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PharmGenEd™: Bridging the Gap Between Science & Practice

Train-the-Trainer Session
Psychiatry II: Antipsychotics
Tuesday, August 24, 2010



UNIVERSITY of CALIFORNIA, SAN DIEGO
SKAGGS SCHOOL of PHARMACY
and PHARMACEUTICAL SCIENCES

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Train-the-Trainer Agenda

<ol style="list-style-type: none"> 1. Introduction <ul style="list-style-type: none"> • Objective of PharmGenEd™ shared curriculum • Author of educational content 2. Review of educational content for selected therapeutic area 3. Future webinar dates <ul style="list-style-type: none"> • Program implementation • Other therapeutic areas 	<ol style="list-style-type: none"> 4. Contact information 5. Survey instruments <ul style="list-style-type: none"> • Post training survey for trainers 6. Question & Answer (Q & A) session
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Overall Objective of PharmGenEd™ Program

- The “Pharmacogenomics Education Program: Bridging the Gap between Science and Practice” (PharmGenEd™) is an evidence-based pharmacogenomics education program designed for pharmacists and physicians, pharmacy and medical students, and other healthcare professionals.
- The overall objective of the PharmGenEd™ program is to increase awareness about current knowledge of the validity and utility of pharmacogenomic tests and the potential implications of benefits and harms from use of the tests.

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Shared Curriculum

- Educational Materials (each 1 hour)
 - Asthma
 - Cardiology I (warfarin & statins)
 - Cardiology II (clopidogrel & beta blockers)
 - Concepts and clinical applications
 - Economic issues
 - Oncology I (solid tumor)
 - Oncology II (hematologic malignancies)
 - Psychiatry I (depression)
 - Psychiatry II (antipsychotics)
- Future webinar dates for these sessions will be provided later

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Therapeutic Area Discussion

- Format
 - Patient case
 - Gene/Allele of interest
 - Functional effect
 - Population prevalence
 - Clinical relevance (dosing/selection, efficacy, and toxicity)
 - Genomic test and testing recommendation
 - Patient case summary

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Learning Objectives

- Upon completion of this program, participants will be able to:
 - Identify specific drug therapies used in which pharmacogenomic testing can be applied in the clinical setting
 - Summarize evidence-based recommendations for pharmacogenomic testing
 - Using patient case scenarios, formulate a plan for pharmacogenomics testing based upon available scientific evidence

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Antipsychotic Medications

- Primary Indications
 - Schizophrenia, bipolar disorder, autism spectrum disorders, augmentation of antidepressants for major depressive disorder
- Pharmacogenomic studies
 - Response in schizophrenia
 - Side effects
 - Weight gain, tardive dyskinesia (TD)

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Patient Case

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Patient Case

- 25 year-old Caucasian male diagnosed with paranoid schizophrenia presents to the University Health Center
 - CC: “The voices are so loud I can’t concentrate!”
 - Weight: 185 lb, Height: 6’0” (BMI=25.1)
 - HPI: Patient has been hearing derogatory voices in increasing frequency over the past few months. He also has paranoid delusions about the government tracking his movements by satellite.

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Patient Case (continued)

- Substances: Smokes cigarettes and marijuana
- Family History: Uncle (father’s brother) who is “odd”, father (age 63) has had one heart attack 2 years ago
- Patient is prescribed olanzapine and has good response and tolerability. After 6 months, patient complains of a 40 lb weight gain, increasing his BMI to >30.

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Patient Case (continued)

- The weight gain is concerning given the family history of cardiovascular disease
- The patient inquires whether pharmacogenomic testing could predict his risk for side effects from other antipsychotics
- The psychiatrist wonders whether any pharmacogenomic testing could predict the likelihood of the patient’s response or side effects to antipsychotics

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Commonly Observed Antipsychotic Side Effects

- Metabolic Disturbances
 - Second generation agents
 - Clozapine ≥ Olanzapine > risperidone = paliperidone = quetiapine > iloperidone ≥ ziprasidone ≥ aripiprazole
 - Weight gain, hyperlipidemia, diabetes
- Extrapyramidal Side Effects (EPS)
 - First generation agents (e.g. haloperidol) and higher doses of some second generation agents
 - Type of EPS: Dystonia, pseudoparkinson’s, akathisia, tardive dyskinesia

