Overcoming Clinical Inertia in the Management of Type 2 Diabetes

Lindsey Brown DNP Candidate

University of Utah, College of Nursing

In Partial Fulfillment of the Requirement for the Doctor of Nursing Practice
Executive Summary

Overcoming Clinical Inertia in the Management of Type 2 Diabetes
Lindsey Brown RN, BSN

Diabetes is a disease associated with significant, life threatening complications. Adequate glycemic control is essential to prevent micro- and macrovascular complications. Despite the wide dissemination of published evidence and clinical guidelines, fewer than half of individuals with diabetes achieve glycemic control. Providers contribute to this problem by not initiating or intensifying therapy when warranted. Clinical inertia, which is recognizing a clinical problem but failing to act on it, is a significant contributor to uncontrolled hyperglycemia in the care of patients with type 2 diabetes (T2DM).

Causes of clinical inertia include lack of knowledge or experience with insulin management and poor appreciation for the progressive nature of diabetes. Knowledge building tools such as algorithms are effective means of overcoming clinical inertia in healthcare providers. Algorithms increase knowledge, are convenient, and are effective for communicating clinical pathways for intensification of diabetes therapy. A clinical diabetes treatment algorithm was created for the Hope Clinic, a free medical facility for uninsured and underserved patients, to address clinical inertia in diabetes care at the clinic.

The aim of this project was to improve clinical management of patients with T2DM at the Hope Clinic. Specific objectives of this project were to: (1) identify barriers related to the implementation of evidence-based treatment guidelines for T2DM, (2) construct a diabetes clinical pathway algorithm that incorporates current evidence of diabetes care best practices in therapy intensification for patients whose hyperglycemia is not currently being controlled based on American Diabetes Association (ADA) guidelines, (3) improve the consistency of providers' management of patients with T2DM and their adherence to published diabetes management guidelines, (4) increase number of insulin initiations among patients who meet criteria for insulin therapy, and (5) communicate these findings via a professional nursing forum.

Pre- and post-evaluation chart reviews were performed to determine the extent of the problem and to evaluate clinical practices pre- and post-implementation. With use of the algorithm, appropriate initiation and intensification of diabetes therapy increased from 58% to 87%. The rate of insulin initiations also increased from 33% to 91%. Appropriate treatment of pre-diabetes improved from 33% to 83%. Given that intensification of therapy improves uncontrolled hyperglycemia, continued use of the algorithm should improve long-term clinical outcomes in patients with T2DM. However, long term evaluation of patient outcomes and providers diabetes management practices is imperative to evaluate both the effectiveness and sustainability of the algorithm.

Committee Chair: Pamela Phares PhD, APRN-BC, CNM, Program Director: Dianne Fuller, DNP, FNP-BC, Executive Director: Katie Ward, DNP, WHNP, ANP, Content Experts: Davida Kruger MSN, APN-BC, BC-ADM and Brandon Jennings, Pharm-D.
# Table of Contents

Executive Summary .................................................................................................................. 2

Problem Statement .................................................................................................................... 5

Clinical Significance ................................................................................................................. 5

Objectives .................................................................................................................................. 6

Review of Literature ................................................................................................................... 7

- Pathophysiology ..................................................................................................................... 7
- Clinical Inertia .......................................................................................................................... 7
- Implementing Guidelines into practice ....................................................................................... 9

Theoretical Framework .............................................................................................................. 9

Implementation, Evaluation, and Results .................................................................................... 9

Objective 1: Identify barriers related to the implementation of evidence-based treatment
guidelines for T2DM .................................................................................................................... 10

Objective 2: Construct a diabetes clinical pathway algorithm that incorporates current evidence
of diabetes care best practices in therapy intensification for patients whose hyperglycemia is
not currently being controlled based on ADA guidelines .......................................................... 11

Objective 3: Improve the consistency of providers' management of patients with T2DM and
their adherence to published diabetes management guidelines ................................................. 12

Objective 4: Increase number of insulin initiations/referrals to diabetes clinic among patients
who meet criteria for insulin therapy ......................................................................................... 13

Objective 5: Disseminate project findings via a professional nursing forum .................................. 14

Recommendations ..................................................................................................................... 14

Conclusion .................................................................................................................................... 15

References .................................................................................................................................... 17

Appendix A: Algorithm .............................................................................................................. 20

Appendix B: Provider Survey .................................................................................................... 24
Appendix C: ADA approval to adapt table ................................................................. 26
Appendix D: IRB waiver ......................................................................................... 28
Appendix E: Dissemination Memorandum .............................................................. 30
Appendix F: Project Defense PPT ......................................................................... 32
Appendix G: Poster ............................................................................................... 39
Problem Statement

Diabetes affects 26.8 million U.S residents of all ages. It is estimated that 7 million of those with diabetes have not been diagnosed. Diabetes was the seventh leading cause of death in the U.S. in 2007 and it is suspected to be much higher due to underreporting on death certificates. It is estimated that nearly 79 million adults in the U.S. have pre-diabetes (Center For Disease Control and Prevention [CDC], 2011).

Complications of diabetes are numerous. Comprehensive control of diabetes is vital to prevent complications. Not only is adequate glycemic control necessary, blood pressure and lipid management is essential to prevent or delay macrovascular and microvascular disease. It is estimated that only one-third of individuals with diabetes have all risk factors controlled (Zhang, Van Leuven, & Neidlinger, 2012) and less than half of patients reach recommended goals (Ross, 2013).

