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Advance Care Planning - a Reminder

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In my experience, it is very difficult for providers to fit discussions about Advance Care Planning (ACP) in our daily schedules. However, it is also our job to make sure that very thing happens. We are still faced with many people who do NOT have their wishes written down or a proxy to help make decisions for them if needed. One study reported that only 28 percent of home health care patients, 65 percent of nursing home residents and 88 percent of hospice care patients **have** an advance directive on record (Jones 2011). I was shocked to see that not even 100 percent of hospice patients had them, according to this report.

So, what is ACP? ACP means that you look at your options for health care in the event you have a severe event/illness that makes you unable to voice your wishes, you think about what you want, and you make a decision. That decision may be that you designate a health care proxy or Power of Attorney to act on your behalf. Or, it may be that you know exactly what you want and you would like to detail that in an advance directive. We have a document called the Five Wishes- it is a longer document but helps those who wish to write or select details about illnesses and situations that may arise. Or, we have the MOST form- Medical Orders for Scope of Treatment. It is a much shorter form that incorporates a section on resuscitation but also talks about transfer to the hospital, ICU care, IV antibiotics, IV fluids, and feeding tubes.

Sometimes there may be traditions or customs that regulate what can be talked about in terms of end-of-life care. The easiest way to approach this if you are new to an area or are unsure, is to ask if it is ok to discuss death and dying. If it is not, using a third person point-of-view can be helpful. Describe a scenario with another "someone" who is faced with a similar clinical event and ask the patient what he/she thinks that "someone" would want. I also often give the example that I may die on the way home- when I type this, it sounds awfully morbid. But, it lets patients know that we never know *when* our time will come so preparation can be done at any time. I also talk about how I want my family members to be able to grieve and focus on their feelings when I am ill or need rest-of-life care, rather than try to imagine what I would want and wrestle with making decisions.

Because I am a Geriatrician, my conversations are with patients 55 and older, many of whom already know what they want. I have often been very surprised by how many of them have thought about this and made decisions already- they just aren't on paper. I offer to them that I will always support them, no matter what the decision is (even if I would never choose that option). I have struggled with some very difficult situations when I truly felt that continuing the present treatment plan was causing the patient to suffer; in some of these cases the patients told me that living as many days as possible, no matter the quality, was the most important thing to them. I have also struggled with patients whose family members refused to acknowledge the patient's wishes. These situations are heart-breaking, but what I have found to help the most is starting the conversation earlier, when the patient is at his/her best. I also encourage him/her to speak with family members about ACP, so that people are aware of what a family member wants ahead of time. I offer

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to call the family members or ask the patient to have them come to the next visit if the patient is uncomfortable bringing it up.

I usually start my conversations about ACP with patients in two ways: "have you ever thought about what you want if something happens to you and you have a stroke or heart attack?" or "have you thought about advance care plans?" That is usually followed by the patient asking "what do you mean?" "Well, if you die- your heart stops and you stop breathing, do you want medical people to try to bring you back to life?" or a description of what ACP is. The language I use is very specific. I use the word "die", and the phrase "bring back to life" to make sure the patient hears twice that I am saying death occurred. This is followed by a description of resuscitation, sometimes statistics of survival, how it relates to their medical problems, etc. Sometimes they are ready and they have known for a long time what they want- they were just waiting on you to ask. Sometimes they are surprised, and need time to think about things. This is just the tip of the ACP iceberg, but it is a start. If they DO know, you have made a huge step in helping to accomplish their wishes when the time comes.

One of the things you have to get comfortable with is your description of resuscitation. I have heard many different ways of explaining this, and you have to find the explanation that works best for you. When I describe resuscitation, I explain it with arm movements and hand gestures- I go over the pounding on the chest, drugs to re-start the heart, and putting a tube down the throat to breathe for the patient. Some people may feel this language is too harsh- but I would argue that the process itself is VERY harsh and should be described as such. I also make it a point to describe how function may be affected afterwards- I was trained that so often people think about being resuscitated how it occurs on TV. Boom- wake up and talk to your family 30 seconds after being coded. We all know that it doesn't happen that way, especially for my frail older patients. I wouldn't be providing a good explanation if I didn't talk about their chances of survival and likelihood of functional decline and/or dependence after going through such an event. For example, In-hospital CPR for cardiopulmonary arrest was associated with 30.4% success right after CPR completion, but only 12% were survived at the time of discharge in one study. Duration of CPR >10 minutes indicated a significantly decreased survival to discharge (Saghafinia 2010). This leads to questions like "what is important to you", or "what makes life meaningful for you?" Sometimes a patient may just want to be able to lie around and watch his/her favorite TV show; others want to be able to keep mountain-climbing. Each person is different, and you can't predict what he or she will say about ACP.

