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From Tundra to Table: One Alaskan organization's journey to bring traditional foods to its Inupiat elders

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The importance of traditional foods to Alaska Native and American Indian Elders cannot be overestimated. Imagine if in your last years you were prohibited from eating the foods that sustained you and your family for countless lifetimes; that in the place where you live there are no familiar smells of moose or sheefish boiling in the kitchen. Imagine someone said you had to eat turkey tetrazzini and spaghetti, not your comfort foods like muktuk or fish soup. That is just what happened in Kotzebue, Alaska in early 2012, when Utaqqanaat Inaat (place for elders) first opened. In the time since, the Farm Bill passed in Congress with an addendum to allow traditional foods to be served in senior care facilities and schools. Maniilaq staff, state and federal agency regulators, dietitians and statewide tribal health organizations have worked together to change regulations to allow for traditional foods to be prepared and served in the nursing home.

Traditional Alaska Native foods are some of the healthiest foods in the world. Moose and caribou meat is high in protein and low in saturated fat. Alaskan wild blueberries have more antioxidants than cultivated blueberries. Three ounces of bearded seal meat has 14mg of iron in it, 80% of the recommended daily value. You would have to eat 25 ounces of beef pot roast or 48 ounces of chicken nuggets to get that amount of iron. Seal oil, a cultural favorite, is an excellent source of omega-3 fatty

acids, which aids in heart and mental health. A study that looks at dietary intake of Alaska Native people indicates that a higher proportion of nutrients come from the traditional foods, especially protein, iron and omega-3 fatty acids. The mean intakes of omega-3 from fish and sea mammals of participants in the study are over twenty times greater than the general U.S. population (Johnson, et.al.).

Being able to choose what you eat, what time you eat and making individual choices for your care is now known as "person centered care." More and more it is becoming a way to improve quality for nursing home residents. According to the 2008 CMS Action Plan for Nursing Home Quality both person centered care and a facility's

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participation in the culture change movement toward a more homelike environment are components surveyors can identify to help ensure quality. Culture change in nursing homes includes changing from a clinical, hospital like setting to one that more reflects where someone lived prior to entering the nursing home. Naturally this type of environment would include individual life choices.

Paul Hansen, hospital administrator for Maniilaq Association, said that, “for a long time it’s been a goal of our community to keep our elders at home as they got older and beyond the point where their families cannot take care of their medical needs. We had an assisted living center here but all our elders were being sent to Anchorage or Fairbanks for long-term care. It’s shameful that elders in the last year of their lives were separated from their families in the place they’ve lived their entire life. So we built a long-term care facility and it’s been operational for three years now, and it’s really all about the *quality of life*. We looked at all the building philosophies, and they all suggested making the clinical residential environment to be more “home like”. We wanted an open kitchen, so elders were not served [from the hospital kitchen] on carts; we wanted the noise, smells, and chatter of a home kitchen. We wanted the place to smell like moose stew.”

Steps to Regulatory Change

Traditional Alaska Native foods are important to Alaska Native elders for variety of cultural, social and nutritional reasons. However, these foods have not been widely used in long term care facilities due a lack of familiarity and safety concerns. The road to defining and determining how Maniilaq could store and prepare traditional foods in their kitchen proved daunting. Staff had conversations with no less than eight federal and state agencies, which ended with conflicting and confusing areas of jurisdiction with no solid resolution. Before these conversations began nursing homes were prohibited from serving traditional foods unless they were a part of an activities program or a potlatch. The barrier was a federal regulation known as F Tag 371. This rule required all foods to be obtained from an approved federal, state or local source, yet failed to define an approved source.

After numerous discussions, in the fall of 2014 federal agencies deferred their authority to the State of Alaska Department of Environmental Conservation (DEC). This placed the DEC in the position of being able to allow traditional foods to be served if the provisions of the Alaska Food Code (18 AAC 31.210) were being followed. Section 18AAC 31.205 speaks specifically to traditional foods. A kitchen which holds a permit from the state DEC can store and prepare the traditional foods without further inspection or certification. This decision opened the door for long term care facilities to serve traditional foods to their Elders.

