Objectives
- Identify labs to monitor in patients diagnosed with CHF
- Recognize appropriate laboratory levels for disease monitoring and pharmacotherapy
- Discuss crucial medications used in the management of CHF

CHF Serial Monitoring
- Serum electrolytes
- Renal function
- Vital Signs
- Body Weight
- Volume Status

To monitor or not to monitor?
- BNP
- NT-proBNP
- ECHO
- Chest X-ray
- Additional cardiac biomarkers
  - CK-MB
  - Troponin

BNP
- BNP: Brain natriuretic peptide
- Influences salt, water, myocardial structure and function
- Limits vasoconstriction and sodium retention
- BNP Levels
  - <100 pg/mL = no heart failure (HF)
  - 100-300 pg/mL suggest HF
  - >300 pg/mL suggest mild HF
  - >600 pg/mL suggest moderate HF
  - >900 pg/mL suggest severe HF
- Variable: Age, BMI, & gender can change levels

NT-proBNP
- NT-proBNP: N-terminal prohormone of brain natriuretic peptide
- Higher levels seen with LV dysfunction
- A level >900 pg/mL ≈ >100 pg/mL of BNP
- Elevated in the elderly, women, & renal failure
- Lower levels seen in obese
- Account for age, gender, & BMI
CK-MB
- CK-MB: creatine kinase myoglobin
- Found in skeletal muscle
- Elevated with myocardial damage
- Desired levels:
  - <6.7 ng/mL for males
  - <3.8 ng/mL for females
- Normally assessed in ACS

Troponin
- Cardiac enzyme that controls calcium-mediated interaction of the heart
- Troponin I vs T
  - I is expressed in the myocardium (specific)
  - T is expressed in minor skeletal muscle
  - Troponin is released when the heart is stressed
- Desired level <0.03
- Normally assessed in ACS

Medication Monitoring
Multiple classes of medications that provide symptom control and/or mortality/morbidity benefit
- ACE Inhibitors
- ARB
- Potassium-Sparing Diuretics/Aldosterone Receptor Antagonists
- Loop/Thiazide Diuretics
- Beta-Blockers
- Nitrates
- Statins
- Cardiac glycosides

ACE Inhibitors
- Electrolyte levels
  - Potassium level periodically
- BUN
- Creatinine
- Blood pressure
- Liver Enzymes
- S/Sx of Edema

ARB
- Blood pressure
- Renal function
- Electrolytes
  - Potassium
- S/Sx of Edema

Aldosterone Receptor Antagonists
- Blood pressure
- UOP
- Creatinine
- Electrolytes
  - Potassium (EKG)
- S/Sx of fluid/electrolyte imbalance
Thiazide Diuretics
- Blood pressure
- UOP
- Electrolytes
- Renal Function
- Hepatic Function
- CBC
- Blood glucose
- Uric acid
- S/Sx of Edema

Loop Diuretics
- Blood pressure
- S/Sx of Edema
- Electrolytes
- Glucose
- Creatinine/BUN
- Liver/Renal Function
- Ototoxicity
- Sulfur

Beta-Blockers
- Blood pressure/HR
- EKG
- S/Sx of ischemic heart disease
- Liver/Renal Function
- Pulmonary conditions

Nitrates
- Blood pressure
- HR
- S/Sx of chest pain
- CBC

Statins
- Lipid Panel
- Liver/Renal Function
- CPK

Digoxin: Cardiac Glycoside
- Commonly used in either stage III or IV heart failure
- Monitor drug levels: therapeutic range: 0.5-2 ng/mL
- Monitor electrolytes periodically
- Monitor renal function
- S/Sx of toxicity:
  - N/V
  - CNS (weakness, disorientation, agitation, nervousness)
  - Visual changes (halos, blurred vision/flickering lights, yellow/green tinting, red-green color blindness)
  - Arrhythmias
Digoxin Sensitivity

<table>
<thead>
<tr>
<th>Increases Sensitivity</th>
<th>Decreases Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypomagnesemia</td>
<td>Atrial Fibrillation</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>Hyperkalemia</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>Hyperthyroidism</td>
</tr>
<tr>
<td>CAD or prior MI</td>
<td>Sepsis</td>
</tr>
<tr>
<td>Cor Pulmonale</td>
<td>Hypoxemia</td>
</tr>
<tr>
<td>Chronic renal failure</td>
<td>Post thoracotomy</td>
</tr>
<tr>
<td>Metabolic alkalosis</td>
<td></td>
</tr>
<tr>
<td>Hyper/hypocalcemia</td>
<td></td>
</tr>
</tbody>
</table>

Digoxin: Major DDI

- Amiodarone & verapamil significantly increases digoxin levels (as much as 70%)
  - Dose reduce digoxin by 50%
- Diuretics due to electrolyte imbalance
- P-glycoprotein substrate!

Fun Fact!!

Patient Case Example

- 65 year old Caucasian male
- CC: SOB/ascites, & abdominal pain
- PMH: Non-ischemic cardiomyopathy, CVA, depression, obstructive sleep apnea, DM type II, atrial fibrillation, and HTN
- Denied fever, chills, N/V
- History of noncompliance!

Home Medications

- Furosemide 100 mg twice daily
- Digoxin 0.125 mg daily
- Isosorbide mononitrate 30 mg daily
- Spironolactone 175 mg daily
- Carvedilol 12.5 mg every morning and 6.25 mg every evening
- ASA EC 81 mg daily
- Lisinopril 12.5 mg daily
- Ferrous sulfate 325 mg three times daily
- Gabapentin 300 mg twice daily
- Tamsulosin 0.4 mg at bedtime
- Ipratropium inhalation per nebulizer every 6 hours PRN

Labs/Tests Performed

- pro-BNP = 46535 pg/mL
  - Suggests severe heart failure
- ECHO:
  - Severe left ventricular dysfunction
    - LVEF: <10%
  - Prior ECHO performed one year prior
- Chest X-ray: Right pleural effusion
- Troponin T: 0.10
- Daily BMP drawn
Lopez Cabezas et al.

- Randomized control trial involving 134 patients admitted due to heart failure
- Intervention by pharmacist at discharge:
  - Education on disease, diet, medications
  - Monthly follow-ups via telephone for 6 months and followed by every 2 months
- Outcome:
  - Readmission time, % readmitted, & total readmits
  - Total days spent in hospital
- Results:
  - Readmissions at 2 months: 16 (25%) vs 8 (11.4%); p = .041
  - Readmissions at 6 months: 27 (42.2%) vs 17 (24.3%); p = .028
  - Days spent in hospital at 2 months: 3.5 ± 7.8 vs 1.7 ± 7.7; p = .034
  - Days spent in hospital at 6 months: 6.8 ± 12.5 vs 4.3 ± 13.1; p = .02

Outpatient Heart Failure Clinic

- Advancement in pharmacist’s role
- Underutilizations of medications results in an increase of mortality and morbidity
- ACE inhibitors and ARB are commonly prescribed with β
- Titration is crucial
- Specific protocols for titration and follow-up needed

Clinical Interventions

- Untreated indications
- Improper choice of medication
- Subtherapeutic dose
- Supratherapeutic dose/overdosage
- Prevention of adverse drug reactions
- Drug-drug interactions
- Improper treatment
- Drug Monitoring

Rainville et al.

- Randomized controlled trial with a total of 34 heart failure patients
- Compared pharmacist and nurse specialist
  - Risk factors for readmission
  - Patient education tools
  - Medication changes
- Outcome:
  - Hospital readmission at or over 1 year
  - Death at or over 1 year
- Results:
  - Readmissions for HF: 10 (58.8%) vs 4 (23.5%); p < .05
  - Death: 14 (82.3%) vs 5 (29.4%); p < .01

Titration Example

Dose Adjustments
Case Study

- Target ACEI/ARB doses were reached at a much higher rate for patients enrolled in the titration clinic ran by pharmacists vs physicians/nurses: 52.9% \( n = 27 \) versus 31% \( n = 28 \), \( p = 0.007 \)
- Optimal doses of \( \beta \beta \) were also reached at a higher rate: 49% \( n = 23 \) versus 24.7% \( n = 23 \), \( p = 0.012 \)
- Patients achieved a combined higher average percentage of target doses: \( p = 0.004 \) and \( p = 0.04 \), respectively

Gastelurrutia et al.

- 97 HF patients were followed for 6 months
- An interdisciplinary team reviewed each patient case
  - Found 147 DNOs/rDNOs: mean of 1.5 ± 1.4 per patient
  - 94% were preventable
  - 5.5% were considered clinically serious
- Results with pharmacist intervention: 83% were solved or prevented

True/False Questions

1. Potassium needs to be monitored with spironolactone therapy.
2. A patient with poor renal function would have higher than normal pro-BNP levels.
3. Monitoring CBC values in CHF patients routinely is necessary.

Conclusion

PHARMACISTS CAN MAKE A DIFFERENCE!!!!

Questions from the Audience?

References

Lab and Monitoring Parameters for Diabetes

Barbara C Jimenez, PharmD
PGY1 Pharmacy Practice Resident
Miami VA Healthcare System
January 25-26, 2014

Objectives
- Review the different lab values used in diabetes management
- Interpret pertinent lab values in diabetes
- Discuss monitoring parameters of HTN, HLD, and CKD in diabetic patients
- Describe significant monitoring parameters for the different diabetes drug classes

Objectives

Types of Labs

<table>
<thead>
<tr>
<th>Diagnostic</th>
<th>Glycemic Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1C</td>
<td>HbA1C</td>
</tr>
<tr>
<td>FPG</td>
<td>SMBG</td>
</tr>
<tr>
<td>75g 2 hour OGTT</td>
<td></td>
</tr>
</tbody>
</table>

HbA1C

- Average blood glucose (BG) control for the past 2-3 months
- Added to diagnostic criterion in 2010
- Levels may vary with race/ethnicity
- Only studied in adult populations
- Inaccurately reflects glycemia
  - Anemias
  - Hemoglobinopathies
- Strong predictive value for DM complications

HbA1C Continued

Advantages
- Greater convenience
  - No fasting!
- Greater preanalytical stability
- Less day-to-day variations
  - Stress
  - Illness

Disadvantages
- Greater cost
- Limited availability
- Incomplete correlation between HbA1C and average glucose

Correlation of HbA1C with Average Glucose

<table>
<thead>
<tr>
<th>HbA1C (%)</th>
<th>Mean plasma glucose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mg/dL</td>
</tr>
<tr>
<td>6</td>
<td>126</td>
</tr>
<tr>
<td>7</td>
<td>154</td>
</tr>
<tr>
<td>8</td>
<td>183</td>
</tr>
<tr>
<td>9</td>
<td>212</td>
</tr>
<tr>
<td>10</td>
<td>240</td>
</tr>
<tr>
<td>11</td>
<td>269</td>
</tr>
<tr>
<td>12</td>
<td>298</td>
</tr>
</tbody>
</table>
Other Diagnostic Labs

- **Fasting Plasma Glucose**
  - Amount of BG in blood after fasting for ≥ 8 hours
- **Oral Glucose Tolerance Test (OGTT)**
  - 75g of glucose
  - 2 hour exam
  - Measure BG every 30-60 minutes
  - Screen for gestational DM (GDM)
  - FPG normal but DM suspected

### Pertinent Lab Values

<table>
<thead>
<tr>
<th></th>
<th>Prediabetes</th>
<th>Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C (%)</td>
<td>5.7-6.4</td>
<td>≥ 6.5</td>
</tr>
<tr>
<td>FPG (mg/dL)</td>
<td>100-125</td>
<td>≥ 126</td>
</tr>
<tr>
<td>2-H OGTT (mg/dL)</td>
<td>140-199</td>
<td>≥ 200</td>
</tr>
</tbody>
</table>

### HbA1C Goals in Glycemic Control

<table>
<thead>
<tr>
<th>HbA1C (%) Goal</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 6.5</td>
<td>Short duration of DM, long life expectancy, no significant CVD, and young</td>
</tr>
<tr>
<td>&lt; 7</td>
<td>Reduces microvascular complications and associated with long-term reduction in macrovascular disease</td>
</tr>
<tr>
<td>&lt; 8</td>
<td>History of severe hypoglycemia, elderly, limited life expectancy, extensive comorbid conditions, advanced microvascular and macrovascular complications, and those with long-standing DM whose goal is difficult to attain</td>
</tr>
</tbody>
</table>

### HbA1C Monitoring during Glycemic Control

- Meeting treatment goals
  - Perform twice a year
- Therapy changed or not meeting treatment goals
  - Perform quarterly

### Self Monitoring of BG (SMBG)

- Test BG AC and HS
  - Multiple-dose insulin therapy
  - Insulin pump therapy
- Also test BG
  - Prior to exercise
  - Suspect hypoglycemia
  - After treating hypoglycemia
  - Until normoglycemic

### SMBG Continued

- Patients on non-insulin therapy
  - Evidence for SMBG mixed
- Results can guide treatment decisions
- Evaluate each patient’s monitoring technique
**SMBG Goals**

<table>
<thead>
<tr>
<th></th>
<th>Goal BG (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preprandial BG</td>
<td>70-130</td>
</tr>
<tr>
<td>Peak Postprandial BG*</td>
<td>&lt; 180</td>
</tr>
</tbody>
</table>

*Postprandial BG should be measured 1-2 hours after the beginning of the meal.

