

## References for Joslin's Pharmacological Management of Type 2 Diabetes Guideline 1-9-09

### Diagnosis

1. ADA Position Statement: Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 2009; 32 ( suppl 1): S62-S67
2. Nathan, DM, Kuenen,J, Borg,H Translating the A1c assay into estimated average glucose values. *Diabetes Care* 2008; 31: 1473-1478

### Goals of Glycemic Control and Phrmacotherapy

1. American Diabetes Association. Standards of medical care in diabetes. *Diabetes Care* 2009; 32 ( suppl 1): S13-S 61
3. Beaser, RS and Staff of Joslin Diabetes Center. *Joslin's Diabetes Deskbook for Primary Care Providers*. Second edition. Joslin Diabetes Center, Boston; 2007.
4. Diabetes Prevention and Control Program, Diabetes Guidelines Work Group. Massachusetts guidelines for adult diabetes care. Boston (MA): Massachusetts Department of Public Health; 2005 Jun.
5. Institute for Clinical Systems Improvement (ICSI). Management of type 2 diabetes mellitus. Bloomington (MN): Institute for Clinical Systems Improvement (ICS); 2005 Nov.

### Oral Antihyperglycemic Therapy

1. Inzucchi SE. Oral antihyperglycemic therapy for type 2 diabetes: scientific review. *JAMA* 287:360-72, 2002.
2. Kimmel B and Inzucchi S. Oral agents for type 2 diabetes: an update. *Clinical Diabetes* 23:64-76, 2005.
3. Krentz AJ, Bailey CJ. Oral antidiabetic agents. *Drugs* 2005; 65(3):385-411.
4. DeFronzo RA. Pharmacologic therapy for type 2 diabetes mellitus. *Ann Intern Med* 131:281-303, 1999.
5. Kahn SE, Haffner SM, Heise MA, et. al. Glycemic Durability of Rosiglitazone, Metformin, or Glyburide Monotherapy. *New England Journal of Medicine* 2006; 355: 2427-2443
6. Nathan, DM et al Medical management of hyperglycemia in type 2 diabetes: A consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care* 2008; 31: DOI : 10.2337/dc 08-9025

## Metformin

1. Charpentier G, Riveline JP, Varroud-Vial M. Management of drugs affecting blood glucose in diabetic patients with renal failure. *Diabetes Metab* 26 Suppl 4:73-85, 2000.
2. Cryer DR, Nicholas SP, Henry DH, Mills DJ, Stadel BV. Comparative outcomes study of metformin intervention versus conventional approach. *Diabetes Care* 28:539-543, 2005.
3. Dornan TL, Heller SR, Peck GM, Tattersall RB. Double-blind evaluation of efficacy and tolerability of metformin in NIDDM. *Diabetes Care*. 14: 342-343, 1991.
4. Garber AJ, Duncan TG, Goodman AM, Millis DJ, Rohlf JL Efficacy of Metformin in Type II Diabetes: Results of a Double-Blind, Placebo-controlled, Dose-Response Trial. *Am J Med* 103:491-497, 1997.
5. Grant PJ. The effects of high and medium dose metformin therapy on cardiovascular risk factors in patients with type II diabetes. *Diabetes Care* 19: 64-66, 1996.
6. Holstein A, Stumvoll M. Contraindications can damage your health--is metformin a case in point? *Diabetologia* 48:2454-9, 2005.
7. Inzucchi SE. Metformin and heart failure: innocent until proven guilty. *Diabetes Care* 28:2585-2587, 2005.
8. Johansen K. Efficacy of metformin in the treatment of NIDDM. Meta-analysis. *Diabetes Care* 22:33-7, 1999.
9. McCormack J, Johns K, Tildesley H. Metformin's contraindications should be contraindicated. *CMAJ* 173:502-4, 2005.
10. UKPDS Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). *Lancet* 352: 854-865, 1998.
11. Saenz A, Fernandez-Esteban I, Mataix A, Ausejo M, Roque M, Moher D. Metformin monotherapy for type 2 diabetes mellitus. *Cochrane Database of Systematic Reviews* 2006 Issue 4.
12. Salpeter S., Greyber E, Paternak G., Salpeter E. Risk of fatal and nonfatal lactic acidosis with metformin use in type 2 diabetes mellitus. *Cochrane Database Sys Rev* 2006 Issue 4.
13. Sulkin TV, Bosman D, Krentz AJ. Contraindications to metformin therapy in patients with NIDDM. *Diabetes Care* 20:925-8, 1997.

