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Dr. Welch was born and raised in Atlanta. He received his undergraduate degree at Princeton University and then came home to Emory University for Medical School. He did his internship and residency at Emory, Grady Hospital and affiliated hospitals. He did a chief residency at Crawford Long Hospital before doing a Fellowship in Endocrinology at Emory where he did research in the development of a method to measure insulin resistance in Type 2 Diabetes patients.

Mary Ransbotham is a Registered Nurse with more than 25 years of experience specializing in diabetes self management education and management. As a Certified Diabetes Educator, Mary has driven program development and implementation of many educational offerings in the field of diabetes for the community, hospital patients and staff. She is the manager of the Piedmont Atlanta Hospital Diabetes Resource Center, where she manages inpatient and outpatient diabetes services in a 500+ bed urban hospital. She also serves as team leader of the Diabetes Clinical Orders Team, which is responsible for identifying and responding to hospital needs and developing evidence-based standing orders, pathways and protocols for inpatient diabetes care. She has served on the American Diabetes Association Leadership Council, Atlanta Region and numerous other local and regional diabetes conference planning boards, and leadership roles in the Greater Atlanta Diabetes Association of Diabetes Educators.

Dr. Ownby joined Atlanta Diabetes Associates in 2012. He is a Tennessee native and graduated Magna Cum Laude from Lee University. He graduated medical school from the University of Tennessee and completed his Internal Medicine residency at the University of Alabama Birmingham. He then moved to Atlanta and completed his Endocrinology Fellowship at Emory University. Dr. Ownby practices general Endocrinology and is involved in diabetes research.

Dr. Bode is a diabetes specialist with Atlanta Diabetes Associates in Atlanta, Georgia, and is currently on the faculty of Emory University, as a Clinical Associate Professor in the Department of Medicine. He received his medical degree from Emory University School of Medicine and completed an internship and residency in internal medicine at Emory University Affiliated Hospitals and a fellowship in diabetes with Paul C. Davidson, MD.

He has a strong affinity for working with children and young adults with diabetes and is considered one of the leading experts in the world on insulin delivery and glucose sensing. He is very active in clinical research on new diabetes products including pharmacological agents to prevent diabetes and control glucose and new insulin and glucose sensors. He is a prolific writer with over 200 articles and books in the field of diabetes discussing current and future therapies for people with diabetes. He also sits on the advisory board of many of the leading companies in the field of diabetes care and research including the Juvenile Diabetes Research Foundation, the American Diabetes Association (ADA), and the Georgia diabetes camps.
Diabetes is not going away. As America becomes more sedentary and more overweight, and as developing countries “westernize” their diets, the incidence of diabetes – especially Type II – is skyrocketing.

While the incidence of the disease is increasing at an alarming rate, we are continuing to advance our knowledge into the pathophysiology of both Type I and Type II diabetes, leading to new forms of therapy. Our technology to detect and monitor these diseases has advanced as well. Hopefully our advances in pathophysiology, treatment and technology will both prevent future cases of diabetes as well as make the lives of those who have diabetes healthier and happier.

Right now the incidence of diabetes in the U.S. is about one in 10, and there are dire predictions that unless we do something to change our course, one in three Americans
may have diabetes by the year 2050. Diabetes and obesity are closely linked, so as the incidence of obesity goes up the incidence of diabetes goes up.

Unfortunately, this starts at an early age. When I was growing up in the 1960s, the overweight child was the exception. Now in America’s elementary school, every third desk is occupied by an overweight child. Today, in children under the age of 12 presenting with diabetes, the likelihood that it will be Type II Diabetes instead of Type I is 45 percent.

To combat these rising rates, we must educate both parents and children about proper nutrition and exercise. These skills are just as important as any other life skills to ensure that the life expectancy of future generations is just as high as or higher than it is right now.

Due to the efforts of such great researchers like Dr. Ralph De Fronzo, our knowledge of the pathophysiology of Type II diabetes, the most prevalent form, has increased dramatically. Researchers have been peeling away the layers of the onion to get to the core defects of the disease so that we develop specific treatments to target each of these core defects.

In the early 1990s, Dr. De Fronzo outlined the triumvirate of insulin resistance, impaired insulin secretion and increased hepatic glucose output as the basic pathophysiology behind Type II diabetes. However, new research has led Dr. De Fronzo to expand from the triumvirate to the ominous octet.

This means eight separate areas can be targeted therapy. 1) The pancreatic beta cell because of decreased insulin secretion. 2) The pancreatic alpha cell because increased glucagon secretion. 3) Incretin hormones because Type II diabetics are to some degree both incretin deficient and incretin resistant. 4) The kidney because it is responsible for reabsorption of glucose from the urine. 5) The sympathetic nervous system because increased sympathetic tone increases blood glucose. 6) The muscles because insulin resistance decreases glucose uptake in the muscles. 7) The liver because of increased hepatic glucose output and lastly 8) Adipose tissue because increased lipolysis is toxic to the beta cell and increases insulin resistance.

The ominous octet is just our latest stopping point in understanding Type II diabetes, but our understanding of this disease is ever widening.

When I started practice more than 25 years ago, human insulin had just recently become widely commercially available and the sulfonylureas were the only class of oral agents available in the U.S. Now there are five new analog

Right now the incidence of diabetes in the U.S. is about one in 10, and there are dire predictions that unless we do something to change our course, one in three Americans may have diabetes by the year 2050.
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insulins, three rapid acting, two long acting and an inhaled form of human insulin on the way.

The classes of oral agents have expanded from one to nine. In addition to the sulfonylureas, we now have biguanides like metformin that decrease hepatic glucose output, thiazolidinedione like pioglitazone that increase insulin sensitivity in muscle and fat, nateglinides that increase insulin secretion, alpha-glucosidase inhibitors that block carbohydrate absorption in the gut, GLP-1 agonists that give pharmacologic levels of activation of the incretin GLP-1 receptors, DPP-4 inhibitors that decrease the enzymatic degradation of GLP-1, dopamine agonists that decrease sympathetic tone, and the latest class of new anti-diabetic therapy, the SGLT2 transport blockers that decrease the kidney’s ability to reabsorb glucose. Each one of these therapies targets a specific arm of Dr. De Fronzo’s ominous octet.

