***Template*: Developing Nurse Standardized Procedure for Diabetes Management**

Clinical Protocol: Nurse Co-management in Diabetes

Effective date:

Policy & Procedure:

Revision date:

Last reviewed:

**Policy**

It is the policy of \_\_\_\_\_\_\_\_ Health Center to allow qualified RNs to co-manage patients ages 18 years and older with diabetes.

I. Procedure

A. Functions the RN may perform: collect subjective data (patient history), collect objective data (perform physical examinations), assess patient status, order and interpret labs, develop and implement treatment and educational plan of care

B. Scope: under the following circumstances the RN may perform function

1. Setting – within the clinic site

2. Supervision – the RN may operate independently within the constraints and criteria of this policy in partnership with mentoring physician(s) and the designated primary care physician to provide care under the protocol.

3. Patient criteria:

* Patient has a designated primary care provider.
* Patient is diagnosed with type 2 diabetes using American Diabetes Association Standards diagnostic criteria. (Appendix I)
* The patient does not have the following co-morbidities: pregnancy, unstable vascular complications, severe depression or other mental health comorbidities, chronic kidney disease stage 4 or 5, active alcohol or substance abuse, and/or recurrent episodes of severe hypoglycemia.
* Patient does not have unexplained episodes of recurrent or severe hypoglycemia
* The patient’s baseline labs are within normal limits (electrolytes, urea, creatinine, CBC) without signs of ketoacidosis
* The nurse has introduce her/himself utilizing correct title and explain role and the patient accepts RN co-management.

C. Definitions:

Fasting glucose – no caloric intake for at least 8 hours

Impaired Glucose Tolerance (IGT) – an elevated 2-hour plasma glucose concentration (>140 and >200 mg/dl) after a 75-gram glucose load on the oral glucose tolerance test (OGTT) in the presence of a fasting plasma glucose (FPG) concentration <126 mg/dl

Impaired Fasting Glucose (IFG) – an elevated fasting plasma glucose (FPG) concentration (>100 and <126 mg/dl)

Type 1 Diabetes – absolute insulin deficiency resulting from beta cell destruction

Type 2 diabetes – insulin resistance and progressive insulin secretory defect

Body Mass Index (BMI) – person’s weight in kilograms divided by the square of their height in meters; strongly correlated with various metabolic and disease outcomes

Severe hypoglycemia – resulting or likely to result in seizures, loss of consciousness, or needing help from others.

Mild hypoglycemia – recognized signs and symptoms or neuro-glycopenia (e.g. hunger or sweating) that the patient can effectively self-treat.

D. Procedure for Nurse Practice

1. Subjective assessment
* Review relevant health history reported by the patient &/or documented in the EMR.
* Conducted review of systems for complaints consistent with symptomatic hypoglycemia, hyperglycemia and medication side effects.
* Assess mental health and social context (e.g. administer PRAPARE tool).
* Review glucose self-monitoring record.
* Review adherence with medications and lifestyle modifications.
1. Objective assessment
* Check height (baseline), weight, blood glucose, urine dipstick for glucose, protein and ketones
* Lab review: HgA1C, electrolytes (Sodium <135 mEq/L, Potassium >5.5 mEq/L), lipid profile, liver function tests, urine albumin excretion with spot urine albumin-to-creatinine ratio, serum creatinine (>150umol/L) and estimated GFR (EGFR <45). TSH if dyslipidemia or women >50 years.
1. Assessment – type 2 DM
2. Plan
* Treatment goals
	+ HbA1c < 7%; if > 65 years <8%
		- Individualize A1C goals based on risk of hypoglycemia, duration of diabetes, age/life expectancy, extensive comorbidities, known CVD or advanced microvascular complications, and patient resources and support system.
		- Use shared decision-making to set A1C goal
	+ Self-monitoring blood glucose (SMBG) targets:
		- before meals: <65 yrs 70-130mg/dL, if >65 years 100-160mg/dL
		- 1-2 hrs after beginning of meals (postprandial): <180 mg/dL
		- bedtime: 100-150 mg/dL
	+ Avoid hypoglycemia: defined as <54 mg/dL; alert value <70 mg /dL
	+ Blood pressure: SBP <139 mmHg , DBP < 89 mmHg; lower for younger patients
	+ Lipids: LDL cholesterol < 99mg/dL, TG<150, HDL>50
	+ BMI: goal < 25 kg/m2
* Pharmacological management - Follow *Medication Titration Algorithm for Type 2 Diabetes.* (Appendix II)

