SCHOOL OF PHARMACY
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By The University of Washington Community & Ambulatory Pharmacy Residents

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Updated Cholesterol Guidelines Focus on Four Key Changes

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In This Issue:

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The anticipation is finally over. The long awaited update to Adult Treatment Panel (ATP III) is finally here. In November of 2013 the American College of Cardiology (ACC) and American Heart Association (AHA) released updated guidelines addressing treatment of blood cholesterol levels to reduce atherosclerotic cardiovascular disease (ASCVD) risk. The new guideline has four main significant changes.

First, the guidelines focus on 4 major statin benefit groups from whom the ASCVD risk reduction clearly outweighs the risk of adverse events. Individuals 1) with clinical ASCVD (defined as acute coronary syndromes, or a history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin) 2) primary elevations of LDL-C ≥ 190 mg/dL 3) diabetes aged 40 to 75 with LDL-C 70 to 189 mg/dL and without clinical ASCVD or 4) without clinical ASCVD or diabetes with LDL-C 70 to 189 mg/dL and estimated 10-year ASCVD risk ≥7.5%.[1]

Table 1

4 major statin benefit groups
1. Individuals with clinical ASCVD
2. Primary elevations of LDL-C ≥ 190 mg/dL
3. Diabetes aged 40 to 75 years with LDL-C 70 to 189 mg/dL and without clinical ASCVD
4. Individuals without clinical ASCVD or diabetes with LDL-C 70 to 189 mg/dL and estimated 10-year ASCVD risk ≥ 7.5%

The second major change of the updated guidelines relates to treatment goals. The Expert Panel did not find evidence to support titrating cholesterol-lowering drug therapy to achieve optimal LDL-C or non-HDL-C levels because the clinical trials were essentially fixed dose trials. There was an absence of data on titration of drug therapy to specific goals and no recommendations are made for or against specific LDL-C or non-HDL-C goals for the primary or secondary prevention of ASCVD.[1]

The third major change in the guidelines is to focus on statin intensity. The Expert Panel defines the intensity of statin therapy on the basis of the average expected LDL-C response to a specific statin and dose. "High-intensity," "moderate-intensity," and "lower-intensity" statin therapy definitions were derived from systematic reviews.[1] Classifying specific statins and doses by the percent reduction in LDL-C level is based on evidence that the reduction in ASCVD risk from statin therapy is related to the degree by which LDL-C is lowered.[1]

Table 2

High-Intensity Statin	***Moderate-Intensity Statin***	***Low-Intensity Statin***
Daily dose lowers LDL-C on average, by approximately ≥50%	***Daily dose lowers LDL-C on average, by approximately 30% to <50%***	***Daily dose lowers LDL-C on average, by <30%***
Atorvastatin 40-80 mg *Rosuvastatin 20-40 mg*	*Atorvastatin 10-20 mg* *Rosuvastatin 5-10 mg* *Simvastatin 20-40 mg* *Pravastatin 40-80 mg* *Lovastatin 40 mg* *Fluvastatin XL 80 mg* *Fluvastatin 40 mg BID* *Pitavastatin 2-4 mg*	*Simvastatin 10 mg* *Pravastatin 10-20 mg* *Lovastatin 20 mg* *Fluvastatin 20-40 mg* *Pitavastatin 1 mg*

The fourth major change in the guidelines is a recommendation to use a new Pooled Cohort Risk Assessment Equation to estimate the 10-year ASCVD risk, defined as first occurrence nonfatal and fatal MI, and nonfatal and fatal stroke, for the identification of candidates for statin therapy.[1] Table 3 shows the differences between the Framingham risk assessment tool[2] and the new Pooled Cohort Risk Assessment Tool.

