

References for Joslin's Pharmacological Management of Type 2 Diabetes Guideline 1/12/07

Diagnosis

1. Expert Committee on the Diagnosis and Classification of Diabetes Mellitus: Follow-up report on the diagnosis of diabetes mellitus. *Diabetes Care* 26:3160-3167, 2003.
2. Expert Committee on the Diagnosis and Classification of Diabetes Mellitus: Report of the expert committee on the diagnosis and classification of diabetes mellitus. *Diabetes Care* 20:1183-1197, 1997.

Goals of Glycemic Control

1. American Diabetes Association. Screening for type 2 diabetes. *Diabetes Care* 27:S11-S14, 2004.
2. American Diabetes Association. The pharmacological treatment of hyperglycemia in NIDDM. *Diabetes Care* 18:1510-1518, 1995.
3. Beaser, RS and Staff of Joslin Diabetes Center. *Joslin's Diabetes Deskbook for Primary Care Providers*. Revised edition. Joslin Diabetes Center, Boston; 2003.
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. 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.
2. DeFronzo RA, Ratner RE, Han J, Kim DD, Fineman MS, Baron AD. Effects of exenatide (exendin-4) on glycemic control and weight over 30 weeks in metformin-treated patients with type 2 diabetes. *Diabetes Care* 28:1092-100, 2005.
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. 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. Inzucchi SE. Oral antihyperglycemic therapy for type 2 diabetes: scientific review. *JAMA* 287:360-72, 2002.
6. Kimmel B and Inzucchi S. Oral agents for type 2 diabetes: an update. *Clinical Diabetes* 23:64-76, 2005.
7. Krentz AJ, Bailey CJ. Oral antidiabetic agents. *Drugs* 2005; 65(3):385-411.

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. 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.
5. Hoffmann J, Germany E, Spengler M. Efficacy of 24-week monotherapy with acarbose, metformin, or placebo in dietary-treated NIDDM patients: the Essen-II study. *Am J Med* 103: 483-490, 1997.
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. OKPDS 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. Salpeter S, Greyber E, Pasternak G, Salpeter E. Risk of fatal and nonfatal lactic acidosis with metformin use in type 2 diabetes mellitus. *Cochrane Database Sys Rev* 2003; (2):CD002967.
14. Sulkin TV, Bosman D, Krentz AJ. Contraindications to metformin therapy in patients with NIDDM. *Diabetes Care* 20:925-8, 1997.
15. Sulkin TV, Bosman D, Krentz AJ. Contraindications to metformin therapy in patients with NIDDM. *Diabetes Care* 20:925-8, 1997.
16. Waybill MM, Waybill PN. Contrast media-induced nephrotoxicity: identification of patients at risk and algorithms for prevention. *J Vasc Interv Radiol* 12:3-9, 2001.

Thiazolidinediones

1. Amin P. Liver toxicity and pioglitazone: data are missing. *BMJ* 329:918, 2004.

2. Charbonnel1B, Roden M, Urquhart , 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.
3. 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.
4. Fonseca VA, Valiquett TR, Huang SM, Ghazzi MN, Whitcomb RW, and the Troglitazone Study Group. Troglitazone monotherapy improves glycemic control in patients with type 2 diabetes mellitus: a randomized controlled study. *J Clin Endocrinol Metab* 83:3169-76, 1998.
5. 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.
6. 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.
7. 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.
8. 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.

Insulin Secretagogues

1. Bailey CJ, Day C. Antidiabetic drugs. *Br J Cardiol* 10:128-36, 2003.
2. Davies M. Nateglinide: better post-prandial glucose control. *Prescriber* 13:17-27, 2002.
3. DeFronzo RA. Pharmacologic therapy for type 2 diabetes mellitus. *Ann Intern Med* 131:281-303, 1999.
4. 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.
5. Dornhorst M. Insulotropic meglitinide analogues. *Lancet* 358:1709-15, 2001.
6. Hazama Y, Matsuhisa M, Ohtoshi K, Gorogawa 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.
7. Kishikawa H, Okada Y, Kanda K, Tanaka Y. Indication for nateglinide in type 2 diabetes mellitus J UOEH. 27:179-88, 2005.
8. Krentz AJ Bailey CJ. *Type 2 Diabetes in Practice*. London: Royal Society of Medicine Press, 2001.

9. Plosker, GI, Figgitt, DP. Repaglinide: a pharmacoeconomic review of its use in type 2 diabetes mellitus. *Pharmacoeconomics* 22:389-411, 2004.
10. 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. Harrower AD. Pharmacokinetics of oral antihyperglycaemic agents in patients with renal insufficiency. *Clin Pharmacokinet* 31:111-9, 1996.
5. Lebovitz HE. Alpha-glucosidase inhibitors. *Endocrinol Metab Clin North Am* 26:539-51, 1997.
6. 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. 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.
3. 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.
4. 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.
5. 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.
6. 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.

Combination Therapy

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. Barnett AH, Dreyer M, Lange P, Serdarevic-Pehar M. An open, randomized, parallel-group study to compare the efficacy and safety profile of inhaled human insulin (Exubera) with metformin as adjunctive therapy in patients with type 2 diabetes poorly controlled on a sulfonylurea. *Diabetes Care* 29:1282-7, 2006.
3. Ceglia L, Lau J, Pittas AG. Meta-analysis: efficacy and safety of inhaled insulin therapy in adults with diabetes mellitus. *Ann Intern Med* 145:665-75, 2006.
4. 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.
5. Davis SN, Renda, SM. Treating to target in type 2 diabetes. *Diabetes Educ* 32:137S-145S, 2006.
6. Dunn C, Curran MP. Spotlight on inhaled human insulin (exubera((r))) in diabetes mellitus. *Treat Endocrinol* 5:329-31, 2005.
7. 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.
8. Hollander PA, Blonde L, Rowe R, Mehta AE, Milburn JL, Hershon KS, Chiasson JL, Levin SR. Efficacy and safety of inhaled insulin (Exubera) compared with subcutaneous insulin therapy in patients with type 2 diabetes: results of a 6-month, randomized, comparative trial. *Diabetes Care* 27:2356-62, 2004.

9. 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_{1c} on glycemic control in patients with type 2 diabetes. *Diabetes Care* 29:1-8, 2006.
10. 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.
11. Odegard, PS. Inhaled insulin: Exubera. *Ann Pharmacother* 39:843-853, 2005.
12. Quattrin T, Belanger A, Bohannon NJ, Schwartz SL. Exubera Phase III Study Group. Efficacy and safety of inhaled insulin (Exubera) compared with subcutaneous insulin therapy in patients with type 1 diabetes: results of a 6-month, randomized, comparative trial. *Diabetes Care* 27:2622-7, 2004.
13. Riddle MC. The Treat-to-Target Trial and related studies. *Endoc Pract.* 37:495-501, 2006.
14. Rosenstock J et al. Inhaled insulin improves glycemic control when substituted for or added to oral combination therapy in type 2 diabetes. *Ann Intern Med* 143:549-558, 2005.
15. Rosenstock J, Zinman B, Murphy LJ, Clement SC, Moore P, Bowering CK, Hendler R, Lan SP, Cefalu WT. Inhaled insulin improves glycemic control when substituted for or added to oral combination therapy in type 2 diabetes: a randomized, controlled trial. *Ann Intern Med* 143:549-58, 2005.
16. Royle P, Waugh N, McAuley L, McIntyre L, Thomas S. Inhaled insulin in diabetes mellitus. *Cochrane Database Syst Rev* 2004;(3):CD00389.
17. 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.
18. 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.
19. 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.
20. 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_{1c} 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.