Tool for Linking Evidence Reviews to Organizational Guideline Planning

Accompanies Methods Report: Linking Evidence Reviews to Organizational Guideline Planning: A Pilot Test of an Interactive, Web-Based Presentation and Discussion of Evidence

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Understanding the Evidence for Medication and Lifestyle Interventions to Delay the Onset of Diabetes

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The speakers have no conflicts of interest to report.

Genesis and purpose of this seminar

- AHRQ-funded effort to try to improve the uptake/use of evidence reports conducted by Evidence-based Practice Centers (EPC) by health care delivery systems
  - Joint effort with KPRA EPC, RAND EPC and KP CMI
- Interactive format to link reviews (evidence reviewers) to a broad range of stakeholders within KP- those developing clinical guidance and those implementing clinical guidance
- This seminar consists of a brief evidence presentation with ample time for discussion

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Systematic review of interest

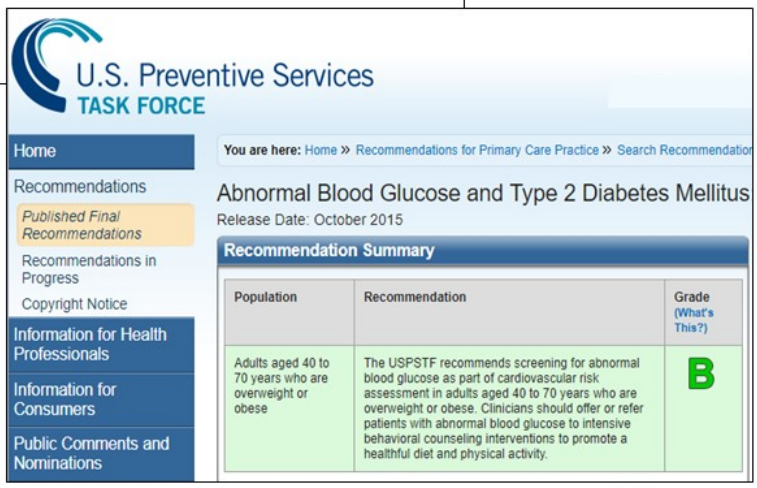
Evidence Synthesis
Number 117

Screening for Abnormal Glucose and Type 2 Diabetes Mellitus: A Systematic Review to Update the 2008 U.S. Preventive Services Task Force Recommendation

AHRQ Publication No. 13-05190-EF-1
April 2015

Selph S, Dana T, Bougatsos C, Blazina I, Patel H, Chou R. *Screening for Abnormal Glucose and Type 2 Diabetes Mellitus: A Systematic Review to Update the 2008 U.S. Preventive Services Task Force Recommendation.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2015 Apr. Report No.: 13-05190-EF-1. PMID: 25973510

Final Recommendation Statement: Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening. U.S. Preventive Services Task Force. November 2016.



Why screen?

- USPSTF recommendation to screen for DM hinges on ability of lifestyle interventions to prevent/delay the onset of DM
  - Intensive lifestyle interventions to prevent the development of diabetes consistently show a moderate benefit in reducing the progression to diabetes.

- Direct evidence that preventing a diagnosis or early identification of diabetes results in improved patient health outcomes is limited.

Key Question 7 in the systematic review

Do interventions for impaired fasting glucose or impaired glucose tolerance delay or prevent progression to type 2 diabetes?

- Lifestyle interventions
- Medications
  - e.g., metformin, thiazolidinediones, alpha-glucosidase inhibitors

As you listen to the evidence today…

- How effective are interventions to delay or prevent the onset of diabetes?
  - Do the benefits of these interventions outweigh the harms?
- What evidence do *you* need that is NOT covered in this systematic review?
  - What else do you need to know that is not addressed?