**Hypertension**

- Measure blood pressure (BP) at every routine visit
- **Goal BP**
  - Systolic < 140mmHg
  - Diastolic < 80mmHg
- **Treatment**
  - ACE Inhibitors (ACEi)
  - Angiotension Receptor Blockers (ARB)
  - Diuretics

**Hyperlipidemia**

- Measure fasting lipid panel annually
- Repeat every 2 years in adults with low risk lipid values
  - LDL < 100mg/dL
  - HDL > 50mg/dL
  - TG < 150mg/dL
- Statin added regardless of baseline lipid levels

**Monitoring ACEi, ARBs, and Diuretics**

- Serum creatinine (SCr)
- Estimated glomerular filtration rate (EGFR)
- Serum potassium levels

**ADA vs ATP IV on Statin Therapy**

**ADA Guidelines**
- With overt CVD
  - Goal LDL < 70mg/dL
- Without CVD who are > 40 yo with one or more risk factors
  - Goal LDL < 100mg/dL

**ATP IV Guidelines**
- Clinical ASCVD
  - High-intensity statin
- Type I or II DM and 49-75 years old
  - Moderate-intensity statin
- Estimated 10 yr ASCVD risk ≥ 7.5%
  - High-intensity statin

**Statin Therapy**

<table>
<thead>
<tr>
<th>High-Intensity Statins</th>
<th>Moderate-Intensity Statins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin 40-80mg</td>
<td>Atorvastatin 10mg</td>
</tr>
<tr>
<td>Rosuvastatin 20mg</td>
<td>Rosuvastatin 10mg</td>
</tr>
<tr>
<td>Simvastatin 20-40mg</td>
<td>Pravastatin 40mg</td>
</tr>
<tr>
<td>Fluvastatin 40mg</td>
<td>Lovastatin 40mg</td>
</tr>
</tbody>
</table>
**Monitoring Statins**
- Lipid panel
- Liver function
  - ALT
  - AST
- Creatinine Kinase

**Chronic Kidney Disease (CKD)**
- Optimize glucose and blood pressure control
  - Reduces risk and slows progression of nephropathy
- Annual test to assess urine albumin excretion
  - Type I diabetics: after 5 years
  - Type II diabetics: ALL
- Measure Scr at least annually

**Albumin Excretion Definition**

<table>
<thead>
<tr>
<th>Category</th>
<th>Spot Collection (µg/mg creatinine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt; 30</td>
</tr>
<tr>
<td>Increased urinary albumin excretion</td>
<td>≥ 30</td>
</tr>
</tbody>
</table>

**CKD Continued**
- ACEi or ARB recommended
  - Modestly elevated urinary albumin
    - 30-299mg/dL
  - Higher levels of urinary albumin
    - ≥ 300mg/dL
- Monitor Scr, potassium levels, and urine albumin excretion
- eGFR < 60mL/min
  - Evaluate and manage potential complications

**Insulin**
- SMBG
- HbA1C
- Serum potassium levels
- Signs/symptoms of hypoglycemia

**Sulfonylureas**
- SMBG
- HbA1C
- Renal function
- Signs/symptoms of hypoglycemia
Biguanides
- SMBG
- HbA1C
- Renal function
- Hematologic parameters
- Vitamin B12 levels

Alpha-glucosidase Inhibitors
- SMBG
- HbA1C
- Liver function tests
- Signs/symptoms of hypoglycemia

Meglitinides
- SMBG
- HbA1C
- Signs/symptoms of hypoglycemia

Thiazolidinediones (TZDs)
- SMBG
- HbA1C
- Liver function tests
- Signs/symptoms of CHF and fluid retention
- Bone health

GLP-1 Agonists
- SMBG
- HbA1C
- Elevated serum calcitonin levels
- Signs/symptoms of acute pancreatitis
- Signs/symptoms of hypoglycemia

Amylin Analogs
- SMBG
- HbA1C
- Signs/symptoms of hypoglycemia
Dipeptidyl Peptidase-4 Inhibitors

- SMBG
- HbA1C
- Renal function

Diabetes Self-Management Education and Support (DSME/DSMS)

- Education given upon diagnosis and as needed thereafter
  - Initiate effective self-management
  - Cope with DM when first diagnosed
  - Maintain effective treatment throughout lifetime
- Diabetes self-care
  - Knowledge, skill, and ability

Benefits of DSME/DSMS

**Improved**
- DM knowledge
- Self-care behavior
- Quality of life
- Use of primary and preventative services

**Lowered**
- HbA1C
- Weight
- Costs
- Use of acute and inpatient hospitals

MORE LIKELY TO FOLLOW BEST PRACTICE TREATMENT RECOMMENDATIONS!

True or False?

- Serum creatinine is monitored in DM patients?

- The BP goal for diabetic patients is less than 125/75?

- HbA1C is the only lab measure validated in RCT as a predictor of risk for microvascular complications?

References

Laboratory and Monitoring Parameters in Hypertension

Kristen Hillebrand, Pharm.D.
PGY-2 Critical Care Pharmacy Resident

Objectives

- Discuss laboratory and monitoring parameters associated with chronic hypertension and subsequent complications
- Evaluate the need for ambulatory blood pressure monitoring (ABPM) in specific patients
- Understand how parameters outside the normal limits may impact overall progression of hypertension (HTN)
- Identify common laboratory and monitoring parameters for each class of antihypertensive

Why is HTN monitoring important?

- Greater risk factor for cardiovascular disease (CVD) than smoking and obesity
- Over 50% of the 76 million adults with HTN are uncontrolled
  - Current practice often results in under or overtreatment
- Adverse effects of drug therapy
- Prevention of future complications
  - Heart failure and myocardial infarction
  - Stroke/TIA
  - Chronic kidney disease (CKD)

Laboratory tests prior to therapy initiation

- JNC 7 recommends the following:
  - Electrocardiogram
  - Urinalysis
  - Hematocrit
  - Routine blood chemistries (i.e. creatinine, electrolytes, glucose), eGFR
  - Lipid profile
  - Optional: albumin/creatinine ratio

4 Components of HTN Monitoring

- BP response to attain goal
- Adherence to lifestyle modifications and pharmacotherapy
- Disease progression
- Drug-related adverse effects
Monitoring Component #1: BP Response to Attain Goal

**BP Goals**
- **≥ 60 years:** \(<150/90 \text{ mmHg} \) (JNC 8)
- **< 60 years, diabetes or CKD:** \(<140/90 \text{ mmHg} \) (JNC 8)
- **CAD/high-risk CAD, Non-CAVD (e.g., stroke, AAA):** \(<130/80 \text{ mmHg} \) (AHA)
- **Left ventricular dysfunction:** \(<120/80 \text{ mmHg} \) (AHA)

**If dehydration or orthostatic hypotension suspected:**
- Measure BP seated and standing
- Consider home BP values when available

**Average of 2 BP values each time**
- Follow-up:
  - Evaluate BP 1-4 weeks after starting or modifying therapy
  - Decreases seen in 1-2 wks; full effects up to 4 wks
  - Hypertensive urgency: assess response in 3 days
  - If BP stable and at goal: 3-6 month intervals
  - More frequent visits for comorbidities or Stage II HTN
  - SCR and K at least 1-2 times per year
  - Pre-hypertension: yearly BP screening

**Resistant Hypertension**
- Definition: DBP > 90 mmHg despite intake of ≥ 3 antihypertensives including a diuretic

**Ingestion of BP-elevating substances**
- White coat HTN
- Non-medical or dietary compliance
- Volume overload
- Suboptimal therapy
- Secondary HTN
- Resistant HTN

**Pharmacist Monitoring:**
- Compliance—medications and lifestyle modifications
- Ingestion of substances that can elevate BP
  - Oral contraceptives, decongestants, corticosteroids, NSAIDs, herals (e.g., ginkgo, licorice), alcohol, drugs of abuse (e.g., cocaine), sodium
- Suboptimal therapy: titrate dosing and modify therapy to meet BP goals; consider compelling indications
- White coat HTN—consider home BP monitoring

**Ambulatory Blood Pressure Monitoring (ABPM)**
- Increasingly recommended for routine practice
- Indications:
  - Suspected white coat HTN in the absence of target organ injury
  - Resistant HTN to increasing medications
  - Hypotensive symptoms
- Device worn over 24-48 hr period providing frequent BP readings
  - Every 15-20 min during day and 30-60 min at night
- Average of daytime and/or nighttime BPs calculated
- 24-hr average goal: \(<130/80 \text{ mmHg} \)
Ambulatory Blood Pressure Monitoring (ABPM)

**ADVANTAGES**
- Useful in suspected masked HTN, white coat HTN and resistant HTN
- Provide a better picture of patient’s BP control
- Stop unnecessary therapy
- Studies have indicated 24hr BP more predictive than office BP for CV risk, CKD progression and mortality

**DISADVANTAGES**
- Not available in most clinician’s offices
- Lack of knowledge on utility
- Cost
- Minimal third-party payer re-imbursement
- Only a one-time measure of BP; still must be followed over time

Kaplan NM. UpToDate® Home Blood Pressure Monitoring in the Literature

Home Blood Pressure Monitoring

- Enables more frequent measurements in nonclinical settings
- Can overcome limitations of office-based monitoring
- Reduces misclassification due to white coat or masked HTN
- Prompts more timely action to manage BP
- Less costly than ABPM
- May improve patient compliance


A Pharmacist-Led, American Heart Association Heart360 Web-Enabled Home Blood Pressure Monitoring (HBPM) Program

- Purpose: to determine whether a pharmacist-led, web-enabled BP monitoring program improves BP control compared with usual care (UC)
- Methods: 348 pts, with uncontrolled BP, randomized to HBPM or UC
  - HBPM:
    - 10 primary care clinics staffed with RPh able to provide MTM and order labs under PCP collaborative
    - Heart360 - a widely available and free Web-enabled software for HBPM; automatically upload data stored on home BP machines and reviewed by RPh


MTM: medication therapy management
PCP: primary care provider

Results:

<table>
<thead>
<tr>
<th>After 6 months</th>
<th>HBPM</th>
<th>UC</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean SBP (mmHg)</td>
<td>128.1</td>
<td>137.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean DBP (mmHg)</td>
<td>76.1</td>
<td>83.1</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Patients at goal BP</td>
<td>54.1%</td>
<td>35.4%</td>
<td></td>
</tr>
<tr>
<td>Added BP medication</td>
<td>70%</td>
<td>25%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Dose increase in medication</td>
<td>43%</td>
<td>12%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>58%</td>
<td>42%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Conclusions: intervention led to greater BP reductions, superior BP control, and higher patient satisfaction than UC

https://www.heart360.org/Default.aspx


Effect of Home Blood Pressure Telemonitoring and Pharmacist Management on Blood Pressure Control

- Purpose: To determine if home BP telemonitoring plus pharmacist management improves BP control compared to usual care (UC)
- Methods: RCT of 450 adults with uncontrolled BP across 16 primary care clinics for 12 months
  - Intervention: patients received home BP telemonitors which transmitted BP data to pharmacists who adjusted medication according to algorithm
Effect of Home Blood Pressure Telemonitoring and Pharmacist Management on Blood Pressure Control

Results:

- Conclusion: home BP telemonitoring and RPh management improved BP control compared with UC during 12 months of intervention and 6 month follow-up.