Allison et al 1999; Nasrallah 2008; Weiden 2007; Weiden et al 2007

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Genes/Alleles of Interest

- Response in Schizophrenia
 - Dopamine-D2 receptor gene (*DRD2*) (11q23.1)
 - A-241G (rs1799978)
 - -141C Ins/Del (rs1799732)
 - 957C/T (rs6277)
 - TaqIA (rs1800497 – also affiliated with *ANNK1* gene (Neville et al 2004)
 - Serotonin-5HT2A receptor gene (*HTR2A*) (13q14-21)
 - C102T (rs6313)
 - His452Tyr (rs6314)
 - -1438A/G (rs6311)
- } rs6313 and rs6311 most commonly studied and are in high linkage disequilibrium

Thompson et al 1997; Jönsson et al 1999; Serretti et al 2007; Lane et al 2005

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Genes/Alleles of Interest

- Side Effects
 - Serotonin-5HT_{2C} receptor gene (*HTR2C*) (Xq24)
 - -759C/T (rs381929)
 - Dopamine-D3 receptor gene (*DRD3*) (3q13.3)
 - Ser9Gly (rs6280)
 - Serine to glycine polymorphism at amino acid number nine (Ser9Gly)

Bakker et al 2006; Lerer et al 2002; DeLuca et al 2007; Hill et al 2007

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Functional Effect

- Response in Schizophrenia
 - Dopamine-2 (D₂) receptor antagonism (1st and 2nd generation agents)
 - Improves positive symptoms
 - Serotonin-2A receptor (5HT_{2A}) antagonism (2nd generation agents)
 - Negative/cognitive symptom benefit?
 - Reduce extrapyramidal side effects of D₂ blockade

Meltzer et al 2008

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Functional Effect

- Side Effects
 - Serotonin-5HT_{2C} receptor gene (*HTR2C*)
 - Modulates satiety and appetite
 - Dopamine-D3 receptor gene (*DRD3*)
 - Dopamine-D3 receptor antagonism and induction in striatum associated with motor hyperactivity
 - Antipsychotic agents (primarily first generation) induce D₃ receptors
 - Glycine allele may confer higher affinity to dopamine and hypothesized to result in increased motor activity subsequent to induction by antipsychotic agents

Nasrallah 2008; Reynolds et al 2005; Lerer et al 2002; Lundstrom et al 1996; Meador-Woodruff et al 1997; Damask et al 1996

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Population Prevalence (MAF)*

- *DRD2*
 - A-241G (rs1799978): 0.03-0.14
 - -141C Ins/Del (rs1799732): 0.02-0.39
 - 957C/T (rs6277): 0.03-0.53
 - TaqIA (rs1800497): 0.23-0.45
- *HTR2A*
 - C102T (rs6313) 0.35-0.50
 - His452Tyr (rs6314) 0-0.16
 - -1438A/G (rs6311): 0.38-0.50
- Serotonin-5HT_{2C} receptor gene (*HTR2C*) (Xq24)
 - -759C/T (rs3813929): 0-0.15
- *DRD3*Ser9Gly
 - (rs6280): 0.24-0.88

*MAF – minor allele frequency

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Antipsychotic Response

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Clinical Relevance

- Dosing/Selection
 - None
- Efficacy (Lencz et al 2006)
 - *DRD2* promoter region variation as a predictor to antipsychotic response in first episode schizophrenia patients
 - Patients (n=61) randomly assigned to 16 weeks of risperidone or olanzapine
 - Genotyped for two *DRD2* promoter region polymorphisms (*A-241G* and *-141C Ins/Del*)
 - Time until sustained response (two consecutive ratings without significant positive symptoms) for *-241G* and *-141Del* carriers versus common allele homozygotes was examined

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Clinical Relevance

FIGURE 1. Time to Sustained Antipsychotic Medication Response in 61 First-Episode Schizophrenia Patients as a Function of *DRD2* Promoter Region Single Nucleotide Polymorphisms^a

^a Note that time of response is marked from the beginning of the period of sustained response.

