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.
# 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 Lindenauser
- Amanda Ellis

# Durham VA MC
- Santanu Datta
- Will Yancy
- Matthew Maciejewski
- Hollis Weidenbacher

# 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

# 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

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## NCP Partners
- Linda Kinsinger
- Michael Goldstein
- Ken Jones
- Susi Lewis
- Sue Raffa
- Greg Moore

## DPSC
- M. Kaye Kramer
- Andrea Kriska
- Linda Semler
- Beth Venditti
- Linda Kinsinger
- Michael Goldstein
- Ken Jones
- Susi Lewis
- Sue Raffa
- Greg Moore

# It Takes a Village
- NCP Partners
- DPSC
- Omada Health
- VA Ann Arbor CCMR
- Durham VA MC
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- Minneapolis VA HCS
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- It Takes a Village
- NCP Partners
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- Milwaukee VA MC
- Minneapolis VA HCS
- VA Baltimore MC
- VA Greater Los Angeles HCS
- It Takes a Village
Funding, Partners, Collaborators

**Partner & Funding:** National Center for Health Promotion and Disease Prevention (NCP)/ MOVE! Program

**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

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

• 9 out of 10 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

Leadership decision to implement DPP in VA

Operational partner request to help evaluate DPP implementation

Operational partner and research partner negotiate study design
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 ≥ 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

Normal glycemic status, n=435 (24%)

Diabetes, n=780 (42%)

Prediabetes, n=387 (21%)

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
Recruitment letters sent to Veterans with prediabetes that were not in MOVE! or VA DPP (N=1182)

- Interested (n=514)
- Not interested (n=338)
- No response (n=330)

Eligible (n=269)

- Not eligible (n=245)

Enrolled in Prevent (n=202)

Withdraw or lost to follow up (n=67)
<table>
<thead>
<tr>
<th>Comparative effectiveness trial</th>
<th>Pilot &amp; Parallel Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-person Lifestyle Interventions</td>
<td>Online Lifestyle Intervention</td>
</tr>
</tbody>
</table>

| National Diabetes Prevention Program | MOVE! Weight Management Program for Veterans | Omada |
Online & VA DPP Study Sites

- VA Durham MC
- VA Milwaukee MC (Online only with all-female cohort)
- VA Milwaukee HCS
- VA Minneapolis HCS
- VA Ann Arbor HCS (coordinating site)
- VA Greater Los Angeles HCS
- VA Baltimore MC
- VA Ann Arbor HCS (cost analysis)
A systematic review of real-world diabetes prevention programs: learnings from the last 15 years

Zahra Aziz, Pilviikki Abetz, John Oldroyd, Nicolaas P. Pronk and Brian Oldenburg

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

**Country**
- US: 40%
- Europe: 30%
- Asia: 20%
- Australia: 10%
- UK: 10%

**Setting**
- Primary Care: 60%
- Community-based: 30%
- Other clinical settings: 10%
- Online: 5%
- UNK: 5%

**Target Population**
- Aults at risk for T2DM: 60%
- Adults with prediabetes: 30%
- Adults with metabolic syndrome: 20%
- Overweight/obese adults: 10%
- Adults with IGT: 5%

**Individual v Group**
- Combination: 60%
- Group: 30%
- Individual: 10%
- Unclear: 5%
Diversity of DPPs in the Real World

Number of Sessions

- **High**: > 14.5 sessions
- **Mod**: 7.4-14.5 sessions
- **Low**: < 7.3 sessions

Percentage of n=38 Studies

Length of Program

- **High**: >12 months
- **Mod**: 6-12 months
- **Low**: < 6 months

Percentage of n=38 Studies

Delivery Mode

- **In person**
- **Online**
- **Telephone**
- **In-person + other modes**

Percentage of n=38 Studies

Use of Standard Curriculum

- **High**: Std curriculum w QA
- **Mod**: Std curriculum w no QA
- **Low**: Neither
- **UNK**

Percentage of n=38 Studies
## Weight & HbA1c Outcomes

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

<table>
<thead>
<tr>
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<th>MOVE!</th>
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<tbody>
<tr>
<td>Mean Change in Weight (kg; 95% CI)</td>
<td>N=113</td>
<td>N=273</td>
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<tr>
<td>Kg weight loss at 6 months</td>
<td>-1.9**</td>
<td>-4.1**</td>
<td>&lt;0.001</td>
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<tr>
<td></td>
<td>(-3.3, -0.6)</td>
<td>(-5.2, -2.9)</td>
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** p<.004 for change from baseline
# Weight & HbA1c Outcomes