The reasons for which patients fail to meet goals in diabetes care are multifactorial. Patients, providers, healthcare systems and availability of treatments all contribute to this problem (Triplitt, 2010). This project specifically focuses on addressing providers’ contribution to uncontrolled hyperglycemia in one primary care setting. Despite evidence of improved outcomes from comprehensive diabetes control, primary care providers often do not appropriately initiate or intensify diabetes treatment as indicated by a patient’s clinical trajectory (Khunti et al., 2013). The complexity of evidence based guidelines and lack of guidance in how to incorporate them into everyday clinical practice perpetuates the problem (Renders et al., 2009).
Clinical Significance

Type 2 diabetes (T2DM) accounts for 90% of adult cases of T2DM diagnosed annually (CDC, 2011). Results of the sentinel UK Perspective Diabetes Study (UKPDS) validated that improved glycemic control reduces the risk of diabetes-related complications (Stratton et al., 2000). According to the State of Diabetes in America report, three out of five individuals with diabetes have one or more complications from the disease (American Academy of Clinical Endocrinologists [AACE], 2007). Diabetes increases an individual’s risk for cardiovascular disease, peripheral vascular disease and stroke two- to four-fold (Hillarie & Woods, 2013). Diabetes is currently the leading cause of blindness, kidney failure and nontraumatic limb amputations. Despite health care providers’ awareness of better patient outcomes with optimal diabetes control, initiation and intensification of therapy is not effectively translating into practice (Harris, Kapor, Lank, Willian, & Houston, 2010). Improvements in current diabetes clinical practice are necessary to prevent and reduce complications of diabetes.

Objectives

The aim of this project is to improve clinical management of patients with T2DM at the Hope Clinic. The Hope Clinic is a free medical facility in Midvale, Utah. The clinic serves the local uninsured and underserved population. There is a large Latino and Pacific Islander population at the clinic. Ethnicity and low socioeconomic status contribute to a high incidence of T2DM within the clinic population. In connection with this project, a new diabetes clinic has been established at the Hope Clinic to specifically target treatment of patients with sustained hyperglycemia on multiple oral antidiabetic medications who require insulin initiation or insulin
intensification to control their T2DM (P. Phares, personal communication, June 1, 2013).

Specific objectives of this project are to: (1) identify barriers related to the implementation of evidence-based treatment guidelines for T2DM, (2) construct a diabetes clinical pathway algorithm that incorporates current evidence of diabetes care best practices in therapy intensification for patients whose hyperglycemia is not currently being controlled based on American Diabetes Association (ADA) guidelines, (3) improve the consistency of providers' management of patients with T2DM and their adherence to published diabetes management guidelines, (4) increase number of insulin initiations among patients who meet criteria for insulin therapy, and (5) and communicate these findings via a professional nursing forum.

**Literature Review**

**Pathophysiology**

Diabetes is a chronic condition caused by either impaired insulin action, production, or both, resulting in uncontrolled hyperglycemia (Hilaire & Woods, 2013). Diabetes has an epigenetic causality and individual susceptibility varies. Risk factors for this disease include physical inactivity, overweight, and excessive calorie consumption (Spollett, 2013).

Islet cell dysfunction and peripheral insulin resistance are key features of T2DM. In early disease, insulin secretion from the beta islet cell may be normal or increased. As disease progresses, peripheral insulin sensitivity declines and insulin secretion is low relative to the hyperglycemic state. In T2DM, beta cells do not release adequate insulin in phase with rising blood glucose levels further exacerbating hyperglycemia. Complicating the hyperglycemia, alpha islet cell dysfunction causes excessive secretion of hepatic glucagon, which in turn dumps more glucose into circulation (Inzucchi et al., 2012). Persistent uncontrolled hyperglycemia
contributes to apoptotic beta cell death, which ultimately results in an insulin deficiency state (Quan, Jo, & Lee, 2013).

**Clinical inertia**

Diabetes is a progressive disease leading to diminished glycemic control over time even in the most compliant patients (Harris, Kapor, Lank, Willian, & Houston, 2010; Tierney, 2013). Due to the progressive nature of T2DM, intensification of therapy and eventual use of insulin is necessary however insulin continues to be underused. A study by Harris et al. revealed that providers often delay starting insulin in many patients who meet criteria for insulin therapy. The study population had diabetes at least nine years or longer and HbA1c levels of 9.5% before their health care providers considered initiating insulin therapy. In addition, providers proved to be insufficiently aggressive in adjusting insulin regimens commensurate with patients’ average HbA1c levels after initiating insulin therapy. The average HbA1c was 7.9% after 3 years of insulin use by study subjects; still well above current ADA recommended HbA1c goals. This is an example of clinical inertia, which is the recognition of a clinical problem by a health care provider who fails to subsequently act on it (Joy, 2008; Harris et al.).

Khunti et al., (2013) examined clinical inertia in diabetes care providers in the United Kingdom (UK). The retrospective study evaluated 80,000 patients with T2DM in the UK. The study results revealed patients with poor glycemic control for greater than seven years before intensification of therapy was initiated with insulin or oral antidiabetic medications. The average HbA1c was 8.7% or greater at the time therapy was intensified. Improvements in clinical practice are clearly needed in the intensification of diabetes treatments to prevent and reduce complications of diabetes.
Potential causes for clinical inertia are varied. Lovshin and Zinman (2013) discuss several causes of clinical inertia. First, providers may not fully appreciate the progressive nature of diabetes and unavoidable beta cell decline. Second, providers’ and patients’ fear of weight gain and hypoglycemia may stall attempts to advance therapy. Third, providers may lack knowledge and comfort with management of insulin therapy. Lastly, many providers are reluctant to use combination therapy in early disease despite evidence that indicates multiple drugs may be necessary to maintain adequate control of blood glucose.