Conclusion: Gene variants in the D2 receptor previously associated with gene expression were associated with the timing and sustainability of response as measured by the Schedule for Affective Disorders and Schizophrenia and the Clinical Global Impression scales. Reprinted with permission from the American Journal of Psychiatry, (Copyright 2006). American Psychiatric Association.

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Clinical Relevance

- Efficacy: Summary of *DRD2* gene
 - *DRD2* genotypes appear to be associated with antipsychotic response
 - Many variants studied
 - Variants associated with response differ across studies
 - Heterogeneity = difficulty identifying “the” variant(s) to assess for Pharmacogenomic tests
 - Effect sizes small but statistically significant
 - Studies determining benefit of prospective genotyping not yet done

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Clinical Relevance

- Dosing/Selection
 - None
- Efficacy (Ellingrod et al 2009)
 - *DRD2* (D2 receptor gene)
 - 3/4 studies of clozapine, 1/1 study of olanzapine, 4/4 studies of risperidone showed positive association with response
 - Markers in promoter or coding regions
 - *HTR2A* (serotonin-5HT2A receptor gene)
 - Meta analysis of 8 clozapine studies, 7/11 studies of clozapine, 2/2 olanzapine studies, 2/3 risperidone studies showed positive association with response
 - Markers in promoter or coding regions

Clinical Relevance

- Efficacy (Arranz et al 1998)
 - Meta-analysis of eight studies on genetic variation in 5-HT2A receptors and clozapine response in treatment of schizophrenia
 - 373 “responders”, 360 “non-responders”
 - *C102T* and *His452Tyr* SNPs evaluated across studies
 - Variants that alter 5HT2A mRNA expression *in vitro*
 - *102C* allele associated with poor response
 - OR = 1.64; *102C/102C* vs *102T* carriers (p=0.004)

Clinical Relevance

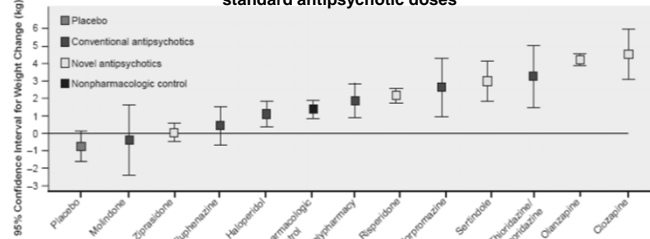
- Efficacy: Summary of *HTR2A* gene
 - *HTR2A 102C* allele is associated with “poor” response to antipsychotics
 - Findings in second generation antipsychotic agents
 - Clozapine
 - Olanzapine
 - Risperidone
 - Effect sizes small but statistically significant
 - Studies determining benefit of prospective genotyping not yet done

Side Effect: Weight Gain

Clinical Relevance

- Toxicity
 - Antipsychotic-associated weight gain has high inter-agent and inter-patient variability
 - Purported mechanisms include receptor activity/affinity
 - Serotonin, Histamine, Dopamine, Adrenergic

95% Confidence interval for weight gain change after 10 weeks on standard antipsychotic doses



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Clinical Relevance

- Toxicity
 - *HTR2C* role in weight homeostasis
 - Serotonin agonists help to reduce weight gain; antipsychotics are 5HT2C antagonists
 - *HTR2C* -759C/T polymorphism
 - May be associated with higher transcription levels of the gene resulting in resistance to obesity and Type II diabetes
 - Frequency of T allele higher in non-obese subjects and non-diabetic subjects

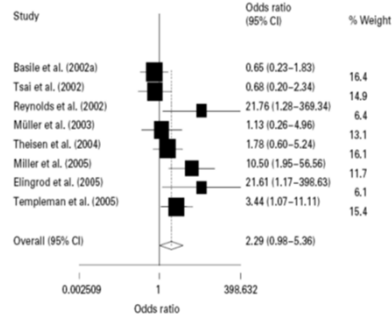
Nasrallah 2008; Reynolds et al 1005; Yuan et al 2000

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Clinical Relevance

- Toxicity
 - Meta analysis investigating -759C/T variant of *HTR2C*
 - T-allele associated with less weight gain in entire sample (OR=2.3, p<0.0001)
 - Effect of ancestry, age, gender, first episode status & study duration was non-significant



Association of the *HTR2C* gene and antipsychotic induced weight gain: a meta-analysis by De Luca, et al. Int J Neuropsychopharmacol; 10(5):697-704. Copyright © 2007 Collegium Internationale Neuropsychopharmacologicum. Reproduced with the permission of Cambridge University Press.

