Preventing Diabetes in Primary Care: Providers' Perspectives About Diagnosing and Treating Prediabetes

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IN BRIEF Offering patient-centered care to prevent diabetes will require collaborative decision-making between patients with prediabetes and their health care providers. From the perspective of primary care providers, prediabetes detection should be targeted to patients who are most likely to benefit from diagnosis and treatment. Improving access to lifestyle intervention programs and educating providers about evidence-based treatments for prediabetes and how to effectively discuss treatment options with patients may improve both providers' and patients' engagement in diabetes prevention.

An estimated 86 million American adults have prediabetes (1), 70% of whom will ultimately develop type 2 diabetes (2). The U.S. Preventive Services Task Force recently recommended screening for prediabetes and diabetes (3), with subsequent referral to intensive lifestyle intervention (ILI) that promotes a healthful diet and physical activity for those who screen positive (4). Large clinical trials, including the Diabetes Prevention Program (DPP), have established that structured ILI and metformin can reduce diabetes incidence by as much as 58 and 31%, respectively (5–8). The reduction in diabetes incidence from these two treatments is durable, lasting >15 years (9). In addition, follow-up studies demonstrate that ILI leads to reduced microvascular and macrovascular disease, cardiovascular mortality, and all-cause mortality (9–11). Despite strong evidence supporting ILI and metformin, neither treatment is routinely used to prevent diabetes (12,13).

Primary care represents an important venue for addressing diabetes prevention, given that >350 million adult ambulatory care visits are made annually, and screening tests are commonly performed in this setting (14). Previous estimates suggest that more than half of primary care patients receive screening tests for abnormal blood glucose (15,16). However, survey studies suggest that primary care providers (PCPs) infrequently counsel patients with prediabetes about lifestyle modification (17,18), and their rate of referral to evidence-based ILI is not known. Metformin is prescribed for diabetes prevention infrequently, estimated at 0.1–3.7% of eligible patients (19,20). These data highlight a substantial gap between the evidence supporting treatments to prevent diabetes and providers' current practice patterns.

Expert guidelines for diabetes management emphasize the importance of individualized treatment goals and plans (21). Similarly, promoting diabetes prevention in primary care will require a patient-centered approach that includes collaborative decision-making between patients and their health care providers. Yet, there is little knowledge of either group's perspectives about prediabetes beyond the results of national

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survey studies. The objective of this interview study was to explore PCPs' perspectives about the usefulness of diagnosing prediabetes, in addition to their attitudes toward ILI and metformin therapy for patients who have the condition.

Methods

A qualitative approach involving in-depth, semi-structured interviews was used to examine PCPs' attitudes and perspectives regarding prediabetes and its medical management. The strength of this research design is that it can provide a deep understanding of the topic by allowing researchers to explore the complexities of PCPs' attitudes and experiences in ways that quantitative methods alone cannot (22). The study protocol was approved by the Northwestern University institutional review board.

Interviews were conducted with 15 PCPs (14 physicians and 1 nurse practitioner), who were recruited from two primary care clinics using emailed recruitment letters. Both clinics were large, urban primary care practices affiliated with an academic medical center and medical school. Neither study site had clinical initiatives focused on identifying patients with prediabetes or offering treatment to those who have it. All providers in each practice were invited to participate. A total of 18 emailed invitations were sent, and 15 potential participants responded (83% response rate). Written informed consent was obtained by the interviewer before conducting the interviews, and participants received a $20 gift card upon completion of their interview.

We conducted in-depth interviews using a semi-structured interview guide that was informed by shared decision-making theory, which represents an effective framework for using evidence in routine clinical practice, including extensive application in diabetes (23,24). Shared decision-making has been defined as "an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options and to achieve informed preferences" (25). The guide was designed to elicit information from PCPs that was relevant to specific elements of shared decision-making, including *1)* patient context, *2)* PCPs' attitudes and practices related to prediabetes, *3)* discussion of evidence-based treatment options, and *4)* benefits, risks, and costs of treatments (26,27).