In the 1980s, home glucose monitors were the size of cassette tape recorders, required a large hanging drop of blood to produce a glucose reading and the test time was two minutes. Insulin pumps were in their infancy, with Auto-Syringes, nicknamed the “blue brick” due to its large size and weight, that could give only a single basal insulin rate.

Now glucose monitors fit in the palm of your hand and require less than 0.5 microliters of blood. There are even smart monitors that can spot trends in blood glucose and can be programmed to calculate insulin doses. Insulin pumps are smaller and smarter. Basal insulin requirements can now be programmed hourly. The pumps can be programmed to calculate mealtime insulin when the patient feeds in their glucose and carbohydrate data.

There are now continuous glucose sensing devices that give a glucose reading every five minutes in real time to help patients on insulin pumps and multiple daily insulin injections avoid lows and combat highs to achieve better control.

The incidence of diabetes is advancing, and we are trying to keep pace with advancing our knowledge, technology and treatment strategies. However, all of these advancements will fall short of their potential unless we have educated patients. Education is still the cornerstone of diabetic therapy because the more our patients know about what diabetes is and the more they know about how to treat it, the more adherent our patients will be. Our most sophisticated therapies will be ineffective unless we give our patients the tools to implement healthy lifestyles that incorporate diet, weight loss and exercise.

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Diabetes is a chronic, progressive disease that requires ongoing complex medical management, and the physician’s role extends well beyond glycemic management. A large body of evidence exists to support a range of interventions to improve diabetes outcomes, including Diabetes Education. Diabetes Education includes Diabetes Self-Management Education (DSME), Diabetes Self-Management Support (DSMS) and Medical Nutrition Therapy (MNT).

According to the American Diabetes Association’s (ADA) Clinical Practice Recommendations, “DSME is an essential...
element of diabetes care.” This fact has been recognized for more than 15 years by the Centers for Medicare and Medicaid Services as evidenced by their DSME reimbursement structure. Medicare reimburses for 10 hours of DSME and three hours of MNT during the first year of diagnosis or the first year under Medicare, if the education is delivered by an education center recognized by the ADA as meeting the National Standards for Diabetes Patient Education Programs.

**Diabetes Self-Management Education (DSME)**

The mission of diabetes self-management education and support (DSME/DSMS) and Medical Nutrition Therapy (MNT) is to help individuals with diabetes acquire the knowledge, skills, attitudes and behaviors needed to optimize both their self-management skills and their quality of life. As the field of diabetes education has developed over the last several decades, the profession has evolved from skill based to helping people with diabetes (PWD) gain the knowledge of behavior change that will help them live with an overall sense of improved well-being. Diabetes Education now includes knowledge and skill acquisition as well as problem-solving, goal setting and coping skills.

Preferably, education will be provided by Certified Diabetes Educators (CDEs). CDEs are experientially and educationally prepared to provide education, support and guidance through the healthcare system.

Comprehensive self-management education is best delivered as a combination of group classes and individual counseling. Groups provide support, socialization, the opportunity to learn from others and to garner support from their peers. Because diabetes management is integral to daily life, it is in some ways a family disease. Family members and significant others are encouraged to participate in all aspect of diabetes education.

In 2014, a “one-size fits all” approach to diabetes education is recognized as ineffective and will likely lead to a discouraged, unengaged patient. There are core elements of education, but each topic will be modified to the individual. Each patient must recognize the importance and relevance to their own life to improve the likelihood of adherence.

Below are the seven components of diabetes self-management as defined by the American Association of Diabetes Educators.

1. Healthy Eating
2. Being Active
3. Monitoring
4. Taking Medications
5. Problem Solving
6. Healthy Coping
7. Reducing Risk

Each of these topics is addressed with the individual at some point in the education process. How and when they are addressed is based on a thorough assessment by the CDE.

Oftentimes, in the outpatient setting, it is more appropriate to begin with problem solving or healthy coping to first prepare the patient for the unavoidable lifestyle changes that lie ahead. Knowledge of healthy eating and being active is of little use to the patient who is unable or unwilling to adapt his/her current lifestyle to incorporate this new knowledge. If a patient is newly diagnosed and insulin therapy is being initiated, monitoring and medication rise to the top of the list for immediate education, even before the patient has had time to develop any coping skills for dealing with diabetes.

**Diabetes Self-Management Support**

DSME is effective and necessary for initial and ongoing diabetes care, but it is taking place in a healthcare setting. Actual self-management takes place in the patient’s home and community. Initial improvements in metabolic control have been found to diminish after about six months.

According to the National Standards for Diabetes Self-Management Education and Support, it is incumbent upon the diabetes educator to help the patient develop a plan...
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for ongoing support. There are many types of support (behavioral, educational, psychological, etc.) and a variety of resources available.

The patient is likely to find support through membership in the American Diabetes Association, ongoing participation in follow-up programs, online communities and local community events as well as from their PCP.

**Medical Nutrition Therapy**

Nutrition therapy recommendations for people with diabetes have changed dramatically over the last 20 years. Gone are the days of confusing exchange lists, the “one size fits all” approach and the elimination of entire food groups. Today’s nutrition focuses on moving patients from a place of unhealthy eating to healthy eating. Meal planning takes into account the individuals’ metabolic goals, current treatment plan, likes and dislikes, their usual eating patterns, comorbidities, ethnicity, literacy and numeracy, income, support system, availability of healthy food and willingness to change. Based on the individual’s need, a number of approaches may by be used.

According to the latest Nutrition Therapy Guidelines published in 2013, the goal of MNT is “to promote and support healthful eating patterns, emphasizing a variety of nutrient dense foods in appropriate portion size, in order to improve overall health. …”

**Highlights of the Guidelines**

- There is no one meal plan or eating pattern that works universally for all people living with diabetes, nor is there an optimal mix of macronutrients.
- A variety of eating patterns are acceptable for the management of diabetes.
- Evidence is inconclusive for an ideal amount of carbohydrate intake.
- For people with DM and diabetic kidney disease (either micro or macroalbuminuria), reducing the amount of protein below usual intake is not recommended because it doesn’t alter glycemic measure, cardiovascular risk or the course of GFR decline.

