



SCHOOL OF PHARMACY

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The Resident Star

By The University of Washington
Community Pharmacy Residents

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Acetaminophen Use during Pregnancy and Child's ADHD Risk

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While some medications used in pregnancy may adversely affect the fetus but most over-the-counter (OTC) drugs are generally considered safe. Acetaminophen (Tylenol) is the most commonly used medication for pain and fever in United States with more than 50% of pregnant women reporting use. Research data suggest that acetaminophen is a hormone disruptor, and abnormal hormonal exposures in pregnancy may affect neurodevelopment and cause behavioral dysfunction.

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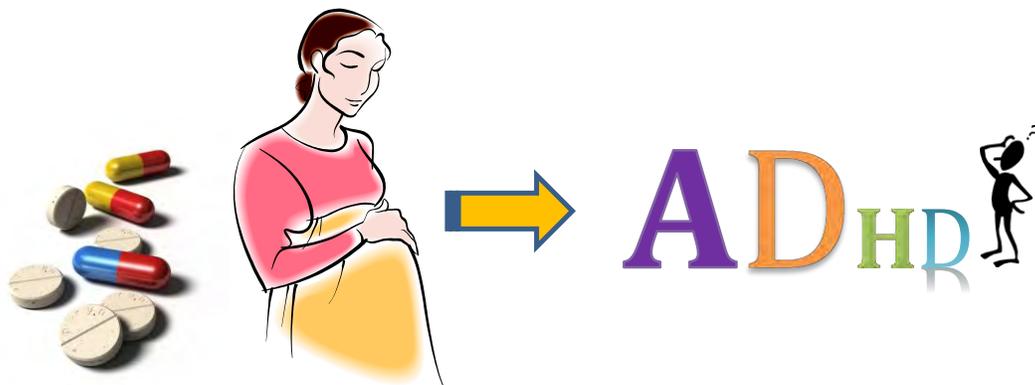
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ADHD, one of the most common neurobehavioral disorders worldwide, is characterized by inattention, hyperactivity, increased impulsivity, and motivational and emotional dysregulation. Hyperkinetic disorder is a particularly severe form of ADHD. The UCLA researchers used the Danish National Birth Cohort, a nationwide study of pregnancies and children, to examine pregnancy complications and diseases in offspring as a function of factors operating in early life. The cohort focuses especially on the side effects of medications and infections.

The researchers studied more than 64,000 children and mothers who were enrolled in the Danish cohort from 1996 to 2002. Acetaminophen use during pregnancy was determined using computer-assisted telephone interviews that were conducted up to three times during pregnancy and again six months after childbirth.

The researchers next followed up with parents when their children reached the age of 7. They first asked parents about any behavioral problems in their children using the Strength and Difficulties Questionnaire, a standard behavioral screening questionnaire used by scientists. It assesses five domains, including emotional symptoms, conduct problems, hyperactivity, peer relationship and social behavior in children and adolescents between the ages of 4 and 16.

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In addition, they obtained diagnoses of hyperkinetic disorder among the cohort's children (at an average age of 11) from the Danish National Hospital Registry or the Danish Psychiatric Central Registry. Last, they identified if ADHD medications, mainly Ritalin, were redeemed for the children using the Danish pharmaceutical prescription database.

Overall, mothers who used the pain reliever to treat headaches or to reduce fevers saw a 37% increased risk in their receiving an ADHD diagnosis and a 29% increased risk in the chances that their kids needed ADHD medications with mothers who didn't use the over-the-counter (OTC) medication at all.

Table 4. Hazard Ratios for HKD Hospital Diagnosis or ADHD Medication Redemption According to Maternal Acetaminophen Use During Pregnancy

Prenatal Exposure and Timing	Hospital-Diagnosed HKD			ADHD Medication		
	No. of Cases (Person-years)	Hazard Ratios		No. of Cases (Person-years)	Hazard Ratios	
		Crude	Adjusted (95% CI) ^a		Crude	Adjusted (95% CI) ^a
Acetaminophen use during pregnancy						
Never used	283 (159 209)	1.00	1 [Reference]	478 (170 264)	1.00	1 [Reference]
Ever used	551 (204 042)	1.52	1.37 (1.19-1.59)	877 (217 945)	1.43	1.29 (1.15-1.44)
1st trimester only	88 (34 887)	1.42	1.35 (1.07-1.72)	120 (37 288)	1.15	1.09 (0.89-1.33)
2nd trimester only	43 (18 714)	1.29	1.26 (0.91-1.73)	70 (20 011)	1.25	1.20 (0.91-1.55)
3rd trimester only	103 (41 418)	1.40	1.22 (0.97-1.53)	182 (44 262)	1.47	1.28 (1.08-1.52)
Both 1st and 2nd trimesters	37 (14 771)	1.41	1.31 (0.93-1.85)	52 (15 789)	1.17	1.09 (0.81-1.45)
Both 2nd and 3rd trimesters	37 (14 009)	1.49	1.30 (0.92-1.84)	77 (14 936)	1.84	1.63 (1.28-2.07)
Both 1st and 3rd trimesters	70 (25 291)	1.56	1.41 (1.08-1.84)	116 (26 938)	1.53	1.39 (1.13-1.71)
All 3 trimesters	120 (36 463)	1.84	1.61 (1.30-2.01)	181 (38 980)	1.65	1.44 (1.21-1.72)
Duration of acetaminophen use throughout pregnancy, wk						
0	283 (159 209)	1.00	1 [Reference]	478 (170 264)	1.00	1 [Reference]
1	128 (51 493)	1.40	1.30 (1.05-1.61)	197 (55 123)	1.27	1.18 (1.00-1.40)
2-5	115 (49 338)	1.32	1.19 (0.95-1.48)	211 (52 807)	1.43	1.29 (1.10-1.52)
6-10	44 (13 026)	1.90	1.65 (1.19-2.28)	68 (13 984)	1.74	1.49 (1.15-1.93)
11-20	43 (12 348)	1.97	1.66 (1.20-2.30)	55 (13 264)	1.49	1.24 (0.94-1.65)
>20	61 (16 341)	2.07	1.84 (1.39-2.45)	88 (17 431)	1.78	1.53 (1.21-1.94)
<i>P</i> value for trend ^b			<.001			<.001

Abbreviations: ADHD, attention-deficit/hyperactivity disorder; HKD, hyperkinetic disorder.