**Implementing Guidelines into Practice**

Education is essential for diabetes care providers to improve their management of T2DM and overcome clinical inertia in practice. Kunt and Snoek (2009) suggest using written materials to aid in prescribing, such as an algorithm that is clearly written and easy to use on a daily basis. Algorithms are convenient and they can clearly communicate the clinical pathway for appropriate diabetes treatment and therapy intensification. Algorithms allow for consistency in clinical practice among providers with diverse levels of training, experience, and education, which is the case at the Hope Clinic in Midvale, Utah.

**Theoretical Framework**

Lewin’s Theory of Planned Change (TPC) is the theoretical framework guiding this project. Lewin’s TPC was created in the early 20th century by social psychologist, Kurt Lewin. Unfreezing, moving, and refreezing are the three stages that form the foundation of this theoretical framework (Shirey, 2013).

Unfreezing is the first phase. In this phase one is essentially getting ready for change. The problem is identified and a solution is selected. It is important in this phase to identify positive and negative influences of the proposed change. Strengthening or weakening these forces is
recommended. Moving, also known as transitioning, is the next phase in Lewin’s TPC. This phase is largely the process of internal reactions that individuals experience as they adopt change. It is necessary to engage and support individuals during implementation of the change. Refreezing is the final phase of Lewin’s theory. This phase occurs when the change is fixed into an individual’s behavioral repertoire (Shirey, 2013).

Implementation, Evaluation and Results

**Objective #1: Identify individual and system barriers related to the implementation of evidence-based treatment guidelines for T2DM at the Hope Clinic.**

The project proposal was approved by IRB on December 3, 2013. Providers at the Hope Clinic were then surveyed to determine their needs regarding the diabetes algorithm. Results were used in the construction of the algorithm. Providers’ survey responses indicated a general lack of provider knowledge about current guidelines, which prompted inclusion of a diabetes management page along with the treatment algorithm.

Prior to implementation of the algorithm, a pre-review of twenty-four charts was performed to assess providers’ documentation of their diabetes management and determine pre-implementation baseline HbA1c levels from a random sample of patients in the clinic to use as a means to evaluate the algorithm. The chart review revealed numerous inconsistencies in providers’ management of diabetes in addition to their management of pre-diabetes, which prompted incorporation of pre-diabetes treatment in the algorithm as well. Only one-third patients with pre-diabetes were started on metformin when their HbA1c was >6%. Additionally, one patient with pre-diabetes was noted to have has his metformin stopped. Currently the AACE recommends starting pharmacological interventions for individuals with pre-diabetes (Garber et al., 2013). The chart review revealed advancement in therapy for 14 out of 24 (58%) patients.
For those patients who had their diabetes therapy advanced, it was frequently not aggressive enough to accomplish glycemic control given the inability of the prescribed medication to effectively lower HbA1c. The chart review also revealed a lag in initiating therapy for patient’s with new onset of diabetes. Two patients with HbA1c of 6.5% did not have any therapy initiated during their visit despite clear documentation of a HbA1c in diabetic range. Providers’ prescribing of metformin, a common first line antidiabetic drug, were variable with many providers not titrating to the recommended effective dose of 1500-2000 milligrams daily (Nathan et al., 2009). Chart documentation also revealed delays in insulin initiation with only one-third of patients’ having uncontrolled hyperglycemia and using multiple oral agents being started on insulin. Prescribing a second oral agent for patients with HbA1c levels above goal was delayed in two-thirds of patients.

Objective #2: Construct a diabetes clinical management algorithm that incorporates current evidence of diabetes care best practices in therapy intensification for patients whose hyperglycemia is not currently being controlled based on ADA guidelines

A review of literature was performed in order to analyze the most current evidence. This evidence was subsequently used in the construction of the algorithm. Content experts and the project chair were then consulted for further revisions and clarifications of the algorithm. The algorithm included a stepwise treatment plan, standards of care in diabetes, diabetes drugs appropriate for the population at the Hope Clinic, a reference table of drug profiles, and a cost plus dosing table for reference. The reference table for the diabetes drug profiles was adapted with permission from the ADA.

The initial plan for this project was to have a three to four month evaluation period for piloting the algorithm, however this plan changed based on a series of delays encountered with
IRB proposal revisions and review periods, the clinic’s holiday hours, and an early revision of the initial algorithm after only three weeks of implementation. The initial treatment algorithm was not as specific or as tailored to the clinic as providers and clinical staff were expecting, which necessitated these revisions. Content experts and the project chair were consulted to advise on modifications of the algorithm and to be responsive to providers’ needs and requests. This revised algorithm was given to the Hope Clinic’s providers on February 11, 2013 for use in the pilot testing period.

**Objective #3: Improve the consistency of providers' management of patients with T2DM and their adherence to published diabetes management guidelines**

The algorithm was made available to clinical staff and education was provided to them when they were available in clinic to review with the author. During follow up visits to the clinic verbal feedback was elicited from staff to improve and finalize the algorithm. Providers were verbally surveyed to evaluate use, convenience, and the algorithm’s influence on providers prescribing behaviors. The final laminated algorithm was given to the clinic on March 25, 2013 (Appendix A).

The informal post-implementation provider survey confirmed the convenience and simplicity of the algorithm. Providers endorsed the algorithm as positively influencing their prescribing practices. The algorithm made the providers aware of the need to intensify therapy more aggressively, however they were not using the algorithm with every patient. One provider dismissed the algorithm and refused to provide any feedback. Nursing staff who were responsible for evaluation of the lab results and making patient callbacks in the clinic found the algorithm convenient, informative, and easy to use. The algorithm allowed nursing staff to evaluate the appropriateness of current diabetes treatment regimens during lab review and
provide clinical recommendations to providers who were responsible for initiating or intensifying therapy when necessary.

