

Diabetes Prevention Program (DPP) Translation in VA



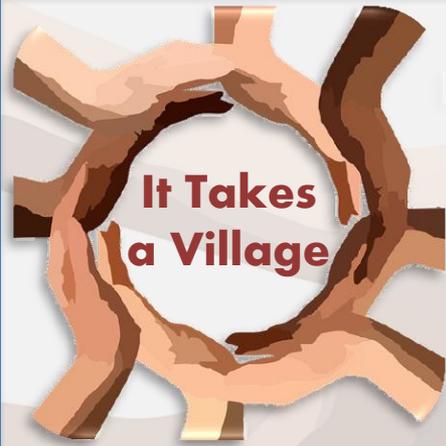
Laura Damschroder

Ann Arbor VA Center for Clinical Management Research
Health Services Research & Development Center of Excellence

&

Personalizing Options through Veteran Engagement (PROVE) QUERI Program, Ann Arbor MI

The views expressed in this presentation are my own and do not reflect the position or policy of the Department of Veterans Affairs or the United States government



**It Takes
a Village**

Omada Health

- Sean Duffy
- Matt Cook
- Tomi Onatunde

VA Ann Arbor CCMR

- **Project's Originator: Caroline R.**

Richardson, MD (Now, Family
Medicine, Univ of Michigan)

- Fatima Makki
- Maria Hughes
- Caitlin Reardon
- Brad Youles
- Sam Lindenauer
- Amanda Ellis
- Rob Holleman
- Jenny Davis
- Molly Harrod
- Jordan Sparks
- Jonathan Berry
- Christine Exe
- Maria Xiang
- Jen Burgess
- Nick Yankey
- Reina Larkin
- Mona AuYoung

Durham VA MC

- Santanu Datta
- Will Yancy
- Matthew Maciejewski
- Hollis Weidenbacher

VA Baltimore MC

- Nanette Steinle
- Samantha Leitzell
- Lillian Pinault
- Tammy Bremmer
- Jana McCanich

VA Greater Los Angeles HCS

- **Key collaborator: Tannaz
Moin, MD**

- Jane Weinreb
- Elena Vasti
- Art Kress
- Beth Sobel
- Aaron Flores
- Dorothy Bernet

Milwaukee VA MC

- Kristyn Ertl
- Kathryn Havens
- Jonette Johnson

Minneapolis VA HCS

- Charles Billington
- Jenessa Humphrey
- Jacquelyn Costabilo
- Catherine Proebstle
- Jerry Gunn
- Mark Benson
- Jessica Serbin

NCP Partners

Linda Kinsinger
Michael Goldstein
Ken Jones
Susi Lewis
Sue Raffa
Greg Moore

DPSC

M. Kaye Kramer
Andrea Kriska
Linda Semler
Beth Venditti

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Funding:  & 



Training: Diabetes Prevention Support Center (GLB Program)



Collaborators: Durham VA Medical Center (Matthew Maciejewski)



Clinical Demonstration Sites

- VA Baltimore Medical Center: Nanette Steinle
- VA Greater Los Angeles Healthcare System: Jane Weinreb & Tannaz Moin
- VA Milwaukee Medical Center: Kristyn Ertl
- VA Minneapolis Healthcare System: Charles Billington



Online Program: Omada Health

Poll (check one)

What is your primary professional role?

- Primary care clinician
- Clinician – other than primary care
- Health Services Researcher
- Other Researcher
- Other

Poll: (single answer)

What is your perception of DPP?

- I don't know enough to know
- DPP has mixed or low effectiveness
- DPP might benefit some patients
- DPP should be more widely available to more patients

DPP - Critical Components

- One consistent health coach X 16 sessions
 - Individual sessions
 - Iterative skill building
 - Relationship building
- Group Identity
 - Everyone has pre-diabetes
- Generic, concrete, assigned goals
 - 150 minutes walking/week
 - Lose 7% of body weight @24 weeks

DPP Outcomes 2002



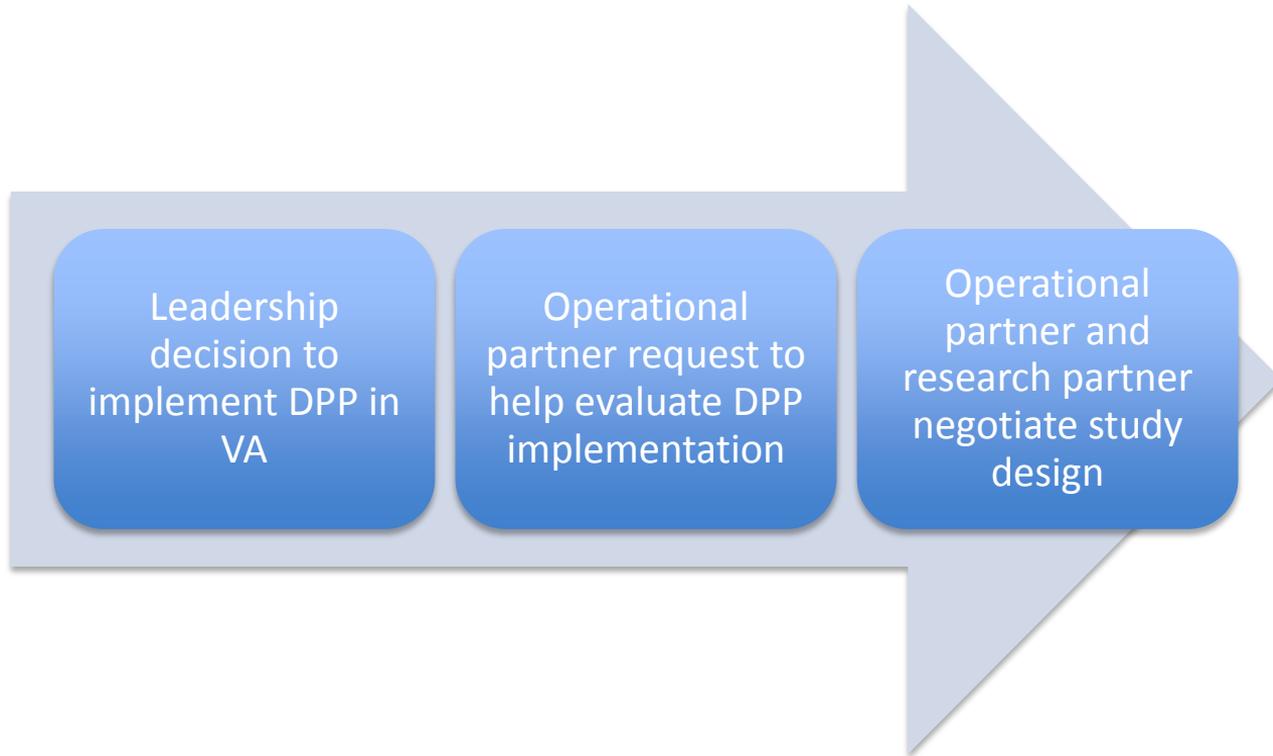
	<u>Placebo</u>	<u>Metformin</u>	<u>Lifestyle</u>
<u>Incidence</u> of diabetes (percent per year)	11%	8%	5%
<u>Reduction</u> in incidence compared with placebo	----	31%	58%
<u>Number needed to treat</u> to prevent 1 case in 3 years	----	14	7



Diabetes Prevention 2017

- 9 out of 10¹ Americans don't know if they have pre-diabetes
- Most Americans don't have access to a DPP.
 - Though options are increasing e.g., via YMCAs
- Diabetes prevalence continues to increase.
- Diabetes care is costly.

Partnered Research



Compare Two Programs

MOVE!

Independent topics

Personalized goals

Open groups

Multiple leaders

Target all overweight/obese

VA DPP

Iterative skill building

Standardized goals

Closed groups

One coach

Target those with prediabetes

Eligibility Criteria for VA DPP

N=1850 Veterans referred to MOVE! were assessed*

*interview, chart review, and/or lab testing

Inclusion Criteria – must meet all criteria:

- Attended MOVE! Orientation Session
 - BMI \geq 30 or BMI 25-30 + obesity-related dx
- Pre-diabetes:
 - Documented prediabetes diagnosis or laboratory confirmation if not previously screened
 - A1c 5.7-6.4% or FPG 100-125
- Live within 1 hour travel time of VAMC

Exclusion Criteria:

Use of anti-glycemic medication (e.g., metformin) within previous 6 months

Screening for VA DPP

N=1850 Veterans referred to MOVE! were assessed*

*interview, chart review, and/or lab testing

Prediabetes, n=387
(21%)

Normal glycemic status, n=435
(24%)

Diabetes, n=780
(42%)

Ineligible Other n=248 (13%)

- Pre-diabetes ineligible (n=123)
 - >1h away
 - no-show
 - other
- Other reason: n=125 (8%)

Assigned to VA DPP
(n=273)

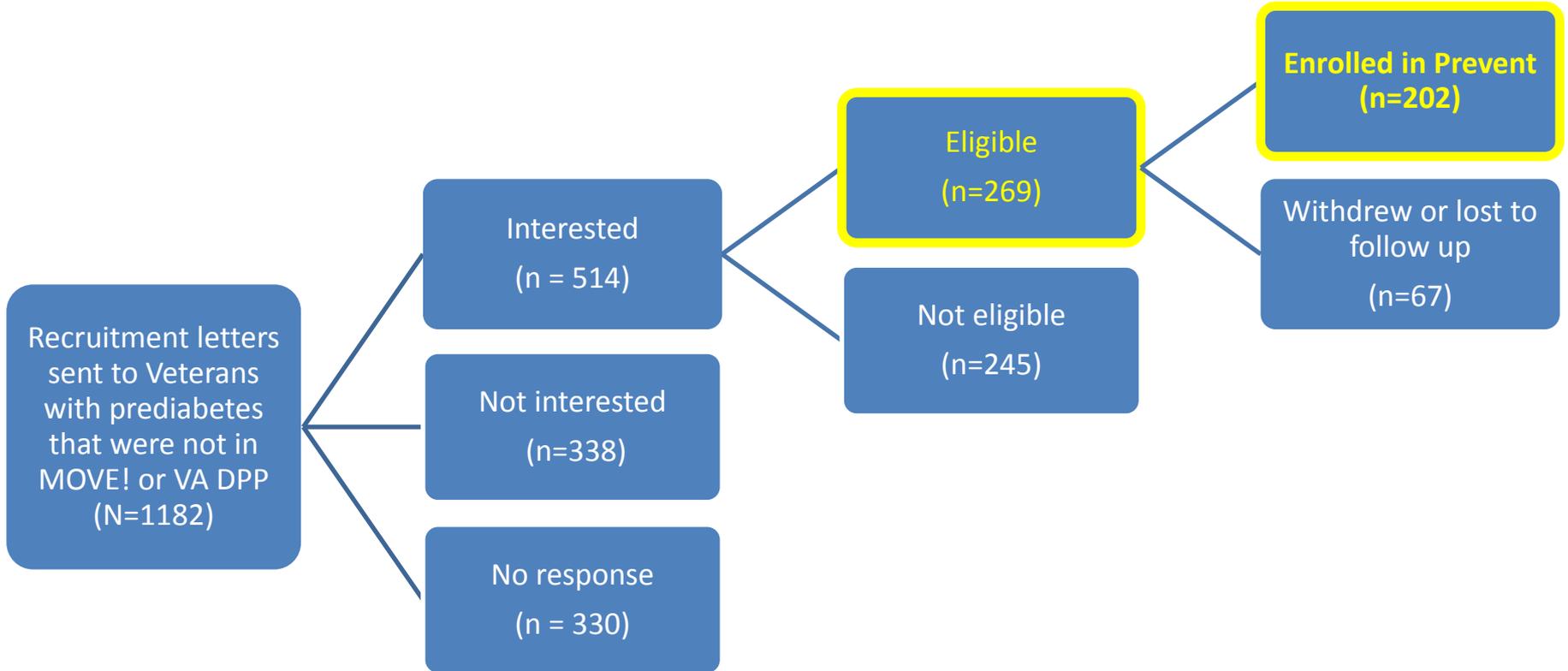
Assigned to MOVE!
(n=114)

Supplemental Funding: Online DPP

- Omada Health: <https://www.omadahealth.com/>
- 16 weeks core curriculum (based on DPP)
 - 6 month maintenance
- Asynchronous communication
 - forum posts
- Data secure and HIPAA compliant
- Scale transmits weights over cellular network

The image displays a screenshot of the Omada Health mobile application interface. On the left, a dark sidebar menu contains icons for 'MESSAGES', 'PROGRESS', 'LESSONS', and 'SKILLS'. The main content area shows a health coach's profile for 'Michele' (HEALTHY COACH) with a 'MESSAGE' button and an 'INTRO VIDEO' button. Below this, a 'GROUP TOTAL WEIGHT LOSS' section indicates '325.8 LBS'. A 'FOOD TRACKER' section is visible, showing a 'BREAKFAST' entry with 'Oatmeal' and 'Greek Yogurt', a 'How healthy was this breakfast?' slider, and a 'What time did you eat?' field set to 'AM'. There is also a 'TOTAL GLASSES OF WATER' section with a row of buttons from 1 to 8. At the bottom, an 'ACTIVITY TRACKER' section is partially visible. On the right side of the app, a forum post is displayed. The post is from 'Denise' and asks 'What's on your mind?'. It has 2 likes and 1 comment. Below it, another post from 'James' asks 'Good luck, Denise! The weather's supposed to be amazing, too. Upload a photo of yourself at the finish line, ok?'. A third post from 'Peggy' asks 'Does anyone know if orange juice with pulp is actually better for you than orange juice without pulp?'. A fourth post from 'Michele' says 'Hey everybody, George is celebrating a birthday today!'. The Omada Health logo is in the top right corner. In the bottom right corner, there is a 'LOAD OLDER POSTS' button. In the bottom left corner, there is a 'Prevent' logo on a black background with a red digital display showing '0.0'.

Screening for Online DPP



Comparative effectiveness trial

In-person Lifestyle Interventions

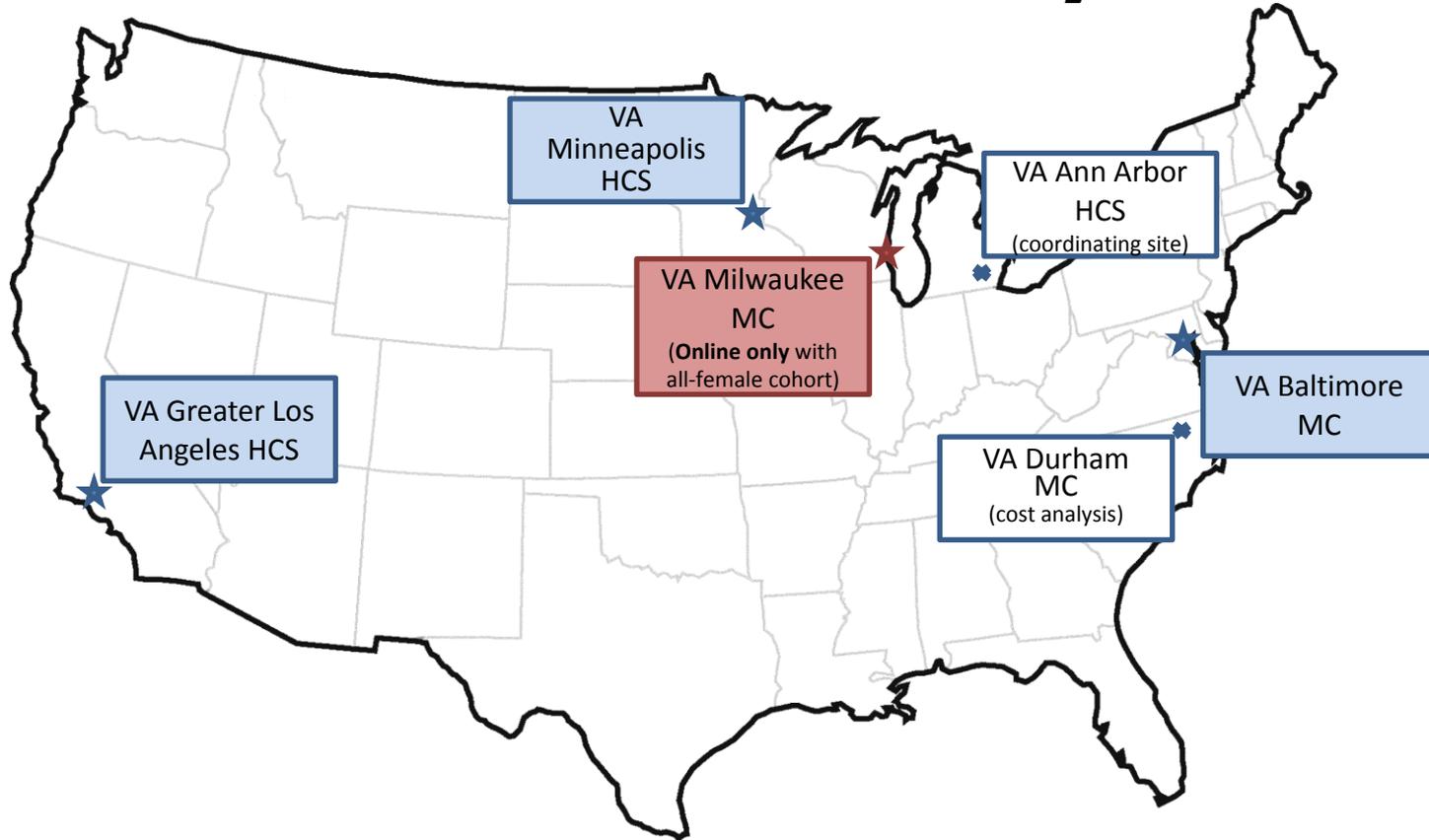


Pilot & Parallel Comparison

Online Lifestyle Intervention



Online & VA DPP Study Sites



SYSTEMATIC REVIEW

Open Access

A systematic review of real-world diabetes prevention programs: learnings from the last 15 years



Zahra Aziz^{1*}, Pilvikki Absetz^{2,3}, John Oldroyd⁴, Nicolaas P. Pronk⁵ and Brian Oldenburg¹

Abstract

Background: The evidence base for the prevention of type 2 diabetes mellitus (T2DM) has progressed rapidly from efficacy trials to real-world translational studies and practical implementation trials over the last 15 years. However, evidence for the effective implementation and translation of diabetes programs and their population impact needs to be established in ways that are different from measuring program effectiveness. We report the findings of a systematic review that focuses on identifying the critical success factors for implementing diabetes prevention programs in real-world settings.

Methods: A systematic review of programs aimed at diabetes prevention was undertaken in order to evaluate their outcomes using the penetration, implementation, participation, and effectiveness (PIPE) impact metric. A search for relevant articles was carried out using PubMed (March 2015) and Web of Science, MEDLINE, CENTRAL, and EMBASE. A quality coding system was developed and included studies were rated independently by three researchers.

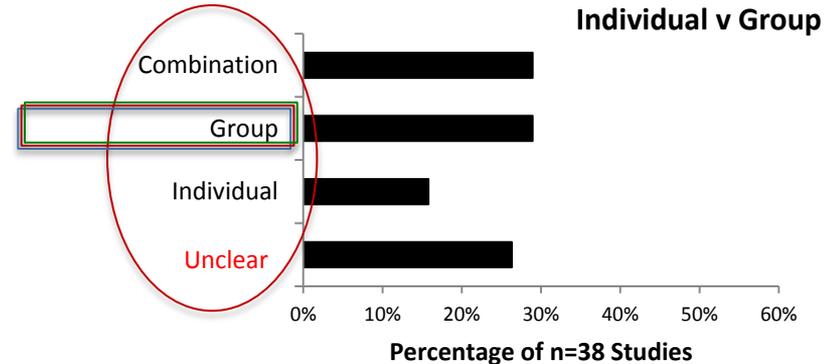
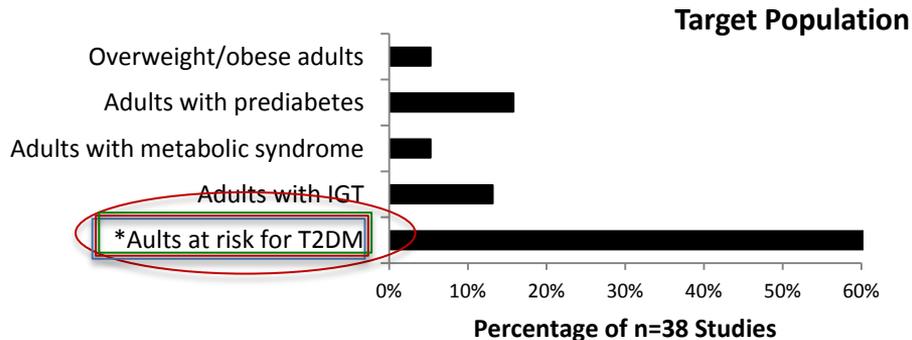
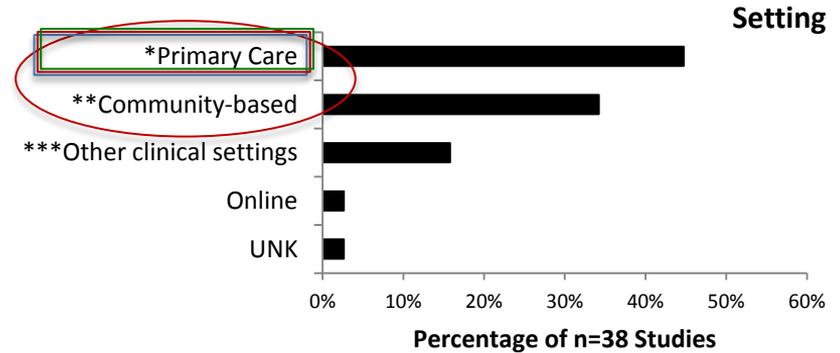
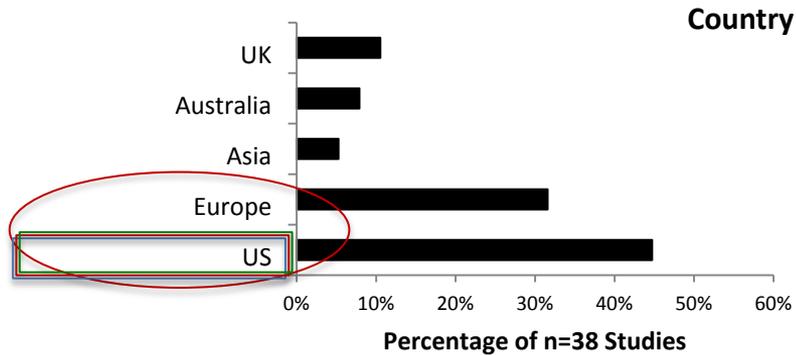
Results: Thirty eight studies were included in the review. Almost all (92 %) provided details on *participation*; however, only 18 % reported the coverage of their target population (*penetration*). *Program intensity or implementation*—as measured by frequency of contacts during first year and intervention duration—was identified in all of the reported studies, and 84 % of the studies also reported implementation fidelity; however, only 18 % of studies employed quality assurance measures to assess the extent to which the program was delivered as planned. Sixteen and 26 % of studies reported ‘highly’ or ‘moderately’ positive changes (*effectiveness*) respectively, based on weight loss. Six (16 %) studies reported ‘high’ diabetes risk reduction but ‘low’ to ‘moderate’ weight loss only.

Conclusion: Our findings identify that program intensity plays a major role in weight loss outcomes. However, programs that have high uptake—both in terms of good coverage of invitees and their willingness to accept the invitation—can still have considerable impact in lowering diabetes risk in a population, even with a low intensity intervention that only leads to low or moderate weight loss. From a public health perspective, this is an important finding, especially for resource constrained settings. More use of the PIPE framework components will facilitate increased uptake of T2DM prevention programs around the world.

Keywords: Implementation, Translational research, Diabetes prevention, Penetration, Implementation, Participation, Effectiveness (PIPE) impact metric, Systematic review, Resource allocation

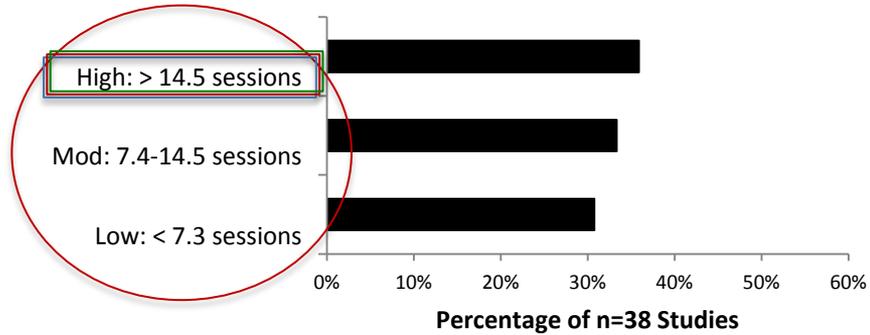
- N=38 “real-world” DPP trials

Diversity of DPPs in the Real World

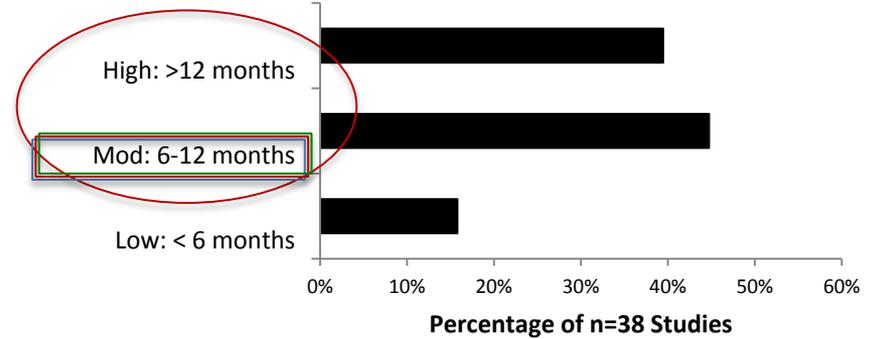


Diversity of DPPs in the Real World

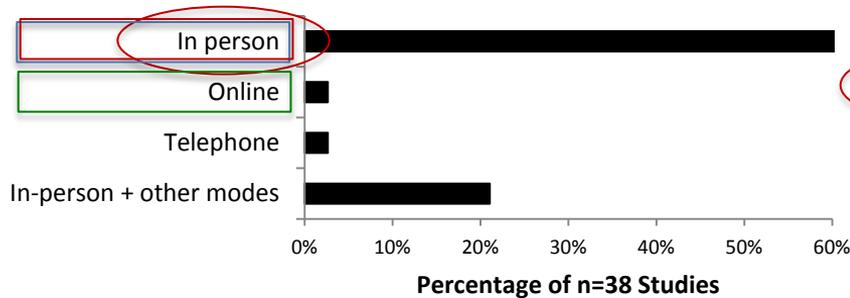
Number of Sessions



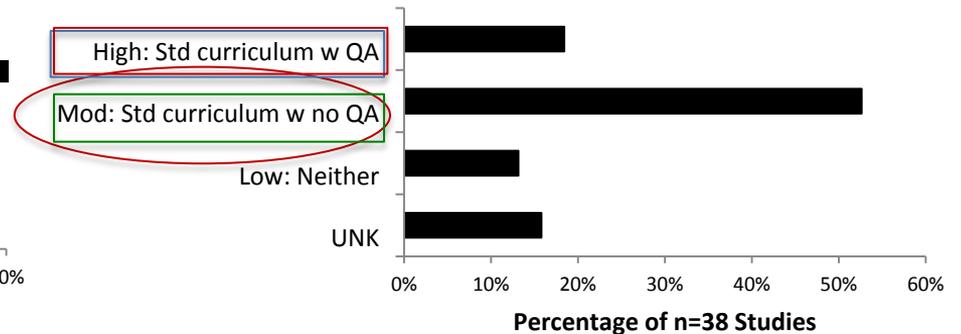
Length of Program



Delivery Mode



Use of Standard Curriculum



Weight & HbA1c Outcomes

Intention-to-treat (ITT) Analyses, Adjusted for age, gender, race/ethnicity, and site

Outcomes	MOVE!	VA-DPP	Difference p-value
Mean Change in Weight (kg; 95% CI)	N=113	N=273	
Kg weight loss at 6 months	-1.9** (-3.3, -0.6)	-4.1** (-5.2, -2.9)	<0.001

** $p \leq .004$ for change from baseline

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Kg weight loss at 12 months	-2.0 (-4.0, 0.2)	-3.4** (-5.2, -1.6)	0.16

** $p \leq .004$ for change from baseline

Weight & HbA1c Outcomes

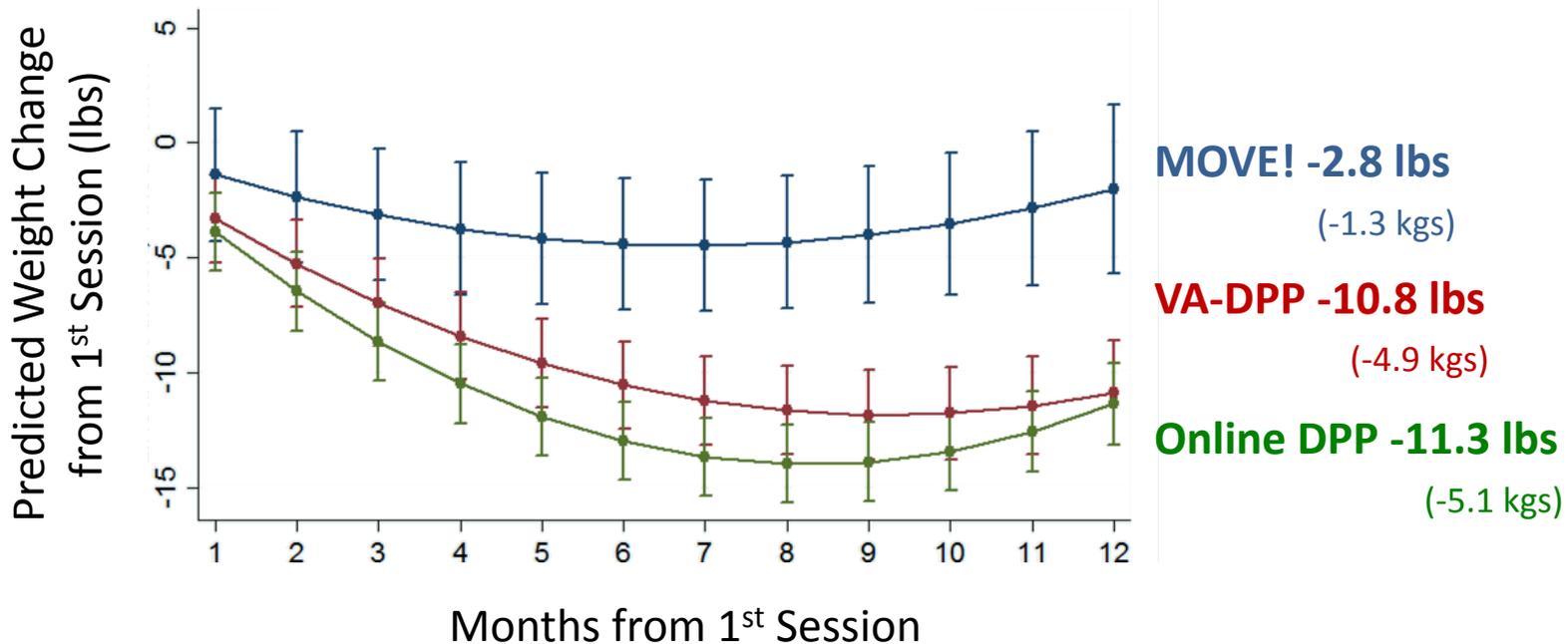
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Mean Change in HbA1c (%; 95% CI)	N = 100	N = 210	
HbA1c % change at 12 months	0.0 (-0.2, 0.2)	0.1 (-0.1, 0.2)	0.41

** $p \leq .004$ for change from baseline

Comparison of 3 Programs

Includes ONLY participants who completed 1+ sessions. Adjusted for gender, time



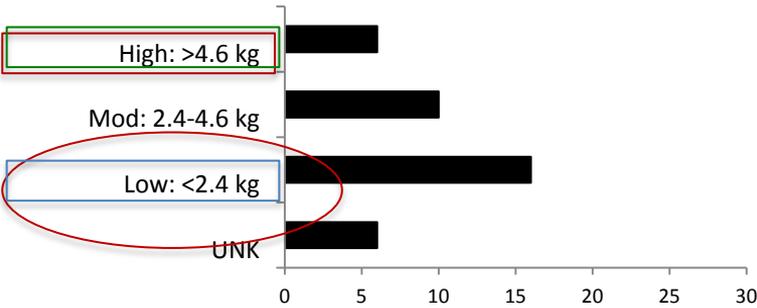
Reach

	MOVE!	VA DPP	Online DPP
Eligible (N)	387*		269
Enrolled (%)	100%		75%
Completed 1+ Sessions (%)	58%	73%	90%

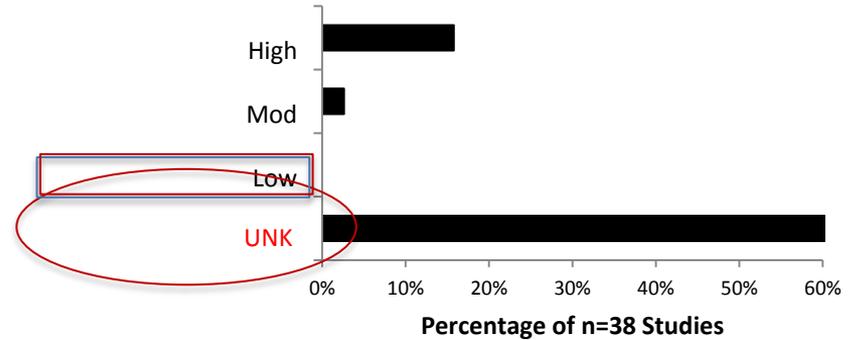
* Sample size goal was N=720

Systematic Review of Real-world DPP: Outcomes

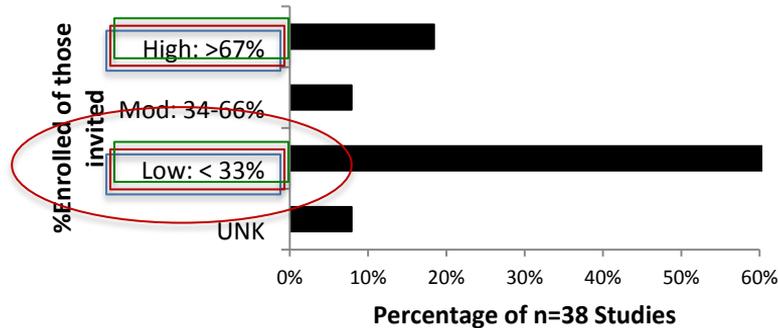
Weight Loss



Risk Reduction



Participation



Types of Evidence

- Focus on internal validity
 - WHAT works?
 - Establish causal pathway

SYSTEMATIC REVIEW

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Background: The evidence base for the prevention of type 2 diabetes mellitus (T2DM) has progressed rapidly from efficacy trials to real-world translational studies and practical implementation trials over the last 15 years. However, evidence for the effective implementation and translation of diabetes programs and their population impact needs to be established in ways that are different from measuring program effectiveness. We report the findings of a systematic review that focuses on identifying the critical success factors for implementing diabetes prevention programs in real-world settings.

Methods: A systematic review of programs aimed at diabetes prevention was undertaken in order to evaluate their outcomes using the penetration, implementation, participation, and effectiveness (PIPE) impact metric. A search for relevant articles was carried out using PubMed (March 2015) and Web of Science, MEDLINE, CENTRAL, and EMBASE. A quality coding system was developed and included studies were rated independently by three researchers.

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Conclusion: Our findings identify that program intensity plays a major role in weight loss outcomes. However, programs that have high uptake—both in terms of good coverage of invitees and their willingness to accept the invitation—can still have considerable impact in lowering diabetes risk in a population, even with a low intensity intervention that only leads to low or moderate weight loss. From a public health perspective, this is an important finding, especially for resource constrained settings. More use of the PIPE framework components will facilitate increased uptake of T2DM prevention programs around the world.

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What have we learned in 15 years?

- Higher intensity programs lead to better outcomes
- But low-intensity programs can have high impact if uptake is high

Reach

X

Effectiveness

=

IMPACT

Impact Assessment

- VA DPP
 - Higher intensity outreach
 - Already referred patients
 - High/Moderate Reach X High Effectiveness = Moderate/High Impact
 - What about patients NOT referred to MOVE!?
 - Lost opportunity? ...indicated by relatively high prevalence of diabetes
- Online DPP
 - Low intensity outreach
 - Hard to reach population not engaged in weight management
 - High/Low Reach X High Effectiveness = Moderate/High Impact
 - 1182 letters sent → 43% interested → 54% eligible

Translating the Diabetes Prevention Program Lifestyle Intervention for Weight Loss Into Primary Care

A Randomized Trial

Jun Ma, MD, PhD; Veronica Yank, MD; Lan Xiao, PhD; Philip W. Lavori, PhD; Sandra R. Wilson, PhD; Lisa G. Rosas, PhD; Randall S. Stafford, MD, PhD

Background: The Diabetes Prevention Program (DPP) lifestyle intervention reduced the incidence of type 2 diabetes mellitus (DM) among high-risk adults by 58%, with weight loss as the dominant predictor. However, it has not been adequately translated into primary care.

Methods: We evaluated 2 adapted DPP lifestyle interventions among overweight or obese adults who were recruited from 1 primary care clinic and had pre-DM and/or metabolic syndrome. Participants were randomized to (1) a coach-led group intervention (n=79), (2) a self-directed DVD intervention (n=81), or (3) usual care (n=81). During a 3-month intensive intervention phase, the DPP-based behavioral weight-loss curriculum was delivered by lifestyle coach-led small groups or home-based DVD. During the maintenance phase, participants in both interventions received lifestyle change coaching and support remotely through secure email

Results: At baseline, participants had a mean (SD) age of 52.9 (10.6) years and a mean BMI of 32.0 (5.4); 47% were female; 78%, non-Hispanic white; and 17%, Asian/Pacific Islander. At month 15, the mean \pm SE change in BMI from baseline was -2.2 ± 0.3 in the coach-led group vs -0.9 ± 0.3 in the usual care group ($P < .001$) and -1.6 ± 0.3 in the self-directed group vs usual care ($P = .02$). The percentages of participants who achieved the 7% DPP-based weight-loss goal were 37.0% ($P = .003$) and 35.9% ($P = .004$) in the coach-led and self-directed groups, respectively, vs 14.4% in the usual care group. Both interventions also achieved greater net improvements in waist circumference and fasting plasma glucose level.

Conclusion: Proven effective in a primary care setting, the 2 DPP-based lifestyle interventions are readily scalable and exportable with potential for substantial clinical and public health impact.

This primary care–based **translational** intervention trial ...led to clinically significant reductions in body weight ...and fasting plasma glucose level compared with usual care over a 15-month period.

Author Affiliations: Department of Health Services Research, Palo Alto Medical Foundation Research Institute, Palo Alto, California (Drs Ma, Yank, Xiao, and Wilson); and Departments of Medicine (Drs Ma, Yank, Wilson, Rosas, and Stafford) and Health Research and Policy (Dr Lavori), Stanford University School of Medicine, Stanford, California.

Cardiometabolic risk factors are a critical target group for intervention.^{2,3} Lifestyle modification focused on modest (5%-10%) weight loss and moderate-intensity physical activity can significantly reduce the incidence of type 2 diabetes mellitus (DM) (as much as 58% as shown in the Diabetes Prevention Program [DPP]) and cardiometabolic risk factors in high-risk individuals,^{4,6} with benefits sustained for at least 10 years.⁷ Evidence-based guide-

See also pages
105 and 111

However, national surveys reveal a continuing failure to incorporate weight management into clinical practice.¹⁰ Implementation of efficacious lifestyle interventions in the real world will require adaptation to improve generalizability and sustainability while maintain-

Efficacy vs Effectiveness

To the Editor The recently published study by Ma et al¹ (Evaluation of Lifestyle Interventions to Treat Elevated Cardiometabolic Risk in Primary Care [E-LITE] trial) tested 2 versions of the Diabetes Prevention Program (DPP) in the primary care setting and showed that both coach-based and DVD-based versions were superior to usual care. The investigators described their study as a “primary care-based translational intervention trial” and that these interventions have now been “proven effective in a primary care setting.”^{1(p113)} We contend that the E-LITE study is an efficacy trial that has once again confirmed that the DPP works. That it works when DVD-delivered is promising because this is less intensive than a

...the trial offers little insight into adapting these interventions in a real-world primary care setting with real patients with metabolic syndrome.

sentative populations.² The E-LITE trial did not employ primary care staff to implement the interventions but instead used staff hired by the research team. Even the DVD-based intervention required staff to send reminders and field questions from participants. They also recruited a highly selective population by using 31 inclusion and exclusion criteria³ and randomizing only 15% of those screened by telephone. It remains unclear to what extent this sample represents typical patients with metabolic syndrome. The

Efficacy vs Effectiveness

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only real-world aspect of the study seems to be that the interventions were physically performed in the primary care clinic as opposed to a research laboratory. This lends very little insight into how to address the key challenges of conducting such interventions in the primary care setting, including identifying staff who can deliver the intervention, determining how staff time will be compensated, establishing whether primary care patients with medical and psychiatric comorbidities will participate and benefit, and determining how to feasibly incorporate the intervention into standard practice. Performing efficacy trials in clinical settings with study staff and

...trials are needed that use real-world settings, employ staff in those settings, impose few exclusion criteria, and are designed to be integrated and delivered within the context of routine care by staff who could realistically and routinely deliver it..

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Sherry L. Pagoto, PhD
Stephenie C. Lemon, PhD

Author Affiliations: Division of Preventive and Behavioral Medicine, Department of Medicine, University of Massachusetts Medical School, Worcester (Pagoto, Lemon).

Corresponding Author: Sherry L. Pagoto, PhD, Division of Preventive and Behavioral Medicine, Department of Medicine, University of Massachusetts Medical School, 55 Lake Ave N, Worcester, MA 01655 (sherry.pagoto@umassmed.edu).

Conflict of Interest Disclosures: None reported.

Types of Evidence

- Focus on internal validity
 - WHAT worked?
 - Establish causal pathway
- Focus on external validity
 - WHAT works WHERE and WHY/HOW?
 - Transferability, generalizability



Diabetes Prevention Program in VA

Damschroder et al. *Implementation Science* (2015) 10:68
DOI 10.1186/s13012-015-0250-0



STUDY PROTOCOL

Open Access

Implementation and evaluation of the VA DPP clinical demonstration: protocol for a multi-site non-randomized hybrid effectiveness-implementation type III trial

Damschroder, Laura J., et al. "Implementation and evaluation of the VA DPP clinical demonstration: protocol for a multi-site non-randomized hybrid effectiveness-implementation type III trial." *Implementation Science* 10.1 (2015): 1-13.

Primary Aim: facilitate and evaluate implementation of the VA DPP at three study sites.

- Unit of analysis: **site**

Secondary Aim: Assess weight and hemoglobin A1c outcomes

- Unit of analysis: patient

RE-AIM Evaluation Framework

Reach

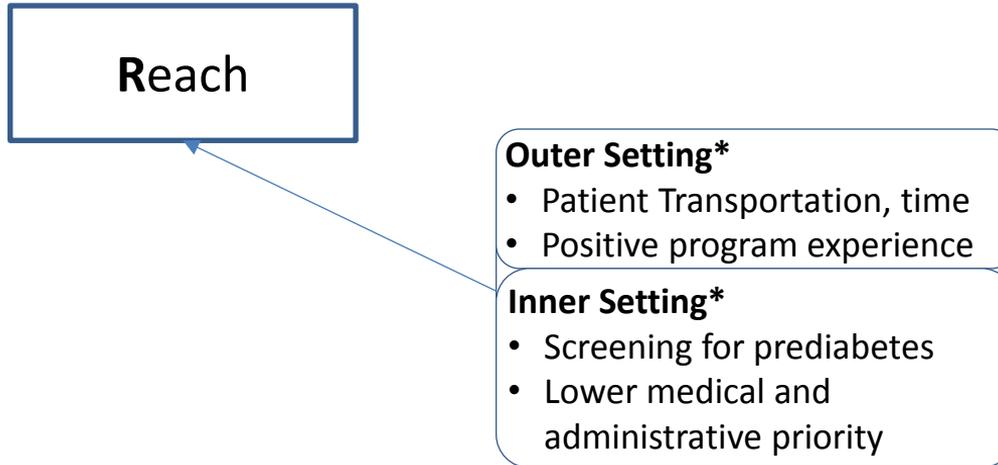
Effectiveness

www.re-aim.org

Glasgow RE, Vogt TM, Boles SM: **Evaluating the public health impact of health promotion interventions: the RE-AIM framework.** *Am J Public Health* 1999, 89:1322-1327.

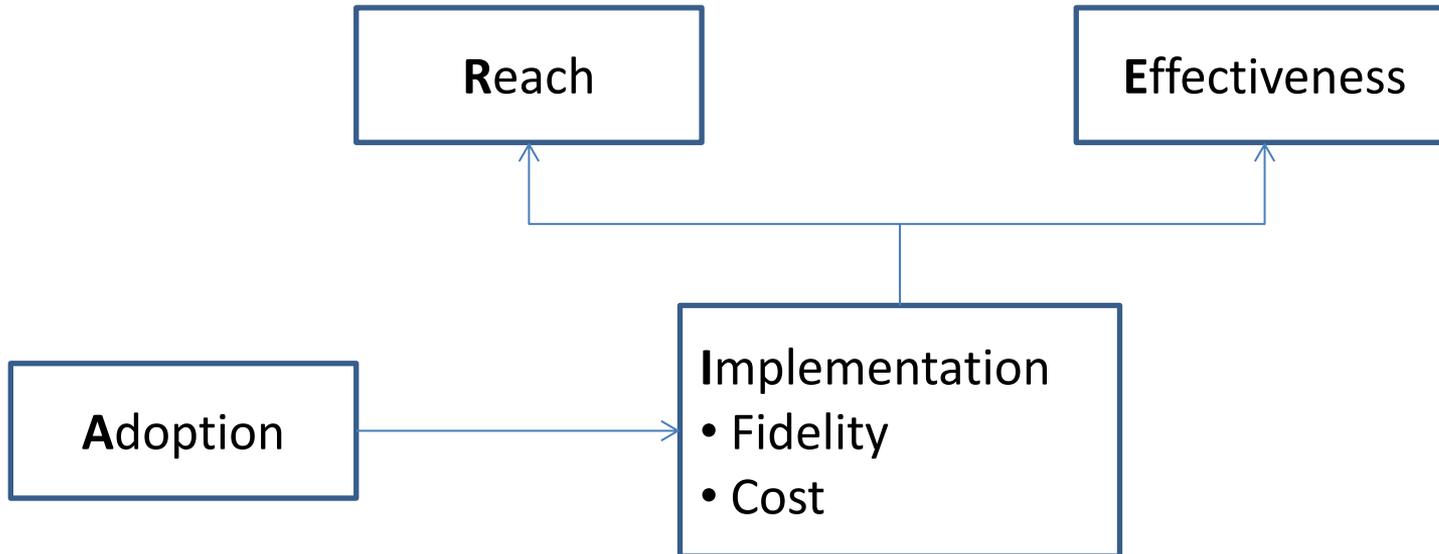
Reach

- ✓ **1. WHO** are you assessing and screening?
 - Risk of screening pool
- ✓ **2. WHEN** are you assessing and screening?
 - Context of clinical flow
- ✓ **3. WHAT** are you doing for outreach?
 - Patient education and awareness
- ✓ **4. WHERE** is your link to primary care?
 - Coordination with primary care
 - Patient management and follow-up
- ✓ **5. HOW** is laboratory screening conducted?
 - A1c, FBG, OGTT
 - POC vs. laboratory testing

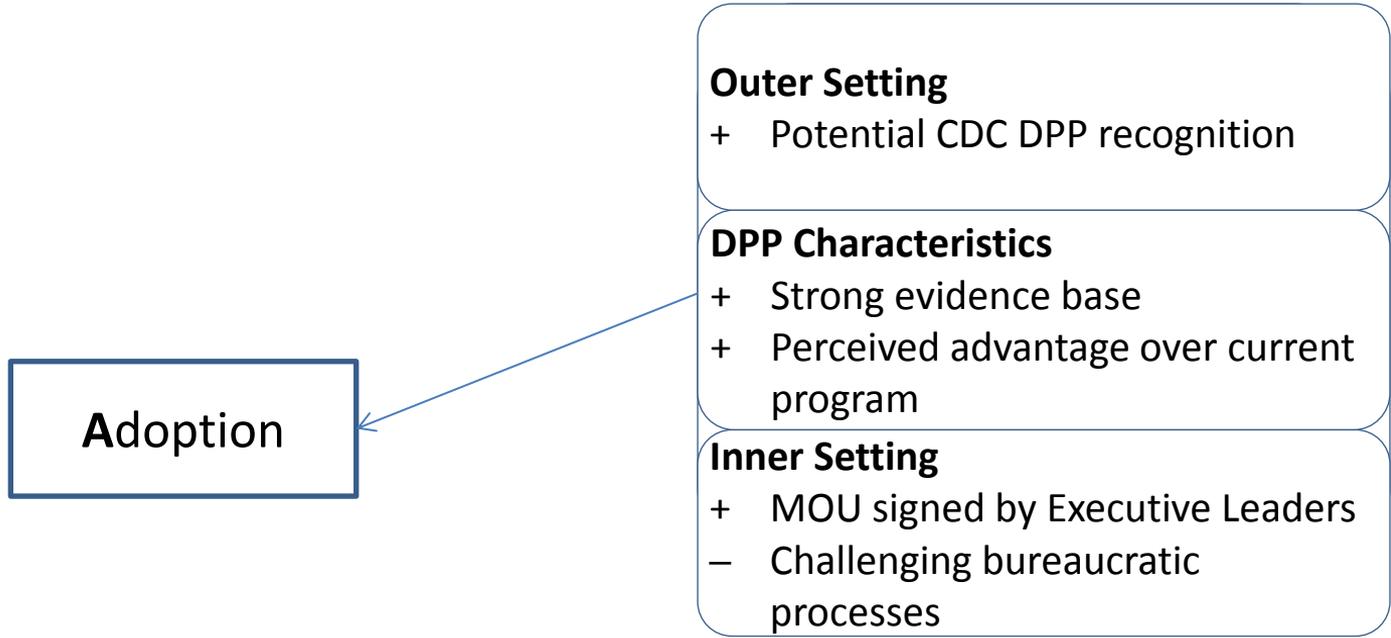


*Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science*, 4(1), 1.

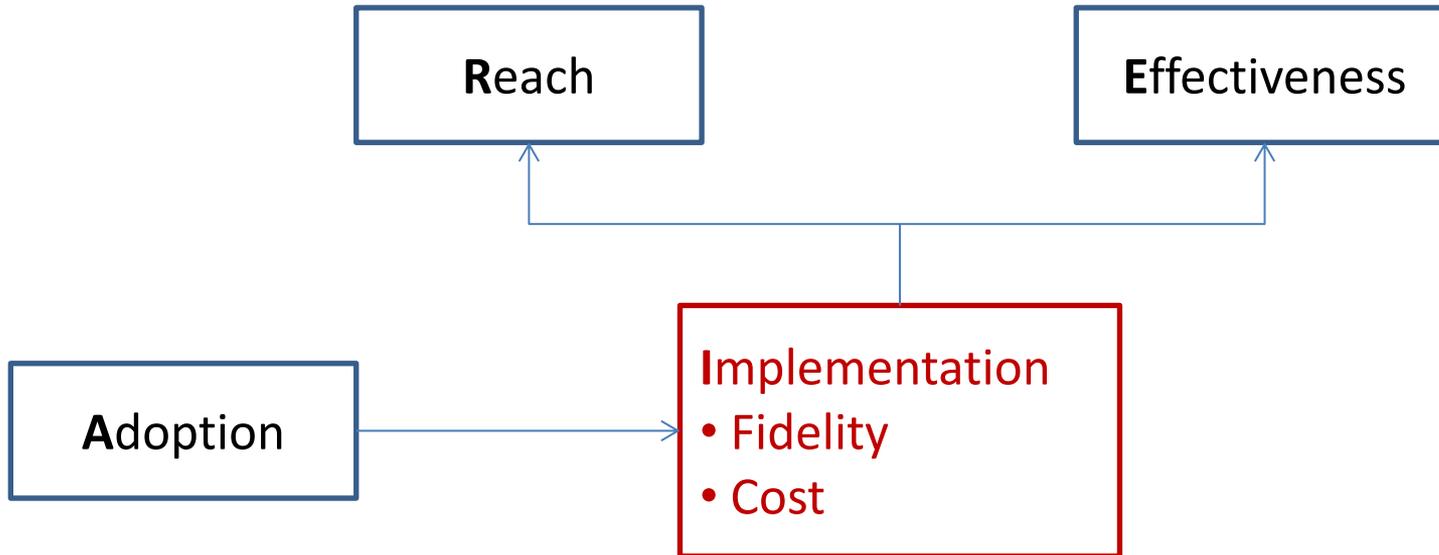
RE-AIM Evaluation Framework



RE-AIM



RE-AIM Evaluation Framework



www.re-aim.org

Glasgow RE, Vogt TM, Boles SM: Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999, 89:1322-1327.

Fidelity of Delivery*

	Item Rated	VA DPP	MOVE!	p-value
Group leader style and organization	• Group leader engaging and respectful	6.79	6.65	.29
	• Group leader prepared and organized	6.85	6.65	.11
Group member communication and participation	• Positive relationships among members	6.16	5.35	.02
	• Members communicated easily with each other	6.10	5.35	.04
Goal review and problem solving	• Group leader elicited discussion of success and challenges	6.38	4.62	<0.01
	• Group leader prompted review of goal progress	6.41	4.76	<0.01
Group identity	• Diabetes prevention discussed as a goal	4.59	1.97	<0.01
	• Group identity of prediabetes acknowledged	5.21	1.47	<0.01

* Based on ratings by team member of sample of sessions

1=strongly disagree - 7=strongly agree

Fidelity of Delivery → Satisfaction

Fidelity

- DPP = MOVE!
 - Group leader style and organization
- DPP > MOVE!
 - Group member communication and participation
 - Goal review and problem solving
 - Group identity

Participant satisfaction

- DPP = MOVE!
 - Coach Characteristics
 - Important questions
 - Treated with respect
- DPP > MOVE!
 - Coach Characteristics
 - Confidence and trust
 - Useful suggestions
 - Meaningful feedback
 - Stay with their assigned group
 - Group cohesion

Cost to Deliver in 1st Year

Per Person, 16 sessions

DPP*	VA DPP*	YMCA Model*	Online DPP	CMS Cap
\$1399 ¹	\$192-736 ²	\$275-325 ³	\$420 ⁴	\$450 ⁵

* Key cost driver: manage group size for greatest cost-benefit
– Not to big, not too small

1. Herman WH, Hoerger TJ, Brandle M, Hicks K, Sorensen S, Zhang P, Hamman RF, Ackermann RT, Engelgau MM, Ratner RE: The cost-effectiveness of lifestyle modification or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance. *Ann Intern Med* 2005, 142:323-332
2. Damschroder LJ, CM Reardon, M AuYoung, T Moin, SK Datta, JB Sparks, ML Maciejewski, NI Steinle, JE Weinreb, M Hughes, LF Pinault, XM Xiang, C Billington, CR Richardson. Evaluation of the VA Diabetes Prevention Program (VA-DPP) Clinical Demonstration in the Veterans Health Administration (VHA): Implementation Findings. *Under development*
3. Ackermann RT, Marrero DG: Adapting the Diabetes Prevention Program lifestyle intervention for delivery in the community: the YMCA model. *Diabetes Educ* 2007, 33:69, 74-65, 77-68
4. Cost was discounted for VA project.
5. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf>

DPP Characteristics

- Strong evidence base
- Perceived advantage over current program
- Competitor to MOVE!
- Packaged DPP materials; coach/patient manuals

Inner Setting

- Hiring challenges
- Space limitations
- High quality training program
- Centralized support
- Compatibility
- Lack of help from leaders

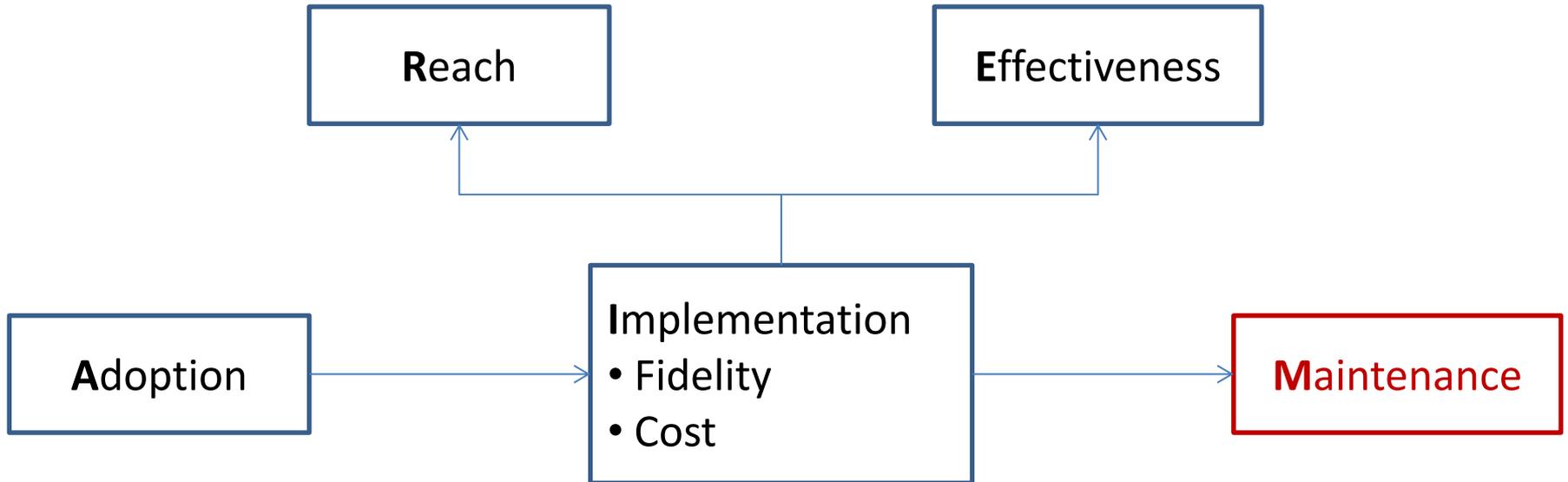
Process

- Highly functioning DPP teams
- Regular team meetings with Coordinating Center

Implementation

- Fidelity

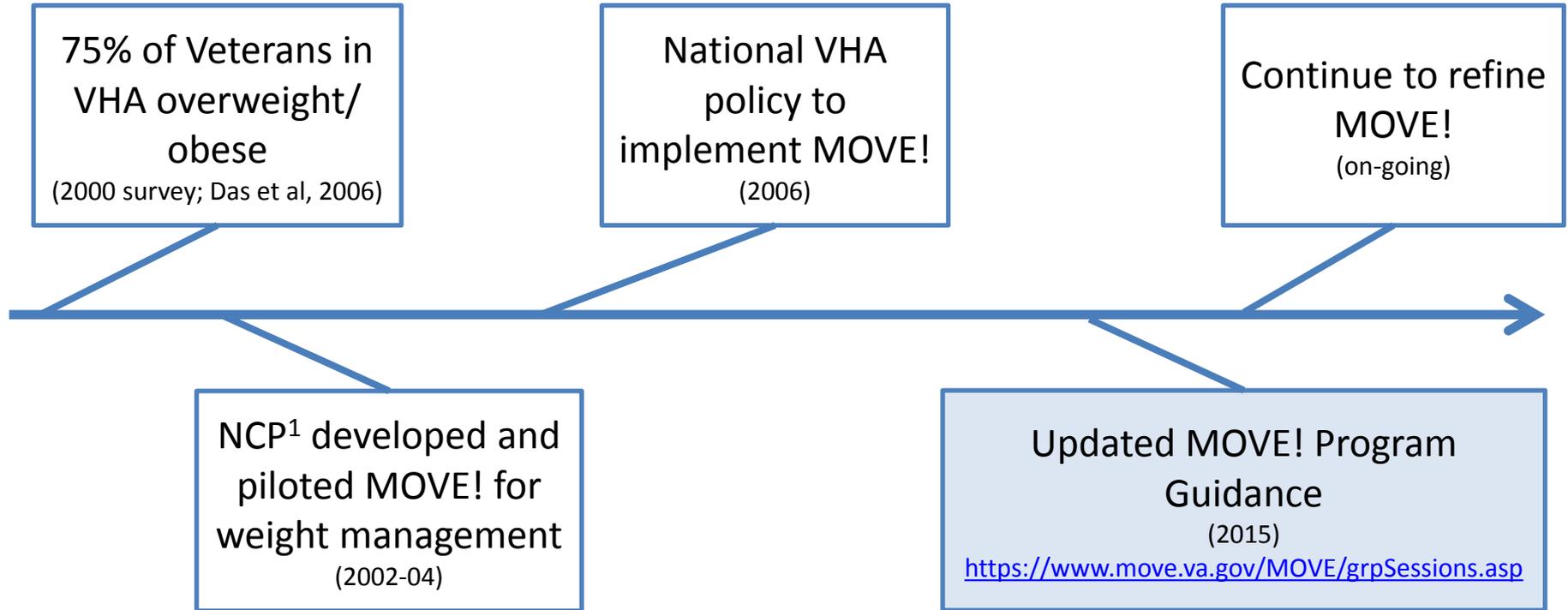
RE-AIM Evaluation Framework



Maintenance

- Setting-level
 - 1 site continued DPP as a separate program
 - National-level decision to more closely align current lifestyle change program (*MOVE!*) with DPP
 - No screening for pre-diabetes

Weight Management in the VA



¹National Center for Health Promotion and Disease Prevention (NCP)

Conclusions

- Organizational Level Considerations
 - Strategy and processes to Reach targeted population
 - Outreach
 - Screening process
 - Costs
 - Higher Participation → lower cost
 - Changing landscape with potential future CMS reimbursement
 - Anticipating barriers
 - Tailor multi-level implementation strategies
 - Centralized support

Conclusions

- Program Delivery
 - Higher quality of delivery → higher participant satisfaction → higher engagement
 - Important to monitor fidelity of delivery

VA DPP Publications (so far)

- Moin, T, LJ Damschroder, B Youles, F Makki, C Billington, W Yancy, ML Maciejewski, LS Kinsinger, JE Weinreb, N Steinle, C Richardson. Implementation of a Prediabetes Identification Algorithm for Overweight/Obese Veterans. *JRRD. In Press*
- Moin T, LJ Damschroder, M AuYoung, ML Maciejewski, SK Datta, JE Weinreb, NI Steinle, C Billington, M Hughes, F Makki, RG Holleman, HM Kim, LS Kinsinger, JA Burns, CR Richardson. Translating the Diabetes Prevention Program (DPP) in the Real World: Results from a Clinical Demonstration Trial in the Veterans Health Administration (VHA). *Am J Prev Med. In Press*
- Damschroder LJ, Reardon CM, AuYoung M, Moin T, Datta S, Sparks J, Maciejewski M, Steinle N, Weinreb J, Hughes M, Pinault L, Xiang X, Billington C, Richardson C. Evaluation of the VA Diabetes Prevention Program Clinical Demonstration (VA-DPP) in Veterans Health Administration (VHA) Medical Centers: Implementation Findings. *In process.*

Poll: (single answer)

What is your perception of DPP?

- I don't know enough to know
- DPP has mixed or low effectiveness
- DPP might benefit some patients
- DPP should be more widely available to more patients

Questions?



Contact Information:

Laura Damschroder: Laura.Damschroder@va.gov

Tannaz Moin: Tmoin@mednet.ucla.edu

Caroline Richardson: caroli@med.umich.edu