^a Adjusted maternal age at birth, sex of child, child's birth year, gestational age, birth weight, parity, socioeconomic status of mother, maternal smoking and

alcohol drinking during pregnancy, maternal prepregnancy body mass index, mother's ever having had mental health problems, and maternal diseases in muscles/joints, fever, or infection/inflammation during pregnancy.

^b Week of acetaminophen use is modeled as a continuous variable in trend test.

More than half of all the mothers reported using acetaminophen while pregnant. The researchers found that children whose mothers used acetaminophen during pregnancy were at a 13 percent to 37 percent higher risk of later receiving a hospital diagnosis of hyperkinetic disorder, being treated with ADHD medications or having ADHD-like behaviors at age 7. The longer acetaminophen was taken — that is, into the second and third trimesters — the stronger the associations. The risks for hyperkinetic disorder/ADHD in children were elevated 50 percent or more when the mothers had used the common painkiller for more than 20 weeks in pregnancy.

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Pharmacists' Role in Improving Medicare Plan Star Ratings and Medication Therapy Management

By Rebecca Schainost Pharm D, MLS (ASCP)^{CM}

“We’re moving to a value-based health care system where providers, hospitals, and other organizations are going to be paid based on their ability to both generate positive outcomes and control costs,” said APhA Vice-President of Professional Affairs Anne Burns, BSPHarm. “This (Medicare Plan Star Ratings) is an opportunity for pharmacists to get on board with: How can I help a health care entity, how can I help a physician, how can I help an Accountable Care Organization meet their quality measure?”¹

The Centers for Medicare and Medicaid Services (CMS) developed the Star Ratings to improve care for patients, improve the health of people and the community, and lower the cost of care. Tables 1 and 2 show the 54 weighting measures that fall into 5 weighting categories (columns 3 and 4, respectively) for 2014. Pharmacists have the ability to influence about 40% of the identified weighting measures (identified in column 2).²

The weighting measures can affect the Star Ratings for Medicare Advantage Plans (also known as Part C Plans) with or without prescription drug coverage (also known as MA-PD Plans) or Medicare Part D Plans (PDP).³ Each weighting measure is rated on a scale of 1 to 3, with a weight of 3 being reserved for those measures that are more established in the weighting system or more critical to a beneficiaries overall health and well-being. CMS then uses a plan’s score in these weighting measures to calculate an overall Star Rating for each plan, with a Star Rating of 5 being the highest performing plans.

Star Ratings affect a MA-PD, Part C Plan, or PDP in various ways. Medicare Advantage Plans that score well receive a quality bonus payment as provided by the Affordable Care Act to improve the plan’s care delivery system. Plans with a 5-Star Rating can open enrollment for beneficiaries year round. Plans with consistently low ratings will receive a “low performer” status indicated by a

specific icon on the Medicare website. Part D Plans do not receive a bonus for Star Ratings, but Star Ratings can affect enrollment. In a CMS study, published in the January 16, 2013 Journal of the American Medical Association, people showed a tendency to pick the higher-Star Rated plans.¹

With improving incentives for plans to increase their Star Ratings, plans are beginning to evaluate the performance of the pharmacies in their networks. Incentives that a plan may receive may be realigned to better reflect the quality of the pharmacies within their network.¹ A pharmacy’s performance in key areas of the weighting measures could ultimately influence networking contracts with Medicare Plans and plan incentives for high performing pharmacies.

A pharmacy’s performance in key areas of the weighting measures could ultimately influence networking contracts with Medicare Plans and plan incentives for high performing pharmacies.

Pharmacists have the opportunity to impact the almost 40% of the weighting measures within their day-to-day activities (Table 1 and Table 2). Every day in the pharmacy a pharmacist has the ability to identify compliance issues, dosing concerns, potentially inappropriate therapy, substitution opportunities, vaccination requirements, and many other opportunities to improve patient care and lower healthcare costs affecting a Medicare Part C’s or Part D’s Star Ratings.

The Pharmacy Quality Alliance (PQA) and Electronic Quality Improvement Platform for Plans and Pharmacies (EQuIPP) are designed to help pharmacists in performing and improving their performance in specific patient care activities associated with Part D Plan Star Ratings.¹

In 2006, Medication Therapy Management (MTM) was introduced to provide medication services directly to the patients to improve outcomes and lower costs.³ MTM services and completion of Comprehensive Medication Reviews (CMRs) is now one of the newer weighting measures and the aspect most influenced by pharmacists. As a newer weighting measure, it currently has a Star Ranking of a weight of 1, but could be changed as data from 2013 is analyzed.³

In addition to the inclusion of MTM services for weighting measure for Star Ratings, CMS has made changes to MTM program requirements effective in January 2014. The program requirement changes affected the enrollment of beneficiaries, the provision and documentation of a CMR, the provision of a CMR with a person who is cognitively impaired or in the Long Term Care (LTC) Setting, beneficiary awareness, and outcomes measurements.⁴ (Refer to the "CY 2014 Medication Therapy Management Program Guidance and Submission Instructions", April 15, 2013 for specific requirements.)⁵

The provision of MTM services is an additional opportunity to impact various additional weighting measures in addition to the weighting measure of the completion of CMRs for eligible beneficiaries. By performing MTM services, pharmacists have the ability to evaluate a patient's medication profile and identify areas for improvement in a patient's overall care. By utilizing MTM platforms, either OutcomesMTM™ or Mirixa®, pharmacists are provided with MTM opportunities for eligible plan beneficiaries, whether the opportunities are comprehensive medication reviews or targeted medication reviews. The provision of MTM services does not only affect a beneficiary's outcomes, but it also could affect a wide range of other Star Rating weighting measures.

