality of medical care and medically related care.

http://www.amda.com/

AMDA - The Society for Post-Acute and Long-Term Care Medicine:

COMPETENCIES FOR POST-ACUTE AND LONG-TERM CARE MEDICINE ATTENDINGS:

I. Foundation (Ethics, Professionalism and Communication)
II. Medical Care Delivery Process
III. Systems
IV. Medical Knowledge
V. Personal QAPI

Appropriate medication use is expected!

Source: http://www.amda.com/

Medication Management: Prescriber Responsibilities

- Prescribe based on evidence (can prescribe off-label, but must document rationale).
- Prescribe considering risk of error/adverse events (may be site specific/patient specific).
- Prescribe based on all of the "rights":
  - Drug
  - Dosage
  - Duration
  - Diagnosis
  - Frequency/timing

Medication Management: Why We Worry

- Errors
  - Omission
  - Commission
- Adverse Events
  - Temporary
  - Serious
    - Prolonged length of stay
    - Hospitalization
    - Permanent damage
    - Death

F329: Unnecessary Medications

§483.25(l) Unnecessary Drugs
(1) General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

> **(i)** In excessive dose (including duplicate therapy); or
> **(ii)** For excessive duration; or
> **(iii)** Without adequate monitoring; or
> **(iv)** Without adequate indications for its use; or
> **(v)** In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
> **(vi)** Any combinations of the reasons above.

Medication Management: Where to Focus Your Efforts (Externally)

National Initiatives:

- CMS National Partnership to Improve Dementia Care
- National Action Plan for Adverse Drug Event Prevention
  - Anticoagulants
  - Diabetic agents
  - Opiods
- Centers for Disease Control & Prevention (CDC) Antibiotic Stewardship for Nursing Homes

Medication Management: Where to Focus Your Efforts (Internally)

- Sentinel events(yours or others)
- Survey issues
- Drug regimen review findings
- Staff/Provider/Pharmacist concerns
- "New" medications
- High risk medications
- High cost medications

Medication Management: Where to FOCUS Your Efforts (Triple Aim)

- **Patient experience**
  - Pain management
  - Medication education
- **Quality**
  - Safe practices
  - Adverse event reduction (hypoglycemia)
- **Cost**
  - Facility
  - Patient

Adverse Events: Skilled Nursing Facilities (SNFs)

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ADVERSE EVENTS IN SKILLED
NURSING FACILITIES:
NATIONAL INCIDENCE AMONG
MEDICARE BENEFICIARIES**

Daniel R. Levinson
Inspector General

February 2014
OEI-06-11-00370

OIG Report: Adverse Events and Temporary Harm Events in SNF

- **22% Adverse events**
  - 37% medication related
    - 12% delirium/AMS
    - 5% excessive bleeding

- **11% Temporary harm events**
  - 43% medication related
    - 16% hypoglycemia
    - 9% fall or other trauma associated with medication

59% of all events, clearly or likely preventable.
66% of preventable events are medication related.

OIG Report: Estimated Cost of Hospitalization for Medication Events (August 2011)

- 7,203 hospitalizations

- $8,372/stay

- $57,729,935

Resident care and infection related events are more costly.

CMS Response: A Call to Action

A Call to Action:
Raising Awareness for Reducing Adverse Events in Nursing Homes

September 23, 2014
Baltimore, Maryland

CMS Response: Adverse Drug Events

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard, Mail Stop C2-21-16

Baltimore, Maryland   21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-47-NH

DATE: **July 17, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Medication-Related Adverse Events in Nursing Homes

CMS Response: Adverse Drug Event Trigger Tool

| Bleeding related to antithrombotic medication use | ☐ Anticoagulant, antiplatelet, or thrombolytic medication use
☐ Concurrent use of more than one antithrombotic medication (e.g., use of aspirin while on anticoagulants)
☐ History of stroke or GI bleed
☐ NSAID medication use while on anticoagulants
☐ Antibiotics use while on anticoagulants
☐ Amiodarone use | ☐ Elevated PT/INR, PTT
☐ Low platelet count
☐ Bruising
☐ Nosebleeds
☐ Bleeding gums
☐ Prolonged bleeding from wound, IV, or surgical sites
☐ Blood in urine, feces, or vomit
☐ Coughing up blood
☐ Abrupt onset hypotension | ☐ Stat order for PT/INR, PTT, platelet count, or CBC
☐ Abrupt stop order for medication
☐ Administration of Vitamin K
☐ Transfer to hospital | ☐ Does the medical record include documentation of clinical indication?
☐ Is there evidence the facility routinely monitors lab results of all residents on anticoagulant/antiplatelet therapy?
☐ Is there a system to ensure lab results, including PT/INRs, are appropriately communicated to the physician including when panic values are obtained?
☐ Is there evidence that the facility educates caregivers on risk factors and symptoms and signs that may be indicative of excessive bleeding due to antithrombotic medications?
☐ Are residents/families educated regarding the risks associated with antithrombotic medication use and the signs and symptoms of excessive bleeding?
☐ Is there evidence of system to alert prescribers |

Disclaimer: This tool is a draft and subject to revision. It is not mandated by the Centers for Medicare & Medicaid Services (CMS) for regulatory compliance nor does its use ensure regulatory compliance.