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Clinical Relevance

- Toxicity: Summary of *HTR2C* gene
 - *HTR2C* -759T allele is associated with less weight gain
 - Second generation antipsychotics
 - Olanzapine
 - Clozapine
 - Effect sizes small but statistically significant
 - Studies determining benefit of prospective genotyping not yet done

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Side Effect: Tardive Dyskinesia

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Side Effect: Tardive Dyskinesia

- Tardive Dyskinesia (TD)
 - Late-onset (>6mo exposure) side effect from medications that have high affinity for dopamine receptors
- Description of TD
 - Choreiform movements of the face, torso, and extremities
 - Hyperkinetic, involuntary movements
 - Interferes with dexterity, stigmatizing, embarrassing, deadly if involves trunk/diaphragm/esophageal muscles
 - May not go away with discontinuation of medications
- First generation antipsychotic (e.g. haloperidol) incidence
 - 12-37% in first generation agents depending on age (older at higher risk), gender (females at higher risk), dose (higher doses increase risk), and duration of treatment (longer duration increases risk)

Kane 1988

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Clinical Relevance

- Toxicity
 - Pharmacogenomics of tardive dyskinesia: combined analysis of 780 patients supports association with dopamine D3 receptor *Ser9Gly* polymorphism
 - Pooled analysis of 780 pts (317 w/ TD, 463 w/o TD)
 - Six centers, eight population groups
 - Logistic regression to assess effects of genotype, age, and gender

Lerer et al 2002

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Clinical Relevance

- Meta-analysis results
 - Pooled OR = 1.33 for glycine allele carriers
 - Glycine (Gly) allele and Gly9Gly genotype significantly associated with tardive dyskinesia

DRD3 Genotype	Adjusted mean AIMS Score (approx.)
DRD3ser-ser	4.5
DRD3ser-gly	5.5
DRD3gly-gly	8.5

Adjusted mean AIMS scores (bars represent standard error) derived from ANCOVA with age as covariates of patients from 6 groups according to *DRD3* ser9gly genotype. *vs. ser-ser, p=.0001; #versus ser-gly, p=.006.

Adapted by permission from Macmillan Publishers Ltd: [Neurpsychopharmacology] 27(1):105-19, copyright (2002)

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Clinical Relevance

- Summary
 - *DRD3 9Gly* allele associated with increased risk for and severity of tardive dyskinesia
 - Studies of first generation antipsychotic agents
 - Schizophrenia
 - Effect sizes small but statistically significant
 - Studies determining benefit of prospective genotyping not yet done

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Pharmacogenomic Test

- *DRD2*, *HTR2A*, *HTR2C*, and *DRD3* tests are not commercially available
- Available at some academic medical center laboratories
 - E.g. *HTR2A*, *HTR2C*, *DRD3* available through the Mayo Clinic Medical Laboratories
 - Other medical centers?

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Testing Recommendations

- *DRD2*, *HTR2A*, *HTR2C*, and *DRD3* polymorphisms appear to have statistically significant associations with response and side effect outcomes in research studies
 - Effect sizes small but statistically significant
 - Studies determining benefit of prospective genotyping not yet done (EGAPP 2010)
 - *HTR2A*, *DRD2*, *HTR2C* and *DRD3* tests are not FDA approved

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Testing Recommendations

- Currently no recommendations for testing included in antipsychotic prescriber information
- Pharmacogenomics testing for antipsychotics not yet addressed by EGAPP*
- Therefore pharmacogenomic tests for antipsychotics currently not recommended as “standard of care”

*EGAPP: Evaluation of Genomic Applications in Practice and Prevention
<http://www.egappreviews.org/>

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Case Summary

- Would a genetic test identifying the presence of *HTR2C* -759C allele enable the prescriber to choose an alternative agent for initial therapy?
- If the patient was identified as having *DRD3* 9Gly polymorphism, how does this impact the choice of future agents – particularly first generation antipsychotics?
- Does *HTR2A/DRD2* genotyping provide any information at this time?

