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Antipsychotics in the Management of Nursing Home Patients with Dementia

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Disclosure

I have no relevant financial relationships with commercial interests to disclose.

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Learning Objectives

- Perform drug reconciliation with special attention to psychotropic medications upon admission
- List the indications for anti psychotic drug use
- Identify the most prevalent atypical antipsychotic medications their effect and major side effects
- Monitor effect and side effects of antipsychotic drugs

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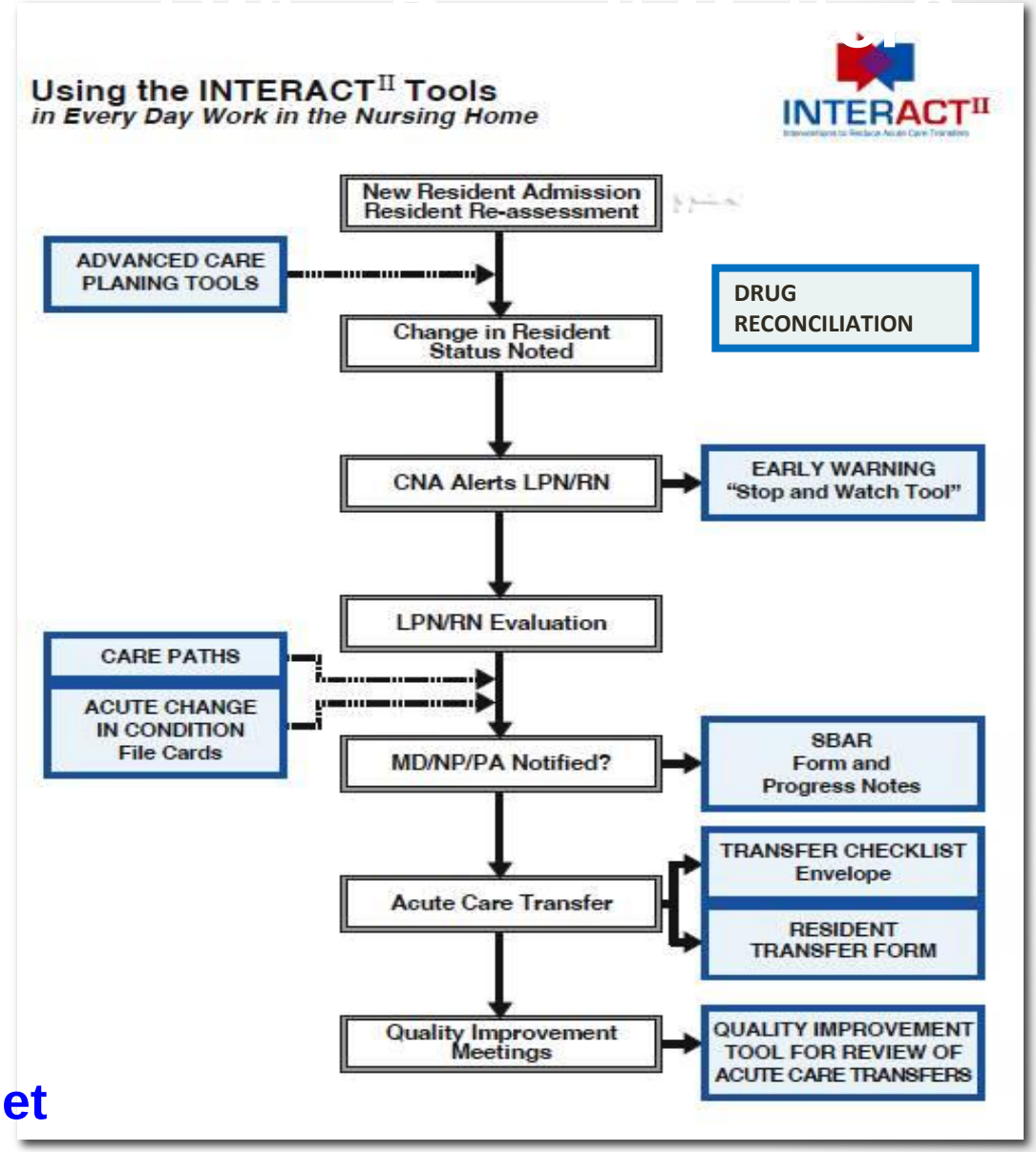