Table 3

Framingham 10 year Risk Tool[2]	*Pooled Cohort Risk Assessment Tool*
Gender	*Gender*
Age	*Age*
Total Cholesterol	*Total Cholesterol*
HDL-C	*HDL-C*
SBP (on treatment Y or N)	*SBP (on treatment Y or N)*
Smoking (Y or N)	*Smoking (Y or N)*
	Race (white/other or AA)
	Diabetes (Y or N)

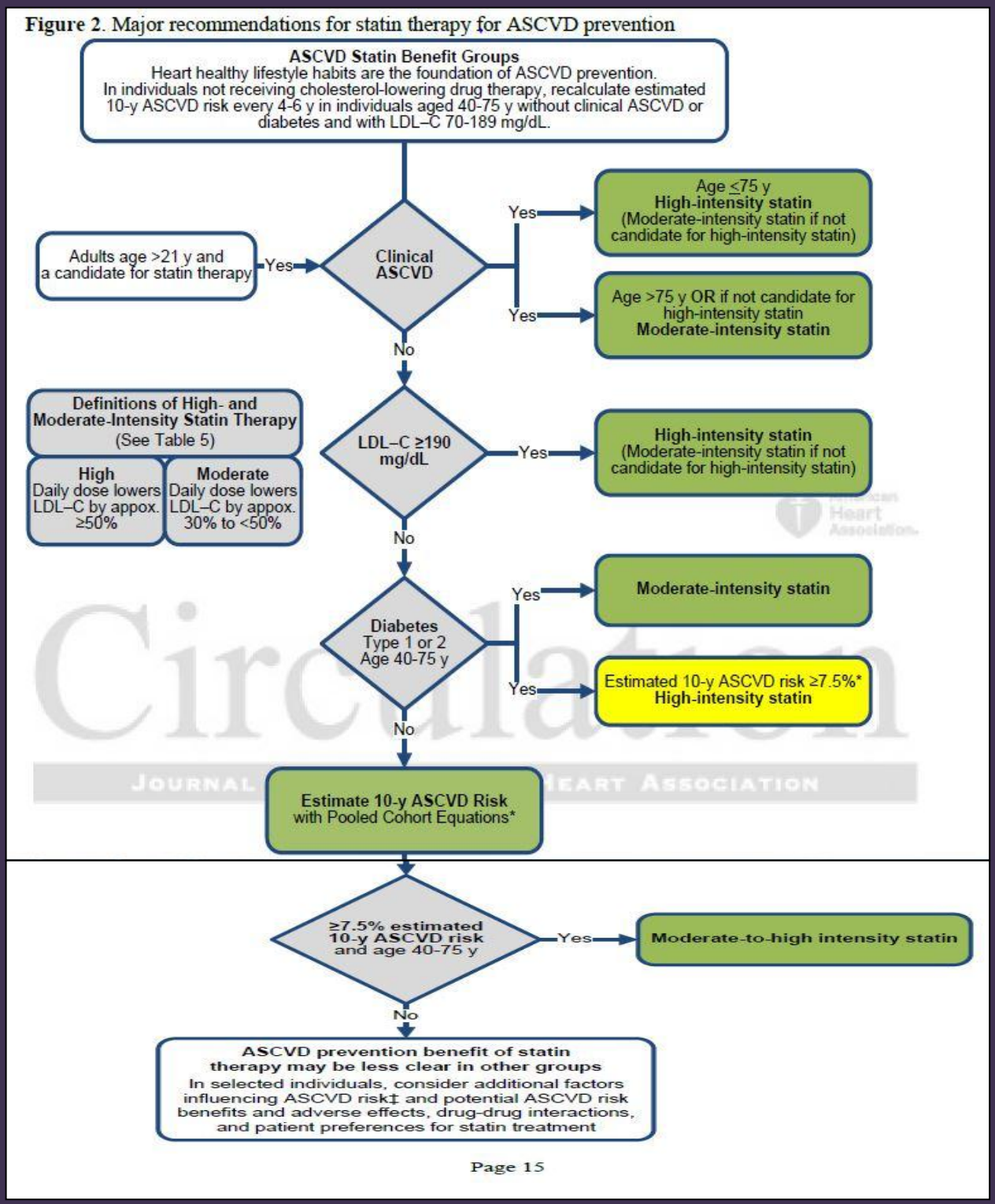
In addition to these new recommendations, lifestyle modifications such as adhering to a heart healthy diet, regular exercise, avoidance of tobacco products and maintenance of a healthy weight continue to be a critical component of health promotion and ASCVD risk reduction.[1]

Table 4 summarizes the recommendations from the guidelines in making the choice to initiate statin therapy based on the 4 statin benefit groups.