General principles:

* Most oral medications lower HgA1C 1-2%; each new class of non-insulin agents added to initial medication regime lowers A1C by approximately 1%
* Over time most patients will require insulin to achieve goals

HgA1C: <2% above goal

* Initiate metformin as first-line choice
	+ Begin with 250mg ½ tablet bid with slow up-titration every 1-2 weeks up to 2,000mg per day
	+ Use alternate agent if contraindications exist
* If not controlled on metformin monotherapy over 3 months, initiate combination therapy using sulfonylurea
	+ Slow up-titration every 2 weeks up to maximum dosage as tolerated
	+ For patients allergic to sulfa or at risk of severe hypoglycemia, use alternate agent for dual therapy: thiazolidinedione, meglitinide, α-glucosidase inhibitor, dipeptidyl peptidase-4 (DPP-4), sodium-glucose contransporter-2 (SGLT-2) inhibitor, or GLP-1 receptor agonist
	+ Select second-line alternative agent considering factors such as cost, comorbidities, patient preferences, adherence, impact on weight, and potential side effects.
* If A1C remains above goal after three months, reevaluate:
	+ If >1% of goal, add basal long-acting insulin - 10U SQ at bedtime; increasing by 2U every 2 days until at target.
		- When adding insulin, consider discontinuing other medications besides metformin
	+ If above goal by <1%, may add basal long-acting insulin or begin triple therapy with an alternate agent.
	+ If risk of severe hypoglycemia, add third oral agent considering patient and disease-specific factors.
* When patient remains at goal, maintain therapy

HgA1C >2% above goal or FBS >300 mg/dL

* + Initiate basal insulin 10U SQ at hs or 0.1-0.2 U/kg/day SQ hs
		- Long acting insulin – Basalgar (PHC formulary), Lantus, Levemir
		- Intermediate – NPH
	+ Monitor blood glucose before breakfast and 2-4 times/day
	+ Adjust insulin 10-15% or 2-4U once or twice weekly to reach FBG target
	+ Target daytime highs with prandial and short-acting insulin
	+ If hypoglycemia is experienced, determine & address cause or if unclear, decrease dose by 4 units or 10-20% and reassess closely.

Treat co-morbidities to reduce the risk for cardiovascular events

* Hypertension – see HTN guidelines\*
* Aspirin therapy for 40-75 years of age\*\*
* Angiotensin-converting enzyme inhibitors (ACEs) and angiotensin receptor antagonists (ARBs) for 18-75 years\*\*
* Dyslipidemia - statins (HMG-CoA reductase inhibitors) for 18-75 years\*\*

\*RCHCManagement of Adult Hypertension 6/27/2016

\*\*PHASE Algorithm 2012

Contraception for women of reproductive age (Appendix V)

* Non-hormonal long acting reversible contraception or sterilization preferred.
* Women desiring pregnancy should be in good control (HgA1C <6.5%) prior to conception. Follow guidelines from California Diabetes and Pregnancy Program (CDAPP).

Immunizations

* Annually influenza vaccine
* Hepatitis B
* Pneumococcal polysaccharide vaccine
	+ Pneumovax (PPSV23) administered to all persons with diabetes; revaccinate after 65 years if more than 5 years
	+ Prevnar (PCV13) >65 yr
* Screening/Referrals
	+ Retinal screening with dilated comprehensive exam by ophthalmologist or optometrist- monitor every 1-2 years unless background retinopathy or more severe disease, then annually
	+ Foot screening – inspection, pulses and annual monofilament test; if abnormal referral to podiatry foot care program. (Appendix VI)
	+ Dental care – comprehensive periodontal exam
	+ Depression screening/ mental health disorder with referral to mental health if indicated
	+ Medical nutrition therapy (MNT) with registered dietitian
* Self-management Education and Support

Assess and provide individualized education at the initial visit and annually. Develop plan to address barriers to self-management using available resources. Adjust the plan when new complicating factors arise, and/or transitions in care occur.