<table>
<thead>
<tr>
<th>Outcome (time point)</th>
<th>Telemonitoring</th>
<th>Usual Care (UC)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite BP control (6 and 12 mo)</td>
<td>57.2%</td>
<td>30%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>BP control (18 months)</td>
<td>38.8%</td>
<td>57.1%</td>
<td>0.003</td>
</tr>
</tbody>
</table>

- Reduction from baseline (12 mo):
  - SBP (mmHg): -22.5 vs. -12.9, P <0.001
  - DBP (mmHg): -9.3 vs. -4.3

- Δ in # medication classes (6 mo): 1.6 to 2.2 vs. 1.4 to 1.6, P <0.001

- Satisfaction with care: improvements shown in intervention group concerning clinicians listening, explaining things clearly and respecting what patients said at 6 months, but not at 12 or 18 months.

Home Blood Pressure Monitoring

Recommendations for patients utilizing HBPM:

- Patient should take 2 seated BP measurements (separated by 1-2 min) in am and pm (4 per day).
- Take BP 30-60 min prior to taking medications.
- Monitor consecutively for ≥ 3 days (1 wk preferred).
- Discard readings from day 1 and average remaining.
- Goal slightly lower at home: <135/85 mmHg.

Monitoring Component #2:
Adherence to Lifestyle Modifications and Pharmacotherapy

Adherence: Pharmacotherapy

- Up to 50% of newly diagnosed HTN patients continuing treatment at 1 year.
- Discuss adherence in non-threatening manner with patients.
  - Needs to be discussed prior to adjusting therapy.
  - Barriers: cost, complex regimens, drug intolerance, understanding of disease.
  - Ways to improve adherence.
  - Discuss patient concerns; clarify misunderstandings.
  - Rebound hypertension with abrupt d/c of certain meds (e.g., clonidine).

Adherence: Lifestyle Modifications

- Encourage persistent lifestyle modifications.
  - Restrict sodium intake: < 2.3 g/day (< 1.5 g ideally).
    - Lowers BP and may decrease risk for CVD.
    - Counsel on salt substitutes.
  - Monitor weight loss/gain
    - Promote exercise and healthy diet.
  - Tobacco avoidance is essential.
  - Limit alcohol intake.
  - Patients may track daily salt intake, activity, weight, tobacco and alcohol use.

Monitoring Component #3:
Disease Progression

CVD: cardiovascular disease.
Disease Progression

- Uncontrolled hypertension can negatively impact progression of disease and overall health
- Patients should be monitored for signs and symptoms of hypertension-associated target organ disease
  - Ischemic heart disease (IHD)
  - Heart failure—results from systolic HTN and IHD
  - Acute MI
  - Stroke/TIA
  - Chronic kidney disease

Disease Progression

- Periodically assess for:
  - Chest pain, palpitations, dizziness, dyspnea, sudden change in vision, one-sided weakness, loss of balance
- Other exams: vision, LHV on EKG, proteinuria, changes in kidney function
- Any sign of deterioration requires immediate assessment and follow-up
- Disease progression may require therapy change and treatment for compelling indications

Monitoring Component #4: Drug-Related Adverse Effects

Agents affecting RAAS

<table>
<thead>
<tr>
<th>Class</th>
<th>Adverse Effects</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACEI</td>
<td>Hyperkalemia, renal impairment, angioedema (less with ARB and aliskiren)</td>
<td>BP, BUN/SCr, serum K</td>
</tr>
<tr>
<td>ARB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct renin-inhibitor agonists</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In patients with CKD, a rise in Scr of as much as 35 percent above baseline with ACEIs or ARBs is acceptable and is not a reason to withhold treatment unless hyperkalemia develops.


Diuretics

<table>
<thead>
<tr>
<th>Class</th>
<th>Adverse Effects</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thiazides e.g., HCTZ (Hydrodiuril)</td>
<td>Hyperglycemia, gout exacerbation, electrolyte disturbances, hypovolemia, orthostasis, dyslipidemia, pancreatitis, BMS</td>
<td>BP, BUN/SCr, serum electrolytes (K, Mg, Na), Ca, uric acid, glucose, weight</td>
</tr>
<tr>
<td>Loops e.g., furosemide (Lasix)</td>
<td>Diuretic disturbances, hypovolemia, hyperglycemia, ototoxicity, nephrotoxicity, orthostasis, pancreatitis, dyslipidemia, metabolic alkalosis</td>
<td>BP, BUN/SCr, serum electrolytes (K, Mg, Na), weight</td>
</tr>
<tr>
<td>Potassium-sparing e.g., triamterene (Dyrenium)</td>
<td>Hyperkalemia, hypovolemia</td>
<td>BP, BUN/SCr, serum electrolytes (K, Mg, Na), weight</td>
</tr>
<tr>
<td>Aldosterone antagonists e.g., spironolactone (Aldactone)</td>
<td>Hyperkalemia, hypostrenemia, hypovolemia, gynecomastia</td>
<td>BP, BUN/SCr, serum electrolytes (K, Mg, Na), weight</td>
</tr>
</tbody>
</table>

BMS: bone marrow suppression

Beta-blockers

<table>
<thead>
<tr>
<th>Class</th>
<th>Adverse Effects</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta-blockers e.g., metoprolol (Lopressor)</td>
<td>Bradyarrhythmia, heart block, hypotension, bronchospasm</td>
<td>BP, HR</td>
</tr>
</tbody>
</table>

*Careful monitoring in diabetics, especially on insulin: beta-blockers mask symptoms of hypoglycemia*

Calcium channel blockers

<table>
<thead>
<tr>
<th>Class</th>
<th>Adverse Effects</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydropyridines (DHP) e.g., amlodipine (Norvasc)</td>
<td>Peripheral edema, tachycardia</td>
<td>BP, HR</td>
</tr>
<tr>
<td>Non-DHP e.g., verapamil (Calan)</td>
<td>Bradycardia, heart block, left ventricular dysfunction</td>
<td>BP, HR</td>
</tr>
</tbody>
</table>

Alternative BP Agents

<table>
<thead>
<tr>
<th>Class</th>
<th>Adverse Effects</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>α1-blockers</td>
<td>Orthostasis, angina, priapism (rare)</td>
<td>BP (standing and sitting)</td>
</tr>
<tr>
<td>e.g., doxazosin (Cardura)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central α2-agonists</td>
<td>CNS depression, orthostasis, AV block, bradycardia</td>
<td>BP (standing and sitting)</td>
</tr>
<tr>
<td>e.g., clonidine (Catapres)</td>
<td></td>
<td>HR, RR</td>
</tr>
<tr>
<td>Arterial vasodilators</td>
<td>Drug-induced lupus (hydralazine), reflex tachycardia, fluid retention, peripheral neuritis</td>
<td>BP (standing and sitting)</td>
</tr>
<tr>
<td>e.g., hydralazine (Apresoline)</td>
<td></td>
<td>HR, CBC, ANA</td>
</tr>
<tr>
<td>Adrenergic neuron blocker</td>
<td>Orthostasis, CNS disturbances, arrhythmias</td>
<td>BP, HR, signs of depression</td>
</tr>
<tr>
<td>reserpine (Serpalan)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CBC: complete blood count  
ANA: antinuclear antibody

Pharmacist Input on Monitoring

- Encourage patients to bring all OTC’s, herbs and Rx’s to each office visit
- Alternative OTCs for pain and cough/cold
  - Acetaminophen > NSAIDs
  - Avoid decongestants (e.g., pseudoephedrine)
- Recommendations for BP monitors
  - [Link](http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/SymptomsDiagnosis/Choosing-a-HomeBloodPressureMonitor_UCM_303322_Article.jsp)
- Monitor prescription refills and alert patients
- Control ≠ cure—encourage continued treatment
- Therapeutic recommendations for uncontrolled BP

Assessment

1. In patients with HTN, Scr and K should be monitored at least 1-2 times per month.  
   False

2. In patients with CKD, a rise in Scr of 10% should warrant discontinuation of ACEI therapy.  
   False

3. ABPM can be utilized for patients with suspected “white coat” HTN in the absence of target organ injury.  
   True

References

- Micromedex®

Laboratory and Monitoring Parameters in Hypertension

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BAPTIST HEALTH SOUTH FLORIDA

Contact: kristenh@baptisthealth.net
Laboratory and Monitoring Parameters in Asthma

Christianne Rodriguez, Pharm.D.
PGY-1 Pharmacy Practice Resident
Baptist Hospital of Miami

Objectives

- Review the assessment and periodic monitoring of severity, control and responsiveness to treatment essential for asthma management
- Emphasize the role of pharmacists in educating patients on self-monitoring techniques to manage the course of their condition
- Review scenarios that would require referral to an asthma specialist or allergist

Four Components of Asthma Management

- Educational partnership
- Pharmacological therapy
- Control of environmental factors/co-morbidities
- Measures of assessment and monitoring

Measures of Asthma Assessment & Monitoring

Severity

- The intrinsic intensity of the disease process
- Most easily & directly measured in patients not receiving long-term treatment (during initial visit)

Control

- Degree to which the manifestations of asthma are minimized and the goals of therapy are met (assessed in subsequent visits)

Responsiveness

- The ease with which asthma control is achieved by therapy
- Variable; requires follow-up assessments

Domains of severity & control
Goal: Asthma Control

1. Reducing impairment
   - Prevent symptoms
   - ↓ use (≤2 days/week) of inhaled short-acting beta agonists (SABA)
   - Maintain normal activity levels and pulmonary function
   - Meet patients' and families' expectations of and satisfaction

2. Reducing risk:
   - Prevent recurrent exacerbations & ↓ need for ED visits or hospitalizations
   - Prevent progressive loss of lung function
   - Provide optimal pharmacotherapy with minimal/no adverse effects

Necessity of Monitoring

- Overall purpose of periodic assessment and ongoing monitoring is to determine whether goal of therapy are being achieved
  - Is asthma under control?
  - Level of control at time of follow-up helps ascertain clinical actions - whether to maintain or adjust therapy
  - Uncontrolled asthma leads to asthma burden:
    - Decreased quality of life (QOL)
    - Increased health care utilization

Assessment of Symptoms

- Detailed symptom history based on 2-4 week recall
  - Should include 4 key symptoms
    - Daytime asthma symptoms
    - Nocturnal awakening due to asthma symptoms
    - Frequent use of SABA for symptom relief
    - Inability/difficulty performing normal activities due to asthma symptoms

Classification of asthma control (patients 12 years old and older)