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http://interact2.net

Defining Behavior targets for Antipsychotic use

- Hallucinations IF distressing
- Delusions
  - stealing things can be a memory related issue
- Aggressive behavior
  - if is a danger to resident or others
- Persistent, distressing behaviors that are a danger to the resident (usually don't respond well to Antipsychotics)
  - Significant decline in function (ex screaming)
  - Unable to receive needed care (ex bathing battles)

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Transition Case

- Mary is an 87yo female who is being transferred from the acute hospital s/p a fall sustained hip fracture after an ORIF. She was living in an ALF prior to hospitalization
- Her medication reconciliation
-

BEFORE HOSPITAL	ON TRANSFER TO SNF
Ramipril 10mg daily	Lisinopril 20mg daily
Amlodipine 5mg daily	Furosemide 20mg daily
Tums PRN GI upset	Pantoprazole 40mg daily
Centrum Silver daily	MVI w/min daily
Levothyroxine 25mcg daily	Risperidone 0.5mg qHS for screaming
Sertraline 25mg qAM	Citalopram 10mg qAM
Donepezil 5mg qAM	Lorazepam 0.5mg q4h PRN anxiety
Memantine 10mg BID	Zolopidem 5mg qHS PRN sleep
Acetaminophen 500mg TID	Norco 5/325mg q4h PRN pain
Ibuprofen 200mg PRN pain	Hydromorphone 1mg IV q2h PRN severe pain

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What should happen with Mary's Care?

- Lab tests
  - Thyroid tests (Levothyroxine)
  - Renal panel (Furosemide)
- Nursing interventions and behavioral care plan
  - Screaming – observe without risperidone
  - Consult geriatrician/psychiatrist
- Add medications
  - Add back Levothyroxine and adjust per labs
  - Add back Donepezil and Memantine
  - Consider calcium w/ Vit D
  - Acetaminophen?
- Discontinue medications
  - Hydromorphone
  - Lorazepam
  - Risperidone?

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Question #1

- Which of Mary's medications missing on the reconciliation might contribute most to changes in behavior ?
    A. Risperidone
    B. Levothyroxine
    C. Donepezil
    D. B and C
    E. A, B and C

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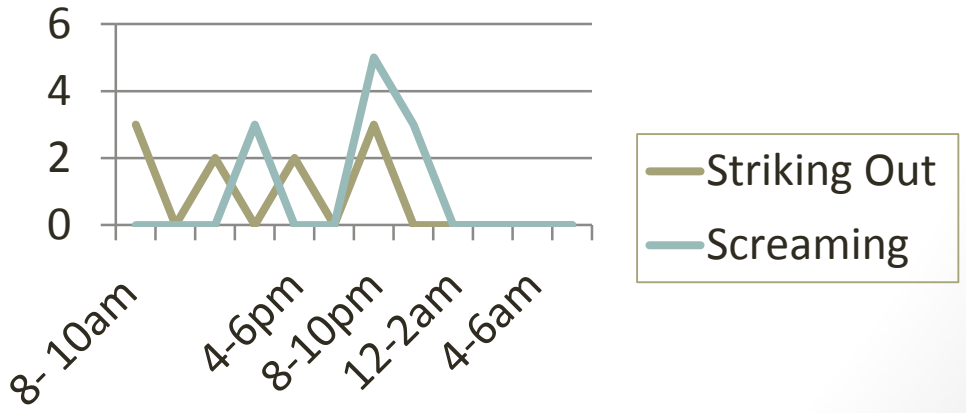
Behavior Mapping