The person living with diabetes must make multiple decisions each day that affect their diabetes management and consequently, their lives. These decisions are difficult even with DSME; without it, these uninformed decisions are likely to be far less than optimal.

Multiple studies have found that DSME is associated with improved diabetes knowledge, self-care behaviors, clinical outcomes and quality of life. In spite of its proven success, less than 50 percent of people living with diabetes have ever received any formal diabetes education. Findings from a study published in 2009 assessing the value of diabetes education indicate that diabetes education is associated with increased use of primary and preventive services and lower use of acute, inpatient hospital services.

Diabetes Education is associated with higher compliance rates for nearly all Healthcare Effectiveness Data and Information Set (HEDIS) measures. Conclusions reached by the studies are that the collaboration between diabetes educators and physicians yield positive clinical quality and cost savings. The cost savings are entirely related to reduced inpatient costs. Conversely, outpatient costs are higher due to increased utilization of primary care and pharmacy services. Over time, however, patients who use diabetes education services are more likely to receive recommended care and have lower average costs and better clinical outcomes.

To locate a Recognized Diabetes Education program near you, consult the American Diabetes Association’s website at www.diabetes.org.

**References**

Elevated glucose in the hospital is very common, occurring in more than 38 percent of patients. The presence of hyperglycemia has been shown to increase morbidity and mortality as well as total cost of care.1,2

Over one third of these patients have newly discovered hyperglycemia and are confirmed upon testing as having pre-existing diabetes.1 Studies have shown that patients with unrecognized diabetes have three times greater mortality and morbidity than those with recognized diabetes.1 If diabetes is not addressed during the hospital stay, in addition to morbidity and mortality being increased, readmission rates are as high as 31 percent in this population.3

Studies to obtain near normal glucose in the hospital environment have had mixed results, often due to unacceptable hypoglycemia (BG <40 mg/dL), which in itself increases mortality.4,5,6 When hypoglycemia is avoided, recent studies have shown very low rates in morbidity or mortality with a reduction in total cost of care when glucose is controlled in the 100 to 140 mg/dL range compared to 140 to 180 mg/dL range.7,8

Based on the above facts, it is essential for all hospitals to have protocols to identify all patients with hyperglycemia, to treat patients safely to near normal glucose without hypoglycemia, and to discharge the patient with a case-specific plan to manage their glucose in a near normal range until seen by their primary care team.

There are steps a hospital or hospital system should do to minimize the impact of hyperglycemia in the hospital. The majority of these steps have been implemented at the Piedmont Hospital, Atlanta campus.

Identify Patients with Hyperglycemia

1 Screen all high-risk patients with a fingerstick point-of-care glucose (POC) measurement upon admission to the ICU or hospital floor. High risk is defined as patients prone to diabetes or hyperglycemia, which include all patients who are elderly, are obese, have an infection, have cardiovascular disease, are in the ICU, are on steroids or have a known family history of diabetes.

2 If glucose is above 140 mg/dL, begin fingerstick POC testing AC TID and HS. If glucose is less than 140 mg/dL upon repeat testing, one can stop testing. If glucose is greater than 140 mg/dL or in all patients with known diabetes, draw an A1C and implement correction dose insulin with rapid-acting insulin (lispro, aspart or glulisine) for any glucose above 140 mg/dL. The formula we use is (BG-100)/correction factor equals units of rapid-acting insulin. The correction factor (CF) is often 40 to start but can be determined by two formulas: CF = 3000/weight in KG or CF = 1700/total daily dose of insulin.

Treatment of Hyperglycemia

1 If the patient’s pre-existing diabetes and glucose is controlled at home on basal bolus insulin, one can continue current insulin regimen and adjust accordingly to keep BG in a safe range (70 to 140 pre-meal and less than 180 post-meal). Always give the basal dose and correction dose but hold the meal dose if not eating. If patient is on pre-mixed insulin, it is best to transition them to basal bolus therapy listed below to avoid hypoglycemia.
If the patient is newly diagnosed with diabetes or pre-existing diabetes with glucoses >180 mg/dl, one must start either SC or IV insulin therapy depending on whether the patient can eat or how high their glucose is.

If the patient is able to eat, not critically ill and glucose is less than 300 mg/dL, one can start weight-based insulin on the following formula: weight in KG times 0.5 (or times 0.3 in renal impaired or age >72 years old) equals the amount of total daily insulin (TDD). The basal dose (glargine or detemir) is 50 percent of the TDD given at bedtime. The meal dose (rapid-acting insulin) is 50 percent of the TDD divided by three given in proportion to the food (carbs) consumed at each meal.

If half the meal is eaten, give one half the meal dose. A correction dose of rapid acting insulin is given for any BG > 140 mg/dL. The correction dose is BG-100/CF where CF is calculated by 1700/TDD. POC BG testing should be done AC TID, HS and 0300.

As stated above, always give the basal dose and correction dose but hold the meal dose if not eating. One must adjust the individual basal and bolus doses to be in a safe and acceptable glucose range, ideally 70 to 140 mg/dL pre-meal, but higher targets may be acceptable (80 to 180 mg/dL). All oral agents should be stopped, especially sulfonylureas.

If the patient is critically ill, unable to eat or has a glucose >300 mg/dL, one should start IV insulin per hospital protocol. This is best done using a computerized system such as Glucommander to avoid any hypoglycemia, obtain near normal glycemia in a reasonable time (<6 hours) as well as simplifying the workload on the nursing staff.

The formula used in the Glucommander is (BG-60) x a multiplier equals units of IV regular insulin given every hour. The starting multiplier is 0.02 for all patients except in post-op CV patients we recommend a starting multiplier of 0.06.

POC glucose testing is done every hour till stable then every two hours. The computerized system adjusts the multiplier and tells the RN when to check the glucose and does all the calculations for the RN to get the glucose in a pre-specified glucose target range.