Table 4

Risk Group	***Statin***
1. Clinical ASCVD	*Age ≤ 75 year, high intensity* *Age > 75 years or if not candidate, moderate-intensity*
2. LDL ≥ 190 mg/dL	*High intensity*
3. Diabetes age 40-75 years + LDL 70-189 mg/dL	*Moderate-intensity statin or* *If estimated 10-year ASCVD risk ≥ 7.5%, high intensity*
4. ≥ 7.5% estimated 10-year ASCVD risk + age 40-75 years + LDL 70-189 mg/dL	*Moderate-to-high intensity*

Figure 2. Major recommendations for statin therapy for ASCVD prevention



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An Update: Human Genome Sequencing, Pharmacogenetics dosing, and Warfarin

Troy Biornstad, PharmD

Tulalip Clinical PHARMACY

With the recent announcement by Illumina of their latest DNA sequencer, HiSeq X, the realization of affordable personal genomics has arrived.[1] The idea that an entire human genome could be sequenced for a 1000 US dollars or less has now been realized. Prior to this innovation, sequence cost was several thousand dollars more. It is anticipated that further advances will allow for even further reductions in cost to sequence the human genome. Despite the reduced cost, the question remains: is personalized prescribing clinically relevant?

Clinical relevance of pharmacogenetic dosing will likely first be demonstrated in narrow therapeutic index medications such as warfarin. Three recent studies concerning warfarin pharmacogenetic dosing from the New England Journal of Medicine (NEJM) are conflicting.[2,3,4] In each of these studies primary endpoints included time to obtain INR 2-3 or time in therapeutic range (INR 2-3). Secondary endpoints included number of ischemic or hemorrhagic events. Combined, these three studies report no difference in safety outcomes or time to therapeutic range. However, one of the studies did find a statistical difference in time in therapeutic range favoring pharmacogenetic versus standard dosing. Despite these latest findings and a large aggregate sample size (2000 patients), the conflicting evidence suggests that more research is needed to determine the usefulness of pharmacogenetic dosing versus traditional methods.

The FDA updated warfarin labeling in 2007 and again in 2010.[5] In 2007, the labeling was updated to state that CYP2C9 and VKORC1 genotypes may be useful in determining the optimal initial dose of warfarin. In 2010, the update included a table describing recommendations for initial dosing ranges for patients with different combinations of CYP2C9 and VKORC1 genotypes (see below). Despite these labeling updates and recent studies, pharmacogenetic dosing is not currently required. However, this may change as genomic data becomes increasingly available due to rapidly decreasing sequencing costs. Costs may reach a point where insurers reimburse 100% for genomic sequencing. Physicians would then be required to implement personalized prescribing with this supplied genetic data. This paradigm shift in pharmacogenetic dosing may lead to improved outcomes in both anticoagulation and other disease states.

VKORC1 Genotype (-1639G>A, rs9923231)	*CYP2C9*1/*1*	*CYP2C9*1/*2*	*CYP2C9*1/*3*	*CYP2C9*2/*2*	*CYP2C9*2/*3*	*CYP2C9*3/*3*
GG	5-7	5-7	3-4	3-4	3-4	0.5-2
GA	5-7	3-4	3-4	3-4	0.5-2	0.5-2
AA	3-4	3-4	0.5-2	0.5-2	0.5-2	0.5-2

Summary:

- FDA updated the warfarin label in 2007 and again in 2010 to included pharmacogenetic recommendations
- Pharmacogenetic dosing is still not required
- Genetic-based algorithms are superior to the FDA table. A genetic based algorithm can be found at http://www.warfarindosing.org
- Some evidence suggests the superiority of pharmacogenetic dosing, however, current data is conflicting.
- Pharmacogenetic dosing guidance will continue to evolve as human genome sequencing costs continue to decrease

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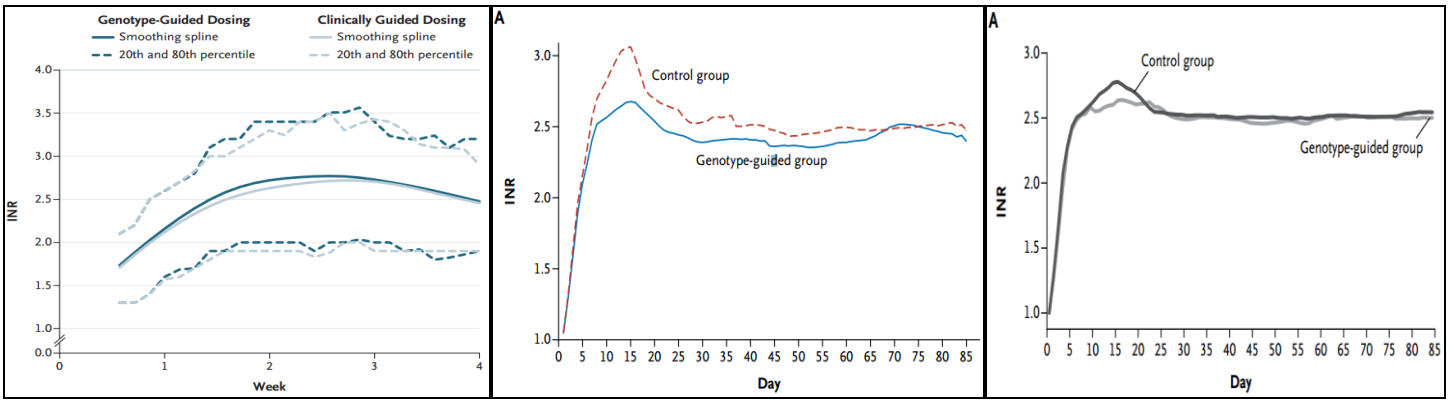
Appendix



Graphs of INR values from 3 recent studies above from left to right Reference 2 (US Study); Reference 3 (England Study); Reference 4 (The Netherlands Study).

Upcoming events

- ***APHA Annual Meeting & Exposition, Orange County Convention Center in Orlando from March 28-31, 2014***
- ***Project Enrichment Seminar with Dr. Beth Devine on March 4th 3:30-5:00PM, HSB E212***

Bartell Drugs Residency Project: Appointment Based Model

Rachel Firebaugh, PharmD, MPH

Why should medication adherence be a top priority?

The *National Council on Patient Information and Education (NCPIE)* defines medication adherence as, the extent to which patients take medications as prescribed by their healthcare providers.[1] Recent data indicates approximately one-half of Americans who take one or more medications do not take their medications as prescribed.[1] Medications are most beneficial for a patient when they are used as prescribed by their health care provider. If medications are not taken properly this can result in decreased therapeutic benefit for the patient and in some cases can result in poor management of chronic medical conditions, increased physician visits or hospitalizations, additional prescription orders, and increased overall cost of healthcare in the United States. There have been a number of studies to support the cost-effectiveness of medication adherence; for example, a study of Medicare patients found that for every 10 percent increase in adherence to a diabetes medication, total healthcare costs declined between 9 and 29 percent.[2, 3]

What is the Appointment Based Model (ABM)?

The Appointment Based Model (ABM) was originally developed in 1996 by a pharmacist in California. It was developed to determine if patients would be more likely to adhere to their medication regimen if they received all of their monthly refills at one time. This system seeks to synchronize all of a patient's medications to being filled on one day each month. Additionally, when patients come in for the monthly appointment day to pick up their medications they have a chance to talk with the pharmacist. The ABM system is essentially a patient care model designed to simplify the refill process for patients and to improve medication adherence with the aim of improving health outcomes for those enrolled.