- short observations periods 15min intervals
- over 1-4 days
- tracking behaviors for
  - Frequency
  - Intensity
  - Duration
  - Time of day

- Consultant pharmacist can assist by looking at behavior patterns and make recommendations as to
  - Timing of medication
  - Nature of prescription



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Antipsychotic Use in Dementia

- Evidence shows risks are greater than benefits for using Antipsychotics for many patients
- Non-drug interventions first
  - control your own voice and responses: **stay calm, tolerate behavior, redirect**
- Use Alzheimer's disease meds first
  - acetylcholinerase inhibitors
    - (Donepezil, Rivastigmine, Galantamine)
  - NMDA antagonist (Memantine)
- Use only for psychosis associated with Dementia for limited duration (≤12 wks)
  - Document treatment targets BEFORE any intervention
  - Monitor outcomes and adjust approach
  - Is the medication meeting targets? improving quality of life ?

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Unnecessary Drugs: Federal Regulation: 42 CFR § 483.25(1) or F-tag – 329

- UNNECESSARY DRUGS
- Each resident's drug regimen must be free of unnecessary drugs. An unnecessary drug is any drug when used:
  - *In excessive **dose** INCLUDING duplicative therapy; or*
  - *For excessive **duration**; or*
  - *Without adequate **monitoring**; or*
  - *Without adequate **indication** for its use; or*
  - *In the presence of **adverse consequences***

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42 CFR § 483.25(1) or F-tag – 329

- 2 Antipsychotics Based on a comprehensive assessment of a resident, the facility must ensure
  - *Residents who have not used antipsychotics are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition diagnosed and documented in the clinical record AND*
  - *Residents who use antipsychotics receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.*
  - *Guidelines Dementia Alzheimer's type with behaviors*
    - *Antipsychotic Use – during 1st year 2 quarters attempt reductions*
    - *Other psychotherapeutic agents- during 1st year 2 quarters attempt reductions*

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HHS – OIG 2011 report on Antipsychotics

- 304,982/2.1 million 14% of at least 1 Medicare claim for an atypical antipsychotic (1/07 to 6/07)
  - Estimated cost $309 million
- 83% of Atypical Antipsychotics were used for off-label indications
  - 88% for indications in the FDA black box warning (not supposed to be prescribed)
- Over 700,000 of the 1.4 million atypical antipsychotics were "erroneous" costing $116 million
  - Not documented as being administered
  - Not used for a medically accepted indication
- 22% were not administered in accordance with CMS guidelines of unnecessary drugs ($63 million)

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http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf

F329 gradual dose reductions

- Clinically contraindicated is:
- (A) For treatment of behavioral symptoms related to dementia, the GDR may be considered clinically contraindicated if:
- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; **AND**
- The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would likely impair the resident's function or increase distressed behavior.

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Interpretive Guidelines

- ***Regulations do NOT mean certain drugs cannot be used***
- ***Need DOCUMENTATION proving why the specific drug is necessary – benefits outweigh risks***
- ***EXCEPTION: Clinically contraindicated***
- Examples
  - poor renal function (CrCl < 30ml/min) on HTCZ
  - Recent history of an internal bleed on ASA, warfarin, heparin, NSAID

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BBW Antipsychotics

- **Antipsychotic FDA boxed warnings:**
- FDA ALERT [6/16/2008]: FDA notified healthcare professionals
  - both conventional and atypical antipsychotics are associated with a 1.6-1.7 increased risk of mortality in elderly patients treated for dementia-related psychosis.
  - (Sudden Cardiac, pneumonia and stroke)

- In April 2005, FDA notified healthcare professionals that patients on atypical antipsychotics (Zyprexa, Risperdal) had
  - an increased risk of Diabetes, Stroke, Hyperlipidemia
  - Need to monitor
- Antipsychotics are not indicated for the treatment of dementia-related psychosis.