After an initial discussion about PCPs' experiences with and attitudes regarding diagnosing and treating prediabetes with ILI or metformin, PCPs were presented with visual depictions of diabetes risk among patients with prediabetes who do not receive treatment, followed by separate images displaying the risk reduction associated with ILI and metformin (28,29). These materials were developed using 3-year data from the DPP clinical trial (30) and included visual representations of numerical data based on current best practices. The materials were developed to convey risk information simply and to facilitate conversation between patients and providers. At the end of the interview, providers were shown additional information from the DPP trial about which participants benefited most from metformin (i.e., those who are <60 years of age, have a BMI ≥35 kg/m^2, or are women with a history of gestational diabetes). Providers were then asked if the information changed their attitudes and whether they would consider using metformin in similar patients.

Interviews lasted ~45 minutes each and were conducted by the project manager (M.R.M.). Data collection was continued until thematic saturation was reached, when no new significant themes or observations emerged (31). Each interview was digitally recorded and professionally transcribed verbatim. To minimize the risk of investigator/interviewer bias, the study interviewer was not a PCP. In addition, when designing the interview guide, the study team had individuals outside the research team, who were experts in health communication, review the guide and provide feedback.

Data Analysis

Transcripts were analyzed using deductive and inductive content analysis simultaneously (32). Deductive content analysis began by grouping participant quotes into codes that followed predefined topics from the interview guide. Three study team members with previous qualitative research experience (N.R.K, M.R.M., and J.W.T.) developed a coding guide a priori that was iteratively refined while reviewing the first four interviews. The resulting codebook included codes reflecting topics from the interview guide, in addition to de novo topics identified inductively. For example, participants' statements in response to information we provided about the risk reduction associated with ILI (e.g., "My take is that the lifestyle modification works very well. Granted it is hard for people to do, but you get very good results with it, and I actually reference that study in talking to my patients.") were classified under the code for "Provider's Perspectives on Evidence-Based Lifestyle Recommendations." These investigators used the codebook to review an additional three transcripts and revised the codebook by consensus.

When the codebook was finalized, at least two of these investigators reviewed each transcript and organized participants' responses by the corresponding codes. Common themes were developed during face-to-face meetings, synthesizing participants' responses across codes to reflect their experiences, perspectives, and attitudes about diagnosing and treating prediabetes in primary care. All members of the investigative team agreed on the final themes and the most representative quotes supporting them. NVivo software version 9 (NVivo, Victoria, Australia) was used

TABLE 1. Characteristics of PCPs (*n* = 15)

	n (%)
Age (years [mean 43 ± 7])	
30–39	4 (27)
40–49	8 (53)
50–59	3 (20)
Sex: female	8 (53)
Degree	
Physician	14 (93)
Nurse practitioner	1 (7)
Race	
White	10 (67)
Black	1 (7)
Asian	4 (27)
Years in practice	
<5	2 (13)
5–9	3 (20)
10–14	3 (20)
15–19	2 (13)
≥20	5 (33)
Panel size*	
<500	2 (13)
500–999	4 (27)
1,000–1,499	2 (13)
1,500–1,999	4 (27)
2,000–2,499	1 (7)

**Total does not add to 15 because the nurse practitioner did not have a regular panel, and information was missing from one other participant.*

to assist the team with organizing and analyzing the data.

Results

Participant Characteristics

Fourteen physicians and one nurse practitioner were interviewed. Their average age was 43 ± 7 years, 53% were women, and two-thirds were non-Hispanic whites. Participants had been in practice for 3–20 years, and their panel sizes ranged from 500 to 2,499 patients (Table 1).

Theme 1. Usefulness of diagnosing and treating prediabetes varied among providers.

Every PCP interviewed had cared for patients with prediabetes, but there was substantial variation in the perceived usefulness of making this clinical diagnosis. Approximately half of the PCPs said that diagnosing prediabetes presented an opportunity to educate patients and motivate them to make lifestyle changes and lose weight (Table 2, comment 1.a). Eight providers reported trying to frame prediabetes as good news (i.e., as an opportunity for patients to catch a problem before it became too serious) (comment 1.b). Providers also saw diagnosing prediabetes as a chance to counsel patients about healthy lifestyle changes and the metabolic benefits of modest weight loss at a time when patients may be receptive to this information.