<table>
<thead>
<tr>
<th>COMPONENTS OF CONTROL</th>
<th>WELL CONTROLLED</th>
<th>POOR CONTROLLED</th>
<th>MILDLY CONTROLLED</th>
<th>MODERATELY CONTROLLED</th>
<th>SEVERELY CONTROLLED</th>
</tr>
</thead>
</table>
| Impairment
  - Symptoms: ≤ 2 days/week
  - Nighttime awakenings: ≤ 2 episodes
  - Interference with normal activity: None
| ≤ 2 days/week
  - > 2 days/week
  - Throughout the day
| ≤ 2 days/week
  - > 2 days/week
  - Several times/day
| ≤ 2 days/week
  - > 2 days/week
  - Several times/day
| ≤ 2 days/week
  - > 2 days/week
  - Several times/day |

| Risk
  - Exacerbations requiring oral systemic corticosteroids: ≤ 2/year
  - Asthma severity and intensity of disease last 12 months,
  - Progressive loss of lung function
  - Treatment related adverse effects
  - History of asthma exacerbations
  - Therapy review for adherence or side effects
| ≤ 2/year
  - > 2/year
  - > 3/year
  - > 5/year
  - ≥ 10/year |

Pulmonary Function

- Spirometry
- Peak Flow Monitoring
Spirometry

- Most widely available & used PFT
- Facilitates diagnosis of asthma
- Helps classify asthma severity
- Assesses risk of future adverse events
- Measures:
  - Forced Vital Capacity (FVC)- volume of air exhaled as forcefully and fast as possible after max inhalation; expressed in liters (L)
  - Forced Expiratory Volume (FEV1)- volume of air exhaled during the first second of FVC maneuver; expressed in liters (L)

- Provides information about obstructive and restrictive disease via FEV1/FVC ratio
  - Obstructive disease: ↓ FEV1 due to increased airway resistance to expiratory flow; FVC may ↓ to premature closure of airway in expiration, not proportionally to FEV1
  - Restrictive disease: FEV1 and FVC are reduced proportionally

- Asthma patient: expected to have FEV1/FVC < 80%

---

**Recommended frequencies for spirometry testing**

1. At time of initial assessment
2. After treatment is initiated; symptoms & PEF have stabilized
3. During periods of progressive or prolonged loss of asthma control
4. At least every 1-2 years

---

**Peak Expiratory Flow Rate (PEFR/PEF)**

- Maximal rate that a person can exhale during a short maximal expiratory effort after a full inspiration
- Provides a simple way to assess lung function & asthma control
- Measured via peak flow meters
- Instruction on use:
  - Stand up straight, take a deep breath. Hold breath when placing mouthpiece over mouth. Blow out as hard & as fast as possible. Write down number. Repeat another 2 times

- Works hand-in-hand with a home asthma action plan
  - Informs patient how to take care of asthma symptoms
  - Requires self-monitoring of PEFs

---

**Asthma Action Plan**

- Based on "personal best" PEF to be used as a baseline against which to compare current lung function
- Establishing "personal best"
  - Use peak flow meter 2-4 times daily for 2-3 week.
  - Highest recorded value = "personal best"

<table>
<thead>
<tr>
<th>PEF zone</th>
<th>Definition of zones</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green</td>
<td>80-100% of personal best</td>
<td>Well controlled, no additional med needed</td>
</tr>
<tr>
<td>Yellow</td>
<td>50-79% of personal best</td>
<td>Use of reliever med, check in 15 mins</td>
</tr>
<tr>
<td>Red</td>
<td>&lt;50% of personal best</td>
<td>Contact physician or visit ED</td>
</tr>
</tbody>
</table>

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Quality of Life

- Any work or school missed because of asthma
- Any reduction in usual activities (either home/work/school or recreation/exercise)
- Any disturbances in sleep due to asthma

Assessment Tools

- Mini Asthma Quality of Life Questionnaire
- Asthma-QOL Questionnaire
- ITG Asthma Short Form
- SF-36
- SF-12
- Generic QOL


Asthma Exacerbations

- Evaluate:
  - Frequency
  - Rate of onset
  - Severity
  - Causes
  - Unscheduled visits to health care providers
  - Use of urgent or emergency care facilities
  - Hospitalizations

Pharmacotherapy Adherence & Potential Side Effects

- At each visit determine:
  - Adherence to the regimen
  - Inhaler technique (e.g., use of a spacer)
  - Side effects of medications


Patient-Provider Communication & Patient Satisfaction

- Open and unrestricted communication among the clinician, the patient, and patient’s family
- Patient satisfaction with asthma control and with the quality of care


Minimally Invasive Markers & Pharmacogenetics

<table>
<thead>
<tr>
<th>Airway responsiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Sequentially increasing doses of a provocative agent (e.g., methacholine), calculating “provocative dose” causing a 20% fall in FEV1 (“PC20”)</td>
</tr>
<tr>
<td>- Expensive, time consuming</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sputum eosinophilia</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Analyzes cells and mediators in sputum induced by hypertonic saline</td>
</tr>
<tr>
<td>- Predicts responsiveness to starting or withdrawing inhaled corticosteroid (ICS) treatment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fraction exhaled nitric oxide</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Reflects the intensity of eosinophilic inflammation in bronchial mucosa</td>
</tr>
<tr>
<td>- Predicts responsiveness to starting or withdrawing ICS or oral corticosteroid</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmacogenetics</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Alox 5 Leukotriene receptor antagonist (LTRAs)</td>
</tr>
<tr>
<td>- B2AR: SABA</td>
</tr>
<tr>
<td>- CRHR1: ICS</td>
</tr>
</tbody>
</table>

Assessment & Monitoring

Clinician Assessment
- Every 2–6 weeks while gaining control
- Every 6 months to when under control for 3 months
- Every 3 months if step down in therapy is anticipated

Patient Assessment
- Daily diary
  - Symptoms, peak flow, med use, restricted activity
- Questionnaires
  - ACQ
  - ACT
  - ATAQ

Questionnaires

Asthma Control Test (ACT)
Asthma Control Questionnaire (ACQ)
Asthma Therapy Assessment Questionnaire (ATAQ)

Daytime symptoms
Nocturnal symptoms
Activity restriction
Reliever use
Long function
Self-perception of control
Symptom severity
Time frame
  - Previous 4 wks
  - Previous week
  - Previous 4 wks & 12 mos.

# of dimensions
5
7
4

Pharmacists’ Role

- Non-adherence rate of asthma patients in the US ~55%
- The National Asthma Education and Prevention Program 2007 guidelines
  - Recommends pharmacists’ intervention
  - 4 randomized, controlled trials revealed a reduction in hospitalizations, improved inhaler technique, improved asthma control and improvement in QOL
- A study by McLean et al.
  - 255 patients randomized to receive advanced pharmaceutical care or the usual care for the treatment of asthma
  - Results: 75% decrease in ED visits, 75% decrease in medical visits, 50% decrease in symptom scores, increase in peak flow readings by 51%, reduction of SABA use by 50%

Questionnaires

Expanding pharmacist’s role in asthma care. APhA. August 2013.


Pharmacists’ Role

- Basic asthma facts: description of asthma, role of inflammation, reasoning behind medications prescribed
  - Contribute to overall asthma education
  - Determine if over- or underutilizing asthma medications
  - Evaluate inhaler technique
  - Emphasize trigger avoidance

Instruct on proper use of peak flow meter

Dispensed in pharmacies and good technique is essential in obtaining an accurate measurement

Review of asthma action plan

Instructions for daily actions to keep asthma controlled and on how to adjust treatment when symptoms or exacerbations occur

Timely follow-up with physician

Encourage patients seen in the ED for acute exacerbation to follow-up with PCP/Patient specialist (~1-4 weeks post ED discharge) or participate in an asthma education program

Referral to an Asthma Specialist

- Includes primary care physicians, pulmonologists, and allergists/immunologists
- Via consultative services and interventions regarding medication-related problems

Scenarios:
  - Patient had life-threatening asthma exacerbation
  - Not meeting goals of therapy after 3-6 months of treatment
  - Co-morbidities that complicate asthma i.e. GERD, sinusitis, severe rhinitis
  - Patient requiring confirmation that a suspected inhalant or ingested substance is provoking or contributing to asthma
  - Requires additional education & guidance on complications of therapy; problems with adherence or allergen avoidance

Expanding pharmacist’s role in asthma care. APhA. August 2013.


Questions

1. The ultimate goal of asthma treatment for patients includes control of chronic symptoms and the prevention of acute exacerbation episodes?
   True

2. The most useful test to assess the risk of future adverse events is serum immunoglobulin E?
   False - spirometry

3. Peak flow measurement provides a simple, quantitative and reproducible assessment on the existence and severity of airflow obstruction?
   True

References

Arthritis: Laboratory and Monitoring Parameters

Fabiola Dabady, PharmD
PGY-1 Pharmacy Practice Resident
Miami VA Healthcare System

Objectives
- Interpret and assess laboratory tests for arthritic conditions/disorders
- Discuss the laboratory and monitoring parameters for medications used to treat arthritis
- Understand and apply monitoring parameters to establish patient’s prognosis and treatment efficacy
- Develop patient-centered monitoring plans to include medication efficacy, drug-drug interactions, adverse effects, and treatment goals

Types of Arthritis
- Osteoarthritis (OA)
- Rheumatoid arthritis (RA)
- Crystalline arthritis
  - Gout
  - Pseudogout

Laboratory Test
- Anti-Cyclic Citrullinated Peptide (Anti-CCP) Antibodies
- C-Reactive Protein (CRP)
- Erythrocyte Sedimentation Rate (ESR)
- Serum Rheumatoid Factor (RF)
- Serum Uric Acid
- Other laboratory test: Synovial/Joint Fluid Analysis

Anti-Cyclic Citrullinated Peptide (Anti-CCP) Antibodies
- Produced as part of the process that leads to joint inflammation
- Several different citrullinated proteins can be found in RA
- Found only in rheumatoid arthritis

Anti-Cyclic Citrullinated Peptide (Anti-CCP) Antibodies
- Normal range:
  - <10 u/mL or <20 u/mL
  - Varies depending on laboratory and assay used
- Sensitivity: 67% & Specificity: 95%
- Most specific marker
- Has prognostic value but no role in monitoring disease activity
C-Reactive Protein (CRP)
- Byproduct of inflammation
- Alternative to Erythrocyte Sedimentation Rate (ESR)
- Fast response to inflammation; ~ 6hrs
- Non-specific test

C-Reactive Protein (CRP)
- Not a diagnostic measure
- Normal range: 0.08 – 3.1 mg/L
  - Varies among laboratories and assays
  - Assays include regular C-reactive protein or highly sensitive C-reactive protein
- Indicates the level of disease activity
  - Used in several arthritic monitoring tools
  - Helps measure treatment efficacy

Erythrocyte Sedimentation Rate (ESR)
- Also called Westergren Erythrocyte Sedimentation Rate
- Rate in which red blood cells sediment over a period of 1 hour
- Slow response to inflammation
- Non-specific yet sensitive test

Erythrocyte Sedimentation Rate (ESR)
- Not a diagnostic measure
- Normal Range:
  - Women: 0 – 20 mm/h
  - Men: 0 – 15 mm/h
- Indicates the level of disease activity
  - Used in several arthritic monitoring tools
  - Helps measure treatment efficacy

Serum Rheumatoid Factor (RF)
- Protein/immunological markers
- Test for autoantibodies against the Fc portion of immunoglobulin G (IgG)
- Found in several autoimmune diseases
- Not a stand alone diagnostic measure

Serum Rheumatoid Factor (RF)
- No role in monitoring disease activity
- Prognostic measures
  - High levels = Severe RA
- Normal results
  - No autoantibodies detected
- Sensitivity: 69% & Specificity: 85%
- Positive in 70-80% of people with symptoms of RA
Serum Uric Acid
- Venous blood sample
- Normal result < 7 mg/dL
- Does not confirm or exclude diagnosis of gout
- Levels may be normal in patients with acute gout