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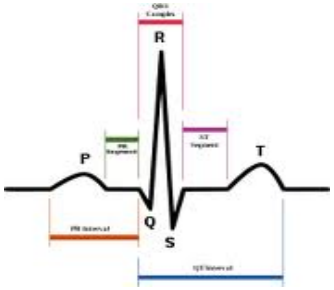
Risks of Antipsychotic Use in the Elderly

- Black Box warning for use in dementia – 1.6 to 1.7 fold increase risk of death (sudden cardiac, stroke, pneumonia)
- Sensitivity to Adverse Effects
  - EKG changes:QTc interval prolongation
  - Movement disorder(EPS) – irreversible
  - Low BP upon rising – risk of a fall
  - Diabetes
  - Hyperlipidemia



- Family dynamics - risk of legal action(?)

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Withdrawal of an Antipsychotic in Patients with Dementia

- If there is NO Benefit within 1 month STOP the medication
- Taper should be slow over days/weeks/months (depending on individual response to taper)
  - The longer taking the medication slower/faster it can be withdrawn- individualize
- Risperidone use effective for 4-6 months may see risk of relapse (NEJM Oct 2012 367;16: 1497-507)

- Withdrawal behaviors (during taper or after stop x 6 wks)
  - Anxiety and irritability
  - Verbal or physical outbursts

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Question #2

- Which of the following side effects may contribute to an increased risk for mortality associated Atypical Antipsychotic use in the elderly (especially if they have DNR in their POLST)?

A. Diabetes
B. Hyperlipidemia
C. Movement disorders
D. QT prolongation

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Highest Risk Antipsychotics Agents for Hypotension

- Risperidone:
  - Tachycardia (1% to 5%)
  - hypertension (I.M. injection 3%)
  - postural hypotension (≤2%)
  - hypotension (≤1%)

- Olanzapine: (1% to 10% for each)
  - Chest pain, tachycardia
  - Hypertension, postural hypotension
  - peripheral edema

- Clozapine:
  - Black Box Warning: Orthostatic hypotension
  - High affinity for the alpha 1 receptor
  - Seen in 25% of geriatric patients

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Case #2

- MJ is an 79yo male who has lost 20lbs in the past 6 months and currently weighs 125 lbs at 5’ 9” tall. He is refusing meals and is having occasional bouts of loose stool/diarrhea. His meds are as follows :
- Donepezil 10mg qHS (Alzheimers)
- Memantine 10mg BID (Alzheimers)
- Metoprolol XL 50mg po daily (HTN)
- MVIw/ min 1 tab po daily (supplement)
- Fish Oil (omega 3) 1gm BID (cholesterol)
- ASA 81mg po daily (CVA prevention)
- Tamsulosin 0.4mg qHS
- Megestrol 40mg po daily (weight loss)
- Vitamin B-12 1000mg IM monthly (supplement)
- Fluoxetine 40mg po qAM (depression)
- Olanzapine 5mg ODT at 12Noon + 5mg PRN (pacing the halls; refusing meals)
- Valproic acid 250mg po q5pm (sundowning)

Medication Regimen Raising ADR of concerns

- Weight loss
  - Donepezil
  - Prozac
  - Megestrol at low doses
- Weight gain
  - Zyprexa
  - Depakote
- Cardiac
  - Zyprexa (lower)
  - Prozac
  - Donepezil
- Lower BP
  - Zyprexa
  - Donepezil
  - Tamsulosin

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Question #3

- Sally is a 75yo patient who presents with a complaint of always being tired and the MD wants to use a antipsychotic to treat Sally's hallucinations that Staff is stealing her food- which of the following Atypical Antipsychotics would be the best choice (with the least sedation)?

