

Barriers to Initiating Insulin in Type 2 Diabetes Patients: Development of a New Patient Education Tool to Address Myths, Misconceptions and Clinical Realities

Meryl Brod · Suzanne Lessard Alolga ·
Luigi Meneghini

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Abstract

Purpose The purpose of this study was to identify patient beliefs as well as clinical realities about insulin that may be barriers to type 2 diabetes patients initiating insulin treatment when recommended by their physician. This information was then used to develop a clinically relevant, cross-culturally valid patient education tool with the goal of providing unbiased, medically informative statements addressing these barriers.

Methods Thirteen focus groups were conducted in five countries (Germany, Sweden, The Netherlands, UK, and USA) to collect qualitative data on attitudes about insulin therapy from type 2 diabetes patients aged 18 or older whose physician had recommended initiating insulin treatment in the past 6 months ($n = 87$). Additionally, a panel of four clinical experts was interviewed to ascertain obstacles they experience in initiating insulin with their patients.

Results On the basis of the interview data, the ten questions that asked about the most important barriers were generated. The clinical expert panel then generated clinically accurate and unbiased responses addressing these concerns, and the educational tool “Questions about Starting Insulin: Information on the Myths, Misconceptions and Clinical Realities about Insulin” was drafted. The draft tool was pilot tested in a group of patients and finalized.

Conclusions Patient misconceptions, as well as some clinical realities, about insulin treatment and diabetes can

influence the decision to initiate insulin treatment and ultimately impact disease management. The educational tool developed through this study was designed to help patients who are deciding whether or not to initiate insulin therapy as recommended by their physician, and facilitate patient–health-care provider interactions.

Key Points for Decision Makers

When a physician has determined a patient with type 2 diabetes should initiate insulin therapy, they may face resistance from the patient due to their beliefs as well as some clinical realities of insulin treatment.

This time point when patients are considering a transition to insulin is a critical junction at which to address any barriers to initiating insulin treatment.

An educational tool that directly responds to the most common issues raised by patients at this junction has the potential to help facilitate the initiation of insulin treatment sooner, improve treatment compliance so that optimal glucose levels can be achieved faster, and improve long-term diabetes management.

M. Brod (✉) · S. L. Alolga
The Brod Group, 219 Julia Avenue, Mill Valley,
CA 94941, USA
e-mail: mbrod@thebrodgroup.net

L. Meneghini
Global Diabetes Program, Parkland Health and Hospital System,
Division of Endocrinology, University of Texas Southwestern
Medical Center, Dallas, TX 75390, USA

1 Introduction

Type 2 diabetes mellitus is a chronic, progressive illness that affects 347 million people worldwide [1] that when poorly controlled often results in complications including

death. The World Health Organization estimates that total diabetes-related deaths will increase by 50 % in the next 10 years, and has characterized the disease as an epidemic [2].

The successful management of diabetes depends on maintaining blood glucose levels within a recommended target range, as well as appropriately modifying other cardiovascular risk factors such as hypertension and dyslipidemia. For example, early control of blood glucose has been shown to reduce risks of morbidity and mortality from coronary disease [3]. Type 2 diabetes is a progressive disease, and as beta cell dysfunction progresses, many patients will eventually need insulin treatment [4, 5]. Earlier initiation of insulin therapy may also improve the health and morbidity of patients with diabetes [3, 6–9]. However, even well-controlled diabetes could over time become more difficult to manage [10, 11].

Unfortunately, both patients and clinicians are often reluctant to begin or intensify insulin treatment, a phenomenon that has sometimes been referred to as psychological insulin resistance (PIR) [12–16]. Clinicians may choose to delay initiation until it is “absolutely necessary,” only after alternative therapies have been attempted and have failed to achieve or maintain glycemic control [17]. However, this strategy runs the risk of initiating insulin only when the disease has significantly advanced and the patient has already experienced more advanced complications [8, 9, 18]. Other clinician barriers to insulin initiation that can be considered as clinical realities of initiating insulin treatment include (a) concern that patients would resist insulin therapy, (b) the impact on the practice’s resources, such as the time needed to properly educate patients and their families on the role of insulin replacement therapy, (c) the intensive monitoring needed during the initial phase of insulin initiation and titration, (d) the education required for the management of any crises, and (e) the risk of hypoglycemia from insulin therapy [19–22]. Finally, clinicians may be apprehensive about weight gain with insulin [23]. For the insulin-naïve patient, PIR may be rooted in logistical obstacles to initiating insulin, such as difficulties in self-injecting the insulin and ability to appropriately estimate and time doses with meals [12]. Other common barriers to insulin initiation among insulin-naïve patients include (a) misconceptions regarding insulin risk, (b) beliefs that needing insulin reflects a personal failure, (c) concerns that insulin is ineffective and that insulin injections are painful, and (d) anxiety about long-term complications and side effects of therapy, loss of independence, and cost [12, 17, 24, 25].