Maniilaq’s Hunter Support Program has operated under the leadership of Cyrus Harris since 1993. Through this program area hunters are provided support for supplies to hunt and fish. This small stipend allows village residents do what they’ve always done, support their elders. Following the discussions with the DEC, Maniilaq expanded this program and built a traditional food processing plant in Kotzebue where younger hunters will be trained by Harris regarding accepting fish and game; and looking for potential signs of illness or contamination of donated meat. As of April 2015, donated meat, fowl and fish will be processed and stored at the plant for cooking at Utaqqanaat Inaat. Elders in Kotzebue will also benefit from the bounty of the tundra. By defining “The Tundra as our Garden” Utaqqanaat Inaat is allowed to serve berries, herbs, and mushrooms fresh from the tundra.

In February 2015 Maniilaq invited state, federal and tribal partners for a two day meeting to tour the new processing facility and develop policies and procedures for the acceptance of donated traditional foods. The facility opened in April 2015.

The last step in the process was to receive approval from state and federal CMS nursing home surveyors to begin serving traditional foods. A special meeting was held with the State of Alaska Department of Environmental Conservation (DEC), the Licensure and Certification branch of Department of Health and Social Services, and leadership from Utaqqanaat Inaat. Consensus was achieved acknowledging DEC as the “Authority Having Jurisdiction” in determining an approved source for wild game, fish, and fowl.

April 23, 2015 was a ground breaking day for Utaqqanaat Inaat, and Elders in long term care facilities across Alaska. After years of deciphering the quagmire of regulations, Maniilaq received final approval from state and federal CMS surveyors to go forward with its program to serve traditional foods to their Elders.

Coming Full Circle

There are still prohibited traditional foods such as walrus and polar bear because of the risk of trichinosis. Seal oil, an important source of vitamin A and a staple in the traditional coastal diet is still off limits due to the risk of botulism. However, the Alaska DEC has expressed interest in working together to create a standard safe process that addresses the botulism hazard. Lorinda Lhotka of DEC stated, “We know it can be done safely because so many people across Alaska are making it. Unfortunately, there have also been people who have become very ill.” Therefore, developing a safe, documented process could reduce the barrier to serving seal oil. The Seal Oil Task Force will begin meeting in June 2015.

There are many traditional values among Alaska Native people living in Northwest Alaska: sharing, cooperation, respect for elders, respect for nature, hunter success, and responsibility to tribe. Maniilaq Association's tribally owned and operated long-term care facility has now been able to institutionalize these values through a unique Hunter Support and Traditional Foods Programs intended to improve the quality of life of its Inupiat elders.

Eating traditional, subsistence foods is more than simply putting food into your mouth. It's an experience. It's taking that first bite of moose or caribou stew and enjoying the warmth, the goodness, and savoring the comfort that it brings. It is the smile on an elders' face when she tastes the goose soup, something she hasn't had in six years. Serving these foods is how we honor our elders.

Paul Hanson summed it up, "long term care is probably the most regulated industry out there, so I'm happy we're all here talking about how, under that highly regulated environment, we can provide a home like environment for our elders and provide safe food that will positively impact our residents. This is not a market hunting program, its people hunting and donating and contributing to an elder's well-being, and everyone gets satisfaction out of that.

"Maintaining the dignity and human integrity of every Elder is paramount in their care. By providing traditional foods for the Elders we are exercising their right to choose to maintain their cultural identity and dignity." Helen McGaw, DON

With thanks to the hard work, dedication and commitment of Maniilaq and Utuqqanaat Inaat staff: Valdeko Kreil, Administrator; Cyrus Harris, Hunter; Helen McGaw, Director of Nursing; and Chris Dankmeyer, Environmental Health Manger.

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REACH Into Indian Country: Helping Native American Dementia Caregivers

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Although there are 566 federally recognized Tribes and Tribal Organizations, very little has been written about American Indian/Alaskan Native (AI/AN) caregivers, with few scholarly articles from 1980-2013.¹ In two studies, about 16-17% of adults were caregivers.^{2,3} The high prevalence of family caregiving has been attributed both to

cultural emphases on familial interdependence and to the lack of resources in rural and reservation settings.⁴ In the examination of 20,996 AI/AN caregivers using data from the 2000 Behavioral Risk Factor Surveillance System, 29.1% of AI/AN caregivers indicated they would provide care themselves if a friend or relative needed short- or long-term care and 25.2% would contact a professional resource.³