A. Clozapine (Clozaril)
B. Olanzapine (Zyprexa)
C. Aripiprazole (Abilify)
D. Quetiapine (Seroquel)

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Weight Gain

- Weight gain observed with atypical antipsychotic agents is usually accompanied by metabolic abnormalities like:[16]
  - dyslipidemia-Weight gain and dyslipidemia are concordant of each other[16]
  - diabetes risk
- Diabetes risk maybe independent of weight gain[16]
- Weight gain and metabolic abnormalities are linked to increased risk of cardiovascular disease[16]

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Question #4

- Jared is an 87yo male patient who is 6’ 3” tall and weighs 310lbs. In addition, he has Diabetes Type II and high cholesterol and Bipolar Disorder. Since he has been hallucinating and it is causing him distress, the PCP wants to add an antipsychotic to his mood stabilizer of Valproic acid. Which antipsychotics might be a possible good choice?

A. Clozapine (Clozaril) or Olanzapine (Zyprexa)
B. Olanzapine (Zyprexa) or Risperidone (Risperdal)
C. Risperidone (Risperdal) or Quetiapine (Seroquel)
D. Aripiprazole (Abilify) or Paliperidone (Invega)

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SGA Cardiovascular Side Effect Summary [19]

Drug[1]	OH	WT GAIN	Lipid	DM	QTc
ARIPiprazole (Abilify®)	Low	Very low	Very low	Very low	Low
Asenapine (Saphris®)	Low / moderate	Low	Very low	Very low	Low
CloZAPine (Clozaril®)	High	High	High	High	Low
Iloperidone (Fanapt™)	Low / moderate	Low / moderate	Very low	Very low	Moderate
Lurasidone (Latuda®)	Low	Very low	Very low	Very low	Low
OLANZapine (ZyPREXA®,ZyPREXA® Zydis®)	Low / moderate	High	High	High	Low
Paliperidone (Invega™)	Moderate	Low	Low	Low	Low
QUEtiapine (SEROquel®)	Moderate	Moderate	Moderate	Low / moderate	Low
RisperiDONE (RisperDAL®)	Moderate	Low / moderate	Low	Low / moderate	Low
Ziprasidone (Geodon®)	Low	Very low	Very low	Very low	Moderate[4]

OH: Orthostatic Hypotension; DM: Diabetes Mellitus;
QTc: correct QT interval prolongation

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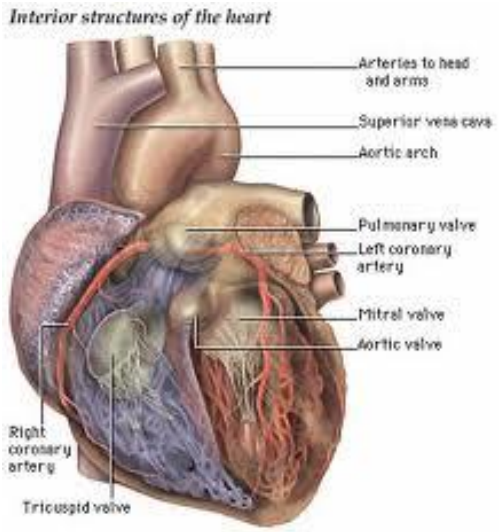
Cardiovascular Side Effects w/Atypical Antipsychotics

- CV Adverse effects
  - QTc prolongation
  - Orthostatic hypotension and compensatory tachycardia
  - Stroke
- Drug Interaction that can potentiate cardiovascular side effects