Synovial/Joint Fluid Analysis
- Invasive procedure
- Analysis includes:
  - Gram stain and culture
  - Cell count with differential
  - Crystal analysis

Synovial/Joint Fluid Analysis
- Normal results
  - Clear appearance, viscous and sterile
  - Leukocyte count:
    - < 2000/µL (non-inflammatory arthritis; OA)
    - < 200/µL (inflammatory arthritis; RA)
  - Negative gram stain
  - Firm mucin clot formation
  - Protein level < 2.5 g/dL

Abnormal Results
  - Osteoarthritis
  - Normal results
  - Rheumatoid Arthritis
  - Fluid is turbid and viscosity is decreased
  - Protein levels are > 2.5 g/dL
  - Mucin clot is friable
  - Crystalline arthritis
    - Monosodium urate crystals (gout)
    - Calcium pyrophosphate crystals (pseudogout)

Summary of Laboratory Studies

<table>
<thead>
<tr>
<th></th>
<th>Osteoarthritis</th>
<th>Rheumatoid Arthritis</th>
<th>Gout</th>
<th>Pseudogout</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-CCP</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>CRP</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>ESR</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>RF</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Uric Acid</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Joint Fluid Analysis</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Osteoarthritis
- Treatment goals
  - Reduce/control pain
  - Minimize disability
  - Return to normal activity
- Non-Pharmacologic treatment
- Pharmacologic treatment
  - Acetaminophen, NSAIDs, topical analgesics, etc.
Osteoarthritis

- Acetaminophen
  - Monitoring parameters
    - Liver and renal function
  - Up to 4000mg/day
- NSAIDs
  - Ibuprofen: up to 3200mg/day
  - Monitoring parameters
    - Gastrointestinal upset
    - Renal & liver function
    - Complete blood count; electrolytes

Rheumatoid Arthritis

- Treatment goals
  - Prevention of chronic joint damage
  - Minimize/control disease activity
  - Pain, stiffness, and inflammation control
  - Remission
- Non-pharmacologic treatment
- Pharmacologic treatment
  - Disease modifying antirheumatic drugs (DMARDs), NSAIDS, corticosteroids

Osteoarthritis

- Cyclooxygenase-2 Inhibitor
  - 100 mg PO BID or 200 mg PO daily
  - Monitoring parameters similar to NSAIDs
  - Less gastrointestinal toxicity

Topical analgesics

- Capsaicin cream; voltaren gel
- Monitoring Parameters
  - Relief of aches and pains

Local glucocorticoid injections

- Methylprednisolone
- Monitoring Parameters
  - Clinical improvement

Rheumatoid Arthritis

Adjunctive Medications

- Acetaminophen
  - Monitoring parameters
    - Liver and renal function
  - Up to 4000mg/day
- NSAIDs
  - Dose varies depending on agent used
  - Monitoring parameters
    - Gastrointestinal upset
    - Renal & liver function
    - Complete blood count; electrolytes

Corticosteroids

- Dose varies depending on agent used
- Monitoring parameters
  - Adverse effects (glaucoma, diabetes, osteoporosis with long term use)
  - Signs and symptoms of infection
  - Electrolytes; blood glucose
  - Mental status changes
  - Reduction in ESR and/or CRP from baseline
### Rheumatoid Arthritis

#### Non-biologic DMARDs

<table>
<thead>
<tr>
<th>Table 1. Recommendations for optimal follow-up laboratory monitoring intervals for complete blood count, liver transaminases, and serum creatinine levels for rheumatoid arthritis patients receiving nonbiologic disease-modifying antirheumatic drugs*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring interval based on duration of therapy</td>
</tr>
<tr>
<td>Therapeutic agents</td>
</tr>
<tr>
<td>Hydroxychloroquine</td>
</tr>
<tr>
<td>Leflunomide</td>
</tr>
<tr>
<td>Methotrexate</td>
</tr>
<tr>
<td>Minocycline</td>
</tr>
<tr>
<td>Sulfasalazine</td>
</tr>
</tbody>
</table>

* More frequent monitoring is recommended within the first 3 months of therapy or after increasing the dose. The same level of the monitoring interval is recommended beyond 6 months of therapy. Listed alphabetically.

#### Biologic DMARDS

<table>
<thead>
<tr>
<th>Table 2. Recommendations on baseline evaluation for starting, resuming, or significant dose increase of a therapy in patients with rheumatoid arthritis receiving nonbiologic and biologic disease-modifying antirheumatic drugs*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic agents</td>
</tr>
<tr>
<td>Hydroxychloroquine</td>
</tr>
<tr>
<td>Leflunomide</td>
</tr>
<tr>
<td>Methotrexate</td>
</tr>
<tr>
<td>Minocycline</td>
</tr>
</tbody>
</table>

* Therapies are listed alphabetically. CBC = complete blood count; X = recommended test.

### Gout/Pseudogout

#### Treatment goals
- Reduce pain and swelling/inflammation
- Improve quality of life

#### Non-Pharmacologic treatment
- Gout vs Pseudogout
- Pharmacologic treatment
  - Gout: Colchicine, NSAIDs, etc.
  - Pseudogout: Hydroxychloroquine, NSAIDs

#### Pharmacologic treatment
- Colchicine
  - 1.2 mg initially then 0.6 mg Q1-2Hr
- Monitoring parameter
  - Complete blood count
  - Renal and hepatic function
- Allopurinol
  - 300 mg PO daily
- Monitoring parameter
  - Uric acid levels
  - Renal and hepatic function

#### NSAIDs
- Monitoring parameters
  - Gastrointestinal upset
  - Renal & liver function
  - Complete blood count; electrolytes

#### Corticosteroids
- Monitoring parameters
  - Adverse effects
  - Signs/symptoms of infection
  - Mental status changes

#### Uloric
- 40 – 80 mg PO daily
- Monitoring parameters
  - Liver function test
  - Serum uric acid

#### Urocosuric agents
- Dose varies depending on agent used
- Monitoring parameters
  - Serum uric acid
Gout/Pseudogout

- Hydroxychloroquine
  - 100 – 400 mg daily
- Monitoring parameters
  - Complete blood counts
  - Liver and renal function
  - Ophthalmologic exams

Osteoarthritis

- Treatment monitoring parameters
  - Adverse effects
  - Drug-drug interactions
  - Clinical improvement
  - Patient centered questionnaires

Rheumatoid Arthritis

- Monitoring Tools
  - Disease Activity Score in 28 joints
  - Simplified Disease Activity Index
  - Clinical Disease Activity Index
  - Rheumatoid Arthritis Disease Activity Index
  - Routine Assessment Patient Index Data

Gout/Pseudogout

- Treatment monitoring parameters
  - Adverse effects
  - Drug-drug interactions
  - Clinical improvement
  - Patient centered questionnaires
  - Laboratory Study
    - Serum uric acid goal of < 6mg/dL

True or False?

1. Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) are measured to determine the level of disease activity.
2. Citrullinated proteins have been observed in the joints of patients with rheumatoid arthritis only.
3. An arthritis laboratory panel includes all of the following:
   - Anti-cyclic citrullinated peptide antibodies
   - C-reactive protein
   - Rheumatoid factor
   - Sedimentation rate
   - Serum uric acid

References

Anatomy of the "SOAP" note

Moe Shwin, Pharm.D.
PGY-2 Oncology Pharmacy Resident

Goals and Objectives

- Describe the role documentation plays in a patient care process
- Compare various formats of documentation
- Identify key characteristics, structure and organization of documentation
- Discuss barriers to documentation

"If you are not documenting the care you provided in a comprehensive manner, then you do not have a practice"

Cipolle RJ, Strand LM, Morley PC. Pharmaceutical Care Practice. The Clinician’s Guide. 2004

Background

ASHP’s survey of hospital practices in 2006:

- Documentation on medication therapy monitoring:
  - Hospital employed pharmacists: 81.3%
- Locations of documentation:
  - Pharmacy practice profile: 70%
  - Patient medical record: 63.5%


Purpose of Documentation

- Improves patient care and outcomes
- Enhances continuity of care
- Serves as a tool for communication among health care professionals
- Establishes the pharmacist’s credibility as a health care provider
- Protects against professional liability
- Ensures compliance with laws and regulations
- Documentation for third-party payers:
  - Should support the use of billing codes designed for use by pharmacists
  - Should specify the amount of time spent on each patient


Background

The Social Security Act:
- Pharmacists and pharmacists’ patient care services are not included

Preventable medication-related adverse events:
- 1.5 million each year

Costs to treat adverse events from inappropriate medication use:
- $290 billion dollars annually

Medication non-adherence:
- $100 billion annually

American Pharmacists Association. The value of provider services. What pharmacists are doing. September 2007
Documentation Formats

- Unstructured notes
- Semi-structured notes
- Systematic records: Data-rich environment
  - SOAP (subjective, objective, assessment, plan)
  - TITRS (title, introduction, text, recommendation, signature)
  - FARM (finding, assessment, recommendations/resolutions, management)
  - Medicare-D MTM Format

Essential Elements

- Patient’s medication history
- Allergies and their manifestations
- Drug therapy monitoring and findings
- Actual and potential drug-related problems
- Drug therapy adjustments
- Clarification of drug orders
- Oral and written consultations provided to other health care professionals
- Physicians’ oral orders received directly by the pharmacist
- Patient education and counseling provided

Key Characteristics of Documentation

- Provides a record of:
  - What a practitioner does
  - Why it is done
  - What outcomes are achieved
  - A real-time trail of care provided to patients
  - Easy to use
  - Produces useful reports
  - Allows for knowledge sharing with other providers

Rules for Appropriate Documentation

- Clear, concise, and comprehensive
  - Avoid use of abbreviations whenever possible
- All entries should be legible
- Lack of judgment language
  - Avoid words that imply blame or substandard care
    (e.g. error, mistake, inadequate, inappropriate)
- Need for inclusion in the Patient Medication Record (PMR)
- Appropriate use of a standard format
- How to contact the pharmacist

SOAP

- Developed in the early 1970s
- The most commonly used format
- Problem-oriented-medical record (POMR)
  - Each medical problem is identified
  - Problems are listed in order of importance

Subjective and Objective Information

- Preliminary Patient Data
  - Data Rich Environment
    - EMR, Paper Chart, PMR
  - Data Poor Environment
    - PIS, PMR
  - Interview Patient

Subjective & Objective Information

EMR: Electric medical record
PMR: Personal medication record
PIS: Pharmacy information system
**S: Subjective**

- Obtained verbally from the patient or caregiver
  - Explains or delineates the reason for the encounter
  - Examples:
    - Patient concerns
    - Symptoms
    - Previous treatment
    - Medication used
    - Adverse events

**O: Objective**

- Details data directly measured or observed by the SOAP writer or another health care professional
  - Information from physical examination
  - Laboratory results
  - Diagnostic tests
  - Pill counts
  - Pharmacy patient profile information
  - Data are measurable and reproducible

**Assessment & Plan**

- Prioritize Medication Issues
- Justify and Explain Plan
- Discuss Plan with patient and/or Provider, Determine Actionable Items
- Documentation, Billing, Communication to other Providers or Patient/Caregiver

**A: Assessment**

- Practitioner’s clinical opinion or judgment about the problem based on data collected, and the practitioner’s previous experiences
  - A brief but complete description of the problem
  - A conclusion/diagnosis that is supported by subjective and objective data
  - Identify a drug-related problem(s)
  - Assessment of actions needed to address the problem

**P: Plan**

- A detailed description of recommendation(s) for:
  - Further workup (laboratory, radiology)
  - Treatment (medications, diet)
  - Patient Education
  - Monitoring & follow-up