Why do we want to learn more about ABM at Bartell Drugs?

Currently, the ABM program at Bartell Drugs is a manual process that is primarily paper-based. In the near future many of our pharmacies will gradually be moving to an automated system, called *Optimum Medsync*. This is a timely transition because one of the steps of NCPIE's *Adherence Action Agenda* advocates for accelerated adoption of new health information technologies that promote medication adherence.[1] The aim is that this new automated system will improve the patient care experience, simplify ABM integration into the pharmacy work flow, and help to facilitate pharmacists providing the highest quality of care.

What is the purpose of this research?

The aim of this research is to gather pharmacist and pharmacy technician perceptions in order to understand the benefits and potential opportunities for improvement with both the manual and automated process for managing the Appointment Based Model (ABM). The data from this study will allow us to compare the manual and automated process for managing ABM in order to give important insight into how ABM should be accomplished in the future. These findings will be beneficial to pharmacists, technicians, and other pharmacy staff members at Bartell Drugs and the larger pharmacy community as we work together to improve the quality, efficiency, and safety of the care we provide to our patients.

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Tulalip Clinical PHARMACY

Diabetes Education:

Prediabetes Handout

Troy Biornstad, PharmD

With the implementation of Obamacare there has been increased emphasis on preventative care. As the diabetic epidemic continues, it is likewise important that preventative care measures are in place to slow this trend. The likelihood that a patient is diagnosed with diabetes is increased by two independent risk factors: elevated A1C and increased body mass index (BMI). However, this knowledge is not commonly known in the general population. At Tulalip, diabetes is also prevalent and diabetes literacy is limited. To confront these issues a handout has been developed to educate patients and potentially halt progression of prediabetes to diabetes.

What is Diabetes?

There are two types of diabetes. Type 1 typically begins at a young age and occurs when individuals have low levels of insulin. Low levels of insulin will result in high levels of glucose or sugar in your blood. Elevated levels of glucose for extended periods of time may result in early destruction of major body organs such as your kidneys and liver. In addition, you may have poor vision which may progress to complete vision loss.

Type 2 diabetes typically occurs later in life and is due to high levels of glucose in your blood. In type 2, glucose levels are elevated due to insulin resistance. Your body does not respond to insulin properly resulting in elevated glucose levels. Long-term problems are similar to type 1 and include early destruction of your kidneys, liver, and eyes.

Those who are type 2, or at risk to develop type 2, may be able to reverse these high sugar levels through diet and exercise. For those who are able to decrease their sugar levels to a normal level, the likelihood of then getting diabetes is significantly reduced. You can do it, we are here to help

Will I get diabetes?

Getting diabetes becomes much more likely if you are overweight and/or have an elevated A1C.

BMI is a measure of determining obesity.

Normal: less than 25

Overweight: 25-29.9, 2x the risk of getting diabetes

Obese: more than 30, 5x the risk of getting diabetes

The A1C is a 3 month average of your blood sugar.

Normal A1C: 5.6% or less

Prediabetic range: 5.7-6.0%

If A1C 5.7-5.9%, 2x the risk of getting diabetes

If A1C 6.0-6.4%, 5x the risk of getting diabetes

How can I reverse prediabetes and diabetes?

You can to reverse prediabetes or diabetes by losing weight and being more active.

- Weight loss of 5-10% of your total weight can make a big difference. For example, if you weigh 200 pounds, your goal would be to lose 10 to 20 pounds.
- Increasing your daily physical activity, example:
  - Walking for at least 30 minutes a day, 5 days a week
  - Taking more steps throughout the day by parking further from the store, or walking around the house during commercials.
- Adjust your diet
- Eat a portion of fruits and vegetables every day. The quantity of fruits and vegetables is less important. Try and include a portion at each meal and replacing sugary/fatty snacks with healthy alternatives
- Reduce portion sizes
- Replace sugary or sweet beverages with water
- Take vitamin C and vitamin D supplements

We are here to help.