I encounter the question often about the ability to determine if a patient has the capacity to make these decisions. Capacity is determined by a health care provider for *that* situation, at *that* time. It is not a legal term, like competence. Any provider can make that decision, based on some basic concepts.

1. Ability to express a choice: The patient must be able to express his or her choice and communicate that choice.
2. Ability to understand relevant information: The patient must be able to understand and remember information about the purpose of treatment and show that he or she can be part of the decision-making process.
3. Ability to appreciate the significance of the information and its consequences: The patient must understand the consequences of treatment refusal and the risks and benefits of accepting or refusing treatment.
4. Ability to manipulate information: The patient must be able to engage in reasoning as it applies to making treatment decisions (e.g., use logical processes, weigh treatment decisions and manipulate information about treatment decisions)

I have seen patients with dementia be asked orientation questions to determine capacity- it is important to acknowledge that just because a patient has dementia doesn't mean that he/she cannot make decisions about things like ACP. Asking a dementia patient what day it is does not assess capacity.

Of course, the paperwork is important. But what is really important is starting the conversation. The more you bring it up on a regular basis, the more comfortable you will become discussing ACP, and the better job you will do in explaining the options.

National Institute on Aging

http://www.nia.nih.gov/health/publication/advance-care-planning

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Indian Health Service
National Pharmacy and Therapeutics Committee
Antibiotic Stewardship
NPTC Formulary Brief
May 2015

Antibiotic resistance has been increasing in the recent decades. Moreover, antibiotic drug development has stagnated, limiting our antibiotic armamentarium to combat bacteria. There is an urgent need for efforts that promote appropriate antibiotic use to minimize the development of microbial resistance and improve patient outcomes, known as Antibiotic Stewardship Programs (ASP). Antibiotic stewardship is defined as coordinated activities to optimize antibiotic selection, dosing, route, and duration of therapy. Antibiotic stewardship programs have been demonstrated to improve antibiotic utilization and are a key prevention strategy to limit the spread of antibiotic resistance.

The goals of ASPs are to optimize clinical outcomes, minimize unintended consequences, improve patient safety and improve the cost-effectiveness of antibiotic use through a multidisciplinary approach. Simply put, antibiotic stewardship is ensuring optimal prescribing when antibiotic therapy is necessary (e.g., the right dose, for the right duration, via the right route) as well as recognizing when antibiotics are not needed. To accomplish this goal nationally, the Center for Disease Control and Prevention (CDC) recommends that all hospitals implement an ASP. In September 2014, President Obama issued the *National Strategy for Combating Antibiotic-Resistant Bacteria which* identified priorities and coordinated investments to prevent, detect and control outbreaks of resistant pathogens. The *National Strategy* outlines goals for the United States government, one of which involves strengthening antibiotic stewardship in inpatient, outpatient and long-term care settings. In March 2015, the *National Action Plan for Combating Antibiotic-Resistant Bacteria* was issued in response to the executive order released in September 2014.

Findings:

The Indian Health Service ASP Workgroup developed specific implementation strategies that include utilizing CDC Stewardship assessment tool, identifying ASP champions within each service unit, the creation of site-specific guidelines for antibiotic selection that integrates local antibiogram information with evidence based guidelines to optimize provider selection of antibiotic therapy.

Resources and Tools currently available to the IHS:

- Arizona Healthcare-Associated Infections (HAI) Program: http://azdhs.gov/phs/oids/hai/
- Association of State and Territorial Health Officials (supported by the CDC) – pages 9-12: http://www.astho.org/Infectious-Disease/Policies-To-Promote-Antimicrobial-Stewardship-Programs/
- CDC: Core Elements of Hospital ASP: http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html
- CDC – Get Smart (outreach materials): http://www.cdc.gov/getsmart/index.html
- Executive Order 137676 – National Plan for Combating Antibiotic Resistance: https://www.whitehouse.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria
- Great Plains Area & Winnebago Service Unit Guidebook: Available upon request: IHSNPTC1@ihs.gov
- National Pharmacy Council Antibiotic Stewardship Program Guidebook (Inpatient & Ambulatory Care): Available upon request: IHSNPTC1@ihs.gov
- VA Directive 1031 – Antibiotic Stewardship Programs: http://va.gov/vhapublications/ViewPublication.asp?pub_ID=2964

Conclusions:

In response to the National Plan for Combating Antibiotic-Resistant Bacteria, the Indian Health Service (IHS) will implement a robust ASP. The success of each facility's ASP is dependent on defined leadership providing prescribers with optimal recommendations based on local susceptibility for treatment of infections and identifying conditions when antibiotic use may be inappropriate. Shared information including the system of change processes will allow service units to implement their ASP in a meaningful and sustainable manner.