MTM services are designed to identify problem recommendations and provide resolutions. Common examples of drug therapy recommendations include patient needs additional therapy, unnecessary drug therapy, dosage too high/low, more effective drug available, adverse drug reaction, or medication non-compliance/non-adherence. Common examples of drug therapy resolutions made as a result of MTM services include: initiating necessary new drug therapy, changing a drug (such as product in different therapeutic class, dose, dosage form, quantity, or interval), discontinuing or substituting a drug (such as discontinuing an unnecessary drug, substituting a generic

drug/therapeutically equivalent drug, or making a formulary substitution), or making a medication adherence intervention.⁵

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With the growing emphasis on Star Ratings, pharmacists have an opportunity to be more involved with the improvement of Medicare Plans' Star Ratings. As the role of the pharmacist in this venue is evaluated, more objective measures will be identified and analyzed with the anticipation that it will increase the role of the pharmacist in improving patient outcomes and lowering health care costs. Until more objective data is available, it will be important for the pharmacist to work vigilantly at improving the pharmacist-influenced weighting measures that ultimately influence Star Ratings for Medicare Advantage Plans with or without prescription drug coverage or Medicare Part D Plans.

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Table 1.
Medicare Part C and Medicare Advantage with Prescription Drug Coverage (MA-PD) Weighting Measures²

<i>Measure ID</i>	<i>Affected by Pharmacist</i>	<i>Weighting Measure</i>	<i>Weighting Category</i>	<i>Part C</i>	<i>MA-PD</i>
C01		Breast Cancer Screening	Process Measure	1	1
C02		Colorectal Cancer Screening	Process Measure	1	1
C03	X	Cardiovascular Care – Cholesterol Screening	Process Measure	1	1
C04	X	Diabetes Care – Cholesterol Screening	Process Measure	1	1
C05		Glaucoma Testing	Process Measure	1	1
C06	X	Annual Flu Vaccine	Process Measure	1	1
C07	X	Improving or Maintaining Physical Health	Outcome Measure	3	3
C08	X	Improving or Maintaining Mental Health	Outcome Measure	3	3
C09		Monitoring Physical Activity	Process Measure	1	1
C10		Adult BMI Assessment	Process Measure	1	1
C11	X	Care for Older Adults – Medication Review	Process Measure	1	1
C12	X	Care for Older Adults – Functional Status Assessment	Process Measure	1	1
C13		Care for Older Adults – Pain Screening	Process Measure	1	1
C14	X	Osteoporosis Management in Women who had a Fracture	Process Measure	1	1
C15	X	Diabetes Care – Eye Exam	Process Measure	1	1
C16	X	Diabetes Care – Kidney Disease Monitoring	Process Measure	1	1
C17	X	Diabetes Care – Blood Sugar Controlled	Intermediate Outcome Measures	3	3
C18	X	Diabetes Care – Cholesterol Controlled	Intermediate Outcome Measures	3	3
C19	X	Controlling Blood Pressure	Intermediate Outcome Measures	3	3
C20	X	Rheumatoid Arthritis Management	Process Measure	1	1
C21	X	Improving Bladder Control	Process Measure	1	1
C22	X	Reducing the Risk of Falling	Process Measure	1	1
C23		Plan All-Cause Readmissions	Outcome Measure	3	3
C24		Getting Needed Care	Patients' Experience and Complaints Measure	1.5	1.5
C25		Getting Appointments and Care Quickly	Patients' Experience and Complaints Measure	1.5	1.5
C26		Customer Service	Patients' Experience and Complaints Measure	1.5	1.5
C27		Overall Rating of Health Care Quality	Patients' Experience and Complaints Measure	1.5	1.5
C28		Overall Rating of Health Plan	Patients' Experience and Complaints Measure	1.5	1.5
C29		Care Coordination	Patients' Experience and Complaints Measure	1.5	1.5
C30		Complaints about the Health Plan	Patients' Experience and Complaints Measure	1.5	1.5
C31		Beneficiary Access and Performance Problems	Measures Capturing Access	1.5	1.5
C32		Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1.5	1.5
C33		Health Plan Quality Improvement	Outcome Measure	3	3
C34		Plan Makes Timely Decisions about Appeals	Measures Capturing Access	1.5	1.5
C35		Reviewing Appeals Decisions	Measures Capturing Access	1.5	1.5
C36		Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1.5	1.5
C36		Special Needs Plans (SNP) Care Management Measure	Process Measure	1	1

Table 2.

Medicare Part D and Medicare Advantage with Prescription Drug Coverage (MA-PD) Weighting Measures²

Measure ID	Affected by Pharmacist	Directly Evaluated*	Weighting Measure	Weighting Category	Part D	MA-PD
D01			Call Center – Foreign Language Interpreter and TTY Availability	Measures Capturing Access	1..5	1.5
D02			Appeals Auto-Forward	Measures Capturing Access	1..5	1.5
D03			Appeals Upheld	Measures Capturing Access	1..5	1.5
D04			Complaints about the Drug Plan	Patients' Experience and Complaints Measure	1..5	1.5
D05			Beneficiary Access and Performance Problems	Measures Capturing Access	1..5	1.5
D06			Members Choosing to Leave the Plan	Patients' Experience and Complaints Measure	1..5	1.5
D07			Drug Plan Quality Improvement	Outcome Measure	3	3
D08			Rating of Drug Plan	Patients' Experience and Complaints Measure	1..5	1.5
D09			Getting Needed Prescription Drugs	Patients' Experience and Complaints Measure	1..5	1.5
D10			MPF Price Accuracy	Process Measure	1	1
D11	X	X	High Risk Medication	Intermediate Outcome Measures	3	3
D12	X	X	Diabetes Treatment	Intermediate Outcome Measures	3	3
D13	X	X	Medication Adherence for Diabetes Medications	Intermediate Outcome Measures	3	3
D14	X	X	Medication Adherence for Hypertension (RAS antagonists)	Intermediate Outcome Measures	3	3
D15	X	X	Medication Adherence for Cholesterol (Statins)	Intermediate Outcome Measures	3	3
D16	X	X	Medication Therapy Management Program Completion Rate for Comprehensive Medication Review	Process Measure	1	1