Although AI/AN caregivers share similarities with other caregivers, cultural practices also influence AI/AN caregiving. Northern Plains (Lakota Sioux) and Southwest (Pima, Maricopa) caregivers of elders with mental or physical difficulties report worse mental and physical health than non-caregivers.⁵ Pueblo caregivers experience types of caregiving burden similar to other non AI/AN caregivers, with guilt tending to be the more common and strongly felt burden.⁶ In early work, Pueblo caregivers, although expressing role strain, family tension, doubt about ability to manage care, and negative health effects, felt less constrained by caregiving. Burden was related to

limitations on the caregiver's ability to fulfill family and tribal roles.⁷

AI caregivers (Lakota Sioux), who tend to be younger age, female, and live in larger household size, report attending and participating in Native events, and endorse traditional healing practices.² Northern Plains caregivers report reciprocal relationships, enjoyment of, and a pattern of mutual assistance with the elders they are providing care for. Consequently, they show low burden and high reward. Care is shared among individuals, leading to relatively low levels of care provision.⁸

The Department of Health and Human Services, Administration for Community Living, funds the Native American Caregiver Support Services Program, which provides information and outreach, access assistance, individual counseling, support groups and training, respite care and other supplemental services for AI/AN/Native Hawaiian caregivers. A core value of the program is that it should not replace the tradition of families caring for their elders but provide support that strengthens the family caregiver role.⁹

The purpose of this paper is to discuss the implementation of a behavioral intervention for dementia caregivers, Resources for Enhancing Alzheimer's Caregivers Health in Tribal Communities (REACH into Indian Country) into Tribal organizations and communities, through adaptation of the Department of Veterans Affairs REACH VA intervention. The implementation into Indian Country is driven by the National Plan to Address Alzheimer's Disease, which mandates that lessons learned through VA caregiver support strategies, specifying REACH VA, should be shared with other federal agencies.¹⁰ In 2013, training began of health care and social service providers, predominantly IHS and Tribal public health nurses serving caregivers of AI/AN veterans with dementia, through the Memphis VA Caregiver Center. These nurses implemented the intervention in several Tribal communities and received positive feedback from caregivers. They also received requests to provide the intervention for all AI/AN dementia caregivers. This fueled the interest on the part of the Indian Health Service (IHS), Administration on Community Living (ACL), and the University of Tennessee Health Science Center (UTHSC) to make the REACH intervention broadly available in Indian Country. The effort to implement REACH across Indian Country has now been funded for three years by the non-profit Rx Foundation.

The REACH Intervention

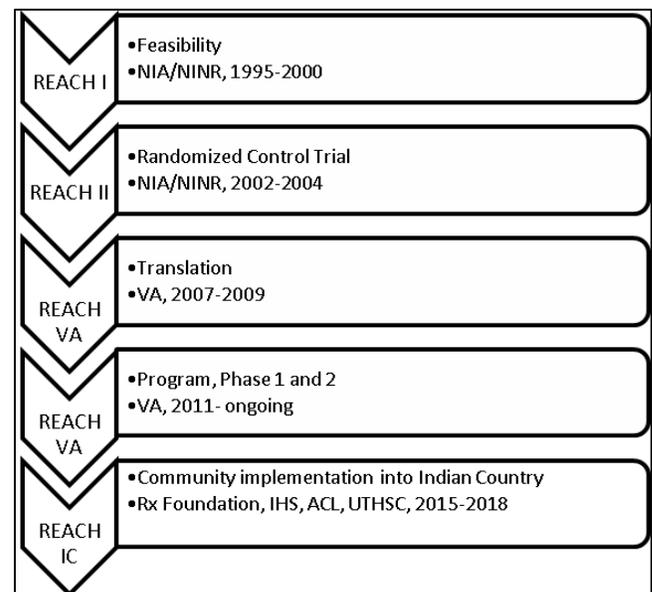
The REACH intervention has followed a trajectory from feasibility studies¹¹ through multisite randomized control trial¹² to a national clinical program in the Department of

Veterans Affairs Veterans Healthcare Administration^{13,14} (Figure 1).

REACH VA^{13,14} is designed to help caregivers manage patient behavioral concerns and their own stress. It is structured to ensure that common risks faced by caregivers are covered – information on the disease, care recipient safety, caregiver health and emotional well-being, social support, and management of patient problem behaviors. It is targeted to the concerns of each caregiver and care recipient by a Risk Priority Assessment because the most effective caregiving interventions are targeted to specific needs.¹⁵ Therefore, each caregiver learns and practices the same skills but targeted to the problems that he or she identifies (Figure 2).