1. IHS will follow Executive Order 1376767 and will be primarily affected by Goals 1 and 2 from the National Action Plan for Combating Antibiotic-Resistant Bacteria:
    a. Goal 1: Slow the emergence of resistant bacteria and prevent the spread of resistant infections
    b. Goal 2: Strengthen national one-health surveillance efforts to combat resistance objectives

2. The primary goal of the IHS ASP Workgroup is to be a resource and a point of contact for all IHS sites during the implementation and maintenance of ASP. This includes providing a current updated repository of educational information, implementation tools and clinical guideline located on the NPTC website.

Clinician Training resources:

- Gauthier TP, Lantz E, Heyliger A, Francis SM, Smith L. Internet-Based Institutional Antibiotic Stewardship Program Resources in Leading US Academic Medical Centers. Clin Infect Dis. 2014; 58(3):445-446. Available at: http://cid.oxfordjournals.org/content/58/3/445.full.pdf
- MAD-ID Antibiotic Stewardship Training Programs (Basic and Advanced) http://mad-id.org/Antibiotic-stewardship-programs/
- Society of Infectious Diseases Pharmacists. Antibiotic Stewardship: A Certificate Program for Pharmacists. http://www.sidp.org/Default.aspx?pageId=1442823
- CDC Checklist for Core Elements of Hospital ASPs: http://www.cdc.gov/getsmart/healthcare/implementation/checklist.html
- American Hospital Association: Antibiotic stewardship toolkit for hospitals: http://www.ahaphysicianforum.org/resources/appropriate-use/Antibiotic/index.shtml
- Joint Commission Resources: Antibiotic Stewardship Toolkit: http://www.jcrinc.com/Antibiotic-stewardship-toolkit/

For questions about this document, please contact the NPTC at IHSNPTC1@ihs.gov. For more information about the NPTC, please visit the NPTC website.

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Indian Health Service
National Pharmacy and Therapeutics Committee
Sulfonylureas
NPTC Formulary Brief
May 2015

Background:

The IHS National Pharmacy and Therapeutics Committee (NPTC) performed a class review of sulfonylureas (SU) at the May 2015 meeting, including clinical, utilization and procurement data. Based on the results of the discussion, the NPTC voted to remove glyburide from the National Core Formulary (NCF). Additionally, it was felt that a Formulary Brief would benefit IHS providers with regard to the place in therapy of SUs in the management of type 2 diabetes mellitus (T2DM).

Discussion:

Sulfonylureas have been the mainstay for controlling blood glucose in T2DM patients since the mid-1950s. Use of SUs has steadily declined from 61% in 1997 to 22% in 2012. This transition occurred with the development of new antidiabetic agents and from guideline changes from the American Diabetes Association (ADA) and American Association of Clinical Endocrinologist and American College of Endocrinology (AACE/ACE). The NTPC's review of the SU class, recent guidelines and systematic reviews is intended to provide pertinent information and clinical guidance for the IHS.

Diabetes is characterized by insulin deficiency, insulin resistance and numerous other metabolic abnormalities including glucagon, amylin, glucagon-like peptide, gastric inhibitory polypeptide, peptide-YY, leptin and ghrelin. The United Kingdom Prospective Diabetes Study (UKPDS) showed that at diagnosis, only half of the pancreas is able to produce insulin. Of interest, progressive beta cell function decline has been observed at a greater rate with SU treatment when compared to metformin, eventually requiring management with insulin. To date, no treatment has been shown to alter this progressive decline in beta cell function. The graph below illustrates this decline. Understanding this concept allows for better utilization of SU in the treatment of T2DM.

Current Guidelines: Metformin continues to be the first-line choice for T2DM for both the ADA and AACE/ACE guidelines. Additionally, patients with the following characteristics are considered better candidates for oral (only) therapy and are likely to respond better to SU therapy:

1. Newly diagnosed T2DM
2. Obesity (body mass index < 30 kg/m2)
3. Absence of symptomatic diabetes mellitus (i.e., rapid weight loss, severe polyuria, severe polydipsia)
4. Hemoglobin A1c (HbA1c) less than 10%
5. Fasting serum glucose less than 250 mg/dL
6. Absence of non-fasting ketonuria

HbA1c Lowering Effects: When considering medication options for T2DM patients, it is important to recognize the HbA1c lowering effects of different therapies and agents. The cornerstone of T2DM treatment centers around lifestyle modifications. Medical Nutrition Therapy (MNT) lowers HbA1c approximately 1-2% (short term: 3 to 6 months; 0.25-2.9%) when provided in concert with a registered dietitian. A general rule is that oral antidiabetic medications lower HbA1c 1-2%, whereas insulin has been demonstrated to lower HbA1c by much as 3.5% without dose limitations in clinical trials. The following chart summarizes the different classes of antidiabetic medications and their potential HbA1c reduction.