Employ health coaching and motivational techniques, use of groups to instruct patient or patient & family on:

* + Glucose targets, relationship between glucose levels, CHO intake and physical activity,
	+ Self-monitoring blood glucose (2-4 times/day)
		- Test 3 or more times/day if taking multiple injections, ill or changing therapies
		- Keep logs including factors that affect blood glucose levels: exercise, meal timing and amount, missed medication doses, injection sites, insulin status
	+ Hypoglycemia: prevention, signs, use of keto sticks
		- Glucagon kit - instruct patient and caregivers/family on use
		- Glucose 15-20 gm preferred treatment for conscious <70 gm/dL
	+ Foot care
	+ Infections and sick day management
	+ Safe disposal of needles & syringes
	+ Physical activity - 30 minutes per day or 150 minutes a week of moderate-intensity aerobic
		- add resistance training twice a week
		- interrupt prolonged sitting every 30 minutes with short bouts of physical activity
		- balance and flexibility training in older adults
	+ Weight management
		- BMI >25 decrease calories by 500-1000/day to sustain weight loss of 5-7%
		- Pharmacotherapy may be indicated for BMI categories >27
		- Metabolic surgery may be indicated for BMI categories > 30
	+ Nutritional guidelines - no advantage to any particular diet (Mediterranean, DASH and plant-based diets acceptable):
		- Eat small, frequent meals throughout the day to maintain blood glucose levels
		- Eat 1-2 servings of carbohydrate before and after physical activity
		- Carbohydrates limited to 45-65% of daily calories, with intake from whole grains, vegetables, fruits, legumes and dairy products; emphasis on foods high in soluble fiber and low glycemic index
		- 20-35 grams fiber daily
		- Reduce saturated fats, trans fat and cholesterol intakes; increase monounsaturated fats, increase intake of foods rich in long-chain ω-3 fatty acids: fish, nuts, and seeds
		- Adequate water intake
		- Avoid sugar sweetened beverages and other foods with added sugar
		- Include 20-35 grams a day of soluble fiber from plant sources
		- Dietary sodium limited to < 2,300 mg/day
		- In nephropathy, avoid excessive protein
	+ Alcohol consumption <1 drink/day for women; <2 drinks for men; caution regarding alcohol consumption increasing risk of hypoglycemia
	+ Tobacco cessation – counseling & pharmacotherapy indicated
1. Patient follow-up
* Follow up at regular intervals (2-4 weeks) and titrate as needed following clinical algorithm (Appendix I) until at goal.
* Once at goal with stable glycemic control, quarterly evaluation:
	+ Medication reconciliation
	+ Assess cognitive function
	+ BP every visit
	+ Ask about symptomatic and asymptomatic hypoglycemia at each encounter
	+ Monitor for complications – e.g. peripheral neuropathy
	+ HgA1C at least two times a year
	+ Assess urinary micro albumin once a year with spot urinary albumin-to-creatinine ratio (UACR)
	+ Estimated glomerular filtration rate (eGFR) once a year (all type 2 and type 1 diabetes duration > 5 years)
	+ If eGFR < 60 mL/min/1.73 m2 evaluate and manage potential complications of chronic kidney disease (CKD)
	+ With long term use of metformin, vitamin B12 level
	+ Monitor for complications, high index of suspicion for infections & cardiovascular events
* If not at goal, increase visit frequency and titrate medications consulting primary care physician
1. Record keeping of patient encounters – all patient care (BP, medications, lab work, and education) and verbal or telephone communications with the clinician, or patient/family shall be documented in the EMR.