Ideally the algorithm should have had a much longer pilot period in order to evaluate its efficacy in changing providers’ behaviors. Given that the revised algorithm had only a six-week pilot period, the post-implementation review of charts did not allow for the use of HbA1c as a measure of the algorithm’s success. As an alternative measure, evaluation of providers’ adherence to the algorithm was used to assess its impact on changing clinical prescribing and diabetes management behaviors. This was accomplished by auditing patient charts for those who were seen in clinic during the pilot testing period, February 11, 2014 to March 19, 2014. A total of thirty-four charts were reviewed following implementation. Results from the post-implementation review were compared to the pre-implementation review findings. The charts were evaluated for proper initiation and intensification of diabetes therapy, adherence to pre-diabetes treatment recommendations, proper titration and dosing of metformin, and the number of insulin initiations or referrals to the diabetes clinic for management of insulin therapy.

The chart review revealed appropriate initiation or advancement in therapy for twenty-six out of thirty (86.6%) patients. With use of the algorithm, appropriate initiation and intensification of diabetes therapy increased from 58% of patients to 86.6% of patients. Four patients were currently at goal and did not require further therapy intensification. Five out of six (83.3%) patients with pre-diabetes were started on metformin when HbA1c was >6%. Treatment initiated for patients with pre-diabetes increased from 33% pre-implementation to 83.3% post-implementation. The charts of two newly diagnosed diabetic patients were reviewed to compare pre-implementation findings of delayed treatment of newly diagnosed patients. Both patients had
appropriate therapy initiated. Appropriate therapeutic dosing and titration of metformin was found in all charts reviewed post-implementation.

**Objective #4: Increase number of insulin initiations among patients who meet criteria for insulin therapy.**

Of the 24 initial charts reviewed, only two patients were found to have returned to clinic during the pilot evaluation period on post-evaluation. Both of these patients were appropriately referred to the diabetes clinic for insulin initiation at their return visit. The alternative evaluation method of a post-implementation chart audit included an evaluation of appropriate insulin initiation or referrals to the diabetes clinic for insulin initiation. The chart audit revealed ten out of eleven patients (90.6%) who met the criteria for insulin initiation were appropriately referred to the diabetes clinic for insulin initiation or were started on insulin the day of their appointment. The pre-implementation chart review revealed that only 33% of patients who met the criteria for insulin therapy were started on insulin. Following implementation of the algorithm, this rate increased to 90.6%.

**Objective #5: Disseminate project findings via a professional nursing forum**

The decision was made to delay submission of a manuscript of the project findings to a refereed nursing journal until the algorithm could be fully evaluated over a longer period of time. The author’s plan is to work with the project chair after graduation to evaluate the effectiveness of the algorithm. The project findings discussed in this manuscript were disseminated to the clinical staff on March 25, 2014 in a brief memorandum.

**Discussion and Recommendations**

Because of delays in deploying the algorithm at Hope Clinic, an insufficient evaluation period resulted. Sustained behavioral changes in clinicians’ practices will take time to occur and
prematurely basing conclusions on an insufficient evaluation period may result in faulty assumptions being made. A much longer evaluation period using HbA1c as a clinical endpoint for evaluation of the algorithm was the intended method for evaluation. Ongoing evaluation of the algorithm continues at the Hope Clinic.

Community clinics with similar patient populations would most definitely benefit from using the algorithm as a clinical tool for prescribing and advancing T2DM therapy appropriately as a means for overcoming clinical inertia. This project was created specifically for the Hope Clinic with low-income and uninsured patients in the community setting in mind. Use of the algorithm by providers who care for similar patient populations would be appropriate. Because the author was outside of the clinic system, making frequent contact with providers was difficult. Being within the clinic system may have facilitated the use of the algorithm among the clinic’s providers and may have provided opportunities for additional observational data as well. It is the author’s recommendation that others developing such algorithms do so as part of their targeted clinical site for implementation.

**Conclusion**

This project incorporated current evidence into a diabetes treatment algorithm for convenient use in a community primary care setting to address clinic inertia in management of T2DM. Clinical inertia is a problem that adversely effects patient outcomes and contributes to disease complications related to poorly managed T2DM (Khunti et al., 2013; Harris et al., 2010). Providing clear pathways to advance therapy is one approach to address clinical inertia. Early and appropriate therapy is vital in preventing and delaying complications of T2DM (Stratton et al., 2000). The project resulted in improvement in therapy intensification, insulin initiation, and treatment of pre-diabetes within the Hope Clinic population during the pilot period. Given that
intensification of therapy improves uncontrolled hyperglycemia, continued use of the algorithm should improve long-term clinical outcomes in patients with T2DM. However, long-term evaluation of patient outcomes and providers diabetes management practices is imperative to evaluate both the effectiveness and sustainability of the algorithm.
References


Kunt, T., & Snoek, F. J. (2009). Barriers to insulin initiation and intensification and how to overcome them. *International Journal of Clinical Practice, 63*(Suppl. 164), 6-10.


Quan, W., Jo, E. K., & Lee, M. S. (2013). Role of pancreatic beta cell death and inflammation in diabetes. *Diabetes, Obesity and Metabolism, 15*(s3), 141-151.