Case Summary

- *DRD2*
 - Specific SNP assessed differs across studies – too much heterogeneity to inform specific testing
- *HTR2A*
 - 102C allele associated with poor response
- *HTRC*
 - -759C allele carrier status associated with more weight gain than T allele
 - Does not mean that T allele carriers experience *NO* weight gain
- *DRD3*
 - 9Gly allele carrier status associated with higher Abnormal Involuntary Movement Scale (AIMS) scores in patients taking first generation agents
 - May eventually provide support for avoiding first generation agents because of increased risk of tardive dyskinesia

Summary

- Antipsychotic selection and dosing currently guided by clinical characteristics, individual antipsychotic properties, and prior patient outcomes from treatment
- No prospective pharmacogenomic studies of antipsychotic drugs
- Does genotyping improve patient outcomes?
 - Currently unknown

Summary

- Antipsychotic drugs commonly used to treat schizophrenia, bipolar disorder, and autism
- Most pharmacogenomic studies conducted to date involve patients with schizophrenia
- Response
 - Side effects
 - Weight gain: Second generation agents
 - Tardive dyskinesia: First generation agents

Summary

- Genes with replicated pharmacogenomic studies
 - *DRD2* – response
 - Clozapine, olanzapine, risperidone
 - *HTR2A* – response
 - Clozapine, olanzapine, risperidone
 - *HTR2C* – weight gain
 - Clozapine, olanzapine
 - *DRD3* – tardive dyskinesia
 - Haloperidol and other first generation agents

Summary

- Pharmacogenomic test approval and availability
 - Not FDA approved
 - Not commercially available
 - Available at some academic medical centers
- Testing recommendations
 - No recommendations or guidelines for testing in prescribing information documents
 - Not yet appropriate for routine clinical care

Acknowledgements

- **Author**
 - Jeffrey R. Bishop, PharmD, MS, BCPP
 - Assistant Professor
 - University of Illinois at Chicago, College of Pharmacy
- **Reviewers and Editorial Staff**
 - Primary Reviewer and Editor
 - Kelly C. Lee, PharmD, BCPP
 - Reviewers and Associate Editors
 - Joseph D. Ma, PharmD
 - Grace M. Kuo, PharmD, MPH
 - Assistant Editors
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 - Ashley To, BA

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END OF CONTENT SECTION

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The program is 100% funded by the CDC
(Grant Number IU38GD000070)

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Future Webinar Dates

(all times are PST)

- **Oncology II: Hematologic malignancies**
 - Tuesday, Aug. 10, 2010 10am-12pm - COMPLETED
- **Concepts and clinical applications of pharmacogenomics**
 - Recorded August 11, 2010
- **Psychiatry II: Antipsychotics**
 - Tuesday, Aug. 24, 2010 10am – 12pm
- **Oncology I: Solid Tumors**
 - Thursday, Aug. 26, 2010 10 am – 12 pm
- **Cardiology I: Warfarin and Statins**
 - Tuesday, Sept. 21, 2010 10am-12 pm
- **Cardiology II: Clopidogrel and Beta Blockers**
 - Thursday, Sept. 23, 2010 10 am – 12 pm
- **Asthma**
 - Wednesday, Sept. 29, 2010 10 am – 12 pm

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Future Webinar Dates

(all times are PST)

- **Economics Issues**
 - Tuesday, Oct. 5, 2010 10 am – 12 pm
- **Psychiatry I: Depression**
 - Thursday, Oct. 21, 2010 10am – 12pm
- **PharmGenEd™ Program Implementation**
 - Thursday, Aug. 12, 2010: 10 am – 12 pm – COMPLETED
 - Thursday, Sept. 9, 2010: 10 am – 12 pm
- Please register at www.pharmacogenomics.ucsd.edu to download materials prior to the scheduled webinar

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Survey Instruments: Evaluation

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Survey Instruments: Evaluation

- Faculty trainers will complete a Post-Training Survey
 - Evaluate knowledge, attitudes, and self-efficacy
- All survey materials will be mailed after completion of all webinars in October 2010
- Further information and details will be discussed during the PharmGenEd™ Program Implementation Webinar:
 - Thursday, Sept. 9, 2010: 10 am – 12 pm (PST)

Question and Answer Session