Agent	Mean drop in HbA1C
Alpha-glucosidase inhibitors, Bile acid Sequestrants, Dopamine Agonists	0.5-1%
Amylin Analogs	0.5-1%
Biguanides, Sulfonylureas, Thiazolidinediones	1-1.5%
Dipeptidyl peptidase 4 (DPP-4) inhibitors	0.5-1%
Glucagon-like peptide-1 (GLP-1) receptor agonists	1-1.5%
Insulin	1.5-3.5%
Meglitinides	0.5-1%
Sodium-Glucose Cotransporter 2 (SGLT2) inhibitors	0.7-1%

In general, SUs have been shown to lower HbA1c between 0.4-1.2%, depending on its use as monotherapy or add-on therapy. The expected HbA1c reduction in treatment-naive individuals following initiation of SU monotherapy is 1% to 2%. The efficacy of SUs as add-on therapy to metformin has been shown to lower HbA1c between 0.47% and 1.3%. There are a limited number of studies that show comparable efficacy between newer antidiabetic agents and SUs. The LEAD-2 trial demonstrated equal efficacy of glimepiride vs. liraglutide as add-on therapy with metformin over a 26-week period.

Adverse Side Effects: The most common adverse effects associated with SU therapy are weight gain, hypoglycemia, and concerns for cardiovascular (CV) morbidity and mortality. In a 6-year period during the UKPDS study, patients randomized to treatment with chlorpropamide and glyburide gained a mean body weight of 5.3 kg. Hypoglycemia remains one of the most significant adverse effects leading to hospitalizations and non-adherence to pharmacotherapy and are classified as mild or severe episodes. With regard to mild hypoglycemia, the yearly rate of episodes is 10%, 1% and 0.05% for insulin, SUs and metformin, respectively. However, varying rates of hypoglycemia among SUs differ as reflected in both the UKPDS and ADOPT studies. The rates of hypoglycemia (1 or more/year) for chlorpropamide vs. glyburide was 11% and 17.7%, respectively. In a meta-analysis glyburide was associated with a 1.44 times relative increased risk in overall hypoglycemic events and a 4.69 times increased risk for severe hypoglycemic events when compared with other SUs. With regard to increasing CV disease, SUs received a black box warning after the 1970s University Group Diabetes Program (UGDP) study showed increase rates of CV events. However, UGDP subjects randomized to tolbutamide experienced more cardiac events at the time the study was initiated. Furthermore, numerous studies including the UKPDS, ADOPT and BARI 2D failed to show SUs causing increased risk of CV events. The differences in CV rates among SUs may be due to different binding affinities to receptors SUR2A (Cardio) and SUR2B (Vascular). Glyburide binds stronger to these receptors than glipizide and glimepiride.

Secondary Failure: Secondary treatment failure is seen in T2DM as progressive beta cell decline occurs over time. The ADOPT study compared failure rates of glyburide, metformin and rosiglitazone over a 5 year period. The failure rates were higher among glyburide patients (34%). Metformin had 21% failure rates, whereas rosiglitazone was 15%. Currently there is a prospective study evaluating add-on therapy to metformin with SUs, DPP-4 inhibitors, GLP-1 receptor agonists and basal insulin and will compare 7 year control and failure rates. The results of this study will help guide the best therapeutic options for long term glycemic control.

Use in Pregnancy: A 2010 meta-analysis (6 studies, 1388 patients) was conducted regarding the use of metformin, SUs and insulin in pregnancy. This retrospective cohort study evaluated fasting glycemic control, postprandial glycemic control, neonatal hypoglycemia, birth weight, large-for-gestational-age and cesarean rates. Results from the meta-analysis support that metformin and glyburide are non-inferior to insulin therapy in gestational diabetes, with no evidence of adverse fetal or maternal outcomes.

Findings:

The current cost of health care is both substantial and rising with the annual cost of medications for diabetes reaching $18 trillion dollars. Sulfonylureas remain as one of the most cost-effective, add-on therapy to metformin available on the market. Additionally, this class of medications has a history of global experience in effectively controlling blood sugars with relatively low incidence of adverse effects and drug interactions. Their HbA1c lowering ability appears ideal for those patient recently diagnosed with diabetes as pharmacologic failure rates increase with beta cell dysfunction over time. It may be best to avoid use of glyburide in patients who have had a past history of CV disease or MI and are at risk for hypoglycemia. Additionally,

several studies have shown that glyburide causes more mild and severe episodes of hypoglycemia then glimepiride and glipizide. Glyburide has been shown to be effective at controlling glucose during pregnancy with minimal adverse effects to the patient or the fetus.

Therefore, SUs still play a role as add-on therapy for patients failing to achieve treatment goals on regimens of 1 or 2 drugs that include metformin, however, their use is limited by increased failure rates as time progresses. The optimal time to use a SU based on UKPDS and ADOPT study results may be during the first one to five years from the date of diagnosis when there is adequate beta cell function.

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