Stratton, I. M., Adler, A. I., Neil, H. A. W., Matthews, D. R., Manley, S. E., Cull, C.,
A.....Holman, R. R. (2000). Association of glycaemia with macrovascular and
microvascular complications of type 2 diabetes (UKPDS 35): prospective observational
when metformin alone is no longer enough. American Academy of Nurse Practitioners,
a changing environment. The American Journal of Managed Care, 16(7), S195-S200.
diabetes management in primary care. The Journal of Nurse Practitioners, 8(10), 822-827.
Appendix A: Algorithm
Diabetes Management Algorithm

START

A1c ≥10%

YES

NO

A1c ≥9%

YES

NO

A1c ≥6.5%

YES

NO

Metformin 1,000 mg with dinner, titrate to 2,000 mg/day

A1c ≥6.5%

Yes

NO

A1c ≥9%

Refer to DM clinic

Metformin 1,000 mg with dinner, titrate to 2,000 mg/day

Glyburide 2.5 - 5 mg QD or BID (max 20 mg/day)

or

Glipizide 5 mg QD (max 40 mg/day)

or

Glimepiride 1 mg QD (max 8 mg/day)

(If PAP eligible see consideration)

(If taking medication, increase dose if not at max dose)

check A1c after 3 months

A1c ≤7%

YES

A1c ≤7%

NO

yes

NO

Refer to DM clinic

CONTINUE THERAPY

Considerations:
- If PAP eligible consider Sitagliptin 100 mg QD or a GLP-1 agonist instead of a sulfonylurea.
- If Metformin is contraindicated, all drug classes are acceptable for first line therapy.
- Any combination of two drug classes is acceptable for two drug therapy.
Managing Diabetes

**Pre-Diabetes Treatment**
- A1c 5.7 - 6.4%
- Metformin
- Weight Loss
- Physical Activity
- 500 mg BID
- 7% of Bodyweight
- 150 min/week

**HbA1c Goal**

- < 7%
- Individually with short duration of T2DM, long life expectancy, and no significant CVD
- < 6.5%
- Individually with history of severe hypoglycemia, limited life expectancy, advanced complications of T2DM, extensive co-morbid conditions, or long standing T2DM
- < 8%

**BP Goals**
- SBP < 140 mmHg
- DBP < 80 mmHg

**CVD**
- Screen lipids annually
- Consider ASA therapy for individuals with 10-years risk > 10%

**Nephropathy**
- Annual quantitate urine albumin excretion
- Start ACE or ARB

**Retinopathy**
- Initial dilated eye exam at T2DM diagnosis
- If no evidence of retinopathy, repeat every 2 years
- If retinopathy present, repeat annually

**Neuropathy**
- Screen at least annually

**Annual comprehensive exam:**
- Inspection, pulses, assess for LOPS: 10-g monofilament test AND vibration turning fork OR ankle reflexes OR vibration perception threshold
## Diabetes Management Algorithm

<table>
<thead>
<tr>
<th>Class</th>
<th>Compound(s)</th>
<th>Cellular mechanism</th>
<th>Primary physiological action(s)</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biguanides</td>
<td>Metformin</td>
<td>Activates AMP-kinase</td>
<td>↓ Hepatic glucose production</td>
<td>Extensive experience</td>
<td>Gastrointestinal side effects (diarrhea, abdominal cramping)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No weight gain</td>
<td>Lactic acidosis risk (rare)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No hyperglycemia</td>
<td>Multiple contraindications (CKD, acidosis, hypokalemia, dehydration, etc.)</td>
</tr>
<tr>
<td>Sulfonylureas</td>
<td>2nd Generation</td>
<td>Closes K+ channels on β-cell membranes</td>
<td>↑ Insulin secretion</td>
<td>Extensive experience</td>
<td>Hypoglycemia</td>
</tr>
<tr>
<td></td>
<td>Glyburide/ glibenclamide</td>
<td></td>
<td></td>
<td>Microvascular risk</td>
<td>Weight gain</td>
</tr>
<tr>
<td></td>
<td>Glipizide</td>
<td></td>
<td></td>
<td></td>
<td>7 Blunts myocardial ischemic preconditioning</td>
</tr>
<tr>
<td></td>
<td>Glimipride</td>
<td></td>
<td></td>
<td></td>
<td>Low durability</td>
</tr>
<tr>
<td>DPP-4 inhibitors</td>
<td>Sitagliptin</td>
<td>Inhibits DPP-4 activity, increasing postprandial active incretin (GLP-1 GIP) concentrations</td>
<td>↑ Insulin secretion (glucose-dependent)</td>
<td>Hypoglycemia</td>
<td>Generally modest HbA1c efficacy</td>
</tr>
<tr>
<td></td>
<td>Saxagliptin</td>
<td></td>
<td></td>
<td>Well tolerated</td>
<td>Uricuria/lipodermia</td>
</tr>
<tr>
<td></td>
<td>Linagliptin</td>
<td></td>
<td></td>
<td></td>
<td>Pancreatitis</td>
</tr>
<tr>
<td>GLP-1 receptor agonists</td>
<td>Exenatide</td>
<td>Activates GLP-1 receptors</td>
<td>↑ Insulin secretion (glucose-dependent)</td>
<td>No hypoglycemia</td>
<td>Gastrointestinal side effects (nausea/vomiting)</td>
</tr>
<tr>
<td></td>
<td>Exenatide extended release</td>
<td></td>
<td>↓ Glucagon secretion (glucose-dependent)</td>
<td>Weight reduction</td>
<td>Acute pancreatitis</td>
</tr>
<tr>
<td></td>
<td>Exenatide</td>
<td></td>
<td>↓ Glucagon secretion (glucose-dependent)</td>
<td>Potentially for improved beta-cell mass/function</td>
<td>C-cell hyperplasia/medullary thyroid tumors in animals</td>
</tr>
<tr>
<td></td>
<td>Linaglutide</td>
<td></td>
<td>Slow gastric emptying</td>
<td>Cardiovascular protective actions</td>
<td>Injectable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>↑ Safety</td>
<td></td>
<td>Training requirements</td>
</tr>
</tbody>
</table>