Three providers felt that focusing on prediabetes in primary care was potentially a waste of time or resources (comments 1.c and 1.d). These providers were ambivalent about the potential benefits of treatment. Said one male PCP who had been in practice for 10–14 years, "It's a mixed bag. Some people will actually significantly lose weight with response to the message of prediabetes, and some will change little. We don't know a lot about how much we impact the risk of macro- and microvascular complications in somebody who has very mild diabetes versus near diabetes."

In addition to acknowledging uncertainty about the benefit of treating prediabetes, four providers voiced concern about potential risks associated with diagnosing the condition, including the possibility of labeling patients and causing unnecessary worry (comments 1.e and 1.f).

Six providers believed that the usefulness of diagnosing prediabetes depends on the patient's individual context—specifically, the presence of comorbidities. Providers generally agreed that prediabetes could help motivate younger, healthier patients without comorbid conditions to make lifestyle changes (comment 1.g).

Theme 2: Lifestyle intervention was the preferred treatment.

Few providers seemed to think about prediabetes as a condition that required pharmacological treatment. Rather, providers reported that they framed discussions with patients around how to avoid developing diabetes in the future. Even before they were shown visual depictions about the comparative effectiveness of ILI and metformin for preventing or delaying diabetes (Figure 1), almost all providers felt that lifestyle change was a better option because it was more effective than metformin in the DPP trial (comment 2.a). However, PCPs' positive attitudes about the effectiveness of lifestyle modification were tempered by their actual experiences with patients who have not made such changes. They repeatedly acknowledged that the exercise and weight loss recommendations for diabetes prevention (150 min/week and 7% weight loss, respectively) were unrealistic for many patients. In addition, 13 providers expressed concerns related to patients' access to effective lifestyle modification programs (comment 2.b).

Providers also recognized the limitations of their own lifestyle modification counseling efforts in the context of brief primary care office visits (comment 2.c) and without patients having additional support for behavior change. For example, one female provider who had been in practice for <5 years said, "… lifestyle changes are best, but our ability to actually get to affect [patients'] lifestyle is hard. How do you encourage people to lose 7% of their body weight, eat healthful, and exercise for 30 minutes five days a week? Most of our patients don't have some sort of intensive support group experience that is helping them do this. On their

TABLE 2. Provider Perspectives on Diabetes Prevention: Themes and Representative Quotes

