

**AWARD NUMBER: FMBB100383695  
DM150083**

**TITLE: Diabetes ROADMAP: An Intervention to Address Health Disparities Through Personalized Diagnosis Communication**

**PRINCIPAL INVESTIGATOR: Christy JW Ledford, PhD, FACH**

**CONTRACTING ORGANIZATION: Uniformed Services University of the Health Sciences (USUHS)**

**REPORT DATE: June 2021**

**TYPE OF REPORT: Final**

**PREPARED FOR: U.S. Army Medical Research and Development Command  
Fort Detrick, Maryland 21702-5012**

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# REPORT DOCUMENTATION PAGE

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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT:</b> Background: Diabetes is a major cause of cardiovascular morbidity and mortality. Ethnic minorities experience a disproportionate burden of diabetes. Studies have shown that culturally-tailored diabetes interventions can improve glycemic control among ethnic minorities who are already managing diabetes. However, research has overlooked the critical moment of diagnosis and how patients respond to the news of pre-diabetes or diabetes. Objective: This study will design and evaluate a culturally-centered intervention to motivate and activate patients newly diagnosed with pre-diabetes and Type 2 diabetes to adopt self-management behaviors. The intervention proposed here, Diabetes ROADMAP (Responding to the Opportunity to Adapt the Diagnosis to Motivate and Activate Patients), will use three strategies: delivering education and training (patient education in self-management and provider training in cultural competency), providing reminders and feedback (patient reminders), and cultural targeting (culturally targeted education materials). Our overall goal is to translate health communication theory into clinical practice by testing a patient-centered intervention in a clinical setting to produce sustained behavior change.					
<b>15. SUBJECT TERMS</b>  NONE LISTED					
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## 1. INTRODUCTION:

This study designed and evaluated a culturally-centered intervention to motivate and activate patients newly diagnosed with prediabetes and Type 2 diabetes to adopt self-management behaviors. The intervention, Diabetes ROADMAP (Responding to the Opportunity to Adapt the Diagnosis to Motivate and Activate Patients), targeted primary care clinicians who deliver the prediabetes and type 2 diabetes diagnosis.

## 2. KEYWORDS:

Prediabetes, type 2 diabetes, cultural competence, communication, patient activation, diabetes self-management

## 3. ACCOMPLISHMENTS:

### What were the major goals of the project?

**Aim 1.** Explore patient mental models of the pre-diabetes and type 2 diabetes diagnoses and compare those mental models across cultural differences.

**Aim 2.** Implement and evaluate a patient-centered diabetes diagnosis intervention that will teach clinicians specific cognitive and affective skills related to discussing a pre-diabetes/type 2 diabetes diagnosis within a cultural framework.

**Aim 3.** Applying a cluster-randomized controlled design, assess the impact of the intervention on 1) patients' perception of diabetes diagnosis communication and 2) patients' self-management behaviors.

**Aim 4.** Translate, implement, and test intervention in the community hospital setting.

### What was accomplished under these goals?

**Aim 1.** In this formative phase, through surveys with more than 1000 patients and interviews with more than 30 patients, we discovered important differences in how patients of different ethnicities, who live in different regions, and who are in different stages of impaired glucose tolerance perceive a diabetes diagnosis. From this data, we have published 8 scientific papers. Two additional papers are currently under review. This data also directly influenced intervention design and development.

**Aims 2, 4.** From September 2017 to March 2019, the Diabetes ROADMAP intervention was in two distinct settings: a community hospital family medicine residency and a group of primary care clinics situated within an academic medical center. Phases. Across three cohorts, 53 clinicians completed the curriculum. The curriculum was published in MedEd Portal and was recognized with an Editor's Choice special distinction.

**Aim 3.** 56 patients enrolled in the trial. Patients who received a T2DM diagnosis from a trained clinician reported higher reassurance from the diagnosing clinician. Patients with T2DM also reported less poor eating and a higher degree of diet decision making, but these differences were not statistically significant. Although not statistically significant, at 6-month follow-up, the T2DM intervention group had a mean A1c in the prediabetes range (6.21), while the control group had a mean A1c still in the diabetes range (6.85).

**What opportunities for training and professional development has the project provided?**

Aims 2 and 4 were directly delivering training. From September 2017 to March 2019, the Diabetes ROADMAP intervention was in two distinct settings: a community hospital family medicine residency and a group of primary care clinics situated within an academic medical center. Phases. Across three cohorts, 53 clinicians completed the curriculum. The curriculum was published in MedEd Portal and was recognized with an Editor's Choice special distinction.

**How were the results disseminated to communities of interest?**

As specified under #6 products, dissemination was a key goal of this study. To date, we have 11 published peer-reviewed papers, with another three in various stages of review. We have presented formative and summative findings at 9 international conferences. We have also shared findings through the use of infographics with clinicians and patients through social media and in clinical spaces.

**What do you plan to do during the next reporting period to accomplish the goals?**

Nothing to report

**4. IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**

The development and evaluation of the Diabetes ROADMAP intervention contributes an evidence-based teaching curriculum to teach medical decision making, diagnosis communication, and clinical documentation in primary care practice. The curriculum was published in MedEd Portal and was recognized with an Editor's Choice special distinction.

**What was the impact on other disciplines?**

Nothing to report

**What was the impact on technology transfer?**

Nothing to report

**What was the impact on society beyond science and technology?**

Scientific findings from the formative phases of this study have increased our knowledge about the diverse perceptions of prediabetes and type 2 diabetes, establishing differences in geographic regions and by race/ethnicity. In addition to the Diabetes ROADMAP intervention developed here, these findings will inform future interventions to delay onset of type 2 diabetes.

## 5. CHANGES/PROBLEMS:

### Changes in approach and reasons for change

Nothing to report

### Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report

### Changes that had a significant impact on expenditures

Nothing to report

### Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

### Significant changes in use or care of human subjects

Two overall Humans subjects protocols are required.

Kimberly Odam, HRPO, also issued A19369 HRPO Memorandum No HRPO Review Required (Proposal No. DM150083); thus all protocols will be reviewed at USUHS level.

#### **Phase 1 Submitted to and Approved by:**

Submitted to USUHS IRB 15 April 2016,

--revised in response to comments 31 May 2016.

Submitted amendment to USUHS IRB to extend interview recruitment, 29 March 2017; approved 19 April 2017.

Submitted continuing review of full protocol to USUHS IRB, 30 May 2017.

--revised in response to comments 2 June 2017, approved with stipulations 13 July 2017

Submitted continuing review of full protocol to USUHS IRB, 30 April 2018.

-- approved 4 June 2018

Submitted continuing review of full protocol to USUHS IRB, 29 April 2019.

-- approved 19 June 2019

Submitted continuing review of full protocol to USUHS IRB, 1 April 2020.

-- approved May 28, 2020

**Status:** *Approved*

#### **Phase 2 Submitted to and Approved by:**

Submitted to USUHS IRB 28 July 2017

— DDEAMC recorded approved deferral under IAIR, 4 August 2017

<p>— approved 16 October 2017</p> <p>Continuing review approved by USUHS 28 September 2018</p> <p>Eglin addition to multisite approved March 2019</p> <p>Closed DDEAMC as a site protocol June 27, 2019</p> <p>Submitted amendment to USUHS IRB to change age range and dates of data pull for Eglin records, 15 July 2019</p> <p>-- approved 8 August 2019.</p> <p>Continuing review approved by USUHS 15 October 2019</p> <p>Continuing review submitted September 2020</p> <p>--approved 8 October 2020</p> <p><b>Status:</b> Approved</p>
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### Significant changes in use or care of vertebrate animals

Not applicable
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### Significant changes in use of biohazards and/or select agents

Not applicable
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## 6. PRODUCTS:

- **Publications, conference papers, and presentations**

<p><b>Peer reviewed publications</b></p> <ol style="list-style-type: none"> <li>1. Ledford, CJW, Cafferty, LC, Fulleborn, S, Carriere, R, Ledford, CC, Seehusen, AB, Rogers, T, Jackson, JT, Womack, J, Crawford, PF, Rider, HA, &amp; Seeshusen, DA. (manuscript in preparation). Patient outcomes of an intervention teaching clinicians how to deliver the diabetes or prediabetes diagnosis.</li> <li>2. Ledford, CJW, Fulleborn, ST, Jackson, JT, Rogers, T, Samar, H. (under review). Dissonance in the discourse of the duration of diabetes: A mixed methods study of patient perceptions and clinical practice.</li> <li>3. Ledford, CJW, Villareal, C, Curry, E, Cafferty, LA, Jackson, JT, Seehusen, DA. (under review). Patient decision making about self-disclosure of a type 2 diabetes mellitus diagnosis: A qualitative study.</li> <li>4. Ledford, C.J.W., Seehusen, D.A., &amp; Crawford, P.F. (2021). Toward a model of shared meaningful diagnosis. <i>Patient Education and Counseling</i>, 104 (1), 143-148. doi: 10.1016/j.pec.2020.07. <i>acknowledgement of federal support: yes</i></li> <li>5. Fisher, C.L., Ledford, C.J.W., Wollney, E., &amp; Crawford, P.F. (2020). Transitioning from active duty to military retirement: Challenges impacting diabetes self-management. <i>Health Education Journal</i>. doi:10.1177/0017896920978675 <i>acknowledgement of federal support: yes</i></li> <li>6. Fisher, C.L., Mullis, M.D., Lee, D., &amp; Ledford, C.J.W. (2020). Family communication central</li> </ol>
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- to mothers' type 2 diabetes self-management. *Families, Systems, & Health*, 38 (4), 396 -405. doi: 10.1037/fsh0000550 *acknowledgement of federal support: yes*
7. Fulleborn, S.T., Crawford, P.F., Jackson, J.T., & Ledford, C.J.W. (2020). How family physicians practice the principle of remission along the glycemic continuum. *Journal of Primary Care and Community Health*, 11. doi: 10.1177/2150132720977744 *acknowledgement of federal support: yes*
  8. Ledford, C.J.W., Seehusen, D.A., Cafferty, L.A., Rider, H.A., Rogers, T., Fulleborn, S., Clauson, E., Ledford, C.C., Trigg, S., Jackson, J.T., & Crawford, P.F. (2020). Diabetes ROADMAP: Teaching guideline use, communication, and documentation when delivering the diagnosis of diabetes. *MedEdPORTAL*, 16. doi: 10959. 10.15766/mep\_2374-8265.10959 (Editor's choice special distinction) *acknowledgement of federal support: yes*
  9. Ledford, C.J.W., Fisher, C.L., Cafferty, L.A., Jackson, J.T., Crawford, P.F., & Seehusen, D.A. (2020). How patients make sense of a diabetes diagnosis: An application of Weick's model of organizing. *Diabetes Research and Clinical Practice*. doi: 10.1016/j.diabres.2020.108117 *acknowledgement of federal support: yes*
  10. Ledford, C.J.W., Fisher, C.L., Cafferty, L.A., Jackson, J.T., Seehusen, D.A., & Crawford, P.F. (2020). Turning points as opportunities to partner with the patient: A qualitative study of patients living with type 2 diabetes or prediabetes. *Journal of the American Board of Family Medicine*, 33 (2), 211 – 219. doi: 10.3122/jabfm.2020.02.190136 *acknowledgement of federal support: yes*
  11. Seehusen, D.A., Fisher, C.L., Rider, H.A., Seehusen, A.B., Womack, J.J., Jackson, J.T., Crawford, P.F., & Ledford, C.J.W. (2019). Exploring patient perspectives of prediabetes and diabetes severity: A qualitative study. *Psychology & Health*, 34 (11), 1314 - 1327. doi: 10.1080/08870446.2019.1604955 *acknowledgement of federal support: yes*
  12. Ledford, C.J.W., Seehusen, D.A., & Crawford, P.F. (2019). The relationship between patient perceptions of diabetes and glycemic control: A study of patients living with prediabetes or type 2 diabetes. *Patient Education and Counseling*, 102 (11), 2097 - 2101. doi: 10.1016/j.pec.2019.05.023 *acknowledgement of federal support: yes*
  13. Ledford, C.J.W., Seehusen, D.A., & Crawford, P.F. (2019). Geographic and race/ethnicity differences in patient perceptions of diabetes. *Journal of Primary Care and Community Health*, 10, 1 - 5. doi: 10.1177/2150132719845819 *acknowledgement of federal support: yes*

#### **Books or other non-periodical, one-time publications.**

None

#### **Other publications, conference papers and presentations.**

##### **International podium presentations**

1. Ledford, C.J.W., & Seehusen, D.A. (2020, September). Patient decision-making about disclosing the diabetes diagnosis: A multi-method inquiry. Paper presented at the 2020 virtual International Conference on Communication in Healthcare.\*
2. Ledford, C.J.W., Seehusen, D.A., & Crawford, P.F. (2019, October). The model of shared meaningful diagnosis. Paper presented at the International Conference on Communication in Healthcare, San Diego, Calif. \*

3. Ledford, C.J.W., Seehusen, D.A., & Crawford, P.F. (2018, November). The relationship between personal models of diabetes and glycemic control: A study of patients diagnosed with prediabetes or type 2 diabetes. Paper presented at the North American Primary Care Research Group Annual Meeting, Chicago, Ill.\*
4. Ledford, C.J.W., Seehusen, D.A., & Crawford, P.F. (2018, June). Discovering regional differences in patient perceptions of diabetes within a practice-based research network. Paper presented at the North American Primary Care Research Group Practice-Based Research Networks Conference, Bethesda, Md.\*
5. Ledford, C.J.W., Seehusen, D.A., Crawford, P.F., & Fisher, C.L. (2019, April). *Exploring patient perspectives of disease severity: Lessons for talking to patients about prediabetes and diabetes*. Paper presented at the Society of Teachers of Family Medicine Annual Spring Conference, Toronto, Ontario, Canada.\*

#### **International poster presentations**

6. Ledford, C.J.W., Fulleborn, S.T., & Seehusen, D.A. (2020, September). The diagnosis and discourse of diabetes remission: A multi-method study. Poster presented at the virtual 2020 International Conference on Communication in Healthcare.\*
7. Cafferty, L.A. & Ledford, C.J.W. (2020, August). Adaptations in multi-site interventions: Navigating differences across clinical settings. Poster presented at the North American Primary Care Research Group Practice-Based Research Network Virtual Conference 2020.
8. Ledford, C.J.W., Fisher, C.L., Cafferty, L.A., Jackson, J.T., Seehusen, D.A., & Crawford, P.F. (2019, October). Turning points as opportunities to partner with the patient: A qualitative study of patients living with type 2 diabetes or prediabetes. Poster presented at the International Conference on Communication in Healthcare, San Diego, Calif.\*
9. Womack, J.J., Fisher, C.L., & Ledford, C.J.W. (2018, June). The role of race/ethnicity in the communicative identity of patients diagnosed with type 2 diabetes. Poster presented at the North American Primary Care Research Group Practice-Based Research Networks Conference, Bethesda, Md.\*
10. Ledford, C.J.W., Seehusen, D.A., Crawford, P. (2017, October). How patients' disease stage and genetic predisposition influences their personal model of diabetes. Poster presented at the International Conference on Communication in Healthcare , Baltimore, Md.\*
11. Ledford, C.J.W., Seehusen, D.A., Crawford, P., & Fisher, C. (2016, November). A mixed-methods approach to understanding the cultural model of diabetes. Poster presented at the North American Primary Care Research Group Annual Meeting, Colorado Springs, Colo.

- **Website(s) or other Internet site(s)**

None

- **Technologies or techniques**

None

- **Inventions, patent applications, and/or licenses**

None

- **Other Products**

This project did create four infographics to communicate findings to both clinicians, patients, and the public. Infographics were shared at conferences, through social media, and in clinical spaces.

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

<b>Name</b>	Christy JW Ledford, PhD
<b>Project role</b>	Principal investigator
<b>Research identifier</b>	<a href="https://orcid.org/0000-0001-5523-454X">https://orcid.org/0000-0001-5523-454X</a>
<b>Nearest person month worked over 5-year study</b>	20
<b>Contribution to project</b>	Dr Ledford directed all phases of the research from design through collection, analysis, and dissemination.
<b>Funding support</b>	As a federal employee at USUHS, Dr Ledford's time was provided in kind.

<b>Name</b>	Dean Seehusen, MD, MPH
<b>Project role</b>	Co- investigator
<b>Research identifier</b>	<a href="https://orcid.org/0000-0002-2139-6484">https://orcid.org/0000-0002-2139-6484</a>
<b>Nearest person month worked over 5-year study</b>	5
<b>Contribution to project</b>	Dr Seehusen assisted in design of the study, oversaw formative phases as Dwight D Eisenhower Army Medical Center, directed implementation of the intervention at DDEAMC, consulted on interpretation of findings, and contributed to dissemination.
<b>Funding support</b>	As a federal employee at DDEAMC, Dr Seehusen's time was provided in kind.

<b>Name</b>	Paul Crawford, MD
<b>Project role</b>	Mentor
<b>Research identifier</b>	
<b>Nearest person month worked over 5-year study</b>	3
<b>Contribution to project</b>	Dr Crawford assisted in design of the study, oversaw formative phases at Mike O'Callaghan Military Medical Center, consulted on interpretation of findings, and contributed to dissemination.
<b>Funding support</b>	As a federal employee at MOMMC, Dr Crawford's time was provided in kind.

<b>Name</b>	Carla Fisher, PhD
<b>Project role</b>	Co-investigator

<b>Research identifier</b>	<a href="https://orcid.org/0000-0003-3903-4278">https://orcid.org/0000-0003-3903-4278</a>
<b>Nearest person month worked over 5-year study</b>	1
<b>Contribution to project</b>	Dr Fisher led the qualitative analysis and dissemination of the formative phases of the study.
<b>Funding support</b>	Dr. Fisher's time was supported by the grant as a sub award to the University of Florida,

<b>Name</b>	Jasmyne Womack, MPH
<b>Project role</b>	Clinical research coordinator
<b>Research identifier</b>	
<b>Nearest person month worked over 5-year study</b>	18
<b>Contribution to project</b>	Ms Womack managed regulatory processes, directed data management, coordinated research staff, supported intervention implementation, and contributed to data analysis and dissemination for the first three years of the award.
<b>Funding support</b>	Ms Womack's time was partially supported by USUHS intramural funding through the Military Primary Care Research Network.

<b>Name</b>	Lauren Cafferty, MA
<b>Project role</b>	Clinical research manager
<b>Research identifier</b>	
<b>Nearest person month worked over 5-year study</b>	18
<b>Contribution to project</b>	Ms Cafferty managed regulatory processes, directed data management, coordinated research staff, contributed to intervention adaptation, supported intervention implementation, and contributed to data analysis and dissemination for the fourth and fifth years of the award.
<b>Funding support</b>	Ms Cafferty's time was partially supported by USUHS intramural funding through the Military Primary Care Research Network.

<b>Name</b>	Angela Seehusen
<b>Project role</b>	Research associate
<b>Research identifier</b>	
<b>Nearest person month worked over 5-year study</b>	36
<b>Contribution to project</b>	Ms Seehusen supported regulatory processes at DDEAMC, led site level implementation of the intervention, performed data entry, and conducted patient recruitment. She also contributed to data analysis and dissemination for the first three years of the award.

<b>Name</b>	Heather Rider
<b>Project role</b>	Research associate

<b>Research identifier</b>	
<b>Nearest person month worked over 5-year study</b>	36
<b>Contribution to project</b>	Ms Rider supported regulatory processes at MOMMC, performed data entry, and conducted patient recruitment. She also contributed to data analysis and dissemination for the first four years of the award.

<b>Name</b>	Jeremy Jackson
<b>Project role</b>	Publications coordinator
<b>Research identifier</b>	
<b>Nearest person month worked over 5-year study</b>	12
<b>Contribution to project</b>	Mr Jackson coordinated the overall dissemination plan. He coordinated study writing teams, managed publication processes, and contributed editorial assistance.
<b>Funding support</b>	Mr Jackson's time was partially supported by USUHS intramural funding through the Military Primary Care Research Network.

<b>Name</b>	Tyler Rogers, MD
<b>Project role</b>	DDEAMC site co-investigator
<b>Research identifier</b>	
<b>Nearest person month worked over 5-year study</b>	1
<b>Contribution to project</b>	Dr Rogers supported implementation of the intervention at DDEAMC. He also contributed to manuscript preparation.
<b>Funding support</b>	As a federal employee at DDEAMC, Dr Rogers's time was provided in kind.

<b>Name</b>	Christopher C Ledford, MD
<b>Project role</b>	Eglin site co-investigator
<b>Research identifier</b>	
<b>Nearest person month worked over 5-year study</b>	1
<b>Contribution to project</b>	Dr Ledford supported implementation of the intervention at Eglin Hospital. He also contributed to manuscript preparation.
<b>Funding support</b>	As a federal employee at Eglin, Dr Ledford's time was provided in kind.

<b>Name</b>	Stephanie Fulleborn, MD
<b>Project role</b>	Eglin site co-investigator
<b>Research identifier</b>	<a href="https://orcid.org/0000-0002-7219-1235">https://orcid.org/0000-0002-7219-1235</a>
<b>Nearest person month worked over 5-year study</b>	1
<b>Contribution to project</b>	Dr Fulleborn supported implementation of the intervention at Eglin Hospital. She also contributed to manuscript preparation.

<b>Funding support</b>	As a federal employee at Eglin, Dr Fulleborn's time was provided in kind.
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**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Final report

**What other organizations were involved as partners?**

Nothing to report

## **8. SPECIAL REPORTING REQUIREMENTS**

Nothing to report

## **9. APPENDICES:** *journal articles and infographics as mentioned above*