## Thiazolidinediones

1. Charbonnel B, Roden M, Urquhart J, Mariz S, Johns D, Mihm M, Wide M, Tan M. Pioglitazone elicits long-term improvements in insulin sensitivity in patients with type 2 diabetes: comparisons with glipazide-based regimens. *Diabetologia* 48:553-60, 2005.
2. Davidson JA, Perez A, Zhang J, The Pioglitazone 343 Study Group. Addition of pioglitazone to stable insulin therapy in patients with poorly controlled type 2 diabetes: results of a double-blind, multicentre, randomized study. *Diabetes Obes Metab* 8:164-74, 2006.
3. Kulenovic I. Impact of rosiglitazone on glycaemic control, insulin levels and blood pressure values in patients with type 2 diabetes. *Med Arh* 60:179-81, 2006.
4. Miyazaki Y, Mahankali A, Matsuda M et al. Improved glycemic control and enhanced insulin sensitivity in type 2 diabetic subjects treated with pioglitazone. *Diabetes Care* 24:710-719, 2001.
5. Nesto RW, Bell D, Bonow RO, Fonseca V, Grundy SM, Horton ES, Le Winter M, Porte D, Semenkovich CF, Smith S, Young LH, Kahn R. American Heart Association; American Diabetes Association. Thiazolidinedione use, fluid retention, and congestive heart failure: a consensus statement from the American Heart Association and American Diabetes Association. *Circulation* 108:2941-8, 2003.
6. Mazzone T, Meyer PM, Feinstein SB, Davidson MH, Kondos GT, D'Agostino RB, Sr. et al. Effect of pioglitazone compared with glimepiride on carotid intima-media thickness in type 2 diabetes: a randomized trial. *JAMA* 2006; 296(21):2572-2581.
7. Yki-Jarvinen, H. Thiazolidinediones. *New England Journal of Medicine* 2004; 351: 1106-1118
8. Nissen, SE, Wolski, K. Effect of rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes. *New England Journal of Medicine* 2007; 356: 2457-2471

## Insulin Secretagogues

1. Bailey CJ, Day C. Antidiabetic drugs. *Br J Cardiol* 10:128-36, 2003.
2. Del Prato S, Heine RJ, Keilson L, Guitard C, Shen SG, Emmons RP. Treatment of patients over 64 years of age with type 2 diabetes: experience from nateglinide pooled database retrospective analysis. *Diabetes Care* 26:2075-80, 2003.
3. Dornhorst M. Insulotropic meglitinide analogues. *Lancet* 358:1709-15, 2001.
4. Hazama Y, Matsuhisa M, Ohtoshi K, Gorigawa S, Kato K, Kawamori D, Yoshiuchi K, Nakamura Y, Shiraiwa T, Kaneto H, Yamasaki Y, Hori M. Beneficial effects of nateglinide on insulin resistance in type 2 diabetes. *Diabetes Res Clin Pract* 71:251-5, 2006.
5. Plosker, GI, Figgitt, DP. Repaglinide: a pharmacoeconomic review of its use in type 2 diabetes mellitus. *PharmacoEconomics* 22:389-411, 2004.
6. Shapiro MS, Abrams Z, Lieberman N. Clinical experience with repaglinide in patients with non-insulin-dependent diabetes mellitus. *Isr Med Assoc J.* 2005 7:75-7, 2005.

## Alpha-Glucosidase Inhibitors

1. Balfour JA, McTavish D. Acarbose. An update of its pharmacology and therapeutic use in diabetes mellitus. *Drugs* 46:1025-54, 1993.
2. Carlson RF. Miglitol and hepatotoxicity in type 2 diabetes mellitus. *Am Fam Physician* 62:315 -318, 2000.
3. Hanefeld M, Cagatay M, Petrowitsch T, Neuser D, Petzinna D, Rupp M. Acarbose reduces the risk for myocardial infarction in type 2 diabetic patients: meta-analysis of seven long-term studies. *Eur Heart J* 25:10-6, 2004.
4. Van de Laar FA, Lucassen PL, Akkermans RP, Van de Lisdonk EH, Rutten GE, Van Weel C. Alpha-glucosidase inhibitors for type 2 diabetes mellitus. *Cochrane Database Syst Rev* 18; (2):CD003639, 2005.