		Representative Quotes
Theme 1. Usefulness of diagnosing and treating prediabetes varied among providers.		
Prediabetes is an opportunity to activate and engage patients.	1.a	*"I think there are some patients who don't need extra motivation, and other patients for whom I have seen a diagnosis of prediabetes really help them by [making them think], 'I do really need to start exercising and changing my habits and everything?'"* (Female, <5 years in practice)
	1.b	*"Isn't it great we found this problem, because there is something we can do about it.… It's just like with high cholesterol or high blood pressure. It is a good thing we know about this because there are some steps we can take to change the natural history of the illness."* (Male, ≥20 years in practice)
Focusing on prediabetes can be a waste of time or resources.	1.c	*"We have a limited time, and prediabetes is one of the things we are addressing in our 20-minute visit, and for most patients, there are often things that seem to be more urgent."* (Male, ≥20 years in practice)
	1.d	*"We have people who have out-of-control diabetes. We have people with out-of-control blood pressure. I am not sure I would put limited resources into talking to people about prediabetes."* (Male, ≥20 years in practice)
Diagnosing prediabetes affects patients differently, depending on their context.	1.e	*"I'm not confident that it's such a great idea to find all these patients. There's definitely some benefit, but there's also a label that you place on patients. You also increase costs significantly. And what's your bang for the buck in doing all of that? So, that's my reason I don't tend to go after all of these patients."* (Male, ≥20 years in practice)
	1.f	*"He is very complicated; and so, given his other medical issues, I was trying to figure out whether even to bring up the issue of prediabetes with him. On his list of problems, I don't even know that I want to give him one more thing to think about. I honestly didn't even mention it."* (Female, 5–9 years in practice)
	1.g	*"There are people who think they are totally healthy, yet have risk factors, and this is the first sign they ever get that they are unhealthy. [Prediabetes] is a nice, motivating rally cry to [say], 'Let's take this seriously. Let's keep you healthy.'"* (Female, 5–9 years in practice)
Theme 2. Lifestyle intervention was the preferred treatment.		
Lifestyle modification is viewed as the best option.	2.a	*"My take is that the lifestyle modification works very well. Granted it is hard for people to do, but you get very good results with it, and I actually reference that study in talking to my patients…. We can do medicine, but the truth is that you get better results with lifestyle modification."* (Female, 15–19 years in practice)
Barriers to lifestyle modification exist for patients and providers.	2.b	*"You certainly could use metformin. But studies suggest that if you can do the lifestyle modifications—the 150 minutes of exercise and the 5–10% of body weight—that's better than metformin. But it's hard for people to do that. That's your Catch 22. Lifestyle is better, but it's hard to do."* (Male, ≥20 years in practice)
	2.c	*"It reminds me to think about the diabetes prevention programs that are out there, like, if there is a YMCA nearby or other places that actually have a good program. My counseling is different than that, for sure; there may be other nondiabetes-related benefits that they get from making the appropriate lifestyle changes with outside help, not just me counseling."* (Female, 10–14 years in practice)
	2.d	*"So, I don't have any real disconnect in trying to promote the lifestyle part of the prevention. I just feel like the barriers to me are: 'So, where is the program? Can my patient do it? Can they pay for it? Do they want to do it? And, will it fit into their life?' I don't have a tool in my office on my desktop to say here are the three places within 2 miles of your home or workplace that could offer those lifestyle modification programs."* (Male, 10–14 years in practice)
	2.e	*"I always try to emphasize the very, very aggressive lifestyle interventions up front. And you know, they've all done great if they can do it."* (Male, 5–9 years in practice)
Theme 3. PCPs' attitudes toward metformin varied.		
Metformin is offered when lifestyle changes fail or glycemic indices worsen.	3.a	*"I do strongly feel that people should try to do the lifestyle modification first. I just don't see myself offering metformin up front, and I also think that people would be rather resistant to it. I think if we hit a brick wall, maybe I could consider it, but I think most patients would opt for lifestyle."* (Female, 15–19 years in practice)

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TABLE 2. Provider Perspectives on Diabetes Prevention: Themes and Representative Quotes, ***continued from p. 62***

	3.b	*"I think it's when their blood sugars are getting a little higher or their A1C is getting a little higher. I don't know if it is a scare tactic because once I bring up the word medication—and metformin is what I am talking about—that is when they get scared enough that they will do something even more drastic, be it exercise or diet change."* (Female, 10–14 years in practice)
Providers express skepticism about the benefits of metformin for diabetes prevention.	3.c	*"The real question to me is, "Is there a real benefit from starting metformin at the time when they have prediabetes?' versus 'Is there harm in waiting until the time that they actually do have diabetes?' I am not convinced that there is."* (Male, ≥20 years in practice)
	3.d	*"[Metformin is] fine, but you have to see what the ultimate complications are. You need to know how many heart attacks you've prevented, how many strokes you've prevented, how many limbs you've salvaged, how many people have you saved from having renal failure."* (Male, ≥20 years in practice)
Metformin can provide a potential benefit to high-risk groups.	3.e	*"Somebody who is really overweight, I would be more likely to prescribe [metformin] because of the little bit of extra weight loss you can get with it, and they'd be at high risk of developing diabetes. And it also depends, too, like if somebody's hemoglobin A1C is like 6.3, I'm a lot more likely to start metformin than if it's 5.8."* (Male, <5 years in practice)
	3.f	*"You got to get deeper into this data, and say, 'Who's at the highest risk? Who of these 30 patients are going to progress? Is it the BMIs over 35? Is it the gestational diabetes? Or is it the strong family history?' Which of those factors is most important?"* (Male, ≥20 years in practice)