**Pros & Cons of SOAP**

**Pros:**
- Most widely used
- Well established
- Systematic

**Cons:**
- No clear-cut distinction between subjective and objective findings
- Inapplicability to non-physician care providers
Medication Therapy Management Program (MTMP)

- The Affordable Care Act:
  - Sec: 10328; amended Sec: 1860D-4(c) (2)(ii)
- A Medicare Part D sponsor must have established an MTMP that:
  - Part D covered medications are used appropriately to optimize outcomes
  - Designs to reduce the risk of adverse events
  - May be provided by a pharmacist or other qualified provider
- Must offer, at a minimum, an annual comprehensive medication review (CMR), and provide written summaries

CMR

- CMR must include:
  - A review of the individual’s medications
  - A recommended medication action plan
  - Written or printed summary of the results of the review provided
  - Must comply with requirements as specified by CMS for the Format as of January 1, 2013
    - To Improve quality of the MTM services
    - To provide consistency in communications

CMR Components

- Written summary included 3 documents:
  - CL
  - MAP
  - PML

Cover Letter (CL)

- Entries in the blanks may be:
  - Typed (preferred) or hand-written
  - 14-point font, unless specified
  - A minimum look-back of medications: 6 months
Medication Action Plan (MAP)

- To assist the beneficiary with resolving issues of current drug therapy
- To help achieve the goals of medication treatment.
- Describes the specific action items resulting from the interactive CMR consultation
  - The beneficiary’s responsibilities
  - Healthcare provider activities that may affect the beneficiary’s tasks

Personal Medication List (PML)

- A reconciled list of all the medications in use (i.e., active medications)
- Must also collect and report
  - The purpose and instructions for the beneficiary’s use of his/her medications
- Intended to help beneficiaries
  - Understand their medications and how they relate to their treatment plans
- To engage beneficiaries in the management of their drug therapy
- To improve both communication about medications and tracking of all medications

MAP:

- Helps the beneficiary with resolving issues of current drug therapy
- Helps achieve the goals of medication treatment
- Describes the specific action items resulting from the interactive CMR consultation

PML:

- A reconciled list of all the medications in use (i.e., active medications)
- Must also collect and report
  - The purpose and instructions for the beneficiary’s use of the medications
- Intended to help beneficiaries
  - Understand their medications and how they relate to their treatment plans
- To engage beneficiaries in the management of their drug therapy
- To improve both communication about medications and tracking of all medications
Barriers To Documentation

- Time
- Organizational policies
- Knowledge
- Awareness
- Reimbursement/ reward

References

- Stetbins, M., Cutler, T., Parker, P. Assessment of therapy and medication therapy management. Applied Therapeutics. 9th edition. 2009
Collaborative Practice Agreements

Frances Varona, Pharm.D.
PGY1 Pharmacy Resident
Mercy Hospital

Goals and Objectives

- Explain collaborative practice agreements (CPAs)
- Collaborative drug therapy management (CDTM)
- Their evolution and practical application
- Describe current Florida statutes and practice related to CPAs
- Importance of provider status
- Illustrate the process of developing a CPA
- Review a sample CPA

Definitions

- **Collaborative Practice Agreement (CPA)**
  - Formalized contract that allows for collaborative drug therapy management program to occur

- **Collaborative Drug Therapy Management (CDTM)**
  - A protocol or written plan delegating legal prescriptive authority to pharmacists under designated circumstances by a physician

Collaborative Practice Agreements

- Formal agreements between physicians and pharmacists
- Expand pharmacists’ role to provide further patient care services
- Perform patient assessment
- Order, interpret, and monitor laboratory tests
- Have prescriptive authority
- Formulate clinical assessment and develop therapeutic plan
- Provide care coordination and other health services for wellness and prevention of disease
- Develop partnerships with patients for ongoing care

History

- 1960s: First CDTM seen in the Indian Health Services
- 1970s: Veterans Affairs (VA) administration credentialed pharmacists as primary care providers
- 1990s – Present: Introduction of pharmaceutical care philosophy
  - 1993: 7 states recognized pharmacists’ collaborative care abilities
  - 1995: VA started allowing pharmacists to participate in CPAs
  - 1996: Asheville Project
  - 1996: Project ImPACT: Hyperlipidemia
  - 2003: Project ImPACT: Osteoporosis
  - 2006: Project ImPACT: Depression
  - 2007: Florida allows pharmacists to enter into CPAs
  - 2009: Project ImPACT: Hypertension
  - 2010: Project ImPACT: Diabetes

ImPACT*: Hyperlipidemia

- Created an exchange of patient care data between patient, physician, and pharmacist
- Demonstrated point-of-care testing usefulness
- Organized documentation and follow-up information between the pharmacist and physician
- Results:
  - 397 patients over 24.6 months
  - 90.1% observed rate of medication compliance
  - 62.5% of patients reached lipid goals

* ImPACT = IMprove Persistence And Compliance with Therapy

ImPACT: Diabetes

The Results

A1C 0.7%

Blood Pressure

Systolic 19 mmHg


US Pharmacists’ Effect on Patient Care

2010: Systematic review and meta-analysis that demonstrated improved health outcomes when pharmacists are involved in patient care

- LDL reduction of 6.3 mg/dL
- SBP reduction of 7.8 mmHg & DBP reduction of 2.9 mmHg
- A1c reduction of 1.8%

Chisholm-Burns MA, Lee JK, Spivey CA. “US Pharmacists’ Effect as Team Members on Patient Care: Systematic Review and Meta-Analysis.” Medical Care (October 2010);48(10):923-33.

Benefit of CPAs

- Patient
  - Increased healthcare access
  - Enhanced care
- Physician
  - Increased one on one time between patient and physician
  - Provides new patient referrals
- Payor
  - Optimized drug therapy management
  - Improved patient care
  - Reduced healthcare costs
  - Improved patient satisfaction scores


Patient Care Services

- Preventative care
  - Vaccinations
  - Travel prophylaxis
  - Smoking cessation management
- Managing chronic disease states
  - Optimizing current medications
  - Point-of-care testing
  - Minimizing re-hospitalization

Current Florida Statutes

- Role of the pharmacist - §465.003(13)
- Pharmacist order, dispensing, and development of drug formularies - §465.186
- Vaccine and epinephrine auto-injection administration - §465.189

- Influenza vaccine (2007)
- Pneumococcal vaccine (2012)
- Shingles vaccine (2012: with an electronic or written prescription)

Currently in Florida

- CPAs
  - Administration of vaccines
  - Provide point-of-care testing

- Medication therapy management services (MTM)
  - Not a CPA
  - Complete medication therapy review
  - Disease management coach/support
Florida Compared to Other States

- All 50 states allow pharmacist to administer vaccines
- Florida is one of 46 states that allows for CPAs
  - 4 states do not allow for CPAs
    - Alabama
    - Michigan
    - Tennessee
    - South Carolina
- Pharmacists have provider status in 11 states
  - Most recently, California announced provider status for pharmacists to start in January 2014
  - Pharmacists in Florida do not have provider status yet they can bill for some MTM services

Road to Provider Status

- Provider status is to be recognized as a provider under the Social Security Act (SSA)
  - To expand Medicare beneficiaries’ access to pharmacists’ services
  - To allow for pharmacists to be part of emerging payment models
- Nurse practitioners have the following advice for attaining provider status in the SSA
  1. Gaining recognition of the potential to expand our role
  2. Documenting the value of the pharmacist
  3. Establishing standards in education and credentialing
  4. Utilize professional organizations to empower individuals
  5. Be willing to accept small steps over time

Entering into a CPA

Step 1: IDENTIFY
- Identify physician or physician group
- Identify patient group

Step 2: MARKET
- Discuss the patient care service that will be provided
  - Describe components
  - Define incentives
  - Emphasize patient benefits
Entering into a CPA

Step 3: EXECUTE

- Draft a CPA/CDTM
- Plan how reimbursement for services will work
- Consult with a pharmacy attorney, the board of pharmacy, and state association

Sample CPA

Sample CDTM

1. Purpose
2. Responsibilities
3. Protocol or algorithm of duties
4. Describes documentation

Sample Agreement

http://www.rxmt.org/documents/HTNprotocolforMPAwebsite.pdf

How To Get Involved

- ADVOCATE
  - Join your state association and lobby for the cause
  - Contact your state and local representatives
    - Senator Bill Nelson
    - Senator Marco Rubio

Summary

- CPAs are formal contracts that allow for CDTMs
  - CDTMs are written protocols delegating prescriptive authority to pharmacists
- Currently, CPAs in FL are limited only to vaccine administrations and point-of-care testing
- Three steps to developing a CPA: identify, market, and execute
- Future for Florida pharmacists:
  - Change regulations to make pharmacists part of the team
  - Attain provider status to be part of emerging payment models

Remember: Together Everyone Achieves More for the patient!
References


True or False?

- In Florida, pharmacists are able to enter into collaborative practice agreements?

- Florida pharmacists widely use collaborative practice agreements in the retail setting?

- Pharmacists have provider status in the state of Florida?

Discussion and Questions

Thank you for your time and attention!
Objective:
1. Define National Provider Identifier (NPI), its purpose and general characteristics
2. Explain how to obtain an NPI and who is eligible
3. Review taxonomy codes for NPI application
4. Identify current procedural terminology (CPT) codes used in pharmacy billing
5. Describe billing models for cognitive pharmacy services

NPI: The Basics
- 10-digit numeric identifier
  - 10th position is a check digit
- Standard unique identifier for health care providers that enables efficient electronic transmission of health information
- Intelligence-free
  - No coded information about the provider

NPI Implementation Timeline
- January 23, 2004
  - Final Rule published
- May 23, 2005
  - Effective date of NPI
- May 23, 2007
  - Covered entities (except small health plans) must obtain and use their NPI for all covered transactions
- May 23, 2008
  - Compliance deadline for small health plans

NPI: The Basics
- Does not expire
- Only one NPI assigned per provider
  - Individual providers
  - Organization providers
    - An organization may have subparts that need their own NPI
- A new NPI is not required if there is a change in
  - State of licensure
  - Healthcare provider taxonomy classification
  - Ownership (organization providers)

NPI
- Does
  - Replace multiple legacy provider identifiers
  - Allow for simplified electronic transmission of HIPAA standard transactions
  - Serve as a standard, unique identifier for health care providers and plans
- Does not
  - Enroll providers in health plans
  - Guarantee reimbursement
  - Convey covered entity status
  - Require providers to conduct HIPAA transactions
Who Assigns NPIs?

- The National Plan and Provider Enumeration System (NPPES)
  - Overseen and managed by the Department of Health and Human Services
    Centers for Medicare and Medicaid Services
  - Uniform system for identifying and uniquely enumerating health care providers at the national level

Who is Eligible for an NPI?

“Health Care Providers” as defined in §160.103

- Individuals and organizations
  - Physicians and other practitioners
  - Pharmacists and pharmacies
  - Hospitals
  - Health maintenance organizations
  - Group practices

Who is Eligible for an NPI?

“Subparts” of organization providers

- Components or separate physical locations of organization providers
- Separately certified or licensed
- Examples: hospital outpatient departments, surgical centers, laboratories, chain constituencies

Who is Eligible for an NPI?