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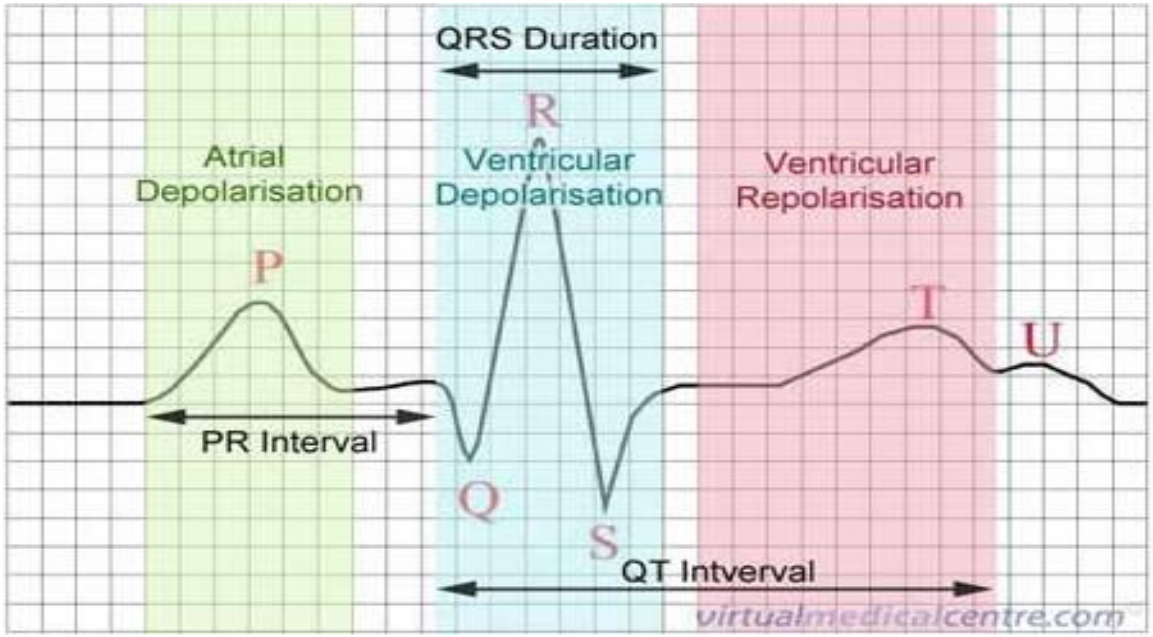
QTc Prolongation

- QT interval: represents both the depolarization and repolarization of the ventricles on a ECG[21]
- QTc interval: QT interval shortens with increasing heart rate and QTc corrects for it[21]
- A QTc interval of <440 msec → normal
- QTc interval > 500msec→ clinically used as cutoff point →greater risk of Torsade de Pointes.



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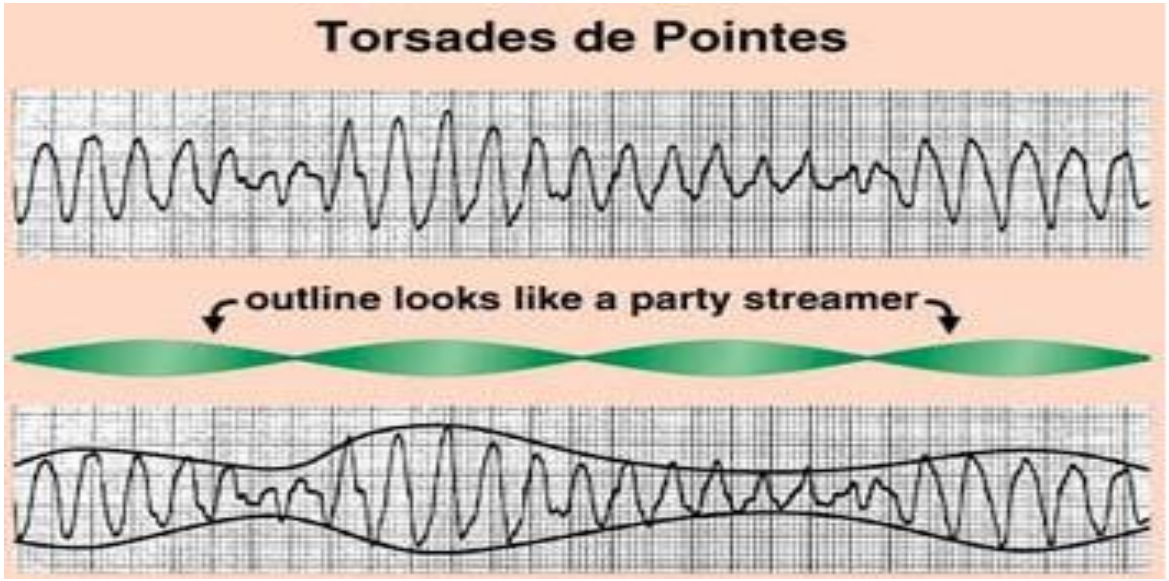
QTc Prolongation