*These measures are directly evaluated by various platforms, including OutcomesMTM™, Mirixa®, ACQ, or EQuIPP,



Past and Upcoming Events:

- ASHP Ambulatory Care Summit, Dallas, Tx March 3-4, 2014
- ASHP CV Review, Accepting CVs for review March 1-15, 2014 (also looking for volunteers to review CVs)
- 16th Annual Fundamentals of Addiction Medicine Conference, Tulalip Resort & Spa, Marysville, WA, March 13-12, 2014
- APhA Annual Meeting & Exposition, Orange County Convention Center in Orlando, March 28-32, 2014
- Presentation for western states due late April TBD

FROM WSPA:

March 2014

Mar 11, Tuesday

- Immunization Practicum
WSPA Conference Room,
Renton, WA
2:00PM - 5:30PM

Mar 18, Tuesday

- Pediatric Drug Therapy
Shoreline Conference Center
- Tobacco Cessation Training
Webinar, 2:00PM-5:00PM

Mar 21-23

- Clinical Vaccinology Course
Renaissance Seattle Hotel

April 2014

Apr 06, Sunday

- 2014 New Drugs New Laws
Spokane
Washington State University
8:00AM - 5:15PM

See website for more details:

<http://www.wsparx.org/>



Zoster Vaccine and the Immunosuppressed Patient

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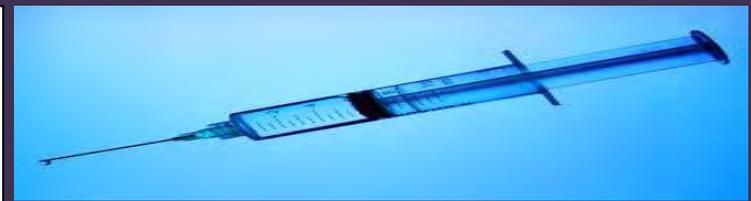
In patients over 50 years of age, administration of the zoster vaccine is recommended. In efficacy trials, the zoster vaccine reduced the risk of Varicella Zoster Virus (VZV) reactivation by 51.3% in patients 60 years of age and older and 69.8% in patients 50 to 59 years old. The zoster vaccine is 66.5% efficacious in preventing Post-Herpetic Neuralgia in patients who do develop a VZV reactivation over 60 years of age.¹ For patients who are in an immunosuppressed state, however, the zoster vaccine is currently not recommended and additional criteria needs to be considered before administration of the zoster vaccine.

In the prevention of VZV reactivation, cellular immunity has been proven to play an important role. Patients who are older or who are in an immunosuppressed state are at an increased risk to experience a VZV reactivation episode due to a decline in their cellular immunity. When patients are immunized with the zoster vaccine, a boost in VZV T cell immunity is observed, which contributes to the zoster vaccine's overall efficacy in preventing VZV reactivation.²

The zoster vaccine is a live attenuated virus vaccine and careful consideration needs to be made in regards to the potential risks of developing a varicella or zoster infection following vaccination in a person who is immunosuppressed. According to the Center for Disease Control and Prevention's (CDC) Guide to Vaccine Contraindications and Precautions³ and the Pink Book⁴, the following information needs to be considered in regards to a patient who is 50 years of age and older and may be in an immunosuppressed state.

Zoster vaccine should not be administered to:

- Persons with leukemia, lymphomas, or other malignant neoplasms affecting the bone marrow or lymphatic system.
- Persons on immunosuppressive therapy, including high-dose corticosteroids (>20 mg/day of prednisone or equivalent) lasting two or more weeks. Defer vaccination for at least 1 month after discontinuation of such therapy.
- Persons with clinical or laboratory evidence of other unspecified cellular immunodeficiency.
- Persons receiving recombinant human immune mediators and immune modulators, especially the antitumor necrosis factor agents adalimumab, infliximab, and etanercept. If it is not possible to administer zoster vaccine to patients before initiation of therapy, assess the immune status of the recipient on a case-by-case basis to determine the relevant risks and benefits. Otherwise, defer vaccination for at least 1 month after discontinuation of such therapy.



Zoster vaccine may be administered to:

- Patients whose leukemia is in remission and who have not received chemotherapy or radiation for at least 3 months.
- Persons on short-term corticosteroid therapy (<14 days); low to moderate dose (<20 mg/day of prednisone or equivalent); topical; intra-articular, bursal, or tendon injections; or long-term alternate-day treatments with low to moderate doses of short-acting systemic corticosteroids.
- Persons on therapy with low doses of methotrexate (<0.4 mg/Kg/week), azathioprine (<3.0 mg/Kg/day), or 6-mercaptopurine (<1.5 mg/Kg/day) for treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease, and other conditions.
- Persons with impaired humoral immunity (e.g., hypogammaglobulinemia or dysgammaglobulinemia).