The intervention has four core individual sessions between interventionist and caregiver during two to three months, with the option for additional sessions based on caregiver need, desires, goal attainment, and clinician judgment. If problems arise there is a maintenance phase, where additional problems/stress issues can be addressed with the caregiver. The intervention can be offered in the home, in facility or clinic, or by telephone or telehealth modalities. There is a protocol that specifies activities to occur at each session accompanied by scripted materials for staff and a Caregiver Notebook with 30 behavioral management topics and 18 caregiver stress and coping topics, written at a fifth grade reading level (Figure 3). The Caregiver Notebook has practical strategies to address problems that caregivers may be having.

Figure 1. REACH Research and Implementation Trajectory



The intervention is structured around components that have been shown to be successful in caregiving

interventions including education, support, and practical skills building, including problem solving, communication strategies, cognitive reframing, and stress reduction.^{12,14,17} Skill building is an integral and critical part of REACH. In problem solving, caregivers learn how to break down a problem into its parts to specify exactly what the problem is. For example, “He is being difficult” could indicate that the patient is wandering, asking repeated questions, or becoming agitated. Only after caregiver and interventionist have determined what the problem is can they determine what happens before and after the problem occurs, its antecedents and consequences. Caregivers are encouraged to think about who is around (e.g., when the grandchildren come) and when the problem happens (e.g., when the patient is tired) in order to formulate a reachable goal and identify practical solutions from the Caregiver Notebook that can be tried. Cognitive reframing helps caregivers think about problems that cannot be changed, focusing on substituting less negative thoughts and feelings.

The intervention produces excellent outcomes. During the course of the intervention, caregivers experience significant decreases in burden, depression, and anxiety. Caregiving frustrations of feeling like yelling at or hitting the patient, stress symptoms (feeling overwhelmed, feeling like crying, being frustrated as a result of caregiving, being lonely), and general stress rating also significantly decrease. For patient care, caregivers report 1.2 fewer troubling patient behaviors and a decrease in safety concerns, both of which are significant findings. Concomitant with these findings, caregivers report a significant decrease of 1.6 hours per day on duty.¹⁴

Figure 2. Risk Areas, Strategies, and Options

Risk Area	Strategies and Options
Safety (e.g., driving)	Problem solving <ul style="list-style-type: none"> • Remove access • Disable devices
Patient behavioral concern (e.g., wandering)	Problem solving <ul style="list-style-type: none"> • Establish safe paths • Modify environment to decrease cues • Use monitoring devices
Caregiver emotional well-being (e.g., needing help)	Problem solving <ul style="list-style-type: none"> • Ask for help using assertive communication

Implementation

As the project moves forward, IHS, Tribal, and Urban program staff members who work with dementia caregivers, such as public health nurses and community health representatives, will be eligible to be an interventionist. Caregiver support staff in Tribal Senior Center programs (Title VI C Native American Caregiver Programs) will also be eligible for training. The UTHSC Caregiver Center will train and certify interventionists and provide staff manuals and Caregiver Notebooks (see sidebar). Training uses telephone and webinar technology. Caregivers are not being evaluated but staff members will be asked for feedback on their experience with the intervention to make any modifications needed. The long term goal is to make this intervention available in every Tribe and communities so that any individual working with AI/AN dementia caregivers can have the REACH into Indian Country intervention as part of their tool kit to help caregivers and every caregiver will have access to support they need and deserve.

Figure 3. REACH Caregiver Notebook Behavioral and Stress/Coping Topics

Behavioral Topics

- Activities
- Bathing
- Combativeness
- Communication with Person with Dementia
- Confusion
- Dental Care
- Depression
- Dressing
- Driving
- Early-stage Dementia
- Eating
- Environment
- Feelings
- Grief
- Hallucinational and Delusions
- Holidays
- Hospitalization
- Incontinence
- Medications
- Nutrition
- Repeated Questions
- Safety
- Sexuality
- Shadowing
- Sleeping