At Piedmont, we use 100 to 140 mg/dL for all patients except CV surgery patients, for which we use 90 to 120 mg/dL. It is recommended to have dextrose containing IVFs; at Piedmont we use D10 at 50 ml/hr or D5 at 100 ml/hr. Potassium levels should be monitored and adjusted at least daily and more often if out of range. Patients should not eat any calories while on IV insulin unless a meal dose is given to cover the carbs of that meal.

Elevated glucose in the hospital is very common, occurring in more than 38 percent of patients.
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up and down by 20 percent to keep the glucose in an acceptable target range (80 to 160 mg/dL). If enteral feedings are temporarily stopped, one should start D10 at 50 ml/hr and hold the basal dose till enteral feedings are resumed.

If transitioning to TPN, one should add 80 percent of the TDD determined by the IV insulin requirement to the TPN and adjust daily to keep the glucose in acceptable range. If the patient has not been on IV insulin, one can add one unit of regular insulin for every 10 grams of dextrose in the TPN bag. Correction dose is given every four hours, and once stable every six hours for any BG >140 mg/dL.

Treatment of Hypoglycemia

1 All hospitals must have a hypoglycemia protocol. If glucose is <70 mg/dL and patient is conscious, one should treat with 15 grams of oral glucose and recheck in 15 minutes and retreat again as needed. If unable to swallow give IV dextrose using formula ml of D50 equals 100 minus the BG multiplied by 0.4 or give ½ amp of D50 IV push.

2 Prevention of hypoglycemia is crucial by using the above formulas and adjusting insulin by 20 percent for any BG <80 mg/dL that was caused by that insulin. Also, giving insulin post meal in proportion to the food consumed also minimizes hypoglycemia. In addition, having a dedicated hyperglycemic team and using computerized IV and SC dosing system prevents most hypoglycemia. Raising glycemic targets higher (80 to 160 mg/dL or 100 to 160 mg/dL) in patients prone to hypoglycemia such as elderly or renal impaired is another option.

Discharge Planning and Recommendations

1 Discharge planning is best started upon admission by screening and recognizing unrecognized diabetes or poorly controlled. If A1C is at goal upon admission without hypoglycemia, one can return to their prior pre-admission diabetes treatment. If A1C is not at goal, one must discharge the patient on a treatment plan that will keep their glucose at goal till seen by their primary care team.

If A1C is above 8 percent, one should recommend full basal bolus therapy upon discharge for most patients. If A1C is above 6.5 percent but less than 8 percent, many patients can be controlled on oral hypoglycemic agents such as metformin and/or DPP-4 inhibitors. If needed, the patient can continue to use correction dose insulin as needed or add basal insulin to metformin with or without incretin therapy. Sulfonylurea use is discouraged due to high risk of hypoglycemia, especially in the elderly and renal impaired patient.

2 All patients new to diabetes should be discharged home with a glucose monitor and have instructions when to see their primary care team and where to receive further self-management training and education about their diabetes.

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Prevalence of type 2 diabetes is increasing rapidly and is commonly diagnosed and treated in the primary care setting. Multiple medicines for the treatment of diabetes have been added to the market in a relatively short period of time, and this may cause hesitancy or confusion in choosing the optimal medicine for a patient.

Some physicians rely on tried and true medicines such as metformin or glyburide, but is this wise? Some may wonder when to start insulin and if it is ever appropriate to start insulin before initiating oral medicines.

The 2013 Comprehensive AACE Diabetes Management Algorithm is a useful guide for primary care physicians on these matters.

First, glycemic goal should be determined. In general, the A1c target should be $\leq 6.5$ in patients who do not have concurrent illness such as coronary disease, advanced age or End Stage Renal Disease (ESRD), as these patients are at high risk for hypoglycemia with aggressive therapy. Logically, tight blood sugar control is preferred, but data from the ACCORD trial indicates that patients who develop hypoglycemia, especially in the setting of hypoglycemia unawareness, have a higher mortality. Thus an otherwise healthy 45 year old should have a goal A1c $\leq 6.5$, but a 75 year old with coronary disease and deconditioning from a recent stroke who is certainly a fall risk should be relegated to an A1c $\geq 6.5$. For this patient, I would suggest a more reasonable target of 7.0-8.0 as long as hypoglycemic events can be avoided.

Once a glycemic goal is in mind, the next step is to choose
the medicine that will be the best fit for the individual patient. If the initial A1c is \( \leq 7.5 \), monotherapy will likely get the patient to a goal blood sugar. Metformin is inexpensive and remains the first-line medicine of choice for me as long as the patient does not have contraindications.

In addition to a decreased glomerular filtration rate (GFR), I would also avoid metformin use for patients who require oxygen therapy, as this population is at high risk for lactic acidosis. If nausea, vomiting or diarrhea occur with metformin, a DPP-4 can be initiated as monotherapy. If a patient wishes to pursue weight loss, a GLP-1 is a reasonable monotherapy, as many patients are willing to use an injectable once they learn that it is not insulin and can lead to weight loss and appetite suppression.

A slightly overweight to normal weight individual may have Maturity Onset Diabetes of the Young (MODY) and likely will not have much benefit from a sensitizer or a secretagogue oral agent. Therefore a SGLT-2 inhibitor, which will eliminate blood glucose via the urine, can be utilized for this type of patient. SGLT-2 medicines are listed to be used with caution as they are a newer medicine on the market, but as post-marketing data continue to show their safety, I expect that they will be shuffled up to be used sooner in future algorithms.

There is a warning of hyperkalemia with the SGLT-2 canagliflozin (Invokana), but patients who developed hyperkalemia during clinical trials were also taking a combination of medicines such as ace inhibitors, arbs and spironolactone, and these medicines were the likely culprit for hyperkalemia. I rarely use alpha-glucosidases inhibitors, given the side effect of gas and bloating and lack of efficacy. Sulfonylureas should be avoided as monotherapy given the risk of hypoglycemia, especially in those who may be prone to hypoglycemia unawareness. I generally shy away from TZD monotherapy as well given the potential for weight gain. If the patient is not at goal at the three-month follow-up after the initiation of monotherapy, dual therapy, at the minimum, should be initiated.