Covered and noncovered providers

- All health care providers may obtain NPIs but only covered health care providers are required to obtain and use NPIs in standard transactions
- Covered health care providers are required to furnish updates to their NPI data within 30 days

NPI Category Types

2 Entity Type codes

- Code 1 for individual providers
  Examples: physicians, pharmacists, dentists, nurses, chiropractors, physical therapists
- Code 2 for organization providers
  Examples: hospitals, home health agencies, clinics, nursing homes, laboratories, group practices, health maintenance organizations, pharmacies

How to Obtain an NPI

- Three ways
  2. Mail complete and signed paper application to the NPS Enumerator
     Request the application (CMS-10114) at 1-800-465-3203 or TTY 1-800-692-2326
  3. An Electronic File Interchange
     Organization may request a provider’s permission to submit an application on the provider’s behalf (bulk enumeration)
Applying Online

Create a username and password

Step 1: User security

Step 2: User information

Applying Online

At least one taxonomy code is required

Taxonomy Codes

- Code designating the provider type, classification, and specialization
- Provider must select the code that most closely describes him/her in the NPI application
- May select more than 1 code but must indicate one of them as the primary

Pharmacy Service Providers

Taxonomy Codes

- Pharmacist - 183500000X
  - General Practice - 1835G0000X (Inactive)
  - Geriatric - 1835G0303X
  - Nuclear - 1835N0905X
  - Nutrition Support - 1835N1003X
  - Oncology - 1835X0200X
  - Clinical Pharmacy Specialist - 1835P0018X
  - Pharmacotherapy - 1835P1200X
  - Psychiatric - 1835P1300X
- Pharmacy Technician - 183700000X

NPI Registry

- NPPES online database that stores providers’ information disclosable under the Freedom of Information Act (FOIA)
- Disclosable data elements: NPI, name, entity type code, business address, taxonomy code, license number, authorized official contact information
- Updated daily
NPI Deactivation

NPI is assigned for life but NPPES may deactivate an NPI if

- Fraud
- Dissolution of an organization provider
- Retirement of an individual provider
- Death of an individual provider

If an individual provider is sanctioned or barred from one or more health plans, the NPI will not be deactivated

NPI Deactivation

If an organization health care provider is disbanded, the NPI will be deactivated

Reimbursement for Cognitive Services

- Successful clinical pharmacy practice models but reimbursement for cognitive services generally lacking
- Payers have historically seen pharmacists as product dispensers
- Medicare Part D
  - Payers to reimburse providers of MTM services for specific patient groups

Cognitive Pharmacy Services

- Different services
  - Hypertension
  - Dyslipidemia
  - Anticoagulation
  - Diabetes
  - Asthma
  - Immunizations
- Different settings
  - Physician-run clinics
  - Hospital-based clinics
  - Community pharmacies
  - Managed health care

Challenges

- Medicare Part B, many state Medicaid plans, and many private payers still do not recognize pharmacists as providers of patient care services
- The goal of PBMs is to reduce the rate of increase of prescription drug utilization and costs
  - Reluctant to pay pharmacists for more services

What are CPT Codes?

- CPT = Current Procedural Terminology
- Provide uniform language that accurately describes medical, surgical, and diagnostic services
- Standard nomenclature for communication between health care providers and health payers
Pharmacy Billing CPT Codes

Pharmacist-only CPT codes to bill for MTM services delivered face-to-face

- **99605** is used to code the initial 15 minutes of an initial encounter with a new MTM patient
- **99606** is used to code the initial 15 minutes with an established patient
- **99607** may be used with either 99605 or 99606 to bill additional 15 minutes

Reimbursement Methods

Direct Billing Model

- Pharmacist bills first or third party payer
- Must obtain payer’s approval to bill for services and negotiate payment rates
- Examples
  - Medicare Part B for immunizations
  - Medicare Part D for MTM services
  - Patient for comprehensive medication review

Reimbursement Methods

Incident-To-Physician Billing Model

- Used only in physicians’ offices
- Services are furnished as an integral, although incidental, part of the physician’s services
- Specific requirements
  - Physician must be physically present on premises, must be involved in the plan of care, services must be deemed medically necessary by physician

Reimbursement Methods

CLIA-waived laboratory

- Clinical Laboratory Improvement Amendments
- Tests must be simple and low-risk for error
- No personnel requirements
- Must follow “good laboratory practices” Proper physical equipment, quality control, manufacturer instructions
- Must obtain CLIA certificate of waiver

How to Obtain a CLIA-Waiver

- CMS Application Form 116
- Renewed every 2 years
- Examples of waived tests
  - Glucose monitoring devices for home use
  - Tests for prothrombin time (PT)
  - Fecal occult blood tests
  - Ketone testing
  - TSH testing
Future Opportunities

- Patient-centered medical homes (PCMH)
  Team-based care is directed by the primary care physician
- Accountable care organizations (ACO)
  Organizations led by primary care providers that manage the full continuum of care for a defined patient population
- Pharmacists are included as PCMH and ACO participants

Barriers for Pharmacists

- Pharmacists’ awareness of contemporary code sets including nomenclature and terminology used in health care
- Some insurance companies fail to recognize pharmacists as health care providers qualified to bill for services
- Coding infrastructure necessary to support billing for pharmacists’ professional services
- Understanding of billing mechanism and reimbursement practices

True and False Assessment

1. An NPI can denote information such as the state where the provider practices
2. Health care providers do not need to be “covered entities” to apply for an NPI
3. There are three NPI entity types: for individuals, for organizations, and for subparts

References

3. HIPAA administrative simplification: standard unique health identifier for health care providers; final rule. 69 Federal Register 3434 (2004 Jan 24), no.15.
Objectives

- To emphasize the importance of outcome measures in regards to quality of patient care
- To describe the ways in which documentation of outcomes may be utilized in quality measurement and improvement
- To discuss specific outcome measures related to selected disease states
- To explain the role of the National Committee for Quality Assurance (NCQA) and Healthcare Effectiveness Data and Information Set (HEDIS) measure requirements in documentation

Defining Quality of Care

"The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Institute of Medicine, 2001)

Aims of a high quality medical care system

- Safe
- Effective
- Patient-Centered
- Timely
- Efficient
- Equitable

What are Outcome Measures?

- The ultimate indicator of the quality of care
  - Other measurable indicators include the structure of care and the process of care
- "Outcomes" refer to a patient’s health status or change in health status resulting from medical care received
- Should include the positive and negative changes
  - Intended/Unintended
  - Desirable/Undesirable

Why Measure Outcomes?

- While measuring processes and structures assess the compliance with an intervention, measuring outcomes establish value
- Intermediate outcome measurements to guide patient therapy
  - Algorithms
  - Response to therapy
- Useful to healthcare organizations to assess quality and improvement
- Role in policy development and implementation

One accurate measurement is worth a thousand expert opinions

G. H. Hopper

http://myhealthoutcomes.com/pages/3001
Limitations

- Health-related outcomes are also affected by many social and clinical factors not related to the treatment provided
  - Quality of life
  - Patient age
- Many relevant outcomes take a long period of time to recognize
- Development of outcome measurements is more difficult than the development of process measurements

Who Cares?

- Health Care Plans
  - Centers for Medicare & Medicaid Services (CMS)
  - Private Insurance companies
- Health care Accrediting Bodies
  - National Committee for Quality Assurance
  - Pharmacy Quality Assurance Alliance
  - Joint Commission
- Patients
- Providers and Clinicians

Outcomes to Document

<table>
<thead>
<tr>
<th>Outcomes that can be measured for current status and change from baseline</th>
<th>Workload statistics and measures of service performance</th>
<th>Impact of service on other outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Percentage of patients using medications correctly</td>
<td>• Time required for appointments</td>
<td>• Total costs of healthcare</td>
</tr>
<tr>
<td>• Percentage of patients achieving clinical goals</td>
<td>• Therapy recommendations made and accepted</td>
<td>• Emergency department visits</td>
</tr>
<tr>
<td>• Patient satisfaction regarding patient care received</td>
<td>• Types of interventions provided</td>
<td>• Hospital stays</td>
</tr>
</tbody>
</table>

National Committee for Quality Assurance (NCQA)

- Private, not-for-profit organization dedicated to improving health care quality
- Works with large employers, policy makers, doctors, patients, and health plans to develop quality standards and performance measures
- Considered the “gold standard” for health plan accreditation

NCQA Accreditation Programs

- Health Plans
  - General Health Plan
  - Disease Management
  - Case Management
  - Wellness and Health Promotion
  - New Health Plans
- Provider Organizations
  - Accountable Care Organizations (ACO)
- Health Plan Contracting Organizations
  - Managed Behavioral Healthcare Organizations
  - Disease Management
  - Case Management

NCQA

41 States* Use or Recognize NCQA Accreditation

*See map for states.
The Healthcare Effectiveness Data and Information Set is the most widely used quality measurement tool in the United States.

- Primarily a measure of process
- Process improvement measures are used to improve outcomes

**Purpose:** To help ensure that state and employer savings do not come at the expense of keeping individuals healthy

- Also includes the CAHPS Survey (Consumer Assessment of Healthcare Providers and Systems)

---

**HEDIS - Components**

<table>
<thead>
<tr>
<th>Effectiveness of Care</th>
<th>Accessibility/ Availability of Care</th>
<th>Experience of Care</th>
<th>Utilization and Relative Resource Use</th>
<th>Descriptive Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Screening</td>
<td>• Access to ambulatory care services</td>
<td>• Health plan experience of plan surveys</td>
<td>• Antibiotic utilization</td>
<td>• Board Certification</td>
</tr>
<tr>
<td>• Immunization status</td>
<td>• Call answer timeliness</td>
<td>• Consumer Assessment of Healthcare Providers and Systems</td>
<td>• Mental health utilization</td>
<td>• Enrollment</td>
</tr>
<tr>
<td>• Appropriate medications</td>
<td>• Privacy and confidentiality</td>
<td>• Drug service utilization</td>
<td>• All-cause readmissions</td>
<td>• Diversity in demographics</td>
</tr>
<tr>
<td>• Follow-up care after hospitalization</td>
<td>• Distribution of rights and responsibilities</td>
<td>• Medicare health Outcomes Survey (HDS)</td>
<td>• Language</td>
<td>• Language</td>
</tr>
<tr>
<td>• Adherence to treatment</td>
<td>• Potentially harmful drug interactions and high risk medications</td>
<td>• PALL care management</td>
<td>• Race/ Ethnicity</td>
<td>-</td>
</tr>
</tbody>
</table>

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**HEDIS/CAHPS**

Most states (39) and many employers require health plans to report HEDIS® quality measures.

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**FLORIDA LAW REQUIREMENTS**

**CS/HB 7107: Medicaid Managed Care**

- Contracted Managed Care Organizations must collect and report audited HEDIS measures, as specified by Florida Agency for Healthcare Administration (AHCA)

- Measures must be published on the plan’s website in a manner that allows recipients to reliably compare the performance of plans

- The agency shall use the HEDIS measures as a tool to monitor plan performance

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**FLORIDA LAW REQUIREMENTS**

- [FAC Rule 59A-12.0071](https://www.sos.state.fl.us/Regs/RuleDetail.aspx?RuleId=59A-12.0071): Accreditation is required for health plans serving the commercial market and health plans contracted with the Medicaid and state employee benefit programs

- [FAC Rule 59A-12.0072](https://www.sos.state.fl.us/Regs/RuleDetail.aspx?RuleId=59A-12.0072): Accreditation is also required for credentialing verification organizations (CVOs)


- These regulations do not specify accrediting body
NCQA Accredited Private Insurance Plans in Florida

- Capital Health Plan
- Health First Health Plans
- Florida Health Care Plans
- AvMed Health Plans
- Cigna Healthcare of Florida
- Aetna Life Insurance
- Neighborhood Health Partnership
- UnitedHealthcare Insurance and Services
- Health Options
- Aetna Health
- UnitedHealthcare of Florida


Value of HEDIS Quality Measure Documentation

- What gets measured gets improved
- Plans that improve quality save lives and money
- Documentation of quality measures allows consumers to choose their care based on quality
- Allows public health Officials to make comparisons and set benchmarks
- Helps states meet federal requirements, reducing the burden on plans that serve multiple state programs