Effective Management of High Risk Medications:

Anticoagulants

- Aspirin and antiplatelet agents
- Warfarin
- New Oral Anticoagulants (NOAC)
    - Rivaroxaban (Xarelto)
    - Apixaban (Eliquis)
    - Dabigatron (Pradaxa)
    - Edoxaban (Savaysa)

Anticoagulants: NOAC vs. Warfarin

- Effective for stroke prevention
- Venous Thromboembolism (VTE) treatment
- VTE prevention
- Safety
  - Renal function
  - Comorbidities
  - No reversal agent
  - Short half life vs. Warfarin
    - Compliance issues/skipped doses
    - Effect lost more quickly than Warfarin

Anticoagulants:

The Washington Post

Problems with a popular anticoagulant

Coumadin (or warfarin) is a medicine often prescribed to older adults for prevention of strokes, blood clots and heart attacks. However, the dose must be closely monitored. Too much can lead to internal bleeding. Too little can allow formation of deadly blood clots.

Source: Medication Error Quality Initiative | The Washington Post   July 12

Nursing Home Residents on Anticoagulants:

Percentage of patients receiving at least one dose per week
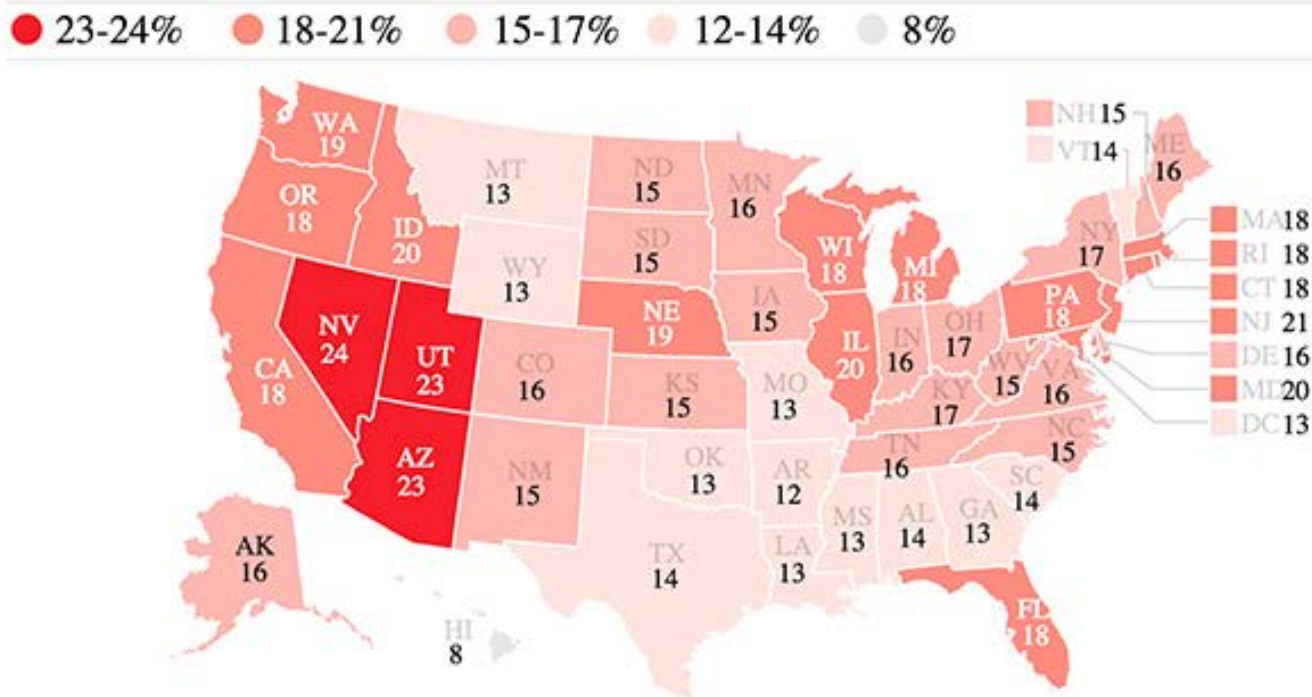
Includes Coumadin, warfarin, heparin and other new anticoagulants

Data for first quarter of 2015

Source: Centers for Medicare and Medicaid Services.