II. Requirements for Registered Nurse

A. Preparation

1. Education/Licensure: nurse must be licensed as Registered Nurse in California and be in good standing with the Board of Registered Nursing (BRN).
2. Experience: a minimum of one year’s experience (full-time or 2080 hours) as an RN is required.
3. RNs are strongly encouraged to become Certified Diabetic Educators (<http://www.ncbde.org>).
4. Training: nurse must successfully complete advanced training on subjective and objective evaluation of patients, pharmacology, and patient education including self-management.
5. Nurse must demonstrate ability to assess glucose home monitoring logs, recognizing and managing hypoglycemia and implementation of the clinical algorithms.

B. Evaluation

Following orientation and training, three cases must be documented and reviewed with Champion (physician mentor) each week for one month; followed by 3 cases per month for 3 months; then 6 cases per year. Nurse must demonstrate appropriate management of patients with type 2 diabetes. If primary care provider disagrees with management plan, cases will be reviewed with Champion. Evidence of successful completion will be documented and included in the nurse’s personnel file

Ongoing Evaluation: Annual competency evaluations will be conducted documenting the RNs ability to function appropriately under the protocol including clinical knowledge, skills/ procedures, appropriate consultation and documentation.

D. Supervision and Review

Roles and responsibilities of Registered Nurses working under the protocol

1. RN must verify that patients have a designated primary care provider and that the patient meets the criteria for standardized procedure.
2. RN will collaborate and work in partnership with mentoring physician(s) and individual patient’s primary care physician to provide care under the protocol.
3. RN will introduce her/himself utilizing correct title and explain role
4. RN will collect subjective data (patient history), collect objective data (perform physical examinations), assess patient status, order and interpret labs, develop and implement treatment and educational plan of care
5. Documentation - RN will maintain pattern management logs including patient ID, glucose pattern, time of pre-meal glucose, insulin type and dose, meal size or CHO amount, exercise, complaints, assessment of adherence to meds, diet, exercise, blood glucose records (home, clinic), pertinent lab results, plan for med changes, follow-up labs and visits; physician notification if needed

Roles and responsibilities of the primary care mentoring physician &/or primary care physician designated as responsible for patient management

1. Physician will be available for consultation and collaboration with RN.
2. The mentoring physician will assure there is a physician available when the nurse requests the physician to consult or see the patient, the patient requests to see the physician, and/or there is an onsite emergency.
3. The physician will see the patient or review the care of each patient at least once a year and renew the patient-specific medication order on an annual basis.

III. Development and Approval of the Standardized Procedure

A. Method – this procedure was developed using the most current guidance from the California Board of Registered Nursing, American Diabetes Association, U.S. Preventive Services Task Force Recommendation Statement and technical references from the PHASE program.

B. Review schedule – the procedure shall be assessed at 3 and 6 months following implementation and then annually.

**Appendix**

I. Diagnostic criteria for type 2 diabetes

Source: ADA, 2017

|  |  |  |  |
| --- | --- | --- | --- |
| **Test** | **Normal** | **IFG or IGT\*** | **Type 2 Diabetes** |
| Hemoglobin A1C level, % | <5.7 | 5.7-6.4 | >6.5 |
| Fasting plasma glucosemg/dL (mmol/L) | <100 (<5.6) | 100-125 (5.6-6.9) | >126 (>7.0) |
| OGTT results¥mg/dL (mmol/L) | <140 (<7.8) | 140-199 (7.8-11.0) | >200 (>11.1) |

\*Behavioral interventions indicated; may delay or avoid progression to type 2 diabetes

¥ Two hours following 75-g oral glucose load

\*\*A random plasma glucose ≥ 200 mg/dL (11.1 mmol/L) in patients with classic symptoms of hyperglycemia or hyperglycemic crisis is also diagnostic for type 2 diabetes.