General Measures

**2013 HEDIS Performance Measures**

- Adult BMI assessment
- Weight assessment
- Annual monitoring for patients on persistent medications
  - Potassium, Scr, BUN for patients on ACEIs/ARBs, Digoxin, Diuretics
  - Drug serum concentrations for patients on anticonvulsants
- Immunization History
- Screening
  - Women and Adolescents
    - Chlamydia
    - Cervical Cancer
  - Breast Cancer
  - Older Adults
  - Glaucoma Screening
  - Osteoporosis
- All Cause Readmissions
- Tobacco Use

Management of Persons with Heart Failure

**HEDIS Physician Performance Measures**

- Percentage of patients aged 18 years and older with diagnosis of heart failure and left ventricular systolic dysfunction who were prescribed:
  - ACE or ARB therapy
  - Beta-blocker therapy

- Annual Monitoring for patients on persistent medications
  - Diuretics
  - Digoxin
  - ACEI/ARB

Management of Persons with Diabetes

**2013 HEDIS Physician Performance Measures**

- Percentage of patients 18-75 years of age with diabetes who received the following during the measurement year:
  - At least one HbA1c Test
  - At least one Foot exam
  - At least one test for microalbumin (or had evidence of medical attention for existing nephropathy)
  - At least one lipid profile

- Percentage of patients whose most recent LDL-C level is <100 mg/dL
- Diabetes Screening for People with Schizophrenia or Bipolar disorder who are using Antipsychotic medications
Management of Persons with Hypertension

**2013 HEDIS Physician Performance Measures**

- Percentage of patients 18-85 who had a diagnosis of hypertension whose blood pressure was adequately controlled during the measurement year
- Annual Monitoring for patients on persistent Medications
  - ACE Inhibitors or ARBS
  - Diuretics
- Percentage of patients with cardiovascular conditions taking Aspirin

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Management of Persons with Asthma

**2013 HEDIS Physician Performance Measures**

- Percentage of patients aged 5-40 years with a diagnosis of mild, moderate, or severe persistent asthma who were prescribed either the preferred long-term control medication (inhaled corticosteroid) or an acceptable alternative treatment
- Percentage of patients aged 5-40 years with a diagnosis of mild, moderate, or severe persistent asthma who were evaluated during at least one visit within 12 months for the frequency of daytime and nocturnal asthma symptoms

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Pharmacists and HEDIS

- Although pharmacists are not measured for performance, being alerted to HEDIS measures provide opportunities for intervention
  - Unique skills and knowledge in evaluating and monitoring medication use
  - Access to information in prescription and patient databases
  - Frequent contact with patients - offer a flu shot, assess tobacco use
- NCQA does not dictate how HEDIS Measure Requirements are fulfilled
- All medication related measurements can be met with pharmacists interventions

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Consumer Assessment of Health Care Providers and Systems (CAHPS) Survey

- Getting Needed Care
- Getting Care Quickly
- How Well Doctors Communicate
- Claims Processing
- Customer Service
- Rating of Personal Doctor
- Rating of Specialist
- Rating of All Health Care
- Rating of Plan

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Sample of CAHPS Survey

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SUMMARY

- Outcome documentation is essential in the establishment of pharmacist's value in primary care
- Outcome documentation should relate to interventions
  - Medication Use
  - Adverse Events
  - Costs
  - Value in relation to practice setting
- Measurable outcomes can be documented at any point in the SOAP Note
  - Subjective: HRQOL
  - Objective: Lab Monitoring and Test Results
  - Assessment: Medication Use, Adherence, Adverse Events
  - Plan: Pharmacists Interventions, Recommendations, Referrals and follow-up
True or False?

1. Documentation of Measurable outcomes should relate to medication use
2. Assessment of tobacco use and cessation should be included as a measurable outcome when managing patients with diabetes
3. Documentation of outcomes can be used for quality improvement purposes

REFERENCES


QUESTIONS?
Barriers to the Transition of Care

Ayesha Syed, Pharm.D.
PGY-1 Pharmacy Resident
Larkin Community Hospital

Objectives
1. Identify barriers to transition of care
2. Describe legal implications for pharmacists
3. Describe the role of the pharmacist in overcoming the barriers to transition of care
4. Discuss the social aspects of pharmacists "new role" as healthcare provider

What is transition of care?
- Actions designed to ensure the continuity of healthcare during patient relocation:

What is transition of care?
- Actions designed to ensure the continuity of healthcare during patient relocation:

Components of a Patient’s Transition
- Comprehensive plan of care
- Improved communication
- Availability of well-trained practitioners
- Safe transition of care
- Patient Education

Statistics
- Geriatric patient population:
  - 23% of hospital patients >65 years are discharged to another institution
  - 11.6% are discharged to home care and hospice care
- Skilled Nursing Facility (SNFs) records indicate:
  - 19% of patients are transferred back to acute care settings within 30 days
  - 42% within 24 months
- 1 in 5 Medicare patients are readmitted

Scenario:
- 75 year-old John with a hip fracture visits an orthopedic clinic for a hip replacement procedure.

Patient’s condition requires care from multiple healthcare professionals occurring in various settings
Statistics
Uninsured Population

Healthcare Provider Status:
Are we ready?

- Pharmacist underutilized due to lack of recognition as healthcare providers under the social security act
- Pharmacists, second most trusted profession, according to Gallup
- Readily available patient information
- Part of new collaborative models

Barriers to “New Role”

- Responsibility:
  - Pharmacist not recognized healthcare providers
  - Involvement in patient care
- Liability:
  - Greater risk associated with care
  - Fear of lawsuits and financial burden
- Insurability:
  - State of insurance market
  - Limitations to malpractice

Barriers to “New Role”

- Political/Sectional:
  - Lack of representation at state level
  - Current laws
- Social:
  - Will physicians, nurses, insurers and patients accept the “new role” of the pharmacists as healthcare providers?
  - Pharmacist’s acceptance of the new role
- Medication Therapy Management (MTM):
  - Inadequate patient services
  - Current lack of referrals and patient information

Impact of Pharmacists as Healthcare Providers

- Research has emphasized the importance of pharmacists in patient care
  - Management of chronic disease states
  - Ability to control prescription drugs
  - Prevent medication errors
- Involvement of pharmacists in multidisciplinary teams has:
  - Reduced healthcare costs, improved patient outcomes, and increase patient satisfaction

Impact of Pharmacists as Healthcare Providers

- Due to the shortage of primary care physicians, pharmacists, as recognized healthcare providers, can improve access to care, expand coverage of care and increase utilization and compliance of medications
- It is during these transitional gaps where pharmacists can step in and play an integral role in serving as patient providers
Pharmacist Provider Role

Provider functions include:

- Patient assessment for medication-related factors
- Order laboratory necessary for monitoring outcomes
- Interpret data related to medication safety
- Initiate or modify regimens based on patient response
- Provide information, education and counseling
- Document and communicate with other providers
- Communicate with payers

Pharmacist Provider Status

Importance of Provider Status:

- Pharmacists not included in sections of Social Security Act (1861)
- Patient: Healthcare Provider ratio is significant, increased gap
- Healthcare reform → Improved quality of care and decreased costs

Pharmacist Provider Status

Pharmacology training:
- Physicians: 1 semester
- Pharmacists: 2 years

Current pharmacist collaborative services:
- Outpatient anticoagulation clinics
- Physician based practices
- CHF clinics
- Asthma Clinics

In order to achieve provider status:

- Pharmacists need to step out of their comfort zone of dispensing pills and verifying prescriptions
- Counseling needs to go beyond timed sessions and incorporate patient’s overall health
- State and federal legislators need to see pharmacists providing patient care services that they seek for recognition and payment
- Strong coalition of pharmacy organizations needed!

Liability

- More responsibilities means more liability
- Fear of pharmacist role expansion and getting sued
- Most Common Allegations (2001-2011)
  - Dispensing errors
  - Independent franchises or national/regional pharmacy chains were the usual settings where such claims occurred
  - Medication overdose was the typical injury reported
- Becoming aware of how and where most errors occur, can aid in the prevention of future occurrences.

Liability

- Wrong Drug
- Wrong Dose
- Compounding errors
- Failure to identify overdosing
- Wrong form or route of drug
- Failure to identify drug allergy
- Failure to counsel
- Infection/Contamination of drug/vial/needle/syringe

- 31.5%
- 13.8%
- 9.6%
- 3.7%
- 3.1%
- 1.9%
- 1.2%
- 1.8%
Liability

- Overcoming barriers:
  - Develop skills and incorporate training to practice clinical and Medication Therapy Management (MTM) services
    - Certifications (various courses)
  - Obtain patient history/profile/drug therapies
  - Maintain up to date on legislature

- Treat the patient, not the disease
- Utilize important alerts and flags
- Identify high risk and error prone drugs
- Question prescriber about unusual prescriptions
  - Unusual number of controlled drugs
- Invest in insurance policies

Insurability

- Insufficient malpractice insurance
  - Employer malpractice insurance may not protect you in all cases.
  - Employer’s policy designed to protect their interest firsts
- State of insurance market
  - Coverage provided by private insurance companies, no state/federal coverage

- State of Insurance Market
  - Ex. APhA sponsored professional liability coverage through Healthcare Providers Service Organization (HSPO)
  - Over 1 million protected with HSPO
  - $1 million per claim and $3 million aggregate professional liability coverage

Medication Therapy Management (MTM)

- Current barriers to MTM:
  - Compensation
    - Achieve provider status in Social Security Act (Collaborative agreements)
    - Receive recognition (NPI)
    - Limited payment towards pharmacist patient care services (CPT codes)
    - Traditional payment and reimbursement mechanisms are for dispensing of a drug product

MTM services

- Florida
- Iowa
- North Carolina
- Minnesota
- Mississippi
- Montana
- Ohio
- Vermont
- Wyoming
- Arkansas
- Montana
- North Carolina
- Ohio
- Vermont
- Wyoming

Pharmacist Provider Status for MTM services
**Medication Therapy Management**

- Lack of patient education
  - Informational Material/Audio/Visual
  - Counseling/Teach back method
  - Home visitation
  - Follow up appointments (Telephone)
  - Limited literacy skills → non-compliance
- Noncompliance — especially with medication regimens — leads to $300 billion in wasteful health expenditures every year.

**Political/Sectional**

- On January 1, 2014 Pharmacists were recognized as healthcare providers in the state of California
- Similar pharmacy practice laws
  - New Mexico
  - Montana
  - North Carolina
  - Massachusetts
California’s New Law

Expansion of Pharmacist roles

- Administration of drugs (inj)
- Provide consultation, training, education on medications
- Discuss disease management/disease prevention
- Participate in multidisciplinary patient reviews
- Order/interpret tests to manage/monitor drug therapy
- Provide hormonal contraceptives, travel medications, nicotine replacement products

Advance Practice Pharmacists (APP)

- Perform activities similar to that of Collaborative Practice Agreements (CPAs) in an outpatient setting
- Perform patient assessment
- Initiate/adjust/discontinue drug therapy in coordination with physicians
- Collaborate with other healthcare providers to evaluate and manage disease and health conditions

Political/Sectional

- Lack of representation in state legislature
  - Organizations (ASHP, AMCP, APhA, NACDS, etc)
  - U.S. Public Health Service pharmacy report to the Surgeon General, Change.org petition, White House We the people petition
- Need alignment of federal and state policies defining the roles and responsibilities of pharmacists
  - Pharmacists scope of practice: drug dispenser → providers of cognitive services

Social Barriers

- Are other healthcare professionals accepting of Pharmacists new role as providers?
  - Costs:
    - 30% – 40% percent less than similar care at doctor’s offices
    - 80% cheaper than at an emergency room

Questions

- T/F: Pharmacist involvement in transition of care models will aid in improving patient safety
- T/F: There will be no increase in liability as pharmacists become more involved in a patient’s transition of care
- T/F: Pharmacist’s will be readily accepted in their role as healthcare providers

References