If a patient has an initial A1c that is \( \geq 7.5 \), monotherapy is likely to fail as a single oral agent will usually only lower the A1c by 1.0. I generally try to use a combo medicine to increase compliance for my patients who fall into this category and often use a combination of metformin and a DPP-4 if there are no contraindications. Another reasonable option is metformin plus colesevelam for a patient with an LDL that is not quite at goal, as the colesevelam will treat the hyperlipidemia and hyperglycemia.

Metformin and a GLP-1 can be used if a patient is willing

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**HCV: Baby Boomers Beware**

If any of your patients were born between 1945 and 1965, they could be at risk for Hepatitis C (HCV). According to the Centers for Disease Control (CDC), three out of four people with HCV are part of the baby boomer generation - and most don’t even know they’re infected.

Because people can live with Hepatitis C for decades with no symptoms, screening for the virus is critical. If left untreated, HCV can cause severe liver damage, including cirrhosis and liver cancer – even liver failure.

Talk to your patients. Ask them to get screened for HCV with a simple one-time blood test. If the test is positive, the specialists at Atlanta Gastroenterology Associates have the latest treatments available to help your patients.
to use an injectable and wants the benefit of appetite suppression and weight loss. Bromocriptine QR (Cycloset) also appears on the dual therapy list and does have good cardiovascular outcomes, but its use is mainly limited by the need to take it upon awakening to avoid nausea and multiple pills must be taken to achieve maximal benefit (six tablets needed to achieve max dose of 4.8mg).

A patient with an A1c >9.0 is unlikely to achieve goal even with dual therapy, and at this point insulin should be considered, especially if the patient is symptomatic. Insulin should be initiated for these patients even if they have never taken a diabetes medicine before, as oral agents alone are unlikely to get them to goal.

A wise strategy is to be aggressive early and taper medicines later, rather than vice versa, because patients who are compliant with a less-aggressive therapy will often have a feeling of failure, frustration or guilt if their blood sugars do not become controlled. I generally start basal insulin at 0.25U/kg daily. If the patient is taking a sulfonylurea, I discontinue it as a sulfonylurea increases the chance of hypoglycemia and the insulin can be titrated much more safely than the sulfonylurea.

It is recommended to titrate the basal insulin based on the fasting blood sugar as follows: fasting blood sugar (FBG) >180 add 4 units, FBG 140-180 add 2 units, FBG 110-139 add 1 unit. If hypoglycemia occurs, it is recommended to decrease the insulin by 10-20% if FBG is <70 and by 20-40% if FBG <40. I would also advise to look at the bedtime blood sugar and avoid titrating a basal insulin further if the blood sugar at night is quite elevated (e.g., bedtime blood sugar is 300 and the following fasting value is 130) as this indicates a post prandial blood sugar problem. This should be addressed instead of continued basal insulin titration, as further basal titration will eventually lead to overnight hypoglycemia with continued poor prandial blood sugar control.

If the patient is still not at goal on basal insulin and is not on a GLP-1 or DPP-IV, these can be added or a rapid-acting bolus insulin can be started. If bolus insulin is added, I usually take 0.25U/kg and divide this value by 3 to get my starting dose of ac bolus insulin.

In summary, diabetes care can be individualized by determining what blood sugar target should be reached and then choosing the appropriate diabetes medicine. There is no one-size-fits-all drug of choice, but metformin is considered first line for most patients. Additional medicine should be started if monotherapy is unlikely to reach the desired blood sugar. Insulin is needed if blood sugars are very poorly controlled even if no oral medicines have been tried previously and can be started as basal insulin plus oral medicine(s) or as basal plus bolus insulin.

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Endocrine Practice Vol 19 No. 2 March/April 2013 327
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Glucose Control Without Insulin
By N. Spencer Welch, M.D.

Last year, a new class of oral hypoglycemic agents, the SGLT2 inhibitors were introduced with the launching of canagliflozin (Invokana), which was joined this year by dapagliflozin (Farxiga).

What makes this latest class of medications unique is that it is the first class of glucose-lowering agents that doesn’t require insulin to exert their effects. All other previous hypoglycemic worked by either increasing insulin levels or making body tissues more sensitive to the effects of insulin. The SGLT2 inhibitors work by inhibiting the kidney’s ability to reabsorb glucose from the proximal tubules so that more glucose is excreted through the urine.

The expanded role of the kidney in glucose homeostasis is still being elucidated, but it has earned the kidney a place in Dr. Ralph De Fronzo’s ominous octet. The kidney not only resorbs filtered glucose, but it is also a producer of glucose via gluconeogenesis and an extensive user of glucose, accounting for approximately 10 percent of total glucose uptake in the body in the fasting state. (1)

In healthy subjects, the kidney filters about 180 grams of glucose per day, and virtually all of it is resorbed in the proximal tubule and returned to the circulation. We were taught in medical school that the renal threshold for glucose in the kidney was 180 mg/dl and anything above that was passed through into the urine. However, the kidneys of patients with type II diabetes have adapted so that their threshold for glucose absorption is increased to 240 mg/dl. (2) Thus, the kidney is now contributing to the hyperglycemia of type II diabetes.

The SGLT2 glucose transporters are responsible for 90 percent of the glucose resorption in the proximal tubule. This makes them a perfect target for altering glucose homeostasis. What canagliflozin and dapagliflozin do is block these SGLT2 transporters. By doing so, they reduce the renal threshold from 240 mg/dl in type II diabetic subjects to less than 100 mg/dl. This increases the net urinary excretion of glucose by approximately 70 grams of glucose per day, or a net loss of 280 calories per day. This is why patients on these drugs should experience a weight loss of five to six pounds over a six-month period.

How does this lowering of the renal threshold for glucose translate into the clinical lowering of our patient’s A1C’s? Both canagliflozin and dapagliflozin have undergone extensive clinical trials as monotherapy and a combination therapy with metformin, sulfonylureas, pioglitazone, sitagliptin and insulin. Depending on the starting A1C, these drugs were able to lower A1C from 0.6 – 1 percentage point. In addition to lowering A1C, the SGLT2 inhibitors
were able to affect a weight loss at six months of around five to six pounds and a reduction of systolic blood pressure of 4mm to 5mm Hg. Therefore, the SGLT2 inhibitors are a second class of antidiabetic drugs behind the GLP-1 agonists to both lower glucose and reduce weight.