Insulin treatment must also be considered within the broader context of treatment regimens and self-

management practices that patients with type 2 diabetes have already experienced. A study exploring patients’ perceptions and experiences with oral medications, for example, revealed several concerns among those who were exclusively on a diet regimen, including potential side effects and fear that oral medications would inevitably lead to a need for insulin therapy, as well as signal that they had “failed” in their self-care efforts [26]. Qualitative research into patients’ perceptions and experiences has identified several challenges that patients face in their efforts to control their diabetes through lifestyle and medication regimens, physically, socially, emotionally, and financially [27]. Self-monitoring blood glucose, for example, may provide patients with a sense of success or reassurance that their diabetes is under control, as well as provide a means for assessing the efficacy of lifestyle practices and medication usage. However, high glucose readings may produce feelings of anxiety, disappointment, and shame, as well as become a source of confusion if the readings do not appear to correspond to a patient’s efforts to maintain a treatment regimen [28–31]. While patients frequently blame themselves for poor outcomes in their diabetes regimen, studies examining patient-provider dimensions have noted the need for improved communications regarding the disease progression of diabetes, the purpose of blood glucose monitoring, establishing expectations and clear instructions for self-care practices, the provision of information in a non-judgmental way, and regimens tailored to meet the unique needs of individual patients [26, 30–34].

Thus patients’ perceptions about insulin treatment, which may be based on a combination of myths, misconceptions, clinical realities, prior experiences with other diabetes regimens, and communications with their health care providers, may present obstacles to appropriate treatment intensification, optimal blood glucose control, and long-term diabetes management. Addressing these barriers is crucially important to timely initiation of insulin treatment. A better understanding of the meaning of, and barriers to, insulin from the patient’s perspective will assist both patients and clinicians by providing needed information that can be used for patient education and patient–health-care provider interactions.

The purpose of this research project was twofold: first, to identify the common beliefs about insulin therapy held by people with type 2 diabetes who are considering initiating insulin treatment; second, to develop in a scientifically rigorous manner an educational tool for diabetes educators and other health care professionals to use in educating patients, which could provide clinically relevant, cross-culturally valid, and unbiased facts that address the myths, misconceptions, and clinical realities that are barriers to initiating insulin.

2 Methods

Data collection and analysis for this study were informed by the Health Belief Model (HBM) [35]. The HBM is based on the premise that health behaviors are derived from an individual's perceptions of a disease and his/her capacity to avoid or mitigate it, including the disease's severity and the individual's personal susceptibility to it; potential benefits to adopting a health behavior to address the disease; potential costs or barriers to adopting the behavior; the ability to successfully carry out the behavior (self-efficacy); and cues or motivations to take action, which may be internal (e.g., symptoms) and/or external (e.g., health education messages, a family member with the same condition, etc.) [35–37]. It should be noted that the relationships between and among these factors are not straightforward and may also be influenced by several other factors, including socioeconomic status, level of education, past experience, and cultural context [37, 38]. In addition, while all dimensions of the HBM are relevant to this research, the primary objective was to identify and address the barriers to initiating insulin treatment. Thus while this model is a useful heuristic tool, it served as an analytic guide rather than a rigid structural framework for organizing and interpreting study findings.

Both patient and clinician data sources were used to identify the barriers to initiating insulin treatment. Additionally, both qualitative and quantitative data were collected from patients to better understand the factors influencing participants' decisions about initiating insulin and patient-held beliefs regarding the process. The qualitative component was designed to elicit the way that patients themselves spoke of their beliefs and concerns about insulin treatment. The quantitative component was designed to rank the importance of factors that patients felt influenced their decisions about initiating insulin treatment.