- Sundowning
- Telling the Patient/Others
- Traveling
- Visiting
- Wandering

Stress/Coping Topics

- Adult Day Care
- Asking for Help
- Communicating with Health Care Providers
- Depression
- Early-Stage Dementia
- Feelings
- Financial and Legal Issues
- Getting Help
- Grief
- Healthy Lifestyle
- Holidays
- Lifting and Moving
- Making New Friends
- Positive Thinking
- Problem Solving
- Sexuality Stress Management
- Visiting

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Newly Revised Traditional Food Guide for the Alaska Native People is an Important Tool for Healthy Living

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Traditional foods are an important part of our Alaska Native cultures and an excellent source of nutrition for health and healing. The Alaska Native Tribal Health Consortium and our tribal partners around the state recognize the cultural importance of traditional foods for a person and their healthcare treatment, but often providers and patients need extra guidance in what foods will work for those managing chronic diseases or being treated for cancer.

To support those patients and healthcare providers, ANTHC published the Traditional Food Guide. Originally intended for cancer patients and released in 2008, the Traditional Food Guide is now in its second edition and available for sale through ANTHC and other retailers.

The first edition of the Traditional Food Guide was designed to support Alaska Native cancer patients who wanted to continue to eat their comforting and nutritious wild foods during treatment. Some healthcare providers were not familiar with the foods and recommended that they not be eaten.

The first edition of the Traditional Food Guide was far more successful than anticipated. Three printings were sold out and 14,000 copies distributed. Even though the book said “cancer” on the cover, many people bought and used the book. Alaska Native elders were proud to see their foods in the book along with other foods from different parts of

Alaska that they did not know about. Since its release, the book has been used by schools, universities, and Community Health Aide Program (CHAP) clinics. Some community tribal councils bought the book for every family. Other health programs around the state, like diabetes management programs, bought the book to share. It was recognized as the only book of its kind and placed in Alaska’s National Park book stores after a lengthy approval process.

With new uses for the guide, the second edition of the guide builds on its initial success and provides more information based on feedback and how people are currently using the guide and recipes. While the foods and nutrition information remain the same, we have added new material including healthy lifestyle information that is printed in our “Traditional Food Guide Activity Book,” which is distributed annually to schools and other programs for children 8-10 years throughout Alaska.

Now, the second Traditional Food Guide is written as an important tool for healthy living across generations and levels of health from the youngest child to the oldest elder. It is also a guide to help people with diseases like cancer, diabetes or heart disease learn more about nutrition and eat better foods.

“Happiness is healing. Elders need to taste the food they’ve grown up on so they can feel good about themselves again- it’s a healing thing” – Frank Wright, Hoonah

For more information or to order the Traditional Food Guide for Alaska Native People, contact the ANTHC Cancer Program at cancer@anthc.org or visit our website at: <http://www.anthc.org/chs/crs/foodguide.cfm>

Big Step Forward for Traditional Foods in Native Communities

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The literature supports the use of traditional foods in the reduction in the chronic illnesses in native people. The 2006 study by Schultz et al. reviewed the difference between the diabetes rates of American (38%) and Mexican (6.9%) Pima Indians. The much lower prevalence of type 2 diabetes in the Pima Indians in Mexico than in the U.S. indicated that even in populations genetically prone to type 2 diabetes, development is determined mostly by environmental circumstances. Differences between the two populations linked heavily to the traditional diet and the physical activity involved in growing, harvesting, preparing, and storing traditional foods. This study suggests that type 2 diabetes is largely preventable and that changes in lifestyle associated with Westernization play a major role in the global epidemic of type 2 diabetes.

When the Agricultural Act of 2014 (P.L. 113-79 also known as the “farm bill”) was reauthorized, its amendments introduced opportunity for increased utilization of traditional tribal foods in both the commodity distribution program and in federal feeding programs like school lunch and the nutrition programs for elders. The farm bill is an omnibus law, renewed every five years, that governs a wide-variety of agricultural and food programs. It provides a predictable opportunity for policy makers address agricultural and food issues comprehensively.

Under current law, state agencies typically administer the major federal food assistance programs, with the exception of the Food Distribution Program on Indian Reservations (FDPIR) and the Special Supplemental Nutrition Assistance Program for Women, Infants and Children (WIC), often operated by tribal organizations. The reauthorization requires USDA to conduct a study to assess the feasibility of tribal organizations administering all federal food programs, services, and activities. In addition, a study would allow at least one tribal organization

administering FDPIR to purchase traditional foods and foods produced locally by Indian producers. There is a \$1 million set-aside for USDA to conduct the study.