The SGLT2 inhibitors are not perfect drugs. They cannot be used in all patients, and they are not without side effects. Since they rely on the kidneys for their mechanism of action, renal impairment will decrease their effectiveness. Canagliflozin is not indicated in patients with eGFRs of less than 45 ml/min./1.73 m^2. Monitoring of periodic eGFRs is necessary, and if the eGFRs drop persistently below the indicated eGFR’s for their respective drugs, then the drugs should be stopped. Because of the osmatic diuresis due to the urinary excretion of glucose, SGLT2 inhibitors may cause hypotension, especially in elderly patients and patients already on diuretics. This diuretic effect may also cause increases in serum creatinine and lower eGFR. Therefore, it is important that all patients and especially the elderly be euvoletic before starting these drugs.

Hypoglycemia is seen more frequently when these drugs are added to insulin or insulin secretagogues, and their doses must be lowered when initiating SGLT2 inhibitors to avoid hypoglycemia. Genital mycotic infections are more common in patients taking SGLT2 inhibitors and are more likely to occur in patients who have already experienced this type of infection. There is also an increase in urinary tract infections. Increases in LDLs also occur with these drugs, and patients should be monitored and treated to standard of care. Hyperkalemia also can occur and is more of a concern with canagliflozin. It was initially thought to be an increased signal for bladder cancer with dapagliflozin, but on further investigation this proved not to be the case.

In summary, SGLT2 inhibitors are an important addition to our armamentarium of diabetic drugs. Because of their unique mechanism of action, they can be used in combination with virtually any other diabetic medication. SGLT2 inhibitors are the only drugs that are not dependent on insulin for their glucose-lowering effects. Like all other drugs, they are not without side effects and contraindications. Therefore, patients must be properly screened and properly counselled on side effects before starting on SGLT2 inhibitors.

References
2. De Fronzo RA Diabetes 2009; 58: 773-795
As minimally invasive surgery becomes a more common and popular option for patients undergoing certain medical procedures, the technology used to perform these procedures is constantly evolving. New techniques allow doctors to perform both minor and complex surgeries as outpatient procedures, with only a few small incisions—a great improvement over open surgeries that formerly required much larger incisions, along with lengthier hospital stays and recovery times for patients.

Robotic laparoscopic surgery, performed with the assistance of technology such as the da Vinci® Surgical System, is now considered the gold standard of treatment for many medical conditions. Robotic surgery has reduced the number of open surgeries for common operations by enhancing the surgeon’s capabilities in performing minimally invasive procedures.

Improving patient and surgeon experience

Introduced in the late 1990s, the da Vinci® Surgical System continues to undergo enhancements that are changing and improving the surgical experience for both surgeon and patient.

Recent improvements have created a more efficient surgical environment for the OR staff. During the procedure, the surgeon sits at a console that offers a 3-D high-definition image of the patient—while viewing that image, the surgeon then uses controls to manipulate robotic arms with tools to perform the surgery.

In earlier years, the robot was permanently docked at the beginning of a surgery. If the patient required repositioning, surgical staff then had to stop and also reposition the robot. Today’s da Vinci’s® systems allow the surgeon and OR staff to move around to different regions of the patient’s anatomy without undocking the robot. Also, the system’s camera is no longer stationary as in previous generations of the technology—it can now be moved and placed on any one of the robotic arms at any time.

Additionally, new tools are giving surgeons even better precision for certain procedures, with improved results for the patient.

For example, laparoscopic cholecystectomy (laparoscopic gallbladder removal) – a big advancement over what was previously an open surgery that meant several days in the hospital for the patient — is an outpatient procedure that involves four approximately inch-long incisions in the abdomen. Now, a recent technological improvement has made an even less invasive procedure possible. Single-Site™ Instrumentation is a new operating platform attached to the da Vinci® Si™ Surgical System that allows surgeons to remove the gallbladder through a single incision.

Patrick Kenney, D.O., a board-certified general surgeon at North Fulton Hospital in Roswell, first observed the da Vinci® Surgical System more than 10 years ago.
Though impressed with its ability to increase precision in laparoscopic surgeries, he knew the system was somewhat limited in its applications at the time. Later, when the manufacturer added some helpful tools, Kenney decided to undergo training to begin using the system.

“In the first few years, the system only worked well for certain operations, such as gynecological procedures,” he says. “But when da Vinci developed improved technologies and added devices to seal blood vessels and staple, it opened up new applicability.”

Dr. Kenney, who began performing laparoscopic procedures using the da Vinci® Si™ Surgical System a little over two years ago, says the newest development is making some procedures, such as gallbladder removal, less invasive than ever before.

“The single-site platform features improved instrumentation that allows surgeons to perform certain procedures with only one incision,” he explains. “So now, a gallbladder removal can be done by making one small incision through the belly button – and the patient has less pain and scarring.”

The single-incision technique also offers surgeons much-improved control over the instrumentation, according to Dr. Kenney.

**About Single-Port Laparoscopy**

Single-port laparoscopy (SPL), or single-incision laparoscopic surgery, is a minimally invasive surgical procedure in which the surgeon operates almost exclusively through a single entry point, typically the patient’s navel. Unlike a traditional multi-port laparoscopic approach, SPL leaves only a single scar.

**SPL has been used to perform many types of surgery, including:**

- adjustable gastric banding
- appendectomy
- cholecystectomy
- colectomy
- hernia repair
- hysterectomy
- sleeve gastrectomy
- nephrectomy
- sacrocolpopexy

Benefits include less postoperative pain, less blood loss, faster recovery time and better cosmetic results.

However, there may also be complications from SPL, such as significant postoperative pain, injury to organs, bleeding, infection, incisional hernia, intestinal adhesions and scarring.
“I have better visualization and precision when I perform these procedures,” he states. “I feel that it leads to safer surgeries and improved outcomes for the patients, like less blood loss, less pain, fewer complications and faster recovery time.”

Where’s the scar?