North Carolina Medication Errors:

5.4% of all medication errors

30.9% serious	4.6% 24%	3.2%	3.1%	3.0% Serious errors
Coumadin (warfarin)	Insulin	Oxycodone	Hydrocodone	Lorazepam
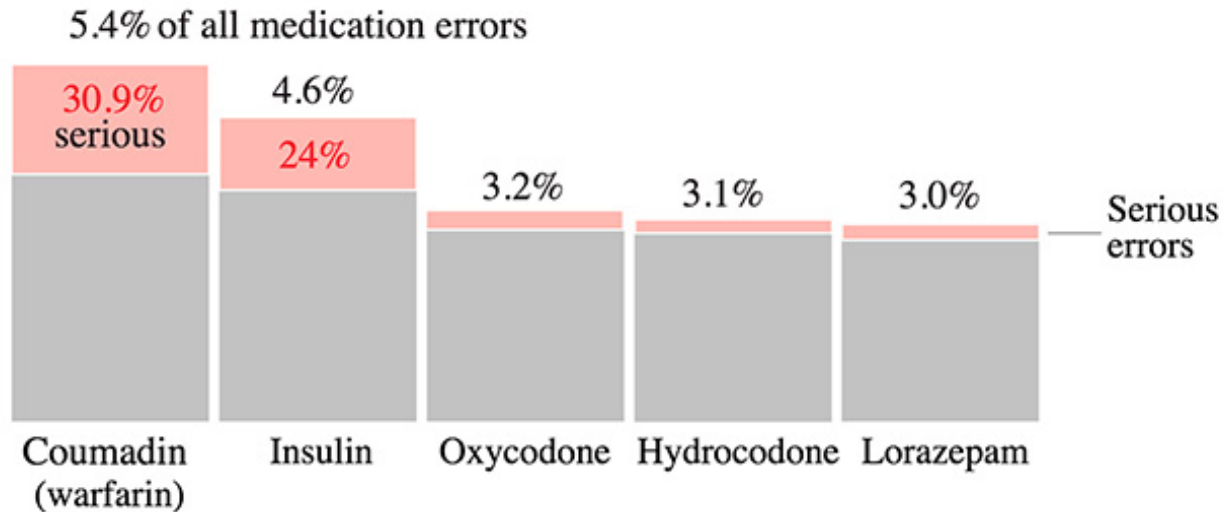
Top five drugs of numerous medicines cited; data from fiscal year 2012

Source: Medication Error Quality Initiative

F329: Unnecessary Medications

TABLE I: MEDICATION ISSUES OF PARTICULAR RELEVANCE

- **Monitoring**
  - Use must be monitored by Prothrombin Time (PT)/International Normalization Ratio (INR), with frequency determined by clinical circumstances, duration of use, and stability of monitoring results.

- **Adverse Consequences**
  - Multiple medication interactions exist (See 42 CFR 483.60(c) F428 for Table of Common Medication-Medication Interactions in Long Term Care), which may include:
    - Significantly increase PT/INR results to levels associated with life-threatening bleeding, or
    - Decrease PT/INR results to ineffective levels, or
    - Increase or decrease the serum concentration of the interacting medication

F329: Deficiency Categorization

Severity Level 4 Considerations:

- Failure to assess or respond appropriately for a resident taking warfarin who had an elevated INR of 9 or greater with or without bleeding, or the elevated INR persisted without assessment/follow-up.
- Failure to monitor PT/INR for a resident on anticoagulant therapy in accordance with current standards of practice and to recognize and/or respond to a life threatening adverse consequence related to anticoagulation.

F329: Deficiency Categorization

Severity Level 3 Considerations:

- Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an INR greater than 4 and less than 9 for a resident who is receiving Warfarin until spontaneous bruising or bleeding occurs, resulting in the need to transfuse or hospitalize the resident.

F329: Deficiency Categorization

Severity Level 2 Considerations:

- Facility failure to take appropriate action (e.g., change or suspend administration of the Warfarin dose) for a resident who has an INR greater than 4 and less than 9 without any bleeding.
- Failure to monitor INR for a resident who has been stabilized on Warfarin, but who has not had bleeding.

Additional Tags to Consider:

- **42 CFR 483.40(a), F385, Physician Supervision**

  Review if the attending physician supervised the resident's medical treatment, including assessing the resident's condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.

- **42 CFR 483.40(b), F386, Physician Visits**

  Review if the attending physician or designee reviewed the resident's total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.

Additional Tags to Consider:

- **42 CFR 483.75(i), F501, Medical Director**

    Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.