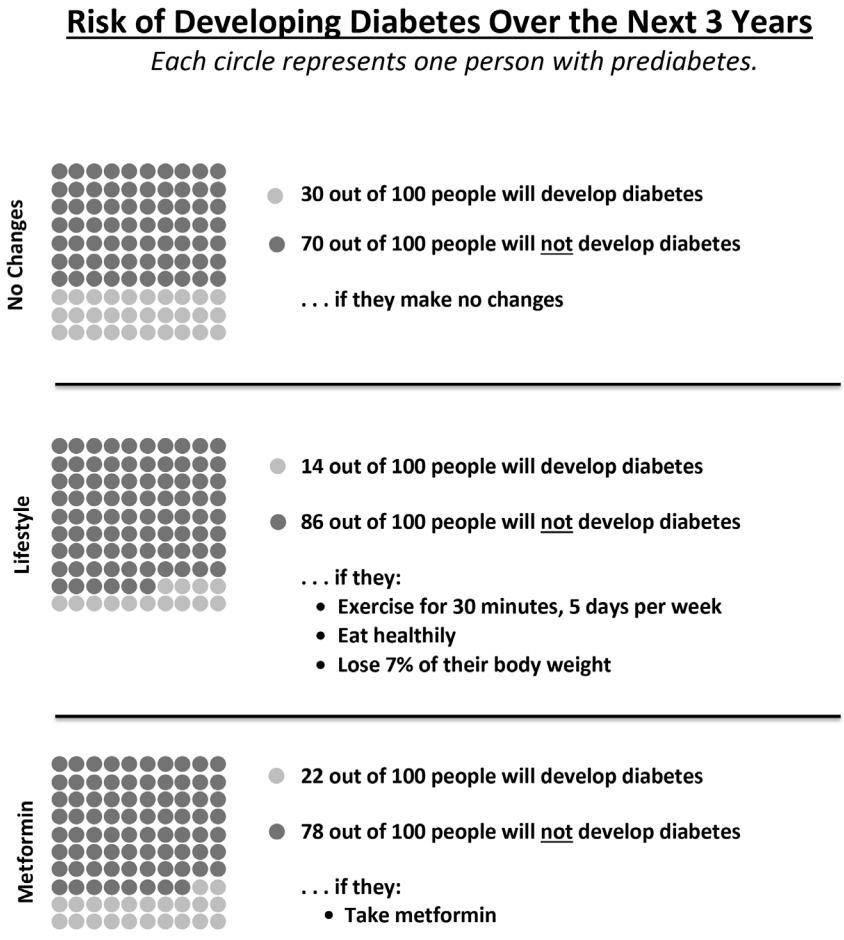

FIGURE 1. Visual depiction of diabetes risk with and without treatment.

own, I think it is hard to help people make those changes."

A common barrier PCPs mentioned was not being able to refer patients to ILI programs similar to those studied in major diabetes prevention trials (comment 2.d). Barriers to referral included a lack of available programs, not having a referral mechanism, and the financial cost of these programs. As a female provider in practice for 10–14 years said, "One thing that could help me, I think, is if our center had a program that insurance would pay for. A support group, which I know is expensive and doesn't get reimbursed, I think that would be ideal to refer patients to." Despite recognizing these significant challenges, providers were firm in their belief that patients with prediabetes would benefit most from lifestyle changes (comment 2.e).

Theme 3: PCPs' attitudes toward metformin varied.

Only one provider reported presenting metformin as a treatment option for all patients with prediabetes. Among the few providers who mentioned discussing metformin with their patients, most did it as a last resort after failed lifestyle counseling efforts (comment

3.a). The belief that patients would not want to take metformin for diabetes prevention was raised by many participants (e.g., one female provider in practice for 10–14 years said, "Most of my patients don't want to go on meds."). Another barrier to prescribing metformin was the limited existing evidence for its effectiveness at preventing diabetes and its complications. Some providers expressed skepticism about whether prescribing metformin before the onset of diabetes benefits patients (comment 3.c). Other providers specifically desired evidence that metformin prevents micro- or macrovascular diseases of interest (comment 3.d). Although the providers reported rarely prescribing metformin for diabetes prevention, they agreed that the medication is inexpensive and safe, with few side effects.