Clara Parry, a patient of Dr. Kenney’s, says she was pleased to have the option of single-site surgery. Parry, who ended up in the emergency room during a recent gall bladder attack, was examined by Dr. Kenney and offered the choice of a four-incision removal or a single incision.

“The single incision just sounded like the right way to go. One incision versus four seems more logical,” she says. “And the recovery was really not bad at all.”

Parry underwent the procedure on a Thursday. By the following Monday, she was already getting out of the house to do errands.

“I’d never had surgery before. But this was not at all what I was expecting. I woke up in the recovery room and asked if it was over!” she recalls. “I was a little uncomfortable, but I didn’t have any nausea and needed very little pain medication. I was able to shower right away and it felt good to get up and walk.”

Parry and Kenney agree that the single incision has an additional benefit.

“Belly buttons hide scars wonderfully!” Dr. Kenney says. “There’s just a small scar,” adds Parry. “You’d have to really be looking for it to see it.”

The Whole Team

The da Vinci Si System is an integration of advanced technologies, including:

**Firefly™ Fluorescence Imaging.** The Firefly Fluorescence Imaging Vision System enables surgeons to use a special video camera and glowing dye to view blood flowing in vessels, and tissue or bile moving through ducts during minimally invasive surgical procedures. It is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. Firefly enables minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extrahepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging.

**Single-Site®.** Single-Site’s transumbilical entry enables a virtually scarless surgery. Instruments and camera cross within the Single-Site port and use remote center technology to avoid cannula collisions, arm interferences and port-site movement. Single-Site is commercially available for laparoscopic cholecystectomy, hysterectomy and salpingo-oophorectomy for benign conditions only.

**Skills Simulator™.** Skills Simulator’s built-in metrics enable users to assess skills, receive real-time feedback and track progress. Administrative tools let users structure their own curriculum to fit with other learning activities in their institution. The open architecture of the system software allows for the future development and incorporation of additional practice modules.

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Hepatitis C, the most common blood-borne infection in the United States today, is considered a public health threat. From new medications just entering the market and clinical trials to educational efforts and a push for identifying those who have the infection, hepatitis C is a hot topic among medical practitioners in Atlanta and elsewhere.

**Baby Boomers at risk; new meds have unprecedented success**

Hepatitis C is most prevalent in the Baby Boomer generation – those born between 1945 and 1965 – many of whom are asymptomatic and don’t yet know they have the infection. Roughly three-fourths of the current population is now aging and falling into the targeted bracket for having the infection, according to Lance Stein, M.D., a transplant hepatologist at Piedmont Transplant Institute.

“Age is important. If you are infected with hepatitis C, it can do significant damage to the liver … and it actually takes approximately 30 years for that to happen in most patients. So, let’s say if a person was infected in 1970 and is now turning 65, that’s when we’ll begin seeing the problems,” he explains. “Hepatitis C has become a big public health issue. This is why there’s been a huge increase in the establishment of liver cirrhosis clinics and transplant clinics.”

Stein adds that the uptick in patients identified as having hepatitis C just happens, fortunately, to coincide with helpful advances in medicine.

“Hepatitis C has been ‘blowing up’ in terms of new treatment options. These new drugs are much more effective than older treatments like Interferon and Ribavirin, both of which carry significant side effects. But the new treatments are also much more expensive,” he says.

According to Stein, sofosbuvir (Solvadi), which was approved by the FDA in December 2013, is priced at about $84,000 for a three-month treatment. That equates to roughly $1,000 per day. However, the drug has been highly successful to date, with an approximate 89 percent cure rate in people with hepatitis C type 1. Stein says that the high cost upfront may actually end up saving patients and insurers money in the long run.

“The higher cure rate of sofosbuvir, along with fewer side effects than previous treatments, means fewer doctor visits and lab tests than previously required on a regimen like Interferon. It may also prevent the need for a transplant in the future,” he notes. “Some even newer drugs are currently awaiting approval later this year. This is exciting because clinical trials show cure rates for these new treatments are almost 100 percent after a three-month regimen.”

Aasim M. Sheikh, M.D., who specializes in the
treatment and management of liver diseases as a gastroenterologist, hepatologist and clinical researcher with GI Specialists of Georgia, agrees that the new drugs hold great promise for people infected with hepatitis C.

“The envelope is being pushed,” he says. “Researchers – big players like Merck, Gilead, Johnson and Abbott – are looking for regimens that combine drugs to result in a minimum number of pills with the fewest side effects and shortest treatment.”

Sheikh adds that there are four different classifications of drugs that are proving to work well in combination. “These drugs block the hepatitis C virus at different points, shutting down different enzymes that help the virus multiply,” he explains. “Together, they have a synergistic effect in controlling the virus.”

Sheikh states that the most important keys to treating and curing hepatitis C are: identifying people who have the infection; prioritizing and treating those who have the most advanced disease; the development of more effective treatments of shorter duration and fewer side effects; and analyzing the results of various treatment protocols.

“The more people we treat, the more we find out,” he says. “We hope to alter the course of their illness and keep them at a lower risk for further complications.”

Enrique Martinez, M.D., a gastroenterologist and hepatology specialist with Atlanta Gastroenterology Associates, has watched the progression of hepatitis C treatments since he began practicing in 1989.

“This is a very exciting time. It’s amazing when you consider that a disease with only an 8 percent cure rate 25 years ago is now approaching a 100 percent cure rate,” he says. “And it’s interesting that today we consider treatments with a less than 95 percent cure rate to be inferior. Pharmaceutical companies are constantly looking at new combinations of drugs that could result in better and better cure rates for hepatitis C patients.”

Martinez adds that the evolution of drug combinations also holds great promise for special populations with hepatitis C. “People we previously thought could not be treated for hepatitis C are now being considered possible candidates for the new drug regimens,” he says. “These populations include people with immune disorders such as lupus and rheumatoid arthritis, sickle cell disease or colitis. Even people who must undergo dialysis or who are pre- or post-transplant patients have new hope for treatment.”