Medication Management: Anticoagulants

- Establish diagnosis that warrants therapy
- Establish goals of therapy
- Decide on which agent(s) to use
- Explain and document risks and benefits
- Initiate monitoring to meet goals and limit risk
  - Drug interactions
  - Lab monitoring
    - PT/INR
    - Hemoglobin/hematocrit

Medication Management: Anticoagulation Management Program

- Coordinator (physician oversight)
  - Nurse
  - Pharmacist
- Single or multiple facilities
- "Virtual" anticoagulation clinic
- Policies and procedures
- Evidence based guidelines/protocols
- Annual assessment of effectiveness of program
- Staff/provider/resident and family education

VTE Risk Assessment:

- Risk factors
- Type of procedure(s)
- Medical condition(s)

**Risk should be re-evaluated with
each transition of care.**

**Chronic immobility does not warrant long-term
anticoagulation, when that is the only risk factor.**

Atrial Fibrillation Stroke Risk Assessment Tool:

CHADS2 Score

Risk Factors:	Points:
Congestive heart failure	1
Hypertension	1
Age >75 years	1
Diabetes mellitus	1
Prior stroke/transient ischemic attack/thromboembolism	2
Maximum Score =	**6**

Atrial Fibrillation Stroke Risk Assessment Tool:

CHA2DS2-VASc Score

Risk Factors	Points
Congestive heart failure	1
Hypertension	1
Age >75 years	1
Diabetes mellitus	1
Prior stroke/transient ischemic attack/thromboembolism	2
Vascular Disease (prior myocardial infarction, peripheral artery disease, aortic plaque)	1
Age 65-74	1
Sex category (i.e. female gender)	1
Maximum Score =	**9**

Warfarin Bleeding Risk Assessment Tools:

- HAS-BLED
- ATRIA
- HEMORRHAGES

Anticoagulation Management: Role of the Medical Director

- Look at drug regimen review reports and trend anticoagulant issues with QA staff.
- Meet with pharmacy consultant and director of nursing (DON) regularly to discuss anticoagulation management.
- Participate in the development of facility anticoagulation management program.
- Develop and periodically review policies and procedures and program effectiveness.
- Provide feedback to prescribers regarding their management of anticoagulation.
- Education of staff/providers/residents and families.

Medication Management Warfarin: QAPI

- %/# of residents on various anticoagulants
- Assessment/reassessment for need
  - Short term (daily/weekly)
  - Long term (annual/change in condition)
- Assessment/reassessment of bleeding risk (annual/change in condition)
- Time in therapeutic range for Warfarin (>60%)
- Bleeding events
  - Minor vs. serious
  - Transfusion/hospitalization/death

CMS National Partnership to Improve Dementia Care: Antipsychotic Usage

Quarterly Prevalence of Antipsychotic Use for Long-Stay Nursing Home Residents, 2011Q2 to 2015Q2
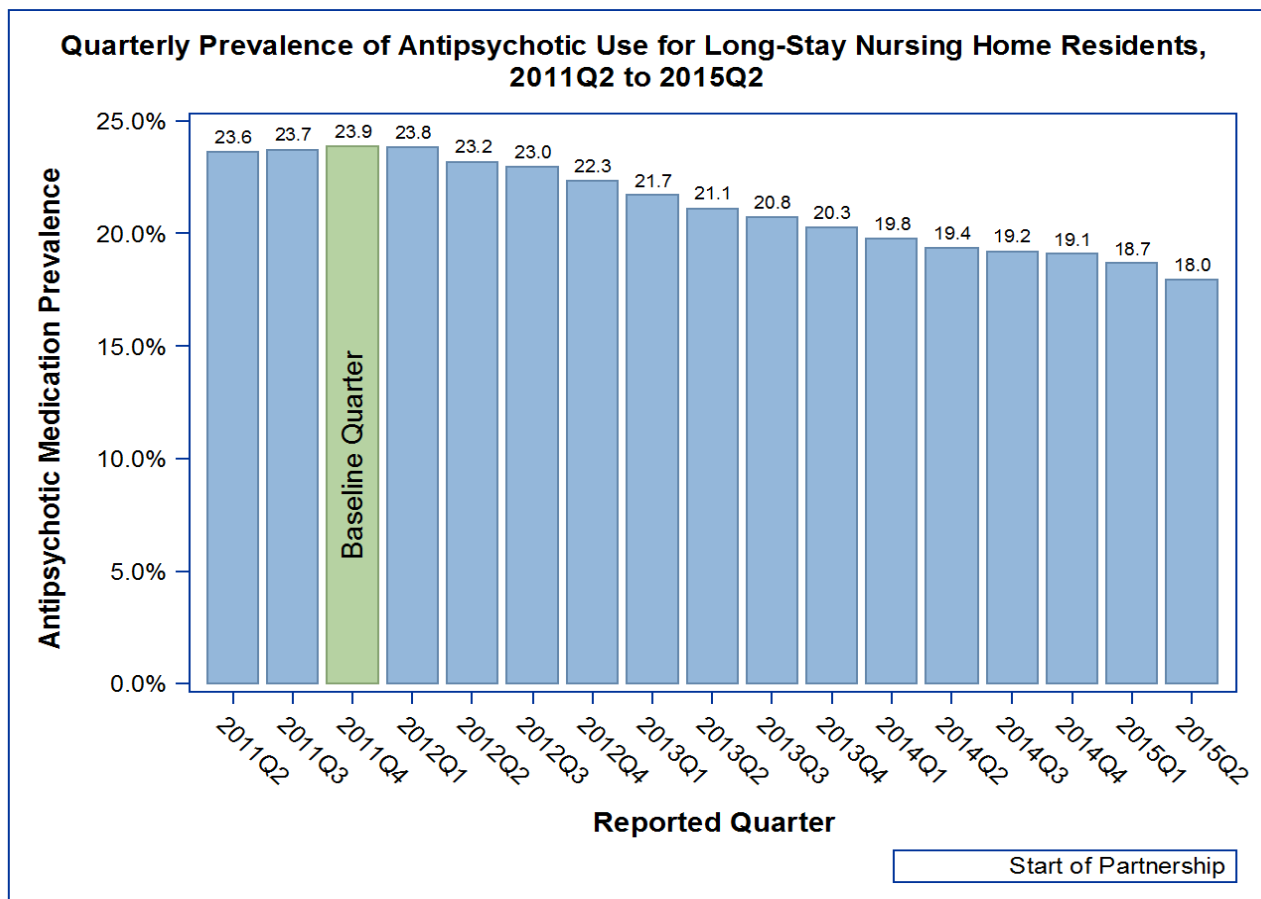
Antipsychotic Use Warning:

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (model duration of 10 weeks) largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to come characteristic(s) of the patients is not clear.

Source:
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm

Nursing Home Antipsychotic Usage: Communication and Collaboration

- Medical Director
- Prescribers (attending physician/physician assistant (PA)/nurse practitioner (NP))
- Consultant Pharmacist
- Mental Health Provider

Do they talk, meet, share data?

American Medical Directors Association (AMDA): Role of the Medical Director in Dementia Care

- Implement policies and procedures that promote evidence based person centered care.
- Educate the team, **including residents and families**, to help them understand that expressions of distress are often a form of communication, for a person with dementia.
- Review data that reflects the care processes in Quality Assessment & Assurance (QA&A).
- Be available for meetings to discuss expressions or indications of distress and care strategies.
- Support the implementation of non-pharmacologic interventions.

Antipsychotics and QAPI:

- Number of residents on antipsychotics
  - Dementia vs. other diagnosis
- Process for initiating antipsychotics
  - Assessment in appropriate time frames
- Process for gradual dose reduction (GDR) and discontinuation of antipsychotics
  - # of residents on GDR and success rate
- Process for resident, family, and/or representative communication regarding risks and benefits of medication
  - Documentation of the discussions

Antipsychotics and QAPI:

- Compliance with individualized care plans
- Clear documentation of expressions or indications of distress
- Hospitalizations and emergency room transfers
- Resident/resident and resident/staff altercations

Effective Management of High Risk Drugs: It is not Just Antipsychotics

- Anxiolytics
- Antidepressants
- Sedative hypnotics

Look at fall rates.
Look for class shift from antipsychotics.

Effective Management of High Risk Medications: Transitions of Care

- **Hospitalization**
  - Old medications discontinued
  - Chronic home medications missed
  - New medications started
  - Dosages changed
  - Formulary substitutions

Medication Reconciliation?
Discharge Summaries?

Effective Management of High Risk Medications: Transitions of Care

- **Nursing Facility Discharge**
  - Who reconciles the medications at discharge?
    - Nurse
    - Pharmacist
    - Physician/NP/PA
  - What medications get reconciled?
    - Home
    - Hospital
    - Nursing home
  - When is the discharge summary done?
    - Day/week/month
    - Content

Effective Management of High Risk Medications: Transitions of Care Rules

- Spend twice as much time discharging a resident, as you do admitting them.
- Educate and teach-back 'one more time,' in case the home health provider arrives later than expected.
- Give residents and families a number to call.
- Contact the resident's physician and send them the information.

Importance of Drug Regimen Review and Medication Reconciliation:
A Pharmacist's Perspective

Nicole Brandt, PharmD, MBA, BCPP, CGP, FASCP

Learning Objectives:

- Understand roles and responsibilities of the pharmacist.
- Define differences between medication regimen review (MRR) and reconciliation.
- Illustrate the application of F329 to a case focusing on high risk medications.

