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Navajo Nation Improves Environmental Health with Vacuum Sewer System

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Every autumn, farmers in Shiprock, New Mexico harvest, steam, and dry their Indian corn to make traditional Nas chizhi stew. Fertile soils and irrigation canals make the town's Mesa Farm area great for farming--but problematic for on-site wastewater disposal. Over three hundred homes in the area use septic tanks with drain fields to dispose of wastewater on-site. Irrigation raises the water table, preventing many drain fields from emptying properly. Instead, wastewater accumulates and then surfaces in yards or homes, causing serious environmental health concerns.

In 2004, Shiprock's community leadership requested that the Indian Health Service (IHS) Division of Sanitation Facilities Construction (DSFC) program plan a community sewer system to eliminate the use of drain fields in the Mesa Farm area. The IHS DSFC program exists to improve the health of Native American people by improving access to sanitation facilities like water and wastewater infrastructure.

The IHS project team began planning a gravity sewer system. However, the team soon discovered many obstacles to a gravity sewer system in the Mesa Farm area. Flat topography required sewer depths exceeding twenty feet in some areas. Narrow roads and existing utilities, like high voltage power lines and aging asbestos cement water lines, provided little space for excavating the proposed deep trenches. The water table was near the surface in some places and the soil was unstable for trenches. The team determined that construction costs for a gravity sewer were too expensive.

The IHS team investigated other types of sewer systems and determined that a vacuum sewer system was more cost effective than a gravity sewer system. Vacuum sewer systems assist wastewater movement with vacuum pumps and air valves. A vacuum sewer system usually allows for more line placement options, shallower trenches, and easier field alignment changes. Therefore, vacuum sewer capital costs can be significantly lower where high groundwater, unstable soils, congested utilities, flat or difficult terrain, right-of-way restrictions, or other challenges exist. Operations and maintenance costs may be higher for vacuum sewer systems unless one vacuum station can replace several proposed gravity lift stations. A vacuum sewer system may be the most economically feasible solution when site constraints make gravity sewer prohibitively expensive.

The IHS team finalized a design in August 2013 and the contractor, the Navajo Engineering and Construction Authority, began construction that same month. They completed the project in August 2015 and the Navajo Tribal Utility Authority began operating and maintaining the system. The project successfully eliminated 83 septic tank and drain field systems. There are still several hundred

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homes in the Mesa Farm area waiting for subsequent phases of the sewer project. This is the first vacuum sewer system on the Navajo Nation. This successful project will serve as a case study for other communities on the reservation seeking to extend community sewer services into areas where gravity sewer systems may not be feasible.



*Indian Health Service
National Pharmacy and Therapeutics Committee
Novel Insulin Delivery Devices
NPTC Formulary Brief
February 2016*



Background:

In August 2015, the Indian Health Service (IHS) National Pharmacy and Therapeutic Committee (NPTC) reviewed novel insulin therapies in the treatment of Type 2 Diabetes Mellitus (T2DM), evaluating the safety and efficacy of insulin and its utilization within the agency. This class of medications was last reviewed in 2010 when insulin detemir, insulin aspart, NPH, regular insulin and insulin aspart protamine and insulin aspart (70/30) mix were added to the National Core Formulary (NCF). The 2015 review included subcutaneous insulin products (human and analog), inhaled insulin (Afrezza®) and a transdermal insulin delivery device (V-Go®). The discussion resulted in **retaining the current NCF insulin products** and the **addition of insulin pen devices** for insulin detemir (Levemir®), insulin aspart (NovoLog®) and insulin aspart protamine and insulin aspart (NovoLog® 70/30 Mix).

Discussion:

Insulin therapy remains the most effective treatment for lowering blood glucose (decreases HbA1c 1.5%-3.5%) and as beta cell function declines, many diabetic patients eventually require insulin treatment to reach and maintain their glycemic goals¹⁻⁴. According to 2015 guidelines from the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE), when starting insulin therapy in T2DM, a basal insulin should be initiated first then either a bolus (rapid-acting) or glucagon-like peptide-1 receptor agonists should be added for prandial glucose reduction if needed^{3,4}. No preferential recommendations are given on which basal or rapid-acting insulin are given, however, the AACE recommends using basal and prandial analogs over NPH, regular and mixed insulin due to the increased incidence of hypoglycemia⁴.

Long-acting insulin analogs are equally efficacious in treating T2DM, however insulin detemir may require twice daily dosing to achieve similar glycemic control^{1,5}. Concerns with insulin use often include the incidence of hypoglycemia and weight gain⁵. Long-acting insulin analogs have a similar rate of symptomatic and nocturnal hypoglycemia and these effects are lower than that with NPH^{1,5}. Weight gain is more common with insulin glargine than once daily insulin detemir but similar when insulin detemir is given twice daily^{1,5}.

Despite its proven efficacy, patients are often reluctant to start insulin out of fear of needles, injections or lack of perceived convenience⁷⁻¹². Patient preference is an important factor in adherence to insulin therapy. Utilizing insulin pen devices has

been shown to reduce barriers to insulin use and improve adherence⁷⁻¹². Insulin pens have been associated with decreased overall healthcare costs, decreased emergency department and hospitalization rates, decreased physician visits and improved glycemic control¹⁰⁻¹⁵. Additionally, IHS-specific utilization data illustrate that procurement of pen devices is prevalent across the agency for both basal and bolus insulin pens¹⁶.