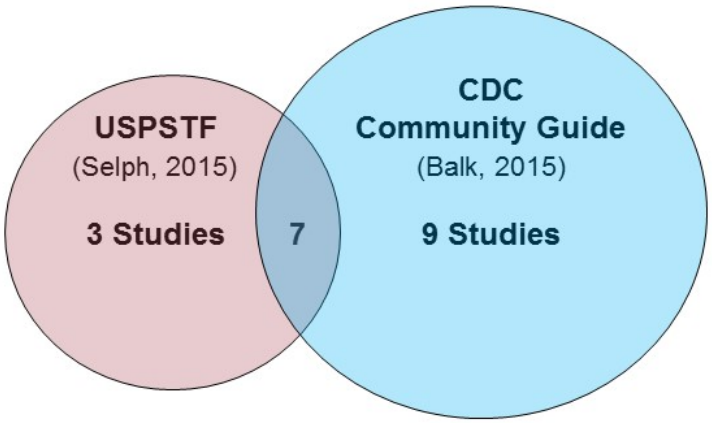
Overall Findings for Key Question 7

	No. studies	Summary of findings on progression to diabetes	Limitations
Lifestyle	10	RR 0.57 (95% CI 0.43, 0.70)	Clinical heterogeneity
Medications			
Metformin	3	RR 0.69 (95% CI 0.49, 0.76)*	Few studies, TZD high statistical heterogeneity
TZD	3	RR 0.51 (95% CI 0.23, 1.06)	
α-gluc inhibitors	4	RR 0.65 (95% CI 0.44, 0.91)	
Multifactorial interventions	2	No pooled analysis, no effect on progression to DM	Clinical heterogeneity, Imprecision

* from DPP trial, no pooled estimate calculated

What is the evidence on lifestyle interventions to prevent the onset of diabetes?

Lifestyle interventions: Overlap with the review for the CDC Community Guide (Balk et al., 2015)



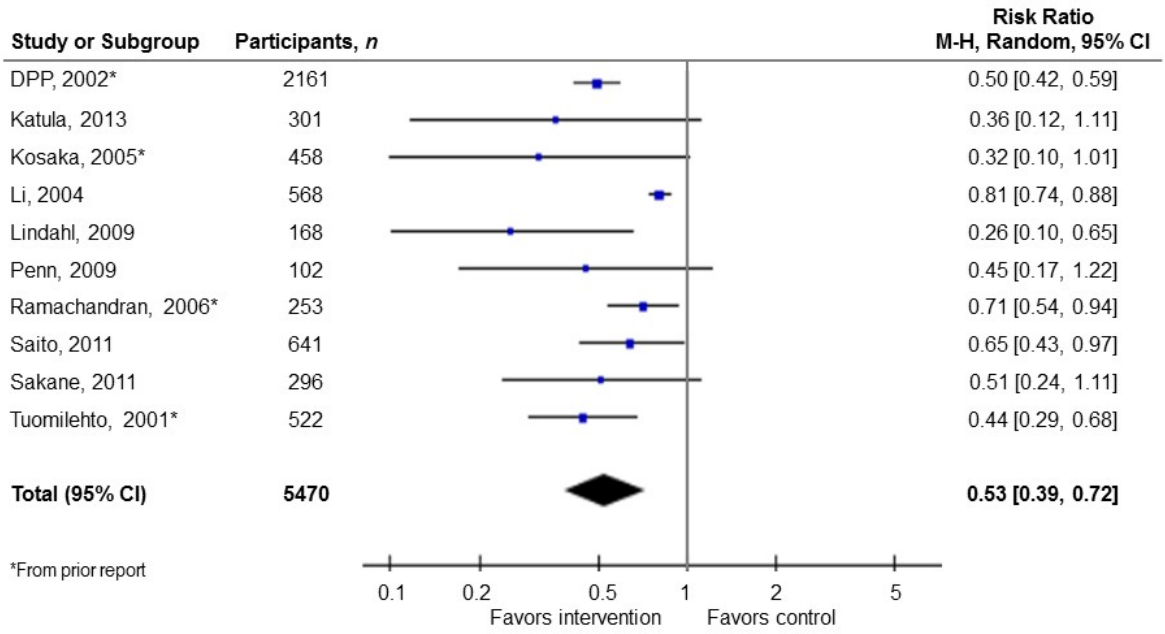
Reasons for non-overlap include:

- Mismatch of review's search dates
- Study design
- Setting less relevant to US
- Error

Selph S, Dana T, Bougatsos C, Blazina I, Patel H, Chou R. *Screening for Abnormal Glucose and Type 2 Diabetes Mellitus: A Systematic Review to Update the 2008 U.S. Preventive Services Task Force Recommendation.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2015 Apr. Report No.: 13-05190-EF-1. PMID: 25973510

Balk EM, Earley A, Raman G, Avendano EA, Pittas AG, Remington PL. Combined Diet and Physical Activity Promotion Programs to Prevent Type 2 Diabetes Among Persons at Increased Risk: A Systematic Review for the Community Preventive Services Task Force. *Ann Intern Med* 2015 Sep 15;163(6):437-51. doi: 10.7326/M15-0452. PMID: 26167912

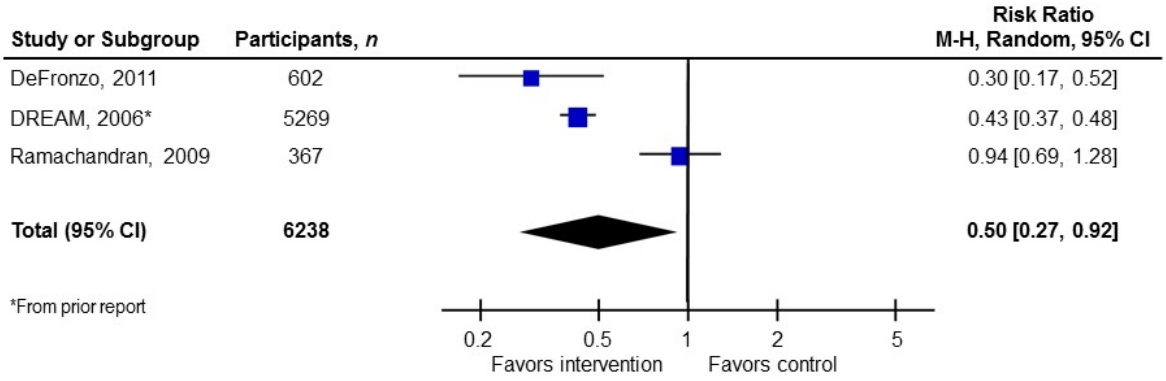
Results for lifestyle interventions



Adapted from "Figure 4. Meta-Analysis of the Effect of Lifestyle Interventions on Incidence of Progression to DM". Source: Selph S, Dana T, Bougatsos C, Blazina I, Patel H, Chou R. *Screening for Abnormal Glucose and Type 2 Diabetes Mellitus: A Systematic Review to Update the 2008 U.S. Preventive Services Task Force Recommendation.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2015 Apr. Report No.: 13-05190-EF-1. PMID: 25973510

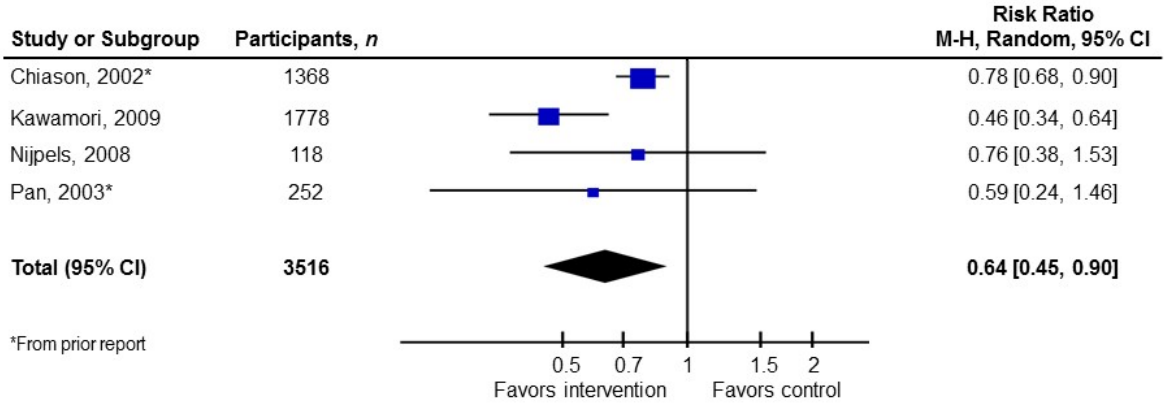
What is the evidence on medications other than metformin to prevent the onset of diabetes?

Results for TZD



Adapted from "Figure 5. Meta-Analysis of the Effect of Thiazolidinediones on Incidence of Progression to DM". Source: Selph S, Dana T, Bougatsos C, Blazina I, Patel H, Chou R. *Screening for Abnormal Glucose and Type 2 Diabetes Mellitus: A Systematic Review to Update the 2008 U.S. Preventive Services Task Force Recommendation.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2015 Apr. Report No.: 13-05190-EF-1. PMID: 25973510

Results for alpha-glucosidase inhibitors



Adapted from "Figure 6. Meta-Analysis of the Effect of Alpha-Glucosidase Inhibitors on Incidence of Progression to DM". Selph S, Dana T, Bougatsos C, Blazina I, Patel H, Chou R. *Screening for Abnormal Glucose and Type 2 Diabetes Mellitus: A Systematic Review to Update the 2008 U.S. Preventive Services Task Force Recommendation.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2015 Apr. Report No.: 13-05190-EF-1. PMID: 25973510

What about harms?

- None of the reviews examine harms of these interventions
  - While lifestyle interventions don't have any hypothesized harms, there is a cost and opportunity cost trade-off
  - An examination of harms of medications is necessary to assess the net benefit for these medications (particularly their long term use) to determine their role in diabetes prevention

As you listen to the implementation issues around lifestyle interventions…

- How far do you want to extrapolate from the evidence?
  - What sort of lifestyle interventions should we be offering our members?
  - Who should be offered intensive lifestyle interventions?
- What else do *you* want to know?

Implementation issues for lifestyle interventions- DPP as the exemplar

- **Intervention goals**
- Comparison group
- Training required
- Mode of delivery
- Intensity of intervention (when and how much)
- Availability of materials
- Target population
  - setting, adherence

- Goals: achieve and maintain weight reduction ≥7% of initial body weight through a healthy low-calorie, low-fat diet and engage in moderate-intensity physical activity for ≥150 min/wk
- Participants taught to record diet and exercise.
- Offered supervised exercise sessions twice per week for duration of intervention (not mandatory).
- Intervention "flexible" culturally sensitive. Lifestyle advice was tailored to the individual with emphasis on self-esteem, empowerment, and social support.

Implementation issues for lifestyle interventions- DPP as the exemplar

- Intervention goals
- **Comparison group**
- Training required
- Mode of delivery
- Intensity of intervention (when and how much)
- Availability of materials
- Target population
  - setting, adherence

- Intervention 2: standard lifestyle recommendations + metformin 850 mg PO BID.
- Control: standard lifestyle recommendations + placebo pill.
- Standard lifestyle recommendations included **written information with annual 20-30 minute individual session** emphasizing healthy lifestyle (diet and exercise).

Implementation issues for lifestyle interventions- DPP as the exemplar

- Intervention goals
- Comparison group
- **Training required**
- Mode of delivery
- Intensity of intervention (when and how much)
- Availability of materials
- Target population
  - setting, adherence

- Primary care provider for recruitment only.
- Program and recruitment coordinators that were trained in motivational interviewing.
- Case manager with training in nutrition, exercise, or behavior modification (details not reported).
- Supervised exercise leader not defined.

Implementation issues for lifestyle interventions- DPP as the exemplar

- Intervention goals
- Comparison group
- Training required
- **Mode of delivery**
- Intensity of intervention (when and how much)
- Availability of materials
- Target population
  - setting, adherence

- Face to face visits (individual and group).

Implementation issues for lifestyle interventions- DPP as the exemplar

- Intervention goals
- Comparison group
- Training required
- Mode of delivery
- **Intensity of intervention (when and how much)**
- Availability of materials
- Target population
  - setting, adherence

- A case manager taught **16 one-on-one sessions over 24 weeks** using a curriculum which followed the Food Guide Pyramid 14.
- **Subsequent sessions** led by the case manager were **monthly** and either **individual or group** focused on behavior reinforcement
- 6 months core curriculum 1.8-4.6 years maintenance (**mean 2.8 years**).
- Optional supervised exercise sessions up to twice per week throughout intervention.
- Semiannual FBG and annual 2 hr oral glucose tolerance test.

Implementation issues for lifestyle interventions- DPP as the exemplar

- Intervention goals
- Comparison group
- Training required
- Mode of delivery
- Intensity of intervention (when and how much)
- **Availability of materials**
- Target population
  - setting, adherence

- Written material: Lifestyle Manuals of Operation (www.bsc.gwu.edu/dpp).
- Modified Block Food-Frequency Questionnaire.
- Modified Activity Questionnaire.

Lifestyle Manuals of Operation. Copyright 1996; 2011; University of Pittsburgh.

Implementation issues for lifestyle interventions- DPP as the exemplar

- Intervention goals
- Comparison group
- Training required
- Mode of delivery
- Intensity of intervention (when and how much)
- Availability of materials
- **Target population**
  - **setting, adherence**

- **Volunteer** participants recruited through 27 (academic) US medical centers.
- **Prediabetics:** participant characteristics included being 25 years or older, BMI of 24 or more (22 or higher in Asians) and fasting plasma glucose of 95-125 or glucose of 140-199, 2 hrs after 75g glucose challenge.
- Adherence and retention actively fostered and used quarterly newsletters.
- 50% of the intervention group achieved weight loss goal by 24 weeks, 74% met exercise goal by 24 weeks, 72% took at least 80% of the prescribed dose of metformin.

What do we know about virtual interventions from the systematic reviews?

- Limited evaluations of different virtual interventions
  - NO trials reported on diabetes incidence as an outcome, all with shorter term follow-up
  - Most informative trial evaluated face-to-face vs DVD-based intensive lifestyle intervention (12+ sessions)
    - Generally high income volunteers, SF Bay area
    - At 15 months, slightly larger effects on weight loss for in person than virtual, but both more than usual care group
  - 2 comparative effectiveness trials evaluated virtual interventions (reality TV, internet) versus enhanced programs (with virtual counseling/interaction), found that enhanced programs resulted in weight loss at 12 months

Conclusions from the systematic reviews

- USPSTF recommendation to screen for DM hinges on ability of lifestyle interventions to prevent/delay the onset of DM
- Using the Balk review for CDC is reasonable, more comprehensive to the USPSTF review, consistent with USPSTF review findings for lifestyle interventions
- Understanding the details of interventions is key to reproducing intervention, as deviations from the tested intervention may result in different outcomes (effectiveness) in practice
- Understanding the harms of longer term use of medications is important before implementation

YMCA program

The YMCA Diabetes Prevention Program is for overweight adults (18+) with prediabetes, confirmed via one of 3 blood tests or has 2 or more risk factors.

The 12 month program (includes a 16 session core program followed by monthly maintenance sessions). Sessions are one hour per week and include 8 to 15 people in a group based, classroom setting.

Classroom-type settings allow for sessions to be conducted anytime or anywhere.

Participants weigh in at each session, their weight is recorded in an online tracking system, and the sessions are facilitated by a Y Lifestyle Coach (a person who is skilled in Listen First and group facilitation).

Source: https://www.slideshare.net/colinpowellcenter/jody-ouziel-ymca-diabetes-prevention. Judy Ouziel, Senior Executive Director, Strategic Initiatives, YMCA of Greater New York. *YMCA Diabetes Prevention Program: Creating Powerful Alliances*, Colin L. Powell Center, New York, NY, May 2, 2012.

Overall results

Health Care Innovation Award

Health Care Innovation Award (HCIA) to The Young Men's Christian Association (YMCA) of the USA (Y-USA).

Feb. 2013 – Jan. 2015

~7,800 beneficiaries

Session Attendance

- 83% ≥4
- 63% ≥9 or more

https://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/ 7

Source: https://innovation.cms.gov/Files/slides/mdpp-overview-slides.pdf

YMCA program results

- Among the 5,696 Medicare beneficiaries who attended four or more sessions, there was a mean weight loss of 5.27 kg (~5% loss of initial weight)
- Compared to a matched cohort of 65+ pre-diabetic individuals in the same county (who did not enroll in DPP)
  - Medicare savings
  - Significantly fewer inpatient admissions and ED stays

Alva ML et.al. *Health Aff* (Millwood). 2017 Mar 1;36(3):417-424.

CMS reimbursement for MDPP 4/1/2018

Proposed Beneficiary Eligibility

- **Must meet Body Mass Index (BMI) Criteria:**
  - ≥ 25 (≥ 23 for Asian beneficiaries)

- **Must have Blood Test Results:**

  Have within the 12 months prior to the first core session:
  - Hemoglobin A1c of 5.7-6.4%; or
  - Fasting plasma glucose of 110-125 mg/dL; or
  - Two-hour plasma glucose of 140–199 mg/dL

- **No previous diagnosis of diabetes (gestational diabetes is allowable) or End-Stage Renal Disease (ESRD).**

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Source: https://innovation.cms.gov/Files/slides/mdpp-overview-slides.pdf

CMS reimbursement for MDPP 4/1/2018

- Program requirements:
  - Minimum 16 core sessions in first 6 months
  - Monthly maintenance sessions, second 6 months
  - Monthly maintenance sessions for up to 2 years

Source: https://innovation.cms.gov/Files/slides/mdpp-overview-slides.pdf

Proposed Curriculum

During the first 6 months of the DPP intervention, the 16 core sessions must address the following curriculum topics:

Core Sessions	
Welcome to the NDPP	Problem Solving
Self-Monitoring Weight and Food Intake	Strategies for Healthy Eating Out
Eating Less	Reversing Negative Thoughts
Healthy Eating	Dealing with Slips in Lifestyle Change
Introduction to Physical Activity (Move those Muscles)	Mixing Up Your Physical Activity: Aerobic Fitness
Overcoming Barriers to Physical Activity (Being Active – A Way of Life)	Social Cues
Balancing Calorie Intake and Output	Managing Stress
Environmental Cues to Eating and Physical Activity	Staying Motivated, Program Wrap Up

Proposed Curriculum Continued

During the second 6 months of the 12-month Core Benefit the curriculum must address a different topic each month:

Maintenance Session Topics:	
Welcome to the Second Phase of the Program	Stress and Time Management
Healthy Eating: Taking It One Meal at a Time	Healthy Cooking: Tips for Food Preparation and Recipe Modification
Making Active Choices	Physical Activity Barriers
Balance Your Thoughts for Long-Term Maintenance	Preventing Relapse
Healthy Eating With Variety and Balance	Heart Health
Handling Holidays, Vacations, and Special Events	Life with Type 2 Diabetes
More Volume, Fewer Calories (Adding Water, Vegetables, and Fibers)	Looking Back and Looking Forward
Dietary Fats	

Virtual sessions—CMS policy

- (Year 1) A supplier may offer no more than 4 virtual make-up sessions within the core services period to an MDPP beneficiary,
  - of which no more than 2 virtual make-up sessions may be core *maintenance* sessions
- (Years 2, 3) A supplier may offer no more than 3 virtual make-up sessions that are ongoing maintenance sessions to an MDPP beneficiary during any rolling 12-month time period.
- Weights can only be recorded in-person

Source: https://innovation.cms.gov/Files/slides/mdpp-overview-slides.pdf

Discussion Questions—Implementation

- What type of lifestyle interventions should be made available?
- To whom should these lifestyle interventions be made available?

- Early insights:
  - Dr.'s Fitzpatrick and Fortmann, researchers at KPCHR in Portland—evaluation study to understand the implementation of virtual and in-person diabetes prevention programs at KPNW

Discussion Questions—Implementation

- When should metformin be offered or initiated?
- Are there medications other than metformin that may be reasonable to consider as prevention?