Providing care to an underserved population

The Grady Liver Clinic at Grady Memorial Hospital, established in 2002, is an innovative model for expanding access to hepatitis C care for urban, underserved patients. This population is disproportionately affected by the infection. Dr.
Lesley Miller, the clinic’s medical director, says the facility is a unique and revolutionary model because it is run and staffed by general internists (rather than specialists), who work together to provide hepatitis C management – including antiviral treatment – to patients regardless of their insurance status.

“Patients without options for specialty care really benefit from this clinic,” Miller says. “We do a lot of education and counseling, and we provide immunizations against hepatitis A and B, evaluation of liver disease and medical comorbidities, and treatment options. We’re one of the only places [in Atlanta] that can offer these services to people who don’t have health insurance.”

A study of the Liver Clinic’s population for its first five years of operation showed that it was primarily African American (76 percent) and uninsured (59 percent). Patients had difficult-to-treat characteristics, including genotype 1 hepatitis C (90 percent), advanced liver fibrosis (28 percent), and high viral loads. Sixty-seven percent had comorbid medical conditions, and 40 percent had psychiatric disease. Fourteen percent of patients were treated for hepatitis C during the study period.

With those early statistics in mind, Miller is pleased with the medical advances that have made hepatitis C treatment easier for the Clinic’s current patients and is excited about the speed at which new treatment options are progressing.

“It’s unbelievable how fast the research and development in the world of hepatitis C are changing. Things I was doing last month are already different,” she says. “More of our patients are now candidates for treatment than have been in the past, because treatment duration is shorter and the regimens are easier or more relevant for people who have other chronic health problems. It’s gratifying to give patients a regimen that’s not going to make them sick and has a high probability of curing them.”

The stats on hepatitis C

In the National Health and Nutrition Examination Survey (NHANES), conducted between 2003 to 2010, researchers studied people with hepatitis C in order to estimate the prevalence of chronic HCV infection and to identify factors associated with the condition. The survey included interviews and testing of serum samples from participants aged six years and older.

Based on 273 participants who tested positive for HCV RNA:

- The estimated prevalence of HCV infection was 1.0 percent (95 percent CI, 0.8 percent to 1.2 percent), corresponding to 2.7 million chronically infected persons (CI, 2.2 to 3.2 million persons) in the U.S. non-institutionalized civilian population.
- Infected persons were more likely to be aged 40 to 59 years, male, and non-Hispanic black and to have less education and lower family income.
- Factors significantly associated with chronic HCV infection were illicit drug use (including injection drugs) and receipt of a blood transfusion before 1992; 49 percent of persons with HCV infection did not report either risk factor.

Based on the data collected, researchers estimated that approximately 2.7 million U.S. residents in the population sampled by NHANES have chronic HCV infection. The study highlighted the continued urgency of identifying the millions of persons who remain infected and linking them to appropriate care and treatment.

In the news

According to a recent article in The New York Times, “sales of the new hepatitis C drug Sovaldi reached $3.5 billion in the second quarter, a huge figure that puts it on track to become one of the world’s best-selling medicines but could intensify concerns about society’s ability to pay for it.”

The FDA-approved drug, manufactured by Gilead Sciences, is for patients with hepatitis C virus (HCV) genotypes 1, 2, 3 or 4 infection. ■
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Larry A. Bartel, M.D.

Dr. Bartel practices Hospitalist Medicine and Palliative Care for the Southeastern Permanente Medical Group, which he has been affiliated with since 1999. Dr. Bartel grew up in Cincinnati, Ohio, and attended Northwestern University for his undergraduate degree in Mechanical Engineering and received his Medical Degree at The Ohio State University in 1991. He did his Internship in internal medicine at the Barnes-Jewish Hospital in St. Louis and his Residency and Chief Residency at Scripps Mercy Hospital in San Diego. He is married and has three children (twins who are 9 and a 14 year old).

Sara Cáceres, M.D.

Dr. Cáceres is a board-certified Family Physician. She received a BS in Biology from the University of North Carolina at Charlotte, where she also completed a certificate in Translation: Spanish/English. She graduated from the Universidad Central del Caribe-School of Medicine in her native Puerto Rico. After that, she completed her Family Medicine Residency in 2002 at Morehouse School of Medicine in Atlanta. After training, Dr. Cáceres worked in private practice until 2008, when she joined The Southeast Permanente Medical Group. She has served as Lead Physician in Adult Ambulatory Medicine for three medical offices and continues to follow her desire to serve medically underserved communities through her involvement in several initiatives, including Ser Familia and Dia de la Mujer Latina, Inc. In addition, she has participated in mission work in the Caribbean and South America. She has been a member of the Board of Directors of the Medical Association of Atlanta since 2010, as well as serving as medical director and board member for the Hispanic Health Coalition of Georgia in 2009-2011.

As Dr. Cáceres continues to find ways to reach more members in the community, she has had numerous media engagements, including health-related pieces for Latina magazine, NBC Latino, as well as a recurrent presence as a guest speaker at CNN Español. She is a member of the American Academy of Family Physicians and its Georgia chapter.

Frances (Dickie) McMullan, M.D.

As an eye surgeon, Dr. Dickie McMullan offers 30 years of experience helping her patients improve their vision, at the same time decreasing their dependency on glasses and contact lenses. Combining procedures of LASIK, PRK, premium implant cataract surgery and lens implants for extreme near-sightedness (ICLs), she offers experience with the latest FDA-approved options for maximizing vision.

Dr. McMullan is currently a Preceptor at Morehouse School of Medicine. Following graduation in the first class of women at the University of Virginia, Dr. McMullan received her M.D. from the Medical College of Virginia. After her residency at Emory University, she completed two post-doctorate fellowships: a cornea fellowship at Tufts-New England Medical Center in Boston, and a Lens Implant/Laser Fellowship in Atlanta. Dr. McMullan is board certified and a Fellow of the American Academy of Ophthalmology. She serves on the board of the Medical Association of Atlanta, and is past president of the Atlanta Ophthalmology Society.

Dr. McMullan has balanced her clinical career serving as an international lecturer and residency instructor. She has participated Flying Doctors of America Mission Trips to Belize, Peru, Guatemala, Tanzania and Bhutan and has worked at The Good Samaritan Center in Atlanta.
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