## Exenatide

1. DeFronzo RA et al. Effects of exenatide (Exendin-4) on glycemic control and weight over 30 weeks in metformin-treated patients with type 2 diabetes. *Diabetes Care* 28:1092-1100, 2005.
2. Buse JB, Henry RR, Han J, Kim DD, Fineman MS, Baron AD; Exenatide-113 Clinical Study Group. Effects of exenatide (exendin-4) on glycemic control over 30 weeks in sulfonylurea-treated patients with type 2 diabetes. *Diabetes Care* 27:2628-35, 2004.
3. Fineman MS, Bicsak TA, Shen LZ, Taylor K, Gaines E, Varns A, Kim D, Baron AD. Effect on glycemic control of exenatide (synthetic exendin-4) additive to existing metformin and/or sulfonylurea treatment in patients with type 2 diabetes. *Diabetes Care* 26:2370-7, 2003.
4. Heine RJ, Van Gaal LF, Johns D, Mihm MJ, Widel MH, Brodows RG; GWAA Study Group. Exenatide versus insulin glargine in patients with suboptimally controlled type 2 diabetes: a randomized trial. *Ann Intern Med* 143:559-69, 2005.
5. Iltz JL, Baker DE, Setter SM, Keith Campbell R. Exenatide: an incretin mimetic for the treatment of type 2 diabetes mellitus. *Clin Ther* 28:652-65, 2006.
6. Kendall, DM et al. Effects of exenatide (Exendin-4) on glycemic control over 30 weeks in patients with type 2 diabetes treated with metformin and a sulfonylurea. *Diabetes Care* 28:1083-1091, 2005.
7. Linnebjerg H, Kothare PA, Skrivaneck Z, de la Pena A, Atkins M, Ernest CS, Trautmann ME. Exenatide: effect of injection time on postprandial glucose in patients with type 2 diabetes. *Diabet Med* 23:240-5, 2006.
8. Poon T, Nelson P, Shen L, Mihm M, Taylor K, Fineman M, Kim D. Exenatide improves glycemic control and reduces body weight in subjects with type 2 diabetes: a dose-ranging study. *Diabetes Technol Ther* 7:467-77, 2005.

## DPP-IV Inhibitors

1. Chia CW, Egan JM. Incretin-based therapies in type 2 diabetes mellitus. *J Clin Endocrinol Metab* 2008; 93(10):3703-3716.
2. Fonseca VA, Rosenstock J, Wang AC, Truitt KE, Jones MR. Colesevelam HCl improves glycemic control and reduces LDL cholesterol in patients with inadequately controlled type 2 diabetes on sulfonylurea-based therapy. *Diabetes Care* 2008; 31(8):1479-1484.
3. Miller S, St Onge EL. Sitagliptin: a dipeptidyl peptidase IV inhibitor for the treatment of type 2 diabetes. *Ann Pharmacother* 2006; 40(7-8):1336-1343.
4. Goldstein BJ, Feinglos MN, Lunceford JK, Johnson J, Williams-Herman DE. Effect of initial combination therapy with sitagliptin, a dipeptidyl peptidase-4 inhibitor, and metformin on glycemic control in patients with type 2 diabetes. *Diabetes Care* 2007; 30(8):1979-1987.

## Bile Acid Sequestrants

1. Bays HE, Goldberg RB, Truitt KE, Jones MR. Colesevelam hydrochloride therapy in patients with type 2 diabetes mellitus treated with metformin: glucose and lipid effects. *Arch Intern Med* 2008; 168(18):1975-1983.
2. Fonseca VA, Rosenstock J, Wang AC, Truitt KE, Jones MR. Colesevelam HCl improves glycemic control and reduces LDL cholesterol in patients with inadequately controlled type 2 diabetes on sulfonylurea-based therapy. *Diabetes Care* 2008; 31(8):1479-1484.
3. Goldberg RB, Fonseca VA, Truitt KE, Jones MR. Efficacy and safety of colesevelam in patients with type 2 diabetes mellitus and inadequate glycemic control receiving insulin-based therapy. *Arch Intern Med* 2008; 168(14):1531-1540.

## Combination Therapy with insulin

1. Aviles-Santa L, Sinding J, Raskin P. Effects of metformin in patients with poorly controlled insulin-treated type 2 diabetes mellitus. *Ann Intern Med* 131:182-88, 1999.
2. Belcher G, Lambert C, Goh1 KL, Edwards G, Valbuena1 M. Cardiovascular effects of treatment of type 2 diabetes with pioglitazone, metformin and glipazide. *Int J Clin Pract* 58:833-7, 2004.
3. Goudswaard AN, Furlong NJ, Valk GD, Stolk RP, Rutten GEHM. Insulin monotherapy versus combinations of insulin with oral hypoglycaemic agents in patients with type 2 diabetes mellitus. *Cochrane Database Sys Rev* 2006 Issue 4.
4. Jones TA, Sautter M, Van Gaal LF, Jones NP. Addition of rosiglitazone to metformin is most effective in obese, insulin-resistant patients with type 2 diabetes. *Diabetes Obes Metab* 5:163-70, 2003.
5. Roberts VL, Stewart J, Issa M, Lake B, Melis R. Triple therapy with glimepiride in patients with type 2 diabetes mellitus inadequately controlled by metformin and a thiazolidinedione: results of a 30-week, randomized, double-blind, placebo-controlled, parallel-group study. *Clin Ther* 27:1535-47, 2005.
6. Rosenstock J, Sugimoto D, Strange P, Stewart JA, Soltes-Rak E, Dailey G. Triple therapy in type 2 diabetes: insulin glargine or rosiglitazone added to combination therapy of sulfonylurea plus metformin in insulin-naive patients. *Diabetes Care* 29:554-9, 2006.
7. Yki-Jarvinen H et al. Insulin glargine or NPH combined with metformin in type 2 diabetes: the LANMET study. *Diabetologia* 3:1-10, 2006.