In 2014, the FDA approved a second-generation inhaled insulin, Afrezza[®] Technosphere insulin. Afrezza[®] is a dry powder, orally inhaled rapid-acting insulin used prior to meals for prandial glucose control⁶. Trials of inhaled insulin (T1DM and T2DM) demonstrated less favorable or non-inferior outcomes to comparator antidiabetic medications¹⁷. Afrezza[®] is contraindicated in patients with chronic lung disease (COPD, asthma), active lung cancer and should not be used in patients who are smoking or recently quit smoking (within the last 6 months)⁶. Inhaled insulin was found to lack key clinical advantages and/or cost-effectiveness compared with currently available NCF insulin products.

Studies of the recently-approved, disposable insulin delivery device (V-Go[®]) were evaluated. Small sample size, drop-out rates and short duration of studies limited the quality and interpretation of most clinical trial results¹⁸. Significant clinical outcomes in the studies presented were not consistently demonstrated with the V-Go[®] device.

Findings:

Insulin detemir is the most commonly prescribed insulin within IHS representing 77% of all prescribed long-acting insulin. This review did not identify new literature indicating superiority in any one insulin medication. Utilizing insulin is an important factor in improving glycemic control and patient satisfaction and adherence are improved with insulin pen use showing decreases in overall healthcare costs. Furthermore, studies and subsequent outcomes from the other insulin delivery devices were limited and did not confer cost-effective advantages to the IHS patient population.

Patient characteristics where insulin pen devices may provide benefit over traditional vial and syringes include the following:

- manual/physical dexterity issues
- visual impairment
- extreme age categories (i.e., pediatrics, elderly)
- trypanophobia (fear of needles and injections)
- small insulin dosage requirements
- lack of social acceptance
- poor (prior) adherence to insulin with vials and syringes

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.

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*Indian Health Service
National Pharmacy and Therapeutics Committee
Atypical Antipsychotic Drugs Update
NPTC Formulary Brief
February 2016*



Background:

In August 2015, the Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) reviewed the atypical antipsychotic drug class, also known as second generation antipsychotic agents. The current IHS National Core Formulary (NCF) currently requires facilities to maintain an atypical antipsychotic agent on formulary but leaves selection of the specific agent at the discretion of the local facility. As a result of the August 2015 meeting, no changes were made to the NCF.

Discussion:

Recent Cochrane reviews comparing quetiapine and aripiprazole to other atypical antipsychotic drugs (asenapine, iloperidone, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, and ziprasidone) demonstrated a lack of clinical superiority universally for any individual atypical antipsychotic agent.^{1,2} Vast differences in adverse effect profiles are noted for the atypical antipsychotic agents that may affect patient adherence and/or tolerability.² Selection of an atypical antipsychotic warrants careful evaluation of its benefits and disadvantages for use in individual patients, specifically potential metabolic issues such as weight gain, elevated cholesterol and an increased risk for diabetes. Clinical guidelines recommend providers engage patients in meaningful discussion (therapeutic alliance) about associated medication adverse effects to help guide antipsychotic selection.³ Agency procurement and utilization data illustrate that selection of atypical antipsychotics across the IHS varies significantly.

Clozapine should be considered for patients who experience positive symptoms (hallucinations, delusions, disorganized thinking/ behavior) after 2 trials of other antipsychotic drugs (can be either typical or atypical) at maximally-tolerated doses for at least 6 weeks. Clozapine has also been shown to reduce suicide attempts and can be used in patients at high risk of suicide.^{4,5} Clozapine has 4 specific black box warnings: agranulocytosis, orthostatic hypotension, seizures, and myocarditis/ cardiomyopathy.

Findings:

The current NCF states “any product” for the atypical antipsychotic drug class. Although no changes were made to the NCF, the NPTC felt it would be useful to provide a reference guide to the field highlighting the adverse effect profile used to help guide clinical decisions for the various atypical antipsychotic agents available. The following table was adapted from UpToDate.⁶

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| Drug | Weight Gain / Diabetes | Elevated Cholesterol | EPS / TD | Prolactin increase | Sedation | Ach* side effects | Orthostatic HTN | QTc prolongation |
|--------------|------------------------|----------------------|----------|--------------------|----------|-------------------|-----------------|------------------|
| Aripiprazole | + | - | ++ | - | + | - | - | -/+ |
| Asenapine | ++ | - | ++ | ++ | ++ | - | + | + |
| Clozapine | ++++ | ++++ | ++++ | - | +++ | +++ | +++ | + |
| Iloperidone | ++ | ++ | - | - | + | + | +++ | ++ |
| Lurasidone | + | - | - | - | ++ | - | + | - |
| Olanzapine | ++++ | ++++ | ++ | + | ++ | ++ | + | + |
| Paliperidone | +++ | + | + | +++ | + | - | ++ | + |
| Quetiapine | +++ | +++ | ++ | - | ++ | + | ++ | ++ |
| Risperidone | +++ | + | +++ | +++ | + | + | + | + |
| Ziprasidone | - | - | + | + | + | - | + | ++ |

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