II. Medication Algorithm

Source: RCHC, May 2017



III. Medications for Management of Type 2 Diabetes

Source: RCHC, May 2017

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Medication** | **Efficacy / Advantages** | **Hypo-glycemic risk** | **Weight** | **Cost** | **Maximum Recommended Dose** | **Optimal Titration Interval** | **Caution/ side effects** |
| **First line oral agent, mono-therapy** | Biguanidesmetformin2 (500, 850, 1000mg)ER2 (500, 750, 1000mg) | High/↓risk CV event | Low | Neutral or Loss | $1 | 2,000mg daily | 1-2 weeks | Serum creatinine; repeat q 12 monthsDo not use if HF class 3-4; LFTs>3xULN; or eGFR<30.Maximum dose 1000mg if eGFR 30-45Increased risk GI side effects -> consider extended releaseLong-term use associated with vitamin B12 deficiency |
| **Dual, second-line oral therapy** | Sulfonylureas (SU)glipizide2 (2.5, 5, 10mg)glimepiride2 glyburide ER (2.5, 5, 10mg)Combination MedGlyburide/metformin1, 2  (1.5-250mg, 2.5/5mg-500mg) | High/ ↓microvascular risk | High | Gain | $1 | 20mg twice daily | 2 weeks | Sulfa allergyHypoglycemiaWeight gainD/C SU with initiation of insulin |
| **Dual therapy; alternative agent** **Dual therapy; alternative agent** | Thiazolidinediones (TZD)pioglitazone2 (15, 30, 45mg)Combination MedPioglitazone/metformin4 (15/500/850mg) | High /↑insulin sensitivity | Low | Gain | $1 | 45mg daily |  | Heart failureEdemaIncreased fracturesBladder cancer concerns |
|  | Meglitinides (Glinide)repaglinide2 (0.5,1, 2mg)nateglinide2 (60,120mg) | ↓A1C lowering / ↓pp glucose | High | Gain | $$1 | 16mg daily360mg daily |  |  |
|  | Alpha-glucosidase inhibitors (AGI)acarbose2 (25,50, 100mg)miglitol2 (25,50, 100mg) |  |  |  | $$ | 300mg | 1-2 months | Often poorly toleratedModest efficacy (0.4-0.7% reduction A1C)Need to be dosed more than once/dayEffective in reducing PPG with high carb intake |
| **Dual therapy; alternative agent** | DPP-4 Inhibitorsalogliptin3 (6.25, 12.5, 25mg)sitagliptin4saxagliptin4linagliptin4Combination Med1, 3alogliptin/pioglitazone2 (12.5-15/30/45, 25-15/30/45mg)alogliptin/metformin2 (12.5-500/1,000mg) | Intermediate | Low | Neutral | $$$$ | 25mg daily |  | Rare |
| SGLT-2 inhibitorscanagliflozin4dapagliflozin4empagliflozin4Combination Medcanagliflozin/metformin, *Invokame*t4empagliflozin/metformin, *Synjardy*4 dapagliflozin/metformin, *Xigduo4*empagliflozin/linagliptin, *Glyxambi*4 | Intermediate/ may improve CV risk; ↓BP | Low | Loss | $$$$ | 5mg daily |  | Increase genital mycotic infectionsDehydrationFracture riskPolyuria↑ LDL-C↑ creatinine |
| GLP-1 R Agonist (SQ pen injector)liraglutide, *Victoza3*dulaglutide4 | High/ ↓CV risk | Low | Loss | $$$$ | 1.8mg daily1.5mg daily |  | GI side effectsPancreatitis risk↑ Heart rate |
| **Insulin** | Long-acting Insulin, basalInsulin glargine, *Basalgar*2, *Lantus*4 insulin detemir, *Levemir*4 | Highest | Highest | Gain | $-$$$ | 10U SQ HS or 0.1-0.2U/kg/d | 10-15%, or 2-4U 1-2x/wk | Hypoglycemia; duration 18 - 26hrsTraining/monitoring requirements |
| Intermediate-acting Insulin, NPH insulin isophane, *HumulinN*3, *NovolinN*3 | Highest | Highest | Gain | $$$ |  |  | Hypoglycemia; duration 16 - 24hrs |
| Short-acting Insulinregular insulin, *HumulinR3*, *NovolinR*3, *Afrezza*4 (inhalation) | Highest | Highest | Gain | $-$$$ |  |  | Hypoglycemia; duration 5 - 8hrs |
| Fast-acting Insulin insulin lispro, *Humalog*3insulin aspart, *Novolog*3insulin glulisine, *Apidra*3 | Highest | Highest | Gain | $ |  |  | Hypoglycemia; duration 3 - 4hrsMonitor blood glucose before breakfast and before meals 2-4 times/day |