Medication Use Process:

1. Prescribing
- Evaluate resident
- Determine need for medication
- Select appropriate medicine

2. Documenting/Transcribing
- Write order in chart to transcribe verbal order
- Transmit order to pharmacy
- Transcribe order to medication administration record (MAR)

3. Dispensing
- Receive, review, and confirm order at pharmacy
- Prepare and dispense medication to facility
- Transport medications to facility

4. Administering
- Review MAR
- Critically think through administration of med
- Administer the right medication, at the right dose or rate, by the right route, at the right time to the right patient
- Record administration in MAR

5. Monitoring
- Assess patient's response to medicine
- Report and document outcomes
- Role of consultant pharmacists

Source: 2008 National Patient Safety Foundation Patient Safety Conference

Medication Regimen Review vs. Reconciliation:

- **CMS definition of Medication Regimen Review:**
  - A thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities, and collaborating with other members of the interdisciplinary team.
- **Joint Commission Definition of Medication Reconciliation:**
  - The process of comparing a patient's medication orders, to all of the medications that the patient has been taking. This process comprises five steps: 1) Develop a list of current medications; 2) Develop a list of medications to be prescribed; 3) Compare the medications on the two lists; 4) Make clinical decisions based on the comparison; and 5) Communicate the new list to appropriate caregivers and to the patient.

Sources:
Centers For Medicare and Medicaid Services, State Operations Manual, F428, accessed at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf
Joint Commission accessed at: http://www.jointcommission.org/assets/1/18/SEA_35.pdf

MLN Connects®

Medication Reconciliation Between Hospitals and Nursing Homes:

- Known: Lack of consistent protocols across settings in medication reconciliations
- Recommendations:
  - Implement interventions that assure indications and diagnoses are documented for all prescribed medications.
  - Increase pharmacy's role in medication reconciliation during transitions of care.
  - Implement an interdisciplinary approach to medication reconciliation that occurs before or during the care transition and that includes hospital, nursing home, and pharmacy staff.

Source: Stratis Health White Paper. Understanding and Improving Medication Reconciliation between Hospitals and Nursing Homes. November 2014.
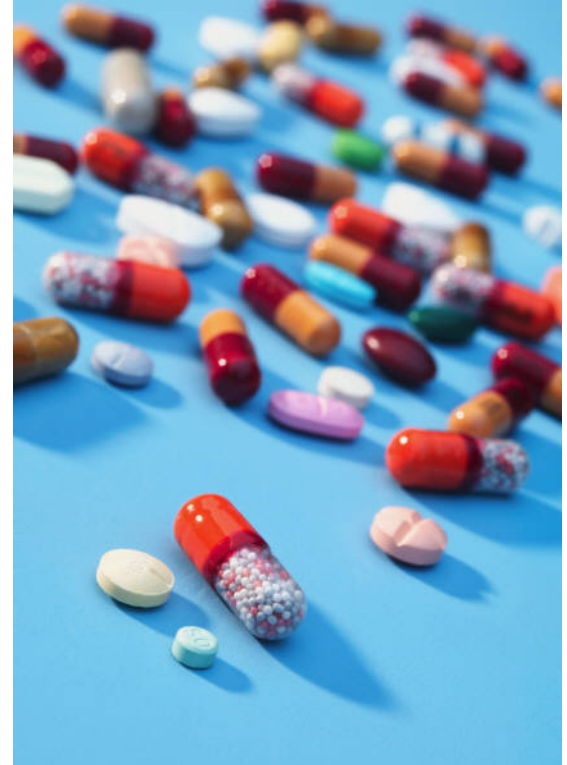
Consultant Pharmacist: F329, F425

F329 Unnecessary Drugs:

- Indication
- Dose/duration
- Efficacy
- Adverse effects
- Monitoring
- GDRs

F425 Pharmaceutical Services:

- Medication availability
- Appropriate pharmaceutical services
- Medication administration
- Policies and procedures

Consultant Pharmacist: F428, F431, F309

F428 Medication Regimen Review:

- Identification of irregularities
- Change-in-condition
- Medication system problems
- Prescriber/nurse follow-up

F431 Medication Storage, Labeling, CDS:

- Labeling
- Access and storage
- Controlled medication processes

F309 Quality of Care:

- Dementia care
- Pain management

Case Example:

This is an 88 year old woman, who is being reviewed for a risk/benefit assessment of Target Specific Oral Anticoagulants (TSOAC) compared to Warfarin. She has a past medical history of atrial fibrillation, and currently takes Warfarin (7 milligrams (mg) each day (qd)).