Additionally, the law enables the donation and serving of traditional foods for Native Americans in public programs. Facilities covered would include residential childcare facilities, child nutrition programs like school lunch, senior meal programs, and food services at hospitals and other health facilities. A number of tribes and programs embrace this opportunity, particularly those programs providing service to Elders (meals on wheels, congregate meals, and meals served in skilled nursing facilities).

The Utuqqanaat Inaat (Elder’s place) at the Maniliq Association Health Care Center in Kotzebue, AK has long questioned the prohibition of traditional foods in the menus for their skilled nursing facility. Elders who come to the center have eaten a subsistence diet of traditionally hunted and gathered foods their entire life but have to give them up when they need care. Val Kreil, the administrator of the facility, has aggressively pursued adding traditional caribou, dried fish, and locally harvested plants to the menu. His advocacy has a great deal to do with the aforementioned changes to the farm bill.

There is much work ahead to assure that traditional foods safely incorporate into menus and commodity distribution programs. Nutrient analysis to understand how the foods contribute to a mixed (traditional and non-traditional food) diet, environmental guidance for safe procurement, and HAACP guides for processing, preparation, and storage are just a few. The time invested today will go far in assuring that tribal members have opportunity for a healthier tomorrow. Taking a step back toward traditional foods can predict a giant step forward in preventing diabetes and the chronic conditions associated with it and improving the quality of life for Native Elders.



*Indian Health Service
National Pharmacy and Therapeutics Committee
Oral Antiplatelet Agents
NPTC Formulary Brief
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The NPTC performed a class review of oral antiplatelet agents at the May meeting. This class of medications was last reviewed in March 2011. Since that time, ticagrelor received FDA approval. Oral antiplatelet agents include aspirin, clopidogrel, prasugrel, ticlopidine, and ticagrelor. Ticlopidine is no longer recommended as a first line agent as it has many life threatening hematologic adverse reactions, and thus, was not included in the review. Aspirin was also not included in the review. Clopidogrel is the only (non-aspirin) oral antiplatelet agent currently named on the National Core Formulary (NCF).

Discussion:

All three agents reviewed are FDA-approved for thrombosis prophylaxis of acute coronary syndrome (ACS) managed with percutaneous coronary intervention (PCI). Ticagrelor and clopidogrel are also approved for thrombosis prophylaxis in ACS managed without PCI. Clopidogrel has the most FDA-approved indications, including ACS, acute ST-segment elevation myocardial infarction (STEMI), stroke, recent myocardial infarction (MI) and peripheral arterial occlusive disease. Clopidogrel is the only agent studied in patients undergoing fibrinolysis. Both prasugrel (Wiviott, 2007) and ticagrelor (Wallentin, 2009) have been associated with lower rates of cardiovascular (CV) events and stent thrombosis than clopidogrel. Prasugrel has shown a marked benefit over clopidogrel in patients with diabetes. Prasugrel is also associated with a higher rate of bleeding than clopidogrel. Patients with a history of stroke/transient ischemic attack (TIA), weight less than 60 kilograms or age greater than or equal to 75 years should not receive prasugrel because risks outweigh the benefits. The overall risk of major bleeding with ticagrelor is not greater than that with clopidogrel, although there is a higher rate of non-CABG related bleeding. Ticagrelor is associated with a 22% lower rate of death from any cause than clopidogrel. This is an effect that is not observed in studies with prasugrel versus clopidogrel. Ticagrelor has a slightly different adverse reaction profile than the other two, notably ventricular pauses that are rarely symptomatic and usually only during the first week of treatment and an increase in serum uric acid levels. Ticagrelor is contraindicated in severe hepatic impairment. Ticagrelor is dosed twice daily versus once daily for clopidogrel and prasugrel. When used as dual antiplatelet therapy (DAPT) with ticagrelor, it is recommended to use no greater than 100mg of aspirin daily.