Researchers continue to study live VZV vaccine administration in immunosuppressed patients. As more research is performed, more information will become available regarding the safety and efficacy of the zoster vaccine in immunosuppressed patients. A retrospective analysis published in the Journal of the American Medical Association⁵ and a cohort study published in PLoS Medicine in 2013⁶ demonstrated that vaccination in patients who are immunosuppressed reduces the incidence of herpes zoster and Post-Herpetic Neuralgia (PHN) as compared to those patients who are immunosuppressed who do not receive the vaccine. Table 1 identifies the efficacy differences between vaccine administration in recommended patients (as identified in the package insert¹) as compared to immunosuppressed patients as identified in the previously mentioned articles.^{5,6}

Future inactivated VZV vaccines are currently being developed and researched. An adjuvanted recombinant glycoprotein E subunit vaccine in Phase I/II trials is showing promising results so far.² Further research is still needed regarding inactivated zoster virus vaccines, especially for those patients that cannot receive the live zoster vaccine due to an immunosuppressed state.

The zoster vaccine for immunosuppressed patients requires careful evaluation. As a pharmacist, it is important to evaluate each patient individually. It is necessary to include the physician in any discussion regarding an immunosuppressed patient's need for the zoster vaccine. The patient also needs to be educated on the risks and benefits of the vaccine while in an immunosuppressed state. With further research on zoster vaccination and future development of zoster vaccines, no patient should have to experience the effects of a VZV infection or have to live with VZV reactivation long-term sequelae.

Table 1. Comparison of Efficacy Data regarding Zostavax® in immunocompetent and immunosuppressed patients.

	Zostavax® Package Insert Immunocompetent Patients		2012 JAMA Immunosuppressed Patients ^a		2013 PLoS Medicine Immunosuppressed Patients ^β			
Subject Age Range	50-59 years old	>/=60 years old	>60 years old		>/=65 years old			
Additional Criteria			<42 days since zoster vaccination	>42 days since zoster vaccination	Antiviral therapy definition ^μ		General Definition ^φ	
<i>Incidence of Herpes Zoster per 1,000 person years</i>								
Vaccinated	1.994	5.4	7.8	6.7	12.1		18.2	
Unvaccinated	6.596	11.1	Not Reported (NR)	11.7	18.3		26.9	
<i>Incidence of Post-Herpetic Neuralgia (PHN) per 1,000 person years</i>								
					30 days ^θ	90 days	30 days	90 days
Vaccinated	NR	0.5	NR	NR	0.22	NR	0.41	NR
Unvaccinated	NR	1.4	NR	NR	0.65	0.33	0.89	0.47

^α The four groups of medications of interest were as follows: anti-TNF biologics (adalimumab, etanercept, infliximab, certolizumab, and golimumab), non-TNF biologics (abatacept and rituximab), non-biologic immunosuppressive medications (or disease modifying antirheumatic drugs [DMARDs]) (methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, leflunomide, cyclosporine, and 6-mercaptopurine), and oral glucocorticoids.

^β Immunosuppression defined as individuals with leukaemia, lymphoma, and HIV or during and for 6 month after a prescription for an immunosuppressive drug, including oral corticosteroids.

^μ Definition requiring antiviral administration within 7 days before or after the diagnostic code for herpes zoster.

^φ Incident herpes zoster cases were identified as those with both the presence of a specific International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic code for herpes zoster, excluding those with specific ICD-9-CM codes for PHN, and the use of antivirals, including acyclovir, famciclovir, or valacyclovir, within 7 days either before or after the diagnostic code for herpes zoster

^θ PHN was identified as those with a first episode of zoster with a further zoster diagnostic code after 90 d with a relevant prescription for analgesia, anticonvulsant, or antidepressant therapy on the same day as the recorded consultation. The presence of codes for non-specific neuralgia or for neurological complications of zoster after 90 days was also consistent with PHN. The PHN analysis was repeated after 30 days using the same diagnostic criteria.

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Substance Abuse Program at Tulalip Clinical Pharmacy

By Muhammad Qudoos, Pharm.D., PGY-1 Pharmacy Resident
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Medication Monitoring

Drug abuse is a growing problem in Washington State where it is estimated that almost 12% of teens use medicines for non-medical reasons.¹ The Tulalip Clinical Pharmacy works with prescribers to help ensure that their patients receive the right medicine at the right time. This one-on-one counseling at the pharmacy entails observed administration of disulfiram (Antabuse®) or buprenorphine/ naloxone (Suboxone®). Pharmacists at the Tulalip Clinical Pharmacy find it rewarding to play a small part in assisting patients go from chemical dependence to individual independence as they make positive changes in their lives.

Antabuse® Direct Observation Program

Patients are prescribed disulfiram (Antabuse®) to maintain alcohol abstinence. In order to ensure patient compliance with the treatment regimen, it is often prescribed to be taken under the direct observation of a health care provider or other care taker. At the Tulalip Clinical Pharmacy there are private counseling rooms where a program patient meets with a pharmacist who

administers the medication and gives counsel about the treatment regimen. The encounter is documented in the clinic-based electronic health record for patient and provider convenience.

Suboxone® Counseling Program

Pharmacists at the Tulalip Clinical Pharmacy play an important role in these programs that are set up by the health care providers. When patients receive Suboxone® treatment to assist their efforts in quitting a dependency on a substance they receive private one-on-one counseling. In these regular counseling sessions with the pharmacist the treatment plan will be discussed, and patients receive encouragement and positive reinforcement for changing their lives.

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Integrative Therapy in Type II Diabetes: A Short Review of Some Commonly Used Products

By Natasha Gorely, Pharm.D.

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Many patients who present to the Tulalip Health Clinic have interest in alternative medicine. Often times, patients will report over-the-counter herbs or supplements that they take in addition to or in place of their prescribed medications in an attempt to control their chronic disease states. Some patients are reluctant or even refuse to take traditional “Western” medication, but are amenable to trying something “natural”.

Having an interest in both diabetes and alternative medicine, I enjoy being challenged with the task of finding safe and effective treatments that the patients are comfortable with and willing to take. According to Natural Standard, there are many integrative therapies used for blood glucose lowering purposes, but only a few have good or strong scientific evidence (Table 1).