Along with the patient data, interviews were also conducted with diabetes experts to ascertain barriers that they had experienced in their practice when trying to initiate insulin treatment with their patients.

This project was approved by Copernicus Group Independent Review Board, Durham, NC, USA, and was conducted between 2012 and 2013.

2.1 Patient Data

In order to capture the patient voice, qualitative data were collected from 13 focus groups conducted in five countries (Germany, Sweden, The Netherlands, UK, and USA). The objective of the interviews was to understand the perspective of people with type 2 diabetes who, because of poor blood glucose control, had recently (in the past 6 months) been faced with the decision about whether or

not to initiate insulin therapy and to identify the relevant factors that impacted their treatment decision-making process. The focus groups followed a semi-structured interview guide that was based on a literature review and interviews with diabetes experts. The literature search included the MeSH terms “decision making AND diabetes mellitus AND insulin,” and terms searched in free text included, but were not limited to the following: decide/decision/deciding; initiate/start/begin insulin or insulin initiation; decision making; and choose/choice/choosing. The rationale for using a semi-structured interview guide was to allow for guided conversation and to encourage issues to arise that may be novel to that particular group or country. The focus group guide emphasized discussion about the pros and cons of initiating insulin and the factors/issues participants thought about when considering adding insulin to their treatment. As a result, participants talked about beliefs they held about insulin and diabetes and about what factors most influenced their treatment decisions. Issues raised by participants were then used to direct and inform subsequent interviews, and allowed us to identify additional factors that influenced decision-making.

Focus group interviews were conducted first in the USA, followed by those in Europe. The iterative methodology utilized resulted in a more open-ended discussion in the USA and a more targeted focus for the European groups. Specifically, themes identified in the first groups were tested as draft statements for the tool under development in the later groups. Furthermore, the focus group guide used in Europe was adjusted to include decision-making scenarios with multiple choice answers to focus the discussion on the kinds of decisions participants faced when advised to initiate insulin.

English-language focus groups were conducted by the first author, who is a trained qualitative interviewer and group facilitator. Focus groups in non-English speaking countries were conducted by experienced group moderators proficient in the native language. One of the authors was on site for all non-English focus groups to train the moderator on the intent of the discussion guide, verify eligibility of participants, and listen and observe body language and expressions in real time in the focus group, using simultaneous translation.

Eligible study participants were over the age of 18, read and spoke the native language of the country in which they resided, had a diagnosis of non-insulin-treated type 2 diabetes, and had, within the past 6 months, self-reported facing the decision to begin insulin treatment as per a clinician's recommendation. Participants were identified by an international professional research organization that recruited and hosted the focus groups at their or their affiliates' facilities in each country. To recruit, the organization contacted individuals enrolled in their proprietary

databases and asked physicians/nurses enrolled in their databases for referrals, and additionally, in Sweden, collaborated with diabetes organizations to invite their members and used a daily newspaper advertisement. All participants were prequalified using a screening script to verify eligibility and were required to show proof of taking diabetes medication (in the form of medications or a prescription). Recruitment goals per country were to enroll approximately an equal mix of those who initiated insulin and those who did not when recommended by their physician.

Focus group transcripts were transcribed into English, if necessary, by the professional research organization and then analyzed thematically using the qualitative analysis software program ATLAS.ti. Descriptive coding was used to identify emerging concepts, and transcripts were coded in the chronological order in which the focus groups occurred. These codes were then aggregated into major themes based on a modified grounded theory approach [39, 40].

Quantitative data were collected at the completion of the focus group discussion, using a brief patient-reported outcome (PRO) survey developed for the study from literature review and previous focus group results. The survey assessed the importance of 24 factors (e.g., weight gain, long-term complications) for participants deciding on whether or not to begin insulin treatment. Respondents ranked each factor from 0 (not at all important) to 10 (extremely important).