- QTc prolongation
  - Mechanism: Blockade of potassium channels[21]
  - Can lead to fatal ventricular arrhythmia called Torsade de Pointes (TdP)and/or sudden death[21]
- Symptoms of TdP: lightheadness, muscular weakness, feeling faint, and syncope[22]



http://allaboutim.webs.com/apps/blog/show/prev?from_id=5367254

QTc Prolongation: Torsade de Pointes

- Factors that increase risk of TdP and/or sudden death in association with drugs contributing to QT prolongation:

  (1) bradycardia

  (2) hypokalemia or hypomagnesemia

  (3) concomitant use of other drugs that prolong the QTc interval (ie Beta blockers, AChE-I, Digoxin)

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Question #5

Fred has a history or bradycardia. Since the MD wants to start an Antipsychotic to treat his behaviors which ones may be the best choice given his risk for QT prolongation?

A. Lurasidone (Latuda) or Olazapine (Zyprexa)
B. Ziprasidone (Geodon) or Risperidone (Risperdal)
C. Risperidone (Risperdal) or Paliperidone (Invega)
D. Clozapine (Clozaril) or Iloperidone (Fanapt)

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ADR: Orthostatic Hypotension and Tachycardia

- **High Risk**: Clozaril[19]
- **Moderate**: Seroquel, Risperdal, Invega[19]
- **Low/Moderate**: Saphris, Fanapt, Zyprexa[19]
- **Low**: Abilify, Latuda, Geodon[19]
- Bottom Line:
  - Avoid Clozaril, Seroquel, Risperdal, and Invega
  - Try Abilify, Latuda, or Geodon

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Stroke

- Clinical placebo controlled trials of Zyprexa, Risperdal, and Abilify demonstrated elevated incidence of stroke among elderly patients with dementia[24]
  - Observational studies found no difference in incidence of stroke between Zyprexa, Risperdal, Abilify, Geodon and Seroquel [34]
  - Observational studies show both increase risk and no increased risk with SGA use[34]
- Bottom line:
  - No clear evidence of whether SGA increase risk of stroke in elderly patients with dementia[34]

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Cytochrome P450(CYP450)Pathway

- What is CYP450 system?
  - Enzymes found in the body, mainly liver, which metabolize medications to inactive forms or forms that are more easily removed from the body
    - One of the body's main way of stopping the effects of medications
  - Many different types of CYP450 enzymes
    - Ex. CYP1A2, 2D6, 2C9, 3A4, and many others
- Many drugs inhibit CYP450 enzymes to cause drug interactions
  - Atypical Antipsychotics are heavily effected by CYP450 inhibitors

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Case #2

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- Fluoxetine 40mg po qAM (depression)
- Olanzapine 5mg ODT at 12Noon + 5mg PRN (pacing the halls; refusing meals)
- Valproic acid 250mg po q5pm (sundowning)

Case #2: Drug interactions

- Weight Gain
  - Depakote + Zyprexa
- Weight Loss
  - Megestrol + Prozac + Donepezil
- Increase bleeding risk
  - ASA + Prozac
  - ASA +Depakote
  - ASA + Omega-3
- Lower BP
  - Tamsulosin + Metoprolol + Zyprexa + Donepezil
- Risk of QTc
  - Donepezil + Zyprexa

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