Some patients report using cinnamon in their diet, or in capsule form, to assist in lowering their blood sugar. While this may be a commonly known alternative therapy, Natural Standard lists cinnamon as having unclear or conflicting results.

Table 1. *Integrative Therapies and Their Respective Level of Scientific Evidence According to Natural Standard (list is not all inclusive of possible integrative therapies)*

<i>Integrative Therapy</i>	<i>Scientific Evidence</i>		
	<i>Strong</i>	<i>Good</i>	<i>Unclear or Conflicting</i>
<i>Alpha-lipoic acid</i>	✓		
<i>Beta-glucan</i>		✓	
<i>Chromium</i>		✓	
<i>Ginseng</i>		✓	
<i>Gymnema</i>		✓	
<i>Magnesium</i>		✓	
<i>Whey protein</i>		✓	
<i>Barley</i>			✓
<i>Cinnamon</i>			✓
<i>Dandelion</i>			✓
<i>Garlic</i>			✓

One integrative therapy not rated in Natural Standard is hops, a plant used in making beer, and was brought to my attention as having blood sugar lowering properties by one of my patients.

In order to provide a more focused review, I will focus on alternative treatments commonly seen or asked about at the Tulalip Health Clinic.

Alpha-Lipoic Acid (ALA)

The theory behind the mechanism of ALA is that oxidative stress increases and there is depletion of cellular antioxidant systems in diabetic patients due to hyperglycemia. The increase in oxidative stress contributes to the progression and complications involved in diabetes. ALA being an antioxidant, works to reduce oxidative stress and in turn reduces the damage caused by hyperglycemia. In addition, ALA’s proposed mechanism in which blood glucose is reduced is that it increases glucose uptake through recruitment of the glucose transporter-4 to plasma membranes and improves glucose disposal.

A study with 38 participants from a Diabetes Clinic in Thailand were randomized into 5 groups to receive placebo, or different doses of ALA (300, 600, 900, or 1200mg/day) for 6 months, along with their current diabetic regimen. After six months, fasting blood glucose levels were unchanged in the placebo group, and reduced with significant correlation to the different doses of ALA, with higher doses providing larger decreases. With all dosage groups pooled and compared to placebo, there was a significant difference in the change in fasting blood glucose. Similarly, a significant difference in the change in hemoglobin A1C (HbA1C) was observed between the pooled ALA dosage groups compared to placebo.¹

Another study with 74 participants were randomized into 4 groups: placebo and ALA at 3 different doses (600mg once daily, twice daily, or thrice daily). Insulin sensitivity was measured and compared among all groups at baseline and after 4 weeks. There was no significant difference among all three treatment groups, but when combined there was a significant increase in insulin sensitivity when compared to placebo.²

Some other studies do not show significant results, thus the reason for mixed results and the need for further research in this topic. If recommending this therapy to a patient either as an adjunct or as monotherapy, use a dose of 600 mg twice a day for optimal results while minimizing potential side effects such as nausea, vomiting, vertigo, or hypoglycemia. Caution should always be observed when adding on additional therapies, and patients should be advised to monitor their blood sugar closely and be aware of the signs and symptoms of a low blood sugar.

Chromium

The knowledge that chromium deficiency can lead to impaired glucose tolerance due to insulin resistance, lead researchers to question whether a chromium supplement could assist diabetic patients in reducing their blood glucose levels. The mechanism behind the connection is as follows: Chromodulin, a carrier protein for chromium ions, activates GLUT4 within the internal matrix of the cell when in the presence of insulin allowing it be transported to the cell's surface membrane. Chromium also increases production of GLUT4 transporter molecules independent of insulin. Finally, recent research has revealed a third mechanism in which chromium activates a signaling pathway called p38 MAPK that contributes to increased glucose uptake independent of the GLUT4 system.⁴

A review of clinical studies using chromium picolinate supplementation in diabetics found some significant results (Table 2) in at least one outcome of glycemic control. The trial with the largest number of participants (n=180) showed significant reductions in HbA1C, fasting blood glucose, and 2 hour post-prandial blood glucose after 2-4 months of using 500 mcg twice daily. While this dose can be recommended for a patient who is interested in trying chromium, it should be noted that it is 5 times higher than the estimated adequate dietary intake. While no upper limit has been established, it is still important to monitor closely any patient starting on a new medication or supplement with intentions to reduce blood glucose in order to avoid hypoglycemia.⁵

Cinnamon

In animal studies, the cinnamon extract containing polyphenol type-A polymers have been shown to have insulin-like properties. Recent studies have shown some promising results in humans, but due to limitations in sample sizes and study design, further research still needs to be conducted for definitive results and implementation in standard practice. See the table below for a summary of these recent studies.³

Doses anywhere from 1-6 grams of cinnamon extract have been shown to have some effect on fasting or postprandial blood glucose. Again while some studies have

shown some effectiveness, others have shown no difference between treatment and placebo groups. Cinnamon is likely a safe supplement to recommend, but should not be the sole modality of treatment if at all possible in someone whose diabetes is uncontrolled.

Hops

Isohumulones are the bitter compounds derived from hops that are present in beer and have been shown to activate the peroxisome proliferator-activated receptors (PPAR) α and γ . PPAR α and $-\gamma$ are dietary lipid sensors that regulate fatty acid and carbohydrate metabolism, and are activated by fibrates and thiazolidinediones (TZDs). In a study using diabetic mice treated with isohumulones, a reduction in plasma glucose, triglycerides, and free fatty acid levels was shown. Pioglitazone (a TZD) showed similar reductions, but also increased body weight by 10.6% compared to the control group. In another study, C57BL/6N mice with insulin resistance and fed a high fat diet were treated with isohumulones. The results showed improved glucose tolerance, reduced insulin resistance, increased liver fatty acid oxidation, a decrease in size, and an increase in apoptosis of their hypertrophic adipocytes. In a double-blind placebo-controlled pilot study in humans, the group treated with isohumulones showed improved glucose tolerance and A1C levels after 8 weeks (Table 4). This study included 20 volunteers with type 2 diabetes who were then randomized to receive either placebo, or a capsule containing 100 mg twice a day of an isomerized hop extract (IHE).²

While results show minimal blood glucose and A1C lowering compared to placebo in the human study, it appears that further research in this area is still needed and may prove to be beneficial. For patients who are almost to a HbA1C goal of <7%, the hop extract might provide that extra push that is needed.