Please do not hesitate to call and set up an appointment for further consultation.

Diabetes Team at Tulalip Health Clinic
360-716-5745

In Honor of St. Valentine's day on February 14th here are some fun facts about chocolate:

- More than 36 million heart shaped boxes of chocolate are sold each year

- Regular chocolate eaters welcome a host of benefits for their health including lower blood pressure, lower LDL and lower risk of heart disease

- Dark chocolate is rich in fiber and can help keep you full

- Theobromine, an ingredient in chocolate, seems to reduce activity of the vagus nerve (part of the brain that triggers coughs)

Source: The Huffington Post

Bartell Drugs Partners with Group Health to Open CareClinic

Rachel Firebaugh, PharmD, MPH

Recently Bartell Drugs has entered into an innovative partnership with Group Health to open what is called CareClinic—a new kind of in-store walk-in clinic. CareClinic offers a very convenient, on-demand care for common minor illnesses, such as: cold and flu, sinus infections, allergies, minor injuries (burns, rashes, and cuts), pinkeye, sore throat, headaches, head lice, sprains and strains, bronchitis, ear infections, urinary tract infections, and intestinal infections. In addition, a limited number of lab procedures and a selection of vaccines and immunizations will be offered. The new CareClinic is open to everyone, not just Group Health members.

Currently these are the locations:

- #31 University Village – 2700 NE University Village St., Seattle, WA 98105. (OPEN NOW)
- #59 Crossroads – 653 156th Ave NE, Bellevue, WA 98007 (OPEN NOW)
- #2 Ballard – 1500 NW Market Street, Suite 101, Seattle, WA 98107-5211 (OPENING EARLY MARCH)

Bartell's is excited to embark on this new relationship with Group Health in order to care for our Northwest neighbors!

CareClinic
Group Health at Bartell Drugs

Pharmacy Residents Expand Clinical Services to Urgent Care

Kara Springer, PharmD

The role of the pharmacist is constantly changing. New opportunities for Pharmacists to become integrated into the patient care team are now more readily available. Pharmacy Residents at Providence Pharmacy Monroe are now providing clinical pharmacy services and resources directly to urgent care providers. One half day a week is spent serving as the pharmacist in this setting. The residents answer drug information questions for providers, assist in dosing specific medications such as antibiotics and perform medication reviews for select patients.

There also are opportunities to go into the room with the physician and work with them triaging the patient and answering any medication related questions from the patient. This new service has been very well received and all feedback has been very positive from the providers.

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Let's Take Action: Pharmacists Can Be Instrumental in Helping Patients Quit Smoking

Rachel Firebaugh, PharmD, MPH

Why should pharmacists get involved now?

In 2014, the Surgeon General released a new report, "The Health Consequences of Smoking – 50 Years of Progress". Therefore, it is timely for pharmacists to refocus on how we might encourage, motivate, and become a resource for patients as they attempt to quit smoking in the new year.

This report outlines the best available evidence regarding the health consequences of smoking and the involuntary exposure to tobacco smoke. It also challenges health care providers to take action in order to reduce tobacco use and the continuing burden of disease and death caused by smoking. Kathleen Sebelius, Secretary of Health and Human Services, warns "***if we continue on our current trajectory, 5.6 million children alive today younger than 18 years of age will die prematurely as a result of smoking***."[1]

What are the current tobacco statistics?

- The prevalence of current cigarette smoking among adults has declined from 42% in 1965 to 18% in 2012, but 42 million Americans still smoke[1]
- Very large disparities in tobacco use remain across racial/ethnic groups and between groups defined by educational level, socioeconomic status, and region.[1]
- Declines in the prevalence of smoking among adults (18 years of age and older) have slowed in recent years.[1]
- The percentage of U.S. middle and high school students who use electronic cigarettes, or e-cigarettes, more than doubled from 2011 to 2012[1]
- Every day, 45 youths in Washington become life-long smokers[2]

What can we do for our patients?