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<td>Kg weight loss at 12 months</td>
<td>-2.0</td>
<td>-3.4**</td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>(-4.0, 0.2)</td>
<td>(-5.2, -1.6)</td>
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## Weight & HbA1c Outcomes

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<td></td>
<td>(-4.0, 0.2)</td>
<td>(-5.2, -1.6)</td>
<td></td>
</tr>
<tr>
<td>Mean Change in HbA1c (%; 95% CI)</td>
<td>N=100</td>
<td>N=210</td>
<td></td>
</tr>
<tr>
<td>HbA1c % change at 12 months</td>
<td>0.0</td>
<td>0.1</td>
<td>0.41</td>
</tr>
<tr>
<td></td>
<td>(-0.2, 0.2)</td>
<td>(-0.1, 0.2)</td>
<td></td>
</tr>
</tbody>
</table>

** p<.004 for change from baseline
Comparison of 3 Programs

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

- MOVE! -2.8 lbs
  (-1.3 kgs)
- VA-DPP -10.8 lbs
  (-4.9 kgs)
- Online DPP -11.3 lbs
  (-5.1 kgs)
## Reach

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<th>VA DPP</th>
<th>Online DPP</th>
</tr>
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<tbody>
<tr>
<td>Eligible (N)</td>
<td>387*</td>
<td>269</td>
<td></td>
</tr>
<tr>
<td>Enrolled (%)</td>
<td>100%</td>
<td></td>
<td>75%</td>
</tr>
<tr>
<td>Completed 1+ Sessions (%)</td>
<td>58%</td>
<td>73%</td>
<td>90%</td>
</tr>
</tbody>
</table>

* Sample size goal was N=720
Systematic Review of Real-world DPP: Outcomes

**Weight Loss**
- Low: < 2.4 kg
- Mod: 2.4-4.6 kg
- High: > 4.6 kg

**Risk Reduction**
- Low: < 33%
- Mod: 34-66%
- High: > 67%

**Participation**
- Low: < 33%
- Mod: 34-66%
- High: > 67%
Types of Evidence

• Focus on internal validity
  – WHAT works?
  – Establish causal pathway
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 $\times$ 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
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.
...the trial offers little insight into adapting these interventions in a real-world primary care setting with real patients with metabolic syndrome.
...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..
Types of Evidence

• Focus on internal validity
  – WHAT worked?
  – Establish causal pathway

• Focus on external validity
  – WHAT works WHERE and WHY/HOW?
  – Transferability, generalizability
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
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
Reach

**Outer Setting***
- Patient Transportation, time
- Positive program experience

**Inner Setting***
- Screening for prediabetes
- Lower medical and administrative priority

---

RE-AIM Evaluation Framework

- **Reach**
  - **Effectiveness**
  - **Implementation**
    - Fidelity
    - Cost

**Adoption**

---

www.re-aim.org

RE-AIM

Adoption

Outer Setting
+ Potential CDC DPP recognition

DPP Characteristics
+ Strong evidence base
+ Perceived advantage over current program

Inner Setting
+ MOU signed by Executive Leaders
  – Challenging bureaucratic processes
RE-AIM Evaluation Framework

Adoption

Reach

Effectiveness

Implementation
- Fidelity
- Cost

www.re-aim.org
## Fidelity of Delivery*

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

* 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 1\textsuperscript{st} Year
Per Person, 16 sessions

<table>
<thead>
<tr>
<th>DPP*</th>
<th>VA DPP*</th>
<th>YMCA Model*</th>
<th>Online DPP</th>
<th>CMS Cap</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1399 \textsuperscript{1}</td>
<td>$192-736 \textsuperscript{2}</td>
<td>$275-325 \textsuperscript{3}</td>
<td>$420 \textsuperscript{4}</td>
<td>$450 \textsuperscript{5}</td>
</tr>
</tbody>
</table>

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

2. Damschroder LJ, CM Reardon, M AuYoung, T Moin, SK Datta, JB Sparks, ML Maciejewski, NJ 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
4. Cost was discounted for VA project.
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

- **Reaching (Reach)**
  - Implementation
    - Fidelity
    - Cost

- **Effectiveness**
- **Adoption**
- **Maintenance**

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

75% of Veterans in VHA overweight/obese (2000 survey; Das et al, 2006)

National VHA policy to implement MOVE! (2006)

Continue to refine MOVE! (on-going)

NCP\(^1\) developed and piloted MOVE! for weight management (2002-04)

Updated MOVE! Program Guidance (2015)
https://www.move.va.gov/MOVE/grpSessions.asp

\(^1\)National 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)


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