It was unclear how providers determined whether a patient had "failed" lifestyle modification or what the appropriate timeline was for recommending metformin. A few PCPs said they would discuss metformin with patients if their glycemic indices were increasing (comment 3.b). The idea of using metformin as a scare tactic or threat was mentioned by several providers. For example, a male provider in practice for 5–9 years said, "I use that as a lever, like starting and not starting it. I may wait until I see a trend line going a certain way. But I'll use that threat of metformin as a thing to sort of get them to relent."

When providers were presented with information from the DPP trial about characteristics of patients most likely to benefit from metformin (i.e., those <60 years old, with a BMI ≥35 kg/m^2, or women with a history of gestational diabetes), a few acknowledged the potential benefit of metformin among these specific high-risk groups (comment 3.e). Several providers said it would be helpful to have tools to systematically identify high-risk patients who might benefit more from metformin (comment 3.f).

Some providers felt open to sharing information about metformin with patients, but they were unclear about when to recommend it, acknowledging the need to learn more about metformin for diabetes prevention. Said one female PCP in practice for 10–14 years, "I think [metformin] is still in the realm of shared decision-making with the patient, because I feel like it is not a slam-dunk recommendation on my read of it. So, I probably need to learn a little bit more about what metformin does for prediabetes, some of the risks and benefits, and having some help having that conversation, because the evidence is complicated, and I haven't been able to keep up on it enough."

Discussion

In this qualitative study, we found substantial variation in PCPs' perspectives about the usefulness of diagnosing patients with prediabetes and offering evidence-based treatments to lower their diabetes risk. Many participants believed that delivering a diagnosis of prediabetes could motivate younger, healthy patients to make lifestyle modifications. However, some reported that the presence of other cardiovascular risk factors and comorbidities dissuaded them from mentioning the diagnosis of prediabetes because of these other competing interests. Some providers were not convinced by the scientific evidence supporting early detection of and intervention for prediabetes, which also influenced their prioritization of prediabetes.

Both before and after reviewing data from the DPP trial, PCPs had a strong preference for lifestyle modification over metformin therapy to prevent or delay diabetes in patients with prediabetes. However, they acknowledged patient-, provider-, and systems-level barriers to sustained lifestyle change. Key barriers to recommending metformin were providers' belief that patients with prediabetes would not want to take metformin for prevention and a perception of limited evidence supporting its use for this indication.

Our findings complement those recently reported by Mainous et al. (33), which indicated that family physicians' attitudes toward prediabetes varied substantially and were associated with their clinical practice among patients with the condition. In this survey study, the half of respondents who had a positive attitude toward prediabetes as a clinical entity were more likely to report following recommended guidelines for prediabetes screening and prescribing metformin for diabetes prevention. Our qualitative study expands on these survey findings to provide evidence about the factors that influence variation in PCP attitudes and behaviors, including *1*) PCPs' interpretation of the evidence regarding diabetes prevention, *2*) competing demands during the clinical visit, and *3*) the patient context, including their other medical problems. Common barriers raised in both studies were providers' inability to offer the intensity of lifestyle counseling that is recommended (4) and patients' inability to modify their lifestyle behaviors. In addition, providers in both studies reported that their inability to refer patients to ILI programs represented a significant barrier to following this evidence-based practice.

Since 2010, a national infrastructure of programs offering ILI for prediabetes has been coordinated by the Centers for Disease Control and Prevention (34), with participating organizations listed on its website. This network of ILI providers is growing quickly and will likely continue to expand in response to a recent decision that Medicare will reimburse ILI delivery for older adults with prediabetes. An opportunity exists to automate referrals to evidence-based ILI programs in the community, which may overcome some provider barriers identified here.