## Insulin

1. Baker A, Ahmed E, Mallias J, Home PD. Optimization of evening insulin dose in patients using the short-acting insulin analog lispro. *Diabetes Care* 21:1162-66, 1998.
2. Davidson J, Vexiau P, Cucinotta D, Vaz J, Kawamori R. Biphasic insulin aspart 30: literature review of adverse events associated with treatment. *Clin Ther* 27:S75-88, 2005.
3. Hirsch B, Bergenstal RM, Parkin CG, Wright E, Buse JB. A real-world approach to insulin therapy in primary care practice. *Clin Diabetes* 23: 78-86, 2005.
4. Kennedy L, Herman WH, Strange P, Harris A for the GOAL A1C Team. Impact of active versus usual algorithmic titration of basal insulin and point-of-care versus laboratory measurement of HbA<sub>1c</sub> on glycemic control in patients with type 2 diabetes. *Diabetes Care* 29:1-8, 2006.
5. Kudva YC, Basu A, Jenkins GD, Pons GM, Quandt LL, Gebel JA, Vogelsang DA, Smith SA, Rizza RA, Isley WL. Randomized controlled clinical trial of glargine versus ultralente insulin in the treatment of type 1 diabetes. *Diabetes Care* 28:10-4, 2005.
6. Riddle MC. The Treat-to-Target Trial and related studies. *Endoc Pract.* 37:495-501, 2006.
7. Scholtz HE, Pretorius SG, Wessels DH, Becker RH. Pharmacokinetic and glucodynamic variability: assessment of insulin glargine, NPH insulin and insulin ultralente in healthy volunteers using a euglycaemic clamp technique. *Diabetologia* 48:1988-95, 2005.
8. Siebenhofer A, Plank J, Berghold A, Jeitler K, Horvath K, Narath M, Gfrerer R, Pieber TR. Short acting insulin analogues versus regular human insulin in patients with diabetes mellitus. *Cochrane Database Syst Rev.* 2006 Apr 19;(2):CD003287.
9. Taylor R, Davies R, Fox C, Sampson M, Weaver JU, Wood L. Appropriate insulin regimen for type 2 diabetes: a multicenter randomized crossover study. *Diabetes Care* 23:1612-18, 2000.
10. Valensi P, Cosson E. Is insulin detemir able to favor a lower variability in the action of injected insulin in diabetic subjects? *Diabetes Metab* 31:4S34-4S39, 2005.

## Pramlintide

1. Hollander P, Ratner R, Fineman M, Strobel S, Shen L, Maggs D, Kolterman O, Weyer C. Addition of pramlintide to insulin therapy lowers HbA<sub>1c</sub> in conjunction with weight loss in patients with type 2 diabetes approaching glycaemic targets. *Diabetes Obes Metab* 5:408-14, 2003.
2. Hollander PA et al. Pramlintide as an adjunct to insulin therapy improves long-term glycemic and weight control in patients with type 2 diabetes: a 1-year randomized controlled trial. *Diabetes Care* 26:784-790, 2003.
3. Weyer C, Gottlieb A, Kim DD, Lutz K, Schwartz S, Gutierrez M, Wang Y, Ruggles JA, Kolterman OG, Maggs DG. Pramlintide reduces postprandial glucose excursions when added to regular insulin or insulin lispro in subjects with type 1 diabetes: a dose-timing study. *Diabetes Care* 26:3074-9, 2003.
4. Whitehouse F, Kruger DF, Fineman M, Shen L, Ruggles JA, Maggs DG, Weyer C, Kolterman OG. A randomized study and open-label extension evaluating the long-term efficacy of pramlintide as an adjunct to insulin therapy in type 1 diabetes. *Diabetes Care* 25:724-30, 2002.