IV. Guidelines for adjusting insulin

Source: J. Minkoff

**Common patterns with prandial insulin**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Pattern** | **↑ Glucoses** | **↓ Glucoses** | **Look for** | **Changes** |
| Elevated glucosesThroughout | Increase insulin to lower next meal’s glucose (e.g. ↑ breakfast dose for ↑ lunch glucose | Watch for glucose-lowering effect of prior insulin dose\*May occur many hours after basal dose | Eating patternsExercise patternsMedication adherence | Ask the patient what they think is happening |
| Elevated AM glucose | ↑ @hs basal insulinIf hypoglycemia overnight may ↓ overnight basal if @hs glucose is at goal | Educate about hypoglycemic symptoms\* | Hypoglycemia nightmares, night sweats, AM headaches | If no hypoglycemia may escalate meal coverage |
| Elevated daytime glucoses | Each meal – consider adjusting prandial insulin | Watch for lows with exercise, especially on AM NPH, Lantus or levemir  | Glucose prior to meal gives you information on prior insulin dose effect | May be able to decrease insulin dose with improved diet and exercise  |
| Hypoglycemia | May occur after corrections | Missed meals, increased exercise, mis-dosing | Unusual events vs consistent pattern | Cut doses and reassess |

\*Common hypoglycemia symptoms: sweating, shakiness, hunger, dizziness, weakness, confusion

**Common patterns on Basal @hs insulin**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Pattern** | **↑ Glucoses** | **↓ Glucoses** | **Look for** | **Changes** |
| Elevated glucosesThroughout the day | Give insulin to lower next meal’s glucose | Watch for glucose-lowering effect of prior insulin dose\* | Eating patternsExercise patternsMedication adherence | Ask the patient what they think is happening |
| Elevated AM glucose | In AM –Increase @hs basal insulin | Educate about hypoglycemic symptoms\* | Hypoglycemia nightmares, night sweats, AM headaches | If still taking glipizide check glucoses at other meals |
| Elevated daytime glucoses | Each meal – consider adding prandial insulin | Watch for lows with exercise, especially on glipizide  | Glucose prior to meal gives you information on prior insulin dose effect | May be able to decrease insulin dose with improved diet and exercise |

\*Common hypoglycemia symptoms: sweating, shakiness, hunger, dizziness, weakness, confusion

V. Contraception

Source: CDC; <https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf>

**U.S. Medical Eligibility Criteria for Contraceptive Use, 2016**

1- No restrictions for the use of this method.

2- Advantages generally outweigh theoretical or proven risks.

3- Theoretical or proven risks usually outweigh advantage.

4- Unacceptable health risk - method is not to be used.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Severity of Diabetes Mellitus** | **Combined hormonal****(pill, patch, ring)** | **Progestin-only pill** | **Injection****DMPAa** | **Implant****(Implanon)** | **LNG IUDb****(Mirena)** | **Copper T** **(ParaGard)** |
| Non-vascular disease (oral or insulin) | 2 | 2 | 2 | 2 | 2 | 1 |
| Nephropathy/retinopathy/neuropathy/ other vascular disease with diabetes OR diabetes of >20 years duration | Initiation- 3 | 2 | 3 | 2 | 2 | 1 |
| Continuation- 4 |
| Continuation- 4 |

a depot medroxyprogesterone acetate

b levonorgestrel-releasing intrauterine system

VI. Foot Screening

Source: American Diabetes Association (ADA) Standards of Medical Care in Diabetes; 2017.