The attitude among some PCPs that prediabetes does not warrant expending clinical resources and

time was another barrier to identifying and treating prediabetes in primary care. A recent economic analysis (35) suggests the opposite, reporting that lifestyle counseling represents a high-value service for maximizing population health among patients with cardiovascular disease risk factors, including prediabetes. Some providers in our study placed greater importance on preventing downstream endpoints such as cardiovascular complications and mortality than on preventing diabetes itself. However, there is mounting evidence that ILI reduces both mortality and the risk of micro- and macrovascular complications in patients with prediabetes (9,10). This new information may help fill providers' perceived evidence gaps and support the value of treating prediabetes with ILI, thereby motivating referral to these programs.

Similar long-term data are needed for metformin. In addition, previous research suggests that patients have a strong desire to know whether they have prediabetes and place a high value on being able to delay or prevent diabetes (29,36). This evidence suggests that patient-centered care for prediabetes should place a greater emphasis on prediabetes as a clinical entity.

PCPs' perception that patients with prediabetes would not be interested in taking metformin stands in contrast to our findings from a recent qualitative study of patients (29). In that analysis, >90% of primary care patients with prediabetes reported a willingness to take metformin if they were not successful with lifestyle modification. Importantly, all patients in that study reported wanting their PCPs to discuss both lifestyle modification and metformin as treatment options.

Because providers may inaccurately assess patients' interest or willingness to take metformin, shared decision-making about treatment options for preventing diabetes is especially important. The same is true in diabetes care, for which certain evidence-based options (e.g., injectable GLP-1 receptor agonists) may not be offered by a provider if a patient previously reported not wanting to use needles for insulin. However, patients may still be interested in an injectable treatment that offers additional benefits that can be communicated through shared decision-making. Our data highlight the need for patient-centered care across the continuum from prediabetes to diabetes and its complications.

Our study found little provider support for using metformin to treat prediabetes. Whereas one-third of family physicians reported recommending metformin to patients with prediabetes in a recent survey (33), our study found that PCPs strongly preferred ILI. Providers in our study also said they did not feel competent to assess when and how to discuss metformin treatment for prediabetes. They expressed interest in learning more about which groups of patients may be more likely to benefit from metformin, a topic they previously knew little about, and a desire for tools to facilitate the conversation. Our study found that only a minority of providers were willing to consider using metformin for patients who were unable to make lifestyle changes. These findings suggest that educating PCPs about the potential benefits of metformin and patient preferences to discuss this treatment option may represent a strategy for promoting metformin recommendations in primary care.

Our study has several limitations. The generalizability of the findings is limited by the nature of the study design, which involved interviewing a convenience sample of self-selected participants from two primary care clinics in Chicago, Ill. Furthermore, the perceptions of academically affiliated PCPs may differ from those of PCPs practicing in community-based settings. Our qualitative methods yielded rich data on PCPs' perceptions and attitudes about prediabetes and its management but did not allow us to examine their actual behavior related to diabetes prevention. Because providers in our study were presented with evidence about the effectiveness of ILI and metformin during the interview, it is likely that this information shaped their opinions about these two treatments.

Conclusion

Primary care is an important setting in which to improve the detection and treatment of prediabetes. From a provider perspective, prediabetes detection should be targeted to patients who are most likely to benefit from diagnosing and treating the condition, despite a lack of consensus about which patients are at highest risk of developing diabetes or its downstream complications. Educating PCPs about evidence-based treatments for prediabetes and how to effectively discuss treatment options with patients may improve decision-making about diabetes prevention. In addition, increasing patient access to effective lifestyle interventions may increase providers' engagement in diabetes prevention efforts. Finally, additional research is needed to help determine whether a patient-centered treatment approach, which incorporates patients' individual risk, values, and preferences (29), can improve care and outcomes for patients with prediabetes.

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Duality of Interest

N.R.K. received salary support from the American Medical Association that was not related to her participation in this study. No other potential conflicts of interest relevant to this article were reported.

Author Contributions

N.R.K. wrote the manuscript, researched data, contributed to discussion, and reviewed and edited the manuscript. All

other authors researched data, contributed to discussion, and reviewed and edited the manuscript. N.R.K. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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