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Table 2.

Chromium

Reference	Intervention	Total participants (n)	Duration of intervention	Outcome measures	Significant results
<u>Kleefstraet al., 2007</u>	Chromium yeast 400 µg	56	6 months	HbA1c Lipid profile BMI Blood pressure Body fat Insulin resistance	No significant differences
<u>Kleefstraet al., 2006</u>	Chromium picolinate 500 µg 1000 µg	46	6 months	HbA1c BMI Lipid profile Blood pressure Insulin requirements	No significant differences
<u>Martin et al., 2006</u>	Chromium picolinate 1000 µg	37	6 months	Fasting glucose HbA1c	FG (p < 0.001) HbA1c (p < 0.05)
<u>Pei et al., 2006</u>	Chromium chloride 400 µg	30	3 months	Fasting plasma glucose Fasting insulin HbA1c Total cholesterol Total triglycerides LDL cholesterol HDL cholesterol	FPG (p < 0.05) FI (p < 0.05) HbA1c (p < 0.05)
<u>Racek et al., 2006</u>	Chromium yeast 400 µg	36	12 weeks	Fasting blood glucose Glutathione peroxidase activity	FPG (p < 0.05)
<u>Vrtovec et al., 2005</u>	Chromium picolinate 1000 µg	60	3 months	QTc interval (related to heart rate) Fasting insulin	QTc (p = 0.01) FI (p < 0.050)
<u>Rabinovitzet al., 2004</u>	Chromium picolinate 400 µg	78	3 weeks	Fasting blood glucose levels HbA1c	FG (p < 0.001) HbA1c (p < 0.01)
<u>Feng et al., 2002</u>	Chromium picolinate 500 µg day ⁻¹	136	3 months	Fasting blood glucose Post- prandial glucose	FG (p < 0.01) PPG (p < 0.01)
<u>Ghosh et al., 2002</u>	Chromium picolinate 1400 µg	43	3 months	Fasting blood glucose Post- prandial blood glucose Fasting insulin HbA1c	FG (p < 0.001) PPG (p < 0.001) FI (p < 0.05) HbA1c (p < 0.05 compared with control)
<u>Anderson et al., 2001</u>	Chromium picolinate 400 µg day ⁻¹	27	6 months	Plasma TBARS Cu-Zn SOD Se GPx in red blood cells, blood lipids and lipoproteins, HbA1c Fasting blood glucose	Plasma TBARS (p < 0.001)
<u>Bahijiri et al., 2000</u>	Chromium yeast 23.3 µg Chromium chloride 200 µg	78	Crossover 8 weeks each stage	Fasting blood glucose Post- prandial blood glucose Fructosamine Triglycerides HDL cholesterol BMI	FPG (p < 0.05) PPG (p < 0.05) Fructosamine (p < 0.05) Triglycerides (p < 0.050)
<u>Anderson et al., 1997</u>	Chromium picolinate 200 µg day ⁻¹ 1000 µg day ⁻¹	180	4 months	HbA1c Fasting blood glucose Post-prandial blood glucose Fasting insulin levels 2-h insulin levels	HbA1c (p < 0.01 for 100mg day ⁻¹ and p < 0.05 for 200 mg day ⁻¹) FG (p < 0.05 for 1000 mg day ⁻¹) PPG (p < 0.05 for 1000 mg day ⁻¹) FI (p < 0.05 for 200 mg and 1000 mg day ⁻¹) PPI (p < 0.05 for 200 mg and 1000 mg day ⁻¹)
<u>Lee and Reasner, 1994</u>	Chromium picolinate 200 µg	30	2 months	Glucose control HDL cholesterol levels LDL cholesterol levels Triglyceride levels	Triglyceride levels (p < 0.05)
<u>Evans, 1989</u>	Chromium picolinate 200 µg day ⁻¹	11	1.5 months	Fasting blood glucose HbA1c Post-prandial blood glucose	FG (p < 0.05) HbA1c (p < 0.05)
<u>Uusitupa et al., 1983</u>	Chromium chloride 200 µg	10	6 weeks	Fasting plasma glucose Post-prandial glucose Fasting serum insulin Post- prandial serum insulin HbA1c Serum cholesterol Serum triglycerides	PP serum insulin (<0.01)
<u>Sherman et al., 1968</u>	Chromium chloride 50 µg	10	16 weeks	Fasting plasma glucose	No effect

Table 3.

Recent intervention studies on cinnamon supplementation on glycemic control in healthy and type 2 diabetes populations.