*Adapted with permission from the American Diabetes Association.*

### Medication Costs

<table>
<thead>
<tr>
<th>Medication</th>
<th>Tablet form</th>
<th>Dosing</th>
<th>Cost @ Costco™ (30 tabs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metformin (Gliclora)</td>
<td>500 mg, 850 mg, 1,000 mg</td>
<td>Initial: 1,000 mg QD, Max: 2,550 mg/day</td>
<td>$6, $9</td>
</tr>
<tr>
<td>Glyburide (Diabeta, Micronease)</td>
<td>2.5 mg, 5 mg</td>
<td>Initial: 2.5 - 5 mg QD or BID, Max: 20 mg/day</td>
<td>$6</td>
</tr>
<tr>
<td>Glipizide (Glucotrol)</td>
<td>5 mg, 10 mg</td>
<td>Initial: 5 mg QD, Max: 40 mg/day</td>
<td>$7</td>
</tr>
<tr>
<td>Glimipride (Amaryl)</td>
<td>1 mg, 2 mg, 4 mg</td>
<td>Initial: 1 mg QD, Max: 8 mg/day</td>
<td>$8</td>
</tr>
<tr>
<td>Sitagliptin (Januvia)</td>
<td>100 mg</td>
<td>Initial: 100 mg QD, Max: 100 mg/day</td>
<td>$304</td>
</tr>
<tr>
<td>Saxagliptin (Onglyza)</td>
<td>2.5 mg, 5 mg</td>
<td>Initial: 2.5 mg QD, Max: 5 mg/day</td>
<td>$298</td>
</tr>
<tr>
<td>Linagliptin (Tradjenta)</td>
<td>5 mg</td>
<td>Initial: 5 mg QD, Max: 5 mg/day</td>
<td>$0.18</td>
</tr>
<tr>
<td>Exenatide (Byetta)</td>
<td>5 mcg, 10 mcg (injection)</td>
<td>Initial: 5 mcg QD, Max: 20 mcg/day</td>
<td>$428</td>
</tr>
<tr>
<td>Exenatide ER (Bydureon)</td>
<td>2 mg (injection)</td>
<td>Initial: 2 mg QW, Max: 2 mg/week</td>
<td>$477</td>
</tr>
<tr>
<td>Linaglutide (Victoza)</td>
<td>1.2 mg (injection)</td>
<td>Initial: 0.6 mg QD for 1 week, increase to 1.2 mg QD, Max: 1.8 mg/day</td>
<td>$400</td>
</tr>
</tbody>
</table>

### Additional considerations:

- If pt’s blood glucose is >500 during office visit AND pt is symptomatic for DKA send pt to ER.

### References:

Appendix B: Provider Survey
Provider Survey
Diabetes Clinical Pathway Algorithm

What barriers do you encounter in initiating and intensifying diabetes therapy at the Hope Clinic? Check all that apply.

___ Time constraints/takes too much time
___ Unfamiliar with current treatment guidelines
___ Lack of training or experience in diabetes care
___ Lack of knowledge about prescribing and/or managing insulin therapy
___ Concerns about the ability of patient’s to comply with prescribed therapy
___ Other:

The proposed diabetes clinical pathway algorithm will include a stepwise algorithm to aid in initiating and intensifying therapy for patients covered by the PAPs. There will be a separate algorithm to minimize cost for those who are not covered by the PAPs. What other components would you like to see as part of a diabetes clinical pathway algorithm for the Hope Clinic? Check all that apply

___ Choosing appropriate medications
___ Correct dosing of diabetes medications
___ Contraindications for certain diabetes medications
___ When to refer for insulin therapy
___ When to refer to a diabetes specialist
___ Other:

Are there areas of diabetes management that you would like to have more education to help you prescribe and intensify therapy? Check all that apply

___ Understanding current ADA guidelines
___ Understanding the progressive nature of diabetes and disease trajectory
___ Insulin initiation and intensification
___ Starting combination therapy in early disease
___ Other:
Appendix C: ADA approval to adapt table
American Diabetes Association LICENSE
TERMS AND CONDITIONS

Feb 10, 2014

This is a License Agreement between Lindsey Brown ("You") and American Diabetes Association ("American Diabetes Association") provided by Copyright Clearance Center ("CCC"). The license consists of your order details, the terms and conditions provided by American Diabetes Association, and the payment terms and conditions.

All payments must be made in full to CCC. For payment instructions, please see information listed at the bottom of this form.

<table>
<thead>
<tr>
<th>License Number</th>
<th>3284870417360</th>
</tr>
</thead>
<tbody>
<tr>
<td>License date</td>
<td>Dec 09, 2013</td>
</tr>
<tr>
<td>Licensed content publisher</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>Licensed content title</td>
<td>Diabetes care</td>
</tr>
<tr>
<td>Licensed content date</td>
<td>Jan 1, 1978</td>
</tr>
<tr>
<td>Type of Use</td>
<td>Thesis/Dissertation</td>
</tr>
<tr>
<td>Requestor type</td>
<td>Author of requested content</td>
</tr>
<tr>
<td>Format</td>
<td>Print</td>
</tr>
<tr>
<td>Portion</td>
<td>chart/graph/table/figure</td>
</tr>
<tr>
<td>Number of charts/graphs/tables/figures</td>
<td>3</td>
</tr>
<tr>
<td>Title or numeric reference of the portion(s)</td>
<td>Table 1-Properties of currently available glucose lowering agents that may guide treatment choice in individual patients with type 2 diabetes &amp; Figure 2 Anthyperglycemic therapy in type 2 diabetes</td>
</tr>
<tr>
<td>Title of the article or chapter the portion is from</td>
<td>Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach</td>
</tr>
<tr>
<td>Editor of portion(s)</td>
<td>n/a</td>
</tr>
<tr>
<td>Author of portion(s)</td>
<td>n/a</td>
</tr>
<tr>
<td>Volume of serial or monograph.</td>
<td>n/a</td>
</tr>
<tr>
<td>Page range of the portion</td>
<td>(p.1367-1368) &amp; 1371</td>
</tr>
<tr>
<td>Publication date of portion</td>
<td>June 2012</td>
</tr>
<tr>
<td>Rights for</td>
<td>Main product</td>
</tr>
<tr>
<td>Duration of use</td>
<td>Current edition and up to 5 years</td>
</tr>
<tr>
<td>Creation of copies for the disabled</td>
<td>no</td>
</tr>
<tr>
<td>With minor editing privileges</td>
<td>yes</td>
</tr>
<tr>
<td>For distribution to</td>
<td>United States</td>
</tr>
</tbody>
</table>