The "5 A's"[3,4]

ASK about tobacco use. Identify and document tobacco use status for every patient at every clinic visit or encounter in the pharmacy.

ADVISE to quit. In a clear and personalized manner, encourage every tobacco user to quit.

ASSESS willingness to make a quit attempt. Is the tobacco user ready to attempt to quit at this time?

ASSIST in quit attempt. For the patient willing to make a quit attempt, offer medication and provide or refer for counseling or additional treatment. For example, you might refer your patient to the *Washington State Tobacco Quitline*

ARRANGE follow-up. For the patient willing to make a quit attempt, arrange for follow-up contacts, beginning within the first week after the quit date.

What medications should we recommend?

The first-line medications (5 nicotine and 2 non-nicotine) that increase long-term smoking abstinence are: bupropion SR, nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, nicotine patch, and varenicline.[3]

As you can see from the chart below, the medications are similar in their effectiveness. Therefore, select a medication that is best considering the side effect profile of the medication, patient specific factors, and what has been tried in the past.

Meta-analysis (2008): Effectiveness and abstinence rates for various medications and medication combinations compared to placebo at 6-months (n=83 studies)[3]

Medication	Number of arms	Estimated abstinence rate (95% C.I.)
Placebo	80	13.8
Monotherapies		
Varenicline (2m/day)	5	33.2 (28.0 – 37.9)
Nicotine Nasal Spray	4	26.7 (21.5-32.7)
High-Dose Nicotine Patch (>25 mg) (These included both standard or long-term duration)	4	26.5 (21.3-32.5)
Long-Term Nicotine Gum (> 14 weeks)	6	26.1 (19.7-33.6)
Varenicline (1mg/day)	3	25.4 (19.6-32.2)
Nicotine Inhaler	6	24.8 (19.1-31.6)
Clonidine	3	25.0 (15.7-37.3)
Bupropion SR	26	24.2 (22.2 – 26.4)
Nicotine Patch (6-14 weeks)	32	23.4 (21.3-25.8)
Long-Term Nicotine Patch (>14 weeks)	10	23.7 (21.0-26.6)
Nortriptyline	5	22.5 (16.8-29.4)
Nicotine Gum (6-14 weeks)	15	19.0 (16.5-21.9)
Combination Therapies		
Patch (long-term; > 14 weeks) + ad lib NRT (gum or spray)	3	36.5 (28.6-45.3)
Patch + Bupropion SR	3	28.9 (23.5-35.1)
Patch + Nortriptyline	2	27.3 (17.2-40.4)
Patch + Inhaler	2	25.8 (17.4-36.5)
Patch + Second generation antidepressants (paroxetine, venlafaxine)	3	24.3 (16.1 -35.0)
Selective Serotonin Re-uptake Inhibitors (SSRIs)	3	13.7 (10.2-18.0)
Naltrexone	2	7.3 (3.1-16.2)

What other resources can we recommend to our patients?

- **Washington Tobacco Quitline**
  1-800-QUIT-NOW (1-800-784-8669)
  The quitline provides tailored telephone-based support, self-help material, and medications (when available and appropriate).[2] Trained quit coaches work one-on-one with patients to identify barriers to quitting, overcome urges and create a quit plan. Anyone who lives in Washington State is eligible for at least one call. Patients may qualify for additional calls and gum or patches if they are 18 or older, are on Medicaid, or have an insurance plan which covers the quitline tobacco cessation program.
  http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/TobaccoRelated/QuittingTobacco.aspx

- **National Cancer Institute**
  1-877-44U-QUIT (1-877-448-7848)
  Printed materials on smoking and health, counseling with cessation specialist
  http://www.cancer.gov/cancertopics/tobacco/smoking

- **American Cancer Society - *Quit For Life***
  1-866-QUIT-4-LIFE (1-866-784-8454)
  Phone counseling, information packet, support line available, and text messaging services that can connect to web tool and quit coach
  https://www.quitnow.net/Program/About/

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