PMH (from the chart):
Atrial Fibrillation (AFib)
Edema
Hypertension (HTN)
Anxiety
Dementia

Medication History (from the MAR):
Risperidone (Risperdal) 0.25mg twice daily for dementia
Digoxin 0.125 mg qd for AFib
Donepezil (Aricept) 10mg qd for dementia

Furosemide (Lasix) 20mg qd
Icy Hot Patch 5% Apply daily for pain
Valsartan (Diovan) 40mg qd for HTN
Verapamil 240mg qd for HTN
Warfarin (Coumadin) 2mg qd for AFib
Warfarin (Coumadin) 5mg qd for Afib to equal 7mg

As needed (PRN):
Acetaminophen 325mg 2 tablets every 6 hours (q6h) as needed (PRN) for pain
Duoneb 1 vial via nebulizer q6h PRN for wheezing
Robafen syrup 100mg/5mL 10 milliliters (mL) q6h PRN for cough
Refresh Optic 1 drop to each eye, twice a day for dry eyes
Ocusoft Lid Scrub to both eyes qd

Case Example:

Risk Calculations:
CHAD VAS: 5
HAS BLED: 2

Pertinent Lab Data (date of review 9/24/15)
INR: **2.77 (9/20)** ; **2.53** on 8/31; **2.25** on 8/24; 1.59 on 8/17/15; 1.93 on 8/10/15; **2.48** on 7/6/15; 1.78 on 5/11/15; 1.86 on 4/13/15; 1.98 on 3/16/15; 1.90 on 2/23/15

SCr: 1.65 on 8/17/15; 1.65 on 6/24/15
CrCL: 23 ml/min
Hgb: 13.2 on 8/17/15; 13.6 on 6/24/15
Hct: 39.8 on 8/17; 40.3 on 6/24/15
PLT: 185 on 8/17/15; 176 on 6/24/15
Weight: 156lb (70kg)
BP on 9/19/15: 153/76 mm Hg

Case Example:

Risk Calculations:
CHAD VAS: 5 (AFib Stroke Risk Assessment tool)
HAS BLED: 2 (Warfarin Bleeding Risk Assessment Tool)

Pertinent Lab Data: (date of review 9/24/15)
International Normalized Ratio (INR) (Target for Afib=2.0 to 3.0): **2.77 on 9/20**; **2.53 on 8/31**; 2.25 on 8/24; 1.59 on 8/17/15; 1.93 on 8/10/15; **2.48 on 7/6/15**; 1.78 on 5/11/15; 1.86 on 4/13/15; 1.98 on 3/16/15; 1.90 on 2/23/15
(INR labs show resident is subtherapeutic more often than therapeutic.)

Serum creatinine (SCr) (Normal=0.6 to 1.2): 1.65 on 8/17/15; 1.65 on 6/24/15
Creatinine clearance (CrCL) (Normal=88 to 128ml/minute): 23 ml/minute

American Society of Consultant Pharmacists (ASCP): Position on Antipsychotics

ASCP believes that the use of antipsychotics in nursing facility residents should include:

- An appropriate indication for use.

- A specific and documented goal of therapy.

- Ongoing monitoring of the resident to evaluate effectiveness in achieving the therapy goal and the development or presence of adverse effects from the medication.

- Use of the medication only for the duration needed, and at the lowest effective dose.
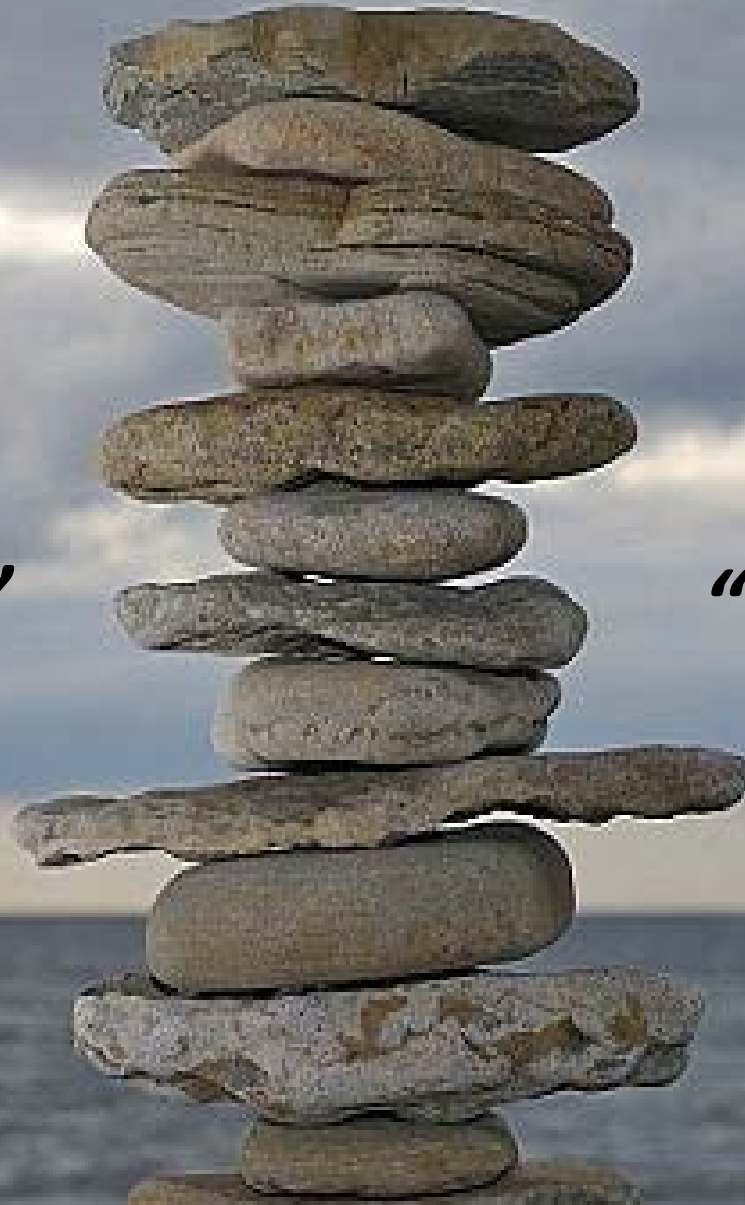
Finding the Perfect Balance:

Bleed
"To Cause"

Stroke
"To Prevent"

64

TSOACs Labeled Indications:

	Dabigatran	Rivaroxaban	Apixaban	Edoxaban
Stroke Prevention in Atrial Fibrillation	150 mg BID	20 mg daily	5 mg BID**	60 mg daily
VTE Treatment	150 mg BID*	15 mg BID x 21 days, then 20 mg daily	10 mg BID x 7 days, then 5 mg BID	60 mg daily*
VTE Extended		20 mg daily		
VTE prevention post TKR/THR		10 mg daily	2.5 mg twice daily	

*Initiate after 5-10 days of parenteral anticoagulant
**2.5 mg BID if ≥ 80 yoa, ≤ 60 kg, or SCr ≥ 1.5 mg/dL

TSOACs Study Comparison: AFIB

	Dabigatran	Rivaroxaban	Apixaban	Edoxaban
Trial	RE-LY	ROCKET-AF	ARISTOTLE	ENGAGE AF-TIMI 48
Number of Patients	18,113	14,264	18,201	21,026
Treatment	150 mg BID	20 mg daily	2.5 mg BID	60 mg daily or 30 mg daily
Warfarin TTR	67%	57.8%	66%	68.4%
Mean CHADS$_2$	2.1	3.5	2.1	2.8
Efficacy vs warfarin	Superior	Non-inferior	Superior	Non-inferior
ICH	Reduced	Reduced	Reduced	Reduced
Major Bleeding	Similar	Similar	Reduced	Reduced
Ischemic Stroke	Reduced	Similar	Similar	Similar

Source: NEJM 2009;361:1139--51. NEJM 2011;365:883-91. NEJM 2011;365:981-992. NEJM 2013;369:2093-104.

TSOACs: Renal Impairment

- Renal function estimated by the creatinine clearance (CrCl) needs to be calculated to assess TSOACs dosing and appropriateness of use.
- Increase in drug exposure or availability is commonly seen in renal impairment this translates to case reports noting:
  - Upper gastrointestinal (GI) bleed resulting in stopping of Dabigatran and aggressive interventions
  - Retroperitoneal, GI and pleural hemorrhage leading to hemorrhagic shock and death

TSOACs: Bleeding Risk

- Bleeding risk is often the predominant factor that dictates anticoagulant therapy in older adults
- All TSOACs differ in their bleed risk and types of bleeds but it is important to note that:
  - All have significantly less risk of intracranial hemorrhage (ICH).
  - GI bleeding was increased, when compared to Warfarin with Dabigatran 150mg, Rivaroxaban, Edoxaban but not Apixaban.

Source: Thrombosis. 2012;2012:108983. Epub

Bleeding Risk: TSOACs & the Older Adult

Clinical Application

- Bleeding with any anticoagulant will always be a concern. Reviewing drug and patient characteristics may dissuade the use of one agent over another.

    - Dabigatran, Rivaroxaban, and Edoxaban are associated with increased GI bleeding.

        - Caution in patients with history of GI bleeding or conditions that predispose them to GI bleeding (e.g. peptic ulcer disorder).

    - ICH is the most feared and lethal complication of oral anticoagulation. The reduction in ICH with the TSOACs is a major benefit. Providers will need to determine if this benefit outweighs added risk in other areas.

Let's Apply the Concepts Discussed to the Case Example:

Case Example – Revisited:

- This is an 88 year old woman, who is being reviewed for a risk/benefit assessment of TSOACs, compared to Warfarin.
- During this review, various medication related considerations are taken into account by the inter-professional team:
  1) *Anticoagulants:*
     - Indications for use
     - Dosing
     - Duration
     - Monitoring
  2) *Antipsychotic medications:*
     - Clinical indications
     - GDR opportunities
     - Non-pharmacologic approaches to care
     - Documentation

National Partnership Update & Closing:

Question & Answer Session:

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