Study design	Study diet	Results
Khan et al. 60 people with type 2 diabetes in controlled study of parallel design	Randomly divided into six groups: Groups 1, 2, and 3 consumed 1, 3, or 6 g of cinnamon daily (<i>Cinnamomum cassia</i>), respectively, and groups 4, 5, and 6 were given placebo capsules corresponding to the number of capsules consumed for the three levels of cinnamon for 40 days	↓ FBG in all three levels of cinnamon ↓ TG, LDL-C, and TC levels in all three levels of cinnamon ↔ HDL-C
Ziegenfuss et al. 22 subjects with prediabetes and the metabolic syndrome in study of parallel design	Randomly assigned to supplement their diet with either Cinnulin PF® (500 mg/d which is equivalent of 10 g of whole cinnamon powder) or a placebo for 12 weeks	↓ Body fat and ↑ lean body mass ↓ FBG ↔ HbA1c levels ↓ Systolic blood pressure ↔ Blood lipids
Vanschoonbeek et al. 25 postmenopausal patients with type 2 diabetes in study of parallel design	Supplemented with either cinnamon (<i>Cinnamomum cassia</i> , 1.5 g/d) or a placebo for 6 weeks	↔ FBG, fasting insulin or HbA1c levels ↔ Whole-body insulin resistance/sensitivity ↔ Blood lipids
Hlebowicz et al. 14 healthy subjects using a crossover trial in 1 session	Randomly ingested of 300 g rice pudding or 300 g rice pudding and 6 g cinnamon	↓ Postprandial glucose response Delayed gastric emptying ↔ Satiety
Wang et al. 15 women with polycystic ovary syndrome in study of parallel design	Randomized to daily oral cinnamon extract (1 g/d) or placebo for 8 weeks	↓ FBG ↔ Fasting insulin and insulin index ↓ Insulin resistance
Blevins et al. 58 subjects with type 2 diabetes in study of parallel design	Randomized to receive either cinnamon (<i>Cinnamomum cassia</i> , 1 g/d) or placebo (wheat flour) for 3 months	↔ Body weight ↔ FBG or HbA1c levels ↔ Blood lipids
Tang et al. 11 young and healthy subjects participated in randomly assigned, crossover study	Randomized to be supplemented doses of cinnamon (3 g/d) and turmeric (2.8 g/d) for 4 weeks each	↔ FBG ↔ TC and TG

Table 4.

Results of the placebo-controlled pilot study of the effects of hop extract in type 2 diabetic patients

Data are indicated as the mean ± S.D.

	Hop extract		Placebo	
	0 week	8 weeks	0 week	8 weeks
Blood glucose (mg/dl)	127.1 ± 10.9	114.3 ± 10.4 ^a	130.5 ± 12.0	122.3 ± 8.37 ^b
HbA1c (%)	7.14 ± 0.36	6.68 ± 0.68 ^a	7.00 ± 0.38	6.76 ± 0.65
Systolic blood pressure (mm Hg)	137.1 ± 13.6	128.6 ± 15.5 ^a	129.0 ± 16.4	127.5 ± 15.3
GPT ^c (IU/liter)	40.8 ± 26	27.2 ± 11.0 ^a	25.4 ± 18.0	24.8 ± 23
GOT ^d (IU/liter)	28.6 ± 13	22.5 ± 6.30 ^b	25.7 ± 10.0	27.0 ± 16
γGTP (IU/liter)	48.1 ± 41	35.8 ± 26.0 ^b	75.3 ± 91.0	78.3 ± 110

^a $p < 0.01$ versus 0 week of each group.

^b $p < 0.05$.

^c GPT indicates glutamic pyruvic transaminase.

^d GOT indicates glutamic oxaloacetate transaminase.



In Honor of St. Patrick's Day:

- St. Patrick's was a dry holiday in Ireland until 1970. Aside from the color green, the activity most associated with St. Patrick's Day is drinking. However, Irish law, from 1903 to 1970, declared St. Patrick's Day a religious observance for the entire country meaning that all pubs were shut down for the day. That meant no beer, not even the green kind, for public celebrants. The law was overturned in 1970, when St. Patrick's was reclassified as a national holiday - allowing the taps to flow freely once again.

Your odds of finding a four-leaf clover are: About 1 in 10,000

Medication Reconciliation Performed by Residents at the Tulalip Health Clinic

By Natasha Gorely, Pharm.D.

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According to the United States Joint Commission:

“Medication reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. It should be done at every transition of care in which new medications are ordered or existing orders are rewritten. Transitions in care include changes in setting, service, practitioner, or level of care. This process comprises five steps: (1) Develop a list of current medications; (2) Develop a list of medications to be prescribed; (3) Compare the medications on the two lists; (4) Make clinical decisions based on the comparison; and (5) Communicate the new list to appropriate caregivers and to the patient.”¹

The Joint Commission added medication reconciliation across the care continuum as a National Patient Safety Goal in 2005.²

In order to help comply with this process at the Tulalip Health Clinic, the pharmacy residents perform medication reconciliations for all patients seen at the health clinic starting with a chart review of all medications and disease states. The patient qualifies for a face to face medication reconciliation if they have 10 or more medications, they are 62 years or older, or they have a diagnosis of diabetes. Face to face medication reconciliations are also performed upon request from the providers, such as new patients or those recently discharged from the hospital. The residents have access to both the patients' electronic health record, and their pharmacy records if they fill their medications at the Tulalip Clinical Pharmacy. Matching these two systems allows the residents to provide a very accurate and updated list of the patients' medications.

For patients that meet the criteria of a face to face interaction, a resident pharmacist will see the patient immediately before the provider to assess for med list accuracy, compliance, patient reported side effects, drug interactions, and any potential therapeutic interventions to bring to the providers' attention. Diabetic patients are screened to determine if they are due for an updated A1C. If so, the resident is able to perform a point of care test via finger-stick, and report that result to the provider within 5-10 minutes. For all other patients, chart reviews encompass most of the same evaluations. Compliance is assessed by looking at their pharmacy records and checking last pick up date, if they pick up regularly, and if they have refills left. In addition, many patients see providers outside of the Tulalip Health Clinic and subsequently receive prescriptions. As residents review those prescriptions, they are added to the patients' electronic health record.

Providers frequently report that they don't really know what a patient is taking due to these “outside” prescriptions and sometimes poor compliance from the patient. This process of performing chart reviews, face to face encounters, and documentation for all patients seen at the clinic prior to their visit, enables the providers to have a more accurate picture from which they can make more informed decisions about the patients' therapy and reduce duplicate treatments and errors.

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