Literature Review:

The following guidelines were reviewed: 2011 European Society of Cardiology (ESC) guidelines for the management of ACS in patients presenting without persistent ST-segment elevation, the 2012 ESC guidelines for the management of acute MI in patients presenting with ST-segment elevation, the 2013 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for the management of ST-elevation MI, and 2014 ACC/AHA guidelines for the management of patients with non-ST-elevation ACS. ESC guidelines recommend the use of ticagrelor or prasugrel over clopidogrel whereas the AHA/ACC guidelines do not state a preferential agent as a Class I recommendation. The ACC/AHA guidelines do give a Class II recommendation stating that it is “reasonable” to use one agent over the others based on patient/disease characteristics.

Primary literature was introduced through the above guidelines. The TRITON-TIMI 38 study evaluated prasugrel and clopidogrel. This multi-centered, international, double-blinded study enrolled 13,608 patients with moderate to high risk ACS who received PCI. Randomized study participants received either prasugrel 60mg load followed by a 10mg daily maintenance dose or clopidogrel 300mg load followed by a 75mg daily maintenance dose for 6 to 15 months. Both treatment arms also took aspirin daily. The primary outcomes measured were death from CV causes, nonfatal MI or nonfatal stroke. DAPT with prasugrel/ASA showed significantly reduced rates of death from CV causes, nonfatal MI and stent thrombosis versus clopidogrel/ASA. Prasugrel had an increased risk of major bleeding versus clopidogrel. The study also reported that patients who are over 75 years, who weigh less than 60 kg, or have a prior history of TIA/stroke may not benefit from prasugrel. Patients with diabetes mellitus or who have suffered STEMI may benefit from prasugrel.

The Study of Platelet Inhibition and Patient Outcomes (PLATO) was a multicenter, double blind, randomized trial that compared ticagrelor and clopidogrel for the prevention of CV events in 18,624 patients admitted to the hospital with ACS, with or without ST-segment elevation. The primary endpoint (composite of death from vascular causes, MI, or stroke) was significantly less in the ticagrelor group versus clopidogrel at 12 months. The difference was apparent within the first

30 days and persisted throughout the study period. For those patients enrolled in North America, the benefit of ticagrelor appeared attenuated. A sub-analysis attributed this to higher doses of ASA (325mg) used in North America versus lower doses (75-100mg) used in Europe. Other groups in which the benefit also appeared attenuated were those weighing less than the median weight for their sex and those not taking lipid-lowering medications at randomization. No differences in rates of major bleeding were noted between the two agents. However, a non-significant higher rate of non-CABG related major bleeding and more episodes of intracranial bleeding were seen in the ticagrelor group.

A 2014 systematic review from the Agency on Healthcare Research and Quality (AHRQ) entitled “Antiplatelet and Anticoagulant Treatments for Unstable Angina/Non-ST Elevation Myocardial Infarction” was also reviewed. This document evaluated the effectiveness and safety of antiplatelet agents used to treat UA/NSTEMI in an early invasive approach, an initial conservative approach, and after hospitalization. In patients on antiplatelet therapy treated with early invasive or PCI-based strategy, findings were consistent with published guidelines and meta-analyses. Prasugrel and ticagrelor were both associated with significant reduction in ischemic endpoints compared with clopidogrel. Ticagrelor did not have a significantly higher incidence of major bleeding compared with clopidogrel at one year as noted with prasugrel. Studies looking at initial conservative treatment utilized injectable glycoprotein IIb/IIIa inhibitors and anticoagulants rather than oral antiplatelet agents. Findings reviewing treatment after discharge were also consistent with current published guidelines. Dual antiplatelet therapy, typically aspirin and another antiplatelet agent, has better outcomes than single antiplatelet therapy but questions remain about the optimal duration of treatment. There is inconsistent data to draw conclusions about use of triple antiplatelet therapy. Additionally, there is a lack of direct comparison of prasugrel and ticagrelor. Safety and efficacy data is lacking for mixed treatment approaches. The duration of DAPT needs to be better defined and requires further study on aspirin doses in DAPT.

Findings:

Although there is evidence to support the use of all three antiplatelet agents reviewed, NPTC retained clopidogrel as the sole (non-aspirin) oral antiplatelet agent on the NCF. Prasugrel and ticagrelor were not added as their use is dependent on diagnosis, procedure, concomitant disease states and preference by local cardiologists. There are currently no head-to-head studies comparing prasugrel versus ticagrelor.

If you have any questions regarding this document, please contact the NPTC at IHSNPTC1@ihs.gov. For more information about the NPTC, please visit the NPTC website at <http://www.ihs.gov/nptc>.

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