2.2 Clinical Data

The first author identified and invited four diabetes clinical experts in the USA and UK who had extensive expertise in treating type 2 patients, were published in the field, had research experience, and were interested in the development of a tool to help educate patients on insulin initiation to serve as the expert panel for the study. The experts included a diabetes education nurse and three practicing physicians (two directors of diabetes treatment centers and one family medicine practitioner). All experts also held academic positions. Individual telephone interviews were held first with the experts, to identify any issues and barriers that they had experienced when trying to initiate insulin treatment with their patients. This information was then combined with the patient information for the qualitative analysis of the interviews and development of the tool questions. Once the tool questions were formulated, the panel was convened by telephone to participate in the writing and editing of responses. Telephone conferences continued until a consensus of all experts was reached that the responses were suitable for a patient education tool and considered accurate and unbiased. Clinical experts were remunerated only for their actual time spent on the project.

2.3 Development of Tool Questions

On the basis of the analysis of the patient and clinical expert data, questions were then generated, which captured the major concern of each barrier identified by either patients or the clinicians. The panel of experts then developed what they believed to be scientifically accurate, factual, and unbiased responses to these questions, which addressed these barriers, and the first version of the tool was drafted.

After clinical panel review and revision, the tool was cognitively debriefed in 11 participants (USA) to confirm the content was clear, understandable, inoffensive, and relevant. Participants were recruited following the same methodology and eligibility criteria as the focus groups, but were unique patients from those who participated in groups. Each participant reviewed the tool in an individual, in-person interview following a structured interview guide that asked about relevance, comprehension, and understanding of each question and response in the tool. The debriefing was an iterative process; issues raised were reviewed and content revised, when appropriate, to eliminate the issue, and then the revised content was used for further interviews.

3 Results

3.1 Patient Sample Characteristics

Eighty-seven people participated in 13 focus groups conducted in five countries. Groups were held first in the USA [Los Angeles ($n = 10$), Chicago ($n = 8$), and New York ($n = 10$)], followed by the UK [London ($n = 15$)], Sweden [Stockholm ($n = 15$)], The Netherlands [Rotterdam ($n = 14$)], and Germany [Munich ($n = 15$)]. One group was held in each US city, two groups were held each in London and Munich, and three groups were held each in Stockholm and Rotterdam. Thematic saturation of the themes relevant to the objective of this paper occurred by the tenth focus group, after which no new themes emerged.

Thirty-eight participants (43.7 %) had decided to begin insulin after recommendation by their clinician, while 49 (56.3 %) had decided not to begin insulin treatment (Table 1). The mean age of participants was 52.9 years (range 20–82 years), with an average age at diabetes diagnosis of 45.5 years (range 15–74 years); 50 (57.5 %) were male, 51 (58.6 %) were married/partnered, and 58 (66.7 %) reported they lived with others. Half (50.6 %) of participants had a college/undergraduate degree or higher, with the remaining 36 (41.4 %) completing up to high school/secondary school and 6 (6.9 %) having less than a high school education. Over half of participants in this study worked for

pay (48.3 % full time, 9.2 % part time). Combined yearly household income was under US\$40,000 for 37 participants (42.5 %) and over US\$60,000 for 31 (35.6 %).

3.2 Patient-Reported Key Barriers to Initiating Insulin Treatment

3.2.1 *Insulin as a Treatment of Last Resort*

The most frequent idea about insulin therapy reported was that insulin was a treatment of “last resort,” a final treatment option in the management of diabetes, with approximately 21.8 % ($n = 19$) endorsing this idea. Similarly, 20.7 % ($n = 18$) of participants also believed that insulin was a treatment appropriate only to advanced diabetes, and 11.5 % ($n = 10$) reported hearing from their practitioners that insulin was a last resort and final treatment option for diabetes. Additionally, many participants discussed making the decision to initiate insulin when there was no longer any other treatment option ($n = 21$; 24.1 %). There were also several participants who were strongly resistant to insulin treatment even before entering into a discussion of insulin with their physician ($n = 11$; 12.6 %), who felt it would require a strong effort—and perhaps even health crisis circumstances—to convince them to consider insulin as an option. Together, these findings suggest that a majority of participants were concerned that insulin was “the end of the road.”

Participants in all countries voiced these concerns. For example:

When I think about using insulin, I think about succumbing to the disease. At that point, it's like, “I surrender.” (New York, USA)

To me it's not the needle. It's nothing to do with the needle, it's the sheer fact of this is final. This is the worