

BRIEF REPORT

Designing and Evaluating a Prediabetes Shared Decision Aid

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Background: Prediabetes is increasing in prevalence and is associated with risk of developing diabetes, heart disease, stroke, and retinopathy. Clinicians have limited tools to facilitate prediabetes discussions within primary care visits.

Purpose: 1) Develop a Patient and Stakeholder Advisory Committee (PASAC) to design, evaluate, and revise a prediabetes shared decision aid, and 2) evaluate the feasibility and experience of implementing the tool within primary care practice.

Methods: A prediabetes decision aid (double-sided infographic with decision questions) was created by a PASAC that included patients, primary care clinicians, diabetes educators, endocrinologists, and pharmacists. Five clinicians within 3 primary care practices tested the prediabetes tool with 50 adult patients with prediabetes. Patients completed 2 surveys immediately after the office visit and 6 weeks later. Clinicians and PASAC members completed a postintervention survey.

Results: The prediabetes shared decision aid was created through a deliberative process over 3 PASAC meetings. Ninety-six percent of patients felt the tool prepared them to decide on a diabetes prevention plan, and 100% of clinicians would use the tool again and felt the tool did not extend visit length.

Discussion: It was feasible to cocreate a prediabetes shared decision aid within a PASAC and implement the tool within a primary care setting. Patients and clinicians reported a prediabetes discussion, which may mitigate rates of progression to diabetes and associated complications. Future research should evaluate which of the intervention components most effectively promotes discussion of prediabetes within a primary care setting. (J Am Board Fam Med 2020;33:262–270.)

Keywords: Decision Support Techniques, Diabetes Mellitus, Prediabetes, Primary Health Care, Surveys and Questionnaires

Introduction

Prediabetes is a condition involving elevated blood glucose (Hemoglobin A1c (A1c), 5.7% to 6.4%) below the diabetic range (A1c \geq 6.5%). Approximately 38% of adults in the United States have pre-

diabetes.¹ Prediabetes is associated with risk of developing diabetes, in addition to macro- and microvascular complications.^{2–4} Previous research has shown that intensive prevention strategies are effective at preventing or delaying diabetes,^{5–6} but are not available to all patients.⁷ Another study shows that patients simply notified that they had prediabetes experienced improvements in glucose tolerance compared with controls.⁸ Unfortunately, many people are unaware of their diagnosis⁸ or have not been presented with options to prevent or delay diabetes.

Shared decision making (SDM) is a process in which patients and clinicians collaborate to make health care decisions. SDM enhances communication, risk awareness, and patient engagement by providing evidence-based education and eliciting patient priorities. Effective SDM includes discussion of choices followed by values-based decision

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making.⁹ Previous research has shown that when patients understand their options, they are more likely to participate in making decisions for their care¹⁰ and to have accurate perceptions of the potential outcomes associated with those decisions.¹¹ SDM may facilitate prediabetes conversations and prevent risk of progression to diabetes.^{11–12} Although there are brief tools for prediabetes SDM,^{13–14} evaluation of these tools are not yet available; additional tools should be developed that include infographics and are designed in collaboration with patients.

Internal and external stakeholders who are end users of health care innovations should be involved in the development, implementation, and dissemination of patient-centered outcomes research. Previous research has shown that their engagement facilitates balanced contributions, and¹⁵ meaningful involvement provides for retention and investment of patients, community members and health care stakeholders.¹⁶ Creating a Patient and Stakeholder Advisory Committee (PASAC) to cocreate a shared decision aid is an innovative approach that may increase likelihood of its utility for patients and clinicians.¹⁷

Study Purpose

This study aimed to 1) develop a PASAC to design, evaluate, and revise a prediabetes shared decision aid and, 2) evaluate the feasibility of implementation of the tool in primary care practice.

Methods

Aim 1

Plan-Do-Study-Act Study Design

The PASAC conducted a Plan-Do-Study-Act (PDSA) cycle to create a prediabetes SDM tool, which was based on the PDSA model of improvement (Figure 1).¹⁸ Plan: A diverse group of PASAC members (n = 12) were recruited including patients, primary care clinicians, endocrinologists, a pharmacist, diabetes educators, and community members. The PASAC met 3 times to design and modify the shared decision aid and review the patient and clinician surveys using the deliberative method.¹⁹ Study: PASAC members engaged in role playing of the shared decision aid among each other as well as with family and friends. Act: The PASAC revised the prediabetes shared decision aid and created recommendations for implementation.

Prediabetes Shared Decision Aid

The prediabetes shared decision aid was 1 doubled-sided page with a prediabetes infographic and questions to prompt goal setting for diabetes prevention behaviors (Appendix). The infographic defined prediabetes and associated risk factors, delineated that prediabetes is reversible, and described strategies to decrease risk of developing diabetes including physical activity, nutrition, and medications. The decision aid component included a pro/con table for the diabetes risk reduction strategy, questions to elicit priorities and goals, and a prediabetes action plan.

Evaluation

PASAC surveys were used to evaluate the process of the PASAC meetings. The Patient and Stakeholder Advisory Committee survey was adapted from previous work in community health partnerships.^{20–21}

Aim 2

Implementation of the Prediabetes Shared Decision Aid

The prediabetes shared decision aid was implemented in 50 clinical encounters across 3 primary care practices. Potential patients were identified through the electronic medical record, and clinical staff were alerted about patients through the electronic medical record. Patients and family medicine clinicians discussed prediabetes during the primary care appointment. Afterward, family medicine clinicians documented the preferred management selection (lifestyle, metformin, other, or none) in a standardized template.

Participants

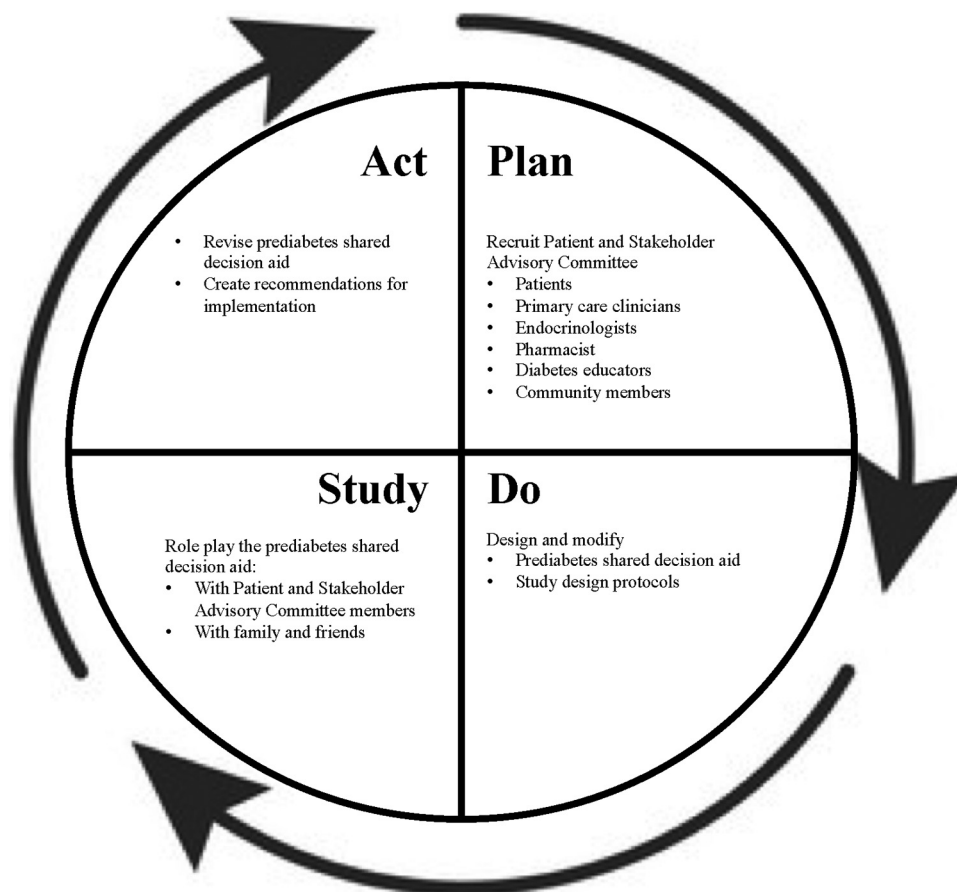
Family medicine clinicians (n = 5) were recruited from 3 family medicine practices within a practice-based research network.

Patients (n = 50) were recruited from the 3 family medicine practices. Inclusion criteria were 1) A1c consistent with prediabetes in the preceding 24 months, 2) age between 18 and 75 years, 3) at least 1 visit with a participating family medicine clinician within the past 24 months, and 4) English speaking. Exclusion criteria included 1) current pregnancy, 2) resolved prediabetes, or 3) progression to type 2 diabetes.

Evaluation

A collaborative team of researchers developed content for both the patient and clinician surveys based on available tools for SDM.^{22–27}

Figure 1. PDSA Cycle for Development of Prediabetes Shared Decision Aid.



Patients completed a survey postintervention assessing their experience with the tool and a mailed survey after 6 weeks to assess short-term sustained behavior change. Patients were asked about information presented in the infographic, the process of using the tool with their clinician, and the decision-making process. The 6-week survey also asked patients about their experiences with their prediabetes prevention plan. All questions utilized a 5-point Likert scale.

Family medicine clinicians completed a survey at the conclusion of eligible patient encounters. The survey measured their experience using the tool, including frequency of decision making and decisional conflict, the process of using the tool, and impact on visit time.

Data Analysis

Descriptive statistics were conducted including frequencies and percentages for categorical variables and means and standard deviations for continuous

variables. Statistical analyses were performed using SPSS (SPSS Inc., Chicago, IL).

Human Subjects Protection

This study was approved by the Institutional Review Board at Lehigh valley health network.

Results

Aim 1

Prediabetes Shared Decision Aid Feedback

PASAC members modified the and provided feedback on the shared decision aid. The original target audience for the shared decision aid was Hispanics; however, the PASAC expanded the audience to include non-Hispanic patients. The PASAC members reduced the number of questions included on the shared decision aid over time and increased the emphasis on action planning. The revised shared decision aid was cleaner, more organized, and contained more visuals and less text.

Table 1. Patient and Stakeholder Advisory Committee's Partnership Self-Assessment Tool Results (n = 8)

Section 1	True	False	Don't Know		
I was notified of this meeting with sufficient notice.	88%	12%	—		
The meeting started and ended on time.	88%	12%	—		
Section 2	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
The agenda is clear.	88%	12%	—	—	—
The objectives are appropriate.	75%	25%	—	—	—
The location of the meeting is functional.	75%	25%	—	—	—
Information shared in this meeting is high yield.	88%	12%	—	—	—
The handouts are useful.	75%	25%	—	—	—
This meeting was productive.	88%	12%	—	—	—
The action or follow-up plan is clearly communicated.	75%	25%	—	—	—
The purpose and function of this committee is well-defined.	71%	29%	—	—	—
Section 3	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
I am generally satisfied with the activities of the partnership.	50%	50%	—	—	—
I have a sense of ownership in what the partnership does and accomplishes.	57%	29%	14%	—	—
Participation in the partnership has increased my knowledge and understanding of the other organizations represented.	50%	25%	25%	—	—
I feel comfortable talking openly and honestly at partnership meetings.	63%	37%	—	—	—
I am comfortable bringing new ideas to the partnership meetings.	63%	37%	—	—	—
Partnership members respect each other's points of view even when they disagree.	100%	—	—	—	—
I am satisfied with the progress that has been made by the partnership to study the problem.	71%	29%	—	—	—
All members of the partnership have a voice in decisions made by the group.	88%	12%	—	—	—

PASAC Partnership Self-Assessment Tool

After the fourth PASAC meeting, all responding members reported a clear agenda, appropriate objectives, productive meetings, and a clearly communicated follow-up plan (Table 1). In addition, all respondents reported that they are comfortable bringing new ideas to the meetings and that members respect each other's opinions.

Aim 2

Implementation of the Shared Decision Aid

Patients were identified through the electronic medical record system. Clinicians reported that the shared decision aid was feasible within the context of a routine clinical office visit despite prediabetes not being the primary reason for the visit. Patients found the shared decision aid acceptable to complete; all consented patients completed the shared decision aid.

Patient Demographics Characteristics

Enrolled patients were predominantly female (66%), white (76%), non-Hispanic (80%), and over the age of 50 years (76%) (Table 2). Participants had an average A1c of 6.0%.

Patient Postintervention and 6-week Surveys

Among participating patients, 92% reported that they decided together with their doctor about how to treat prediabetes (Table 3). Furthermore, 96% felt the SDM tool prepared them to decide on a diabetes prevention plan. After 6 weeks, 80% of responding patients said they had been following the diabetes prevention plan most days.

Clinician Survey

All family medicine clinicians reported that the prediabetes tool helped them provide more information to their patients than they had previously, with 80% (n = 5) stating that the SDM tool made it

Table 2. Patient Demographic Characteristics (n = 50)

Demographics	n (%) / M (S.D.)	
Race		
Black or African American	5	(10%)
White or Caucasian	38	(76%)
Other	7	(14%)
Ethnicity		
Hispanic or Latino	9	(18%)
Not Hispanic or Latino	40	(80%)
Patient Declined/Refused	1	(2%)
Sex		
Female	33	(66%)
Male	17	(34%)
Age		
18 to 35	3	(6%)
36 to 50	9	(18%)
51 to 60	17	(34%)
61 to 70	16	(32%)
71 to 75	5	(10%)
A1c completed in past 2 years	43	(86%)
Average A1c (%)	6.0	0.19
Average days between patients' most recent A1c lab and the shared decision aid intervention	189	140
Average number of visits in 24 months	6.22	5.32

Note. M, mean; S.D., standard deviation.

easier to include patients in the decision-making process. They reported that they would use the prediabetes shared decision aid again, and there was no change in the visit length due to using the tool. The clinicians thought the tool was beneficial because it provided a new framework for explaining prediabetes and a guided conversation about prediabetes management. Previously without the

decision aid, they felt that prediabetes was challenging to express susceptibility.

Discussion

A prediabetes shared decision aid was cocreated in partnership with patients, clinicians, and key stakeholders. The shared decision aid facilitated conversations about diabetes prevention and logistically did not alter the primary care visit length. Patients felt the shared decision aid enabled them to create a diabetes prevention plan; all patients chose an intervention, and a majority of patients followed that plan after 6 weeks. Family medicine clinicians felt the shared decision aid was useful for communicating with their patients and would use it in the future.

Recommendations for PASAC Process

Primary care researchers who participate with a PASAC should consider the lessons learned during this study. Clinical members were more vocal during the initial meeting compared with patient members; the PASAC leader prompted patient members for their opinions with the goal of making them feel comfortable participating. At the end of the first meeting, the leader asked all members to provide final comments by systematically going around the room. Newsletters were used to maintain engagement with PASAC members in between meetings. These strategies increased participation from PASAC members in future meetings.

Recommendations for Implementing the Shared Decision Aid in Primary Care

Family medicine clinicians felt more comfortable addressing prediabetes with a shared decision aid.

Table 3. Patient Post-Intervention and 6-Week Survey

Survey Questions	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Initial post-encounter patient survey (n = 50)					
My doctor and I made a decision together about how to treat my prediabetes during my visit	60%	32%	6%	—	2%
I had an important role in the decision-making process	66%	28%	6%	—	—
The shared decision-making tool prepared me to make a decision about my prediabetes prevention plan	48%	48%	4%	—	—
The shared decision-making tool helped me think about the pros and cons of each option to prevent diabetes	56%	44%	—	—	—
The shared decision-making tool helped me think about which pros and cons are most important to me	57%	43%	—	—	—
6-week post-encounter patient survey (n = 30)					
I have been following the diabetes prevention plan most days	13%	70%	10%	—	7%
My plan reflects what my doctor and I discussed	27%	60%	7%	—	7%
I am considering changing my diabetes prevention plan	7%	20%	23%	30%	20%

Primary care providers who aim to implement the prediabetes shared decision aid in clinical office visits will need to have a clear method of identifying patients with prediabetes. The study team used A1c lab values to identify eligible patients because the problem lists often lacked a diagnosis of prediabetes, impaired fasting glucose, or impaired glucose tolerance. In addition, the lab results did not specify whether or not glucose levels were fasting, making those results ineligible.

Limitations

One limitation of this study is the small pilot sample size of 50 clinical encounters in 3 clinical sites. Future research should include a larger sample in more diverse primary care settings with a control arm to measure the effectiveness of the tool. Only 30 patients completed the 6-week survey. More research is needed to understand long-term adherence to diabetes prevention plans. In addition, this patient population does not have adequate access to a local diabetes prevention program. Future iterations of this tool may include a diabetes prevention program as part of the menu of options for diabetes prevention. During the informed consent process, patients were informed about the prediabetes diagnosis, which sometimes led to more robust conversations on prediabetes. The impact of this process needs to be more fully understood. Furthermore, this study could have underestimated the number of prediabetics since inclusion criteria used A1c lab values, and some patients may not have been screened for A1c.

Conclusions

It was feasible to cocreate a prediabetes shared decision aid within a PASAC and implement the tool within a primary care setting. Patients and family medicine clinicians reported a prediabetes discussion, which may mitigate rates of progression to diabetes and associated complications. Future research should evaluate which intervention components most effectively promoted discussion of prediabetes within a primary care setting and the impact of clinical discussions of prediabetes.

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References

1. Menke A, Casagrande S, Geiss L, Cowie CC. Prevalence of and trends in diabetes among adults in the United States, 1988–2012. *JAMA* 2015; 314:1021–9.
2. Huang Y, Gi X, Mei W, Li M, Hu Y. Association between prediabetes and risk of cardiovascular disease and all cause mortality: systematic review and meta-analysis. *BMJ* 2016;355:i5953.
3. Nguyen TT, Wang JJ, Wong TY. Retinal vascular changes in prediabetes and prehypertension: new findings and their research and clinical implications. *Diabetes Care* 2007;30:2708–15.
4. Sorenson BM, Houben A, Berednschot T, et al. Prediabetes and type 2 diabetes are associated with generalized microvascular dysfunction. *Circulation* 2016;134:1339–52.
5. American Diabetes Association. Standards of medical care in diabetes—2019. *Diabetes Care* 2019;42: S1–S193.
6. Ratner RE. An update on the Diabetes Prevention Program. *Endocrine Pract* 2006;12:20–4.
7. U.S. Department of Health and Human Services. National Healthcare Quality and Disparities Report 2014. AHRQ Publication No. 15-0007.
8. Owei I, Umekwe N, Ceesay F, Dagogo-Jack S. Awareness of prediabetes status and subsequent health behavior, body weight, and blood glucose levels. *J Am Board Fam Med* 2019;32:20–7.
9. Zhuo X, Zhang P, Barker L, Albright A, Thompson TJ, Gregg E. The lifetime cost of diabetes and its implications for diabetes prevention. *Diabetes Care* 2014;37:2557–64.
10. Barry MJ, Edgman-Levitan S. Shared decision making—The pinnacle of patient-centered care. *N Engl J Med* 2012;366:780–1.
11. Stacey D, Legare F, Col NF, Bennett CL, Barry MJ, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2014;1:CD001431.
12. Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361–7.
13. Healthwise. Prediabetes: which treatment should i use to prevent type 2 diabetes? 2018. Available from: <https://www.healthwise.net/ohridecisionaid/Content/StdDocument.aspx?DOCHWID=abp5563>.
14. The Center of Excellence for Medical Multimedia. CEMM decision aid for patients diagnosed with pre-

- diabetes. Available from: <https://diabetes.cemmlibrary.org/Resources/CEMM-Decision-Aid-For-Patients-Diagnosed-with-Pre>.
15. Cashman SB, Adeky S, Allen AJ 3rd, Corburn J, et al. The power and the promise: working with communities to analyze data, interpret findings, and get to outcomes. *Am J Public Health* 2008;98:1407–17.
16. Mallery C, Ganachari D, Fernandez J, et al. Innovative methods in stakeholder engagement: an environmental scan. Prepared by the American Institutes for Research under contract No. HHSA 290 2010 0005 C. AHRQ Publication NO. 12-EHC097-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2012. Available from: <http://www.effectivehealthcare.ahrq.gov/index.cfm/tools-andresources/how-to-get-involved-in-the-effective-health-care-program/>.
17. Forsythe LP, Ellis LE, Edmundson L, et al. Patient and stakeholder engagement in the PCORI pilot projects: description and lessons learned. *J Gen Intern Med* 2016;31:13–21.
18. Langley GL, Moen R, Nolan KM, Nolan TW, Norman CL, Provost LP. *The improvement guide: a practical approach to enhancing organizational performance*. 2nd ed. San Francisco, CA: Jossey-Bass Publishers; 2009. <http://www.ihl.org/resources/Pages/Publications/ImprovementGuidePracticalApproachEnhancingOrganizationalPerformance.aspx>.
19. Abelson J, Forest PG, Eyles J, Smith P, Martin E, Gavin FP. Deliberations about deliberative methods: issues in the design and evaluation of public participation processes. *Soc Science Med* 2003;57:239–51.
20. Giachello AL, Ashton D, Kyler P, et al, eds. *Making community partnerships work: a toolkit*. White Plains, NY: March of Dimes Foundation; 2007.
21. VanDevanter N, Kwon S, Sim SC, Chun KB, Trinh-Shevrin C. Evaluation of community–academic partnership functioning: center for the elimination of hepatitis B health disparities. *Prog Comm Health Partnerships: Res Educ Act* 2011;5: 223–33.
22. Elwyn G, Barr PJ, Grande SW, et al. Developing CollaboRATE: a fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Educ Couns* 2013;93:102–7.
23. Barr PJ, Thompson R, Walsh T, et al. The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. *J Med Internet Res* 2014;16:e2.
24. Barr PJ, Elwyn G. Measurement challenges in shared decision making: putting the ‘patient’ in patient-reported measures. *Health Expect* 2015;19: 993–1001.
25. Sepucha KR, Breslin M, Graffeo C, et al. State of the science: tools and measurement for shared decision making. *Acad Emerg Med* 2016;23:1325–31.
26. Mitchell TM, Beal C. Shared decision making for routine infant circumcision: a pilot study. *J Perinat Educ* 2015;24:188–200.
27. Sempere AP, Vera-Lopez V, Gimenez-Martinez J, et al. Using a multidimensional unfolding approach to assess multiple sclerosis patient preferences for disease-modifying therapy: a pilot study. *PPA* 2017; 11:995–9.

Appendix

Figure A1. Prediabetes Shared Decision Aid.

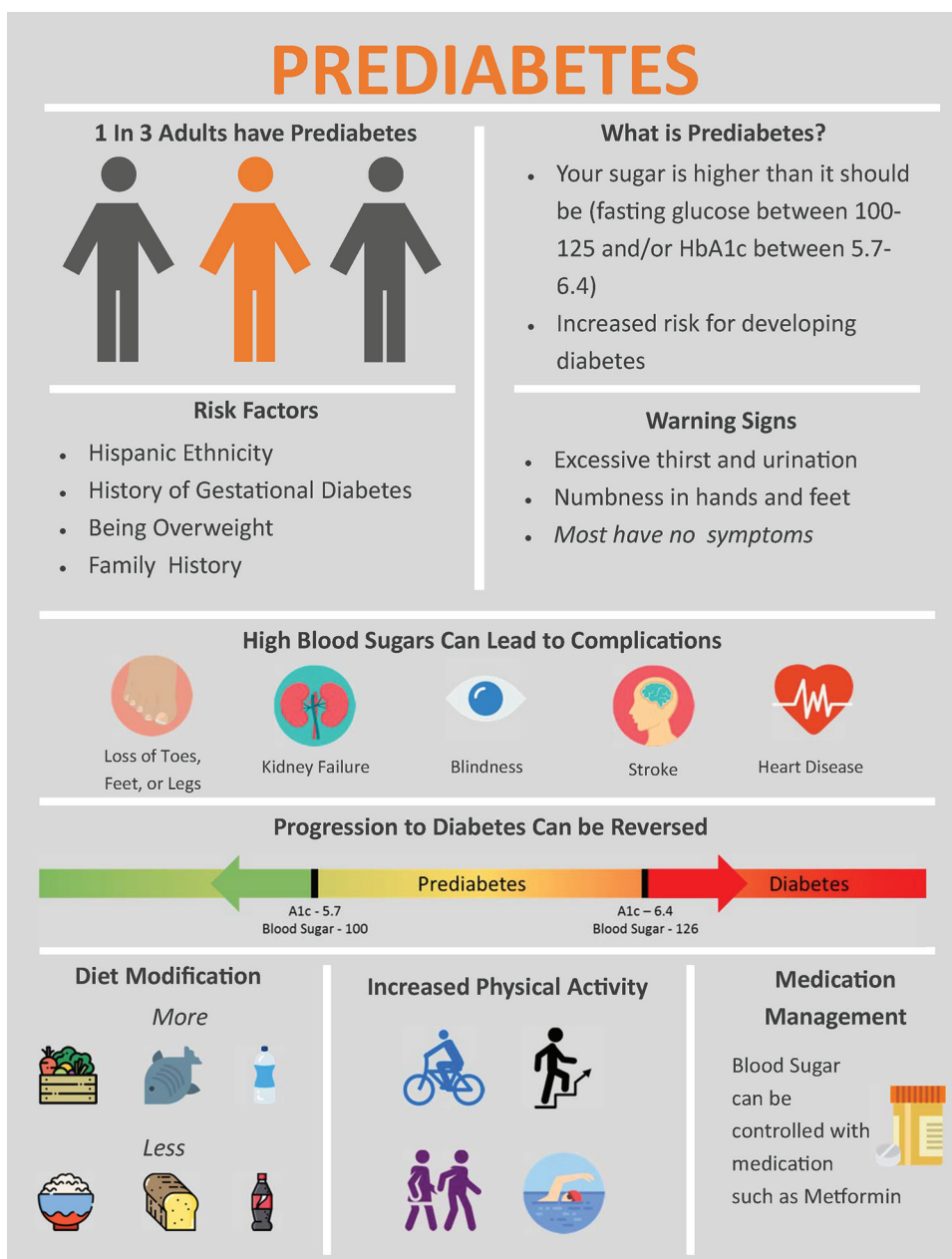




Figure A1. Continued

Prediabetes Treatment Options		
	Pros	Cons
Lifestyle Changes- Nutrition and Physical Activity 	<ul style="list-style-type: none"> - Improve overall health (blood pressure, cholesterol, mood, energy levels, etc.) - No need to remember to take a medicine - May result in weight loss - Lowers blood sugar 	<ul style="list-style-type: none"> - Requires time for physical activity (2 ½ hours per week) - Need to change eating habits (including amount of food and types of foods)
Medicines <i>(Typically Metformin)</i> 	<ul style="list-style-type: none"> - Taking a pill takes less time and effort than changing eating and exercise habits - Lowers blood sugar 	<ul style="list-style-type: none"> - Medicines may have side effects, such as upset stomach - Less likely to have weight loss
Lifestyle Changes and Medicine	<ul style="list-style-type: none"> - Lowers blood sugar 	<ul style="list-style-type: none"> - Need to be ready to make changes to improve exercise and eating habits as well as take a daily pill
No Changes	<ul style="list-style-type: none"> - No work 	<ul style="list-style-type: none"> - Increased risk of diabetes and associated complications - More likely to have continued increase in weight and blood sugar

1. How ready are you to make a change to prevent diabetes (Scale 1-10)?
2. Why do you want to make a change to prevent diabetes?
3. Please answer the following to help decide which option will be best for you:
 How willing are you to change the way that you eat (Scale 1-10)?
 How willing are you to increase your physical activity (Scale 1-10)?
 How willing are you to take a medicine to prevent diabetes (Scale 1-10)?
4. What do you think would be the best option(s) for you? Your options are:
 Nutrition Physical Activity Medicine Other
5. What would make it difficult for you to make this change?
6. What support do you have (or need) to help you to take care of your prediabetes?
7. What part of your diabetes prevention plan do you want to work on between now and your next visit with your doctor? Think about it and write it on the line below. (Here are examples: I will start walking 30 minutes per day for 5 days per week. I will set an alarm to take my medicine every day.)

The step(s) I will take toward my diabetes prevention plan is(are):