https://v100.copyright.com/CustomerAdmin/PLI.jsp?ref=da709552-cbc5-40d4-9eed-a3283cb1808a
Appendix D: IRB approval
INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH
75 South 2000 East Salt Lake City, UT 84112 | 801.581.3655 | IRB@utah.edu

IRB: IRB_00069049
PI: Lindsey Brown
Title: Diabetes Management Algorithm

This New Study Application qualifies for an expedited review by a designated University of Utah IRB member as described in 45 CFR 46.110 and 21 CFR 56.110. The research involves one or more activities in Category 5 (published in 46 FR 60364-60367). The designated IRB member has reviewed and approved your study as a Minimal risk study on 12/2/2013. The approval is effective as of 12/3/2013. Federal regulations and University of Utah IRB policy require this research protocol to be re-reviewed and re-approved prior to the expiration date, as determined by the designated IRB member.

Your study will expire on 12/1/2015.
Any changes to this study must be submitted to the IRB prior to initiation via an amendment form.

DETERMINATIONS

- **Waiver/Alteration Determination:** The IRB has determined that the request for the waiver of consent and authorization is approved for this research under 45 CFR 46.116(d) and 56 CFR 164.512(f)(2)(i).

APPROVED DOCUMENTS

**Literature Cited/References**
IRB Reference.docx

**Other Documents**
Hope Clinic Privacy Policy
Information for accounting disclosures
Reliance Agreement

Click [IRB_00069049](https://ericaresearch.utah.edu/ericaresearch/doc/IRB_00069049) to view the application and access the approved documents.

Please take a moment to complete our [customer service survey](https://ericaresearch.utah.edu/ericaresearch/doc/IRB_00069049). We appreciate your opinions and feedback.
Appendix E: Dissemination Memorandum
Diabetes Treatment

Everyone has been doing a great job intensifying and initiating treatment for the T2DM patients. I hope the algorithm is helpful and useful for your patients. I wanted to share my results from my project with you and recognize you all for the improvements in treatment. Keep up the great work! (Lindsey Brown, DNP student)

Results:

- Appropriate initiation and intensification of diabetes therapy increased from 58% to 87%.
- The rate of insulin initiations also increased from 33% to 91%.
- Appropriate treatment of pre-diabetes improved from 33% to 83%.
- Overall improvement noted for appropriate titration and dosing of metformin.

Key points to remember:

- Metformin should be titrated to effective dose of 2000mg/day (Nathan et al., 2009).
- Pre-diabetes pt's should be started on Metformin 500mg BID when A1c >6% (Garber et al., 2012).
- If initial A1c is >9%, 2 oral agents should be started (ADA, 2014).
- If initial A1c is >10%, 2 oral agents should be started and pt should be referred to DM clinic for possible insulin initiation (ADA, 2014).
- If A1c is >7% and pt is on 2 oral agents at max dose, refer to DM clinic (ADA, 2014).
- Providers may need to start insulin if hyperglycemia is significant and pt should not wait for DM clinic appt. If not PAP eligible, start 70/30.
Appendix F: Project Defense PPT
Diabetes Management Algorithm at the Hope Clinic

Lindsey Brown, RN BSN

In partial fulfillment of the requirements for the Doctor of Nursing Practice degree
October 10, 2013

Background

- Hope Clinic
  - Free medical facility in Midvale, UT
  - Serves uninsured and underserved population
  - Large Latino and Pacific islander population
  - Providers are volunteers

Problem Statement

- Less than half of individuals with Type 2 Diabetes (T2DM) reach glycemic targets.
- Only one-third of individuals have all risk factors controlled.
- Primary care providers often do not appropriately initiate or intensify diabetes treatment as indicated by a patient’s clinical trajectory.
- The purpose of this project is to address clinical inertia in diabetes care at the Hope Clinic.
Clinical Significance

- Clinical inertia: recognition of a clinical problem by a health care provider who fails to act. 
- Leads to uncontrolled hyperglycemia causing microvascular and macrovascular complications. 
- Diabetes is the number one cause of blindness, kidney failure and nontraumatic limb amputations.

Literature Review

- Clinical inertia
  - Canadian study (2010): 
    - HbA1c levels of 9.5% before initiating insulin therapy
    - Average HbA1c was 7.9% after 3 years of insulin use
  - Retrospective UK study (2013): 
    - Patient’s had uncontrolled hyperglycemia for >7 years before intensification of therapy
    - Average HbA1c was 8.7% when therapy was intensified

Literature Review

- Causes of clinical inertia
  - Lack of knowledge and comfort with management of insulin therapy
  - Lack of appreciation for the progressive nature of T2DM
  - Reluctance to use combination therapy in early disease
  - Complexity of guidelines

- Algorithms are effective for educating providers to better manage T2DM and overcome clinical inertia.
Lewin’s Theory of Planned Change\textsuperscript{9}

- Unfreezing
  - Identify problems related to the use of treatment guidelines
  - Construct algorithm
- Moving
  - Present to clinical staff
  - Collect feedback
  - Finalize algorithm
- Refreezing
  - Post implementation chart review

OBJECTIVE #1

Identify individual and system problems related to the use of evidence-based treatment guidelines for T2DM at the Hope Clinic

<table>
<thead>
<tr>
<th>Implementation</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Survey providers for barriers</td>
<td>1. Analyze feedback and incorporate feedback into construction of algorithm</td>
</tr>
<tr>
<td>2. Submit proposal to IRB</td>
<td>2. Review charts (n=25)</td>
</tr>
<tr>
<td>3. Perform chart review of A1C levels</td>
<td></td>
</tr>
</tbody>
</table>

OBJECTIVE #2

Construct a diabetes clinical management algorithm that incorporates current evidence of diabetes care best practices in therapy intensification for patients whose hyperglycemia is not currently being contolled based on ADA guidelines

<table>
<thead>
<tr>
<th>Implementation</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Conduct KOL</td>
<td>1. Final draft of algorithm will be implemented at the Hope Clinic</td>
</tr>
<tr>
<td>2. Incorporate current evidence and best practices</td>
<td></td>
</tr>
<tr>
<td>3. Content experts review and critique algorithm</td>
<td></td>
</tr>
</tbody>
</table>
### OBJECTIVE #3
Improve the consistency of providers’ management of patients with T2DM and their adherence to published diabetes management guidelines

<table>
<thead>
<tr>
<th>Implementation</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Work individually with clinician to facilitate use of the algorithm</td>
<td>1. Final algorithm</td>
</tr>
<tr>
<td>2. Continue to elicit written and verbal feedback</td>
<td>2. Chart review will show adherence with algorithm</td>
</tr>
<tr>
<td>3. Construct final algorithm based on provider feedback and clinical use</td>
<td></td>
</tr>
</tbody>
</table>

### OBJECTIVE #4
Increase number of insulin initiations among patients who meet criteria for insulin therapy

<table>
<thead>
<tr>
<th>Implementation</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Post-implementation chart review of A1C levels</td>
<td>1. Charts will reveal improved A1C levels</td>
</tr>
<tr>
<td>2. Evaluate percentage of insulin starts following initiation</td>
<td>2. Increased number of patients with therapy intensification and/or number of insulin starts</td>
</tr>
</tbody>
</table>

### OBJECTIVE #5
Disseminate project findings to The Journal for Nurse Practitioners (JNP)

<table>
<thead>
<tr>
<th>Implementation</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Abstract will be written of project findings</td>
<td>1. Abstract will be submitted to JNP</td>
</tr>
</tbody>
</table>
Summary

- Improvements in clinical initiation and intensification of diabetes therapy is essential to improve glycemic control among individuals with T2DM.
- Providing education to providers in the form of a treatment algorithm can help address clinical inertia.

Acknowledgments

- Project Chair: Pamela Phares PhD, APRN-BC, CNM
- Committee members serving as content experts:
  - Davida Kruger MSN, APRN-BC, BC-ADM
  - Past chair of the ADA Research Foundation
  - Past president, healthcare and education of the ADA
  - Current Editor in Chief of Clinical Diabetes
  - Brandon Jennings Pharm D
  - Assistant Professor (Clinical) University of Utah

References

References


Appendix G: Poster
Overcoming Clinical Inertia in Type 2 Diabetes
Lindsey Brown DNP candidate, Family Nurse Practitioner Program

Clinical inertia, the recognition of a clinical problem but failure to act on it, is a significant contributor to uncontrolled hyperglycemia in the care of patients with T2DM. The purpose of this project is to address clinical inertia in diabetes care at the Hope Clinic.

Background
- Adequate glycemic control is essential to prevent micro- and macrovascular complications, however fewer than half of individuals with diabetes achieve glycemic control.
- Low socioeconomic and ethnicity contribute to an increased incidence of T2DM. The Hope Clinic in Midvale, UT is a free clinic that serves the underserved and uninsured population in the area. The clinic population consists of a high percentage of Latinos and Pacific Islanders.
- Providers often fail to initiate or intensify therapy for reasons including lack of knowledge or experience with insulin management and poor appreciation for the progressive nature of diabetes.

Objectives
- Identify barriers related to the implementation of evidence-based treatment guidelines for T2DM
- Construct a diabetes clinical pathway algorithm that incorporates current evidence of diabetes care best practices in therapy intensification
- Improve the consistency of providers' management of patients with T2DM and their adherence to published diabetes management guidelines
- Increase number of insulin initiations among patients who meet criteria for insulin therapy
- Communicate findings via a professional nursing forum

Methods
- A clinical diabetes treatment algorithm was developed for the Hope Clinic based on current evidence and provider survey
- Multiple drafts and revisions were made of the algorithm
- The algorithm was piloted with providers in the clinic from February 11 to March 19, 2014
- Pre- and post-chart reviews were performed to determine the extent of the problem and to evaluate clinical practices pre- and post-implementation

Results & Future Recommendations
- With use of the algorithm, appropriate initiation and intensification of diabetes therapy increased from 59% to 97%
- The rate of insulin initiations after implementing the algorithm increased from 33% to 91%
- Treatment of prediabetes increased from 33% to 83%
- Given that intensification of therapy improves uncontrolled hyperglycemia, continued use of the algorithm should improve long-term clinical outcomes in patients with T2DM
- Long term evaluation of patient outcomes and providers diabetes management practices is imperative to evaluate both the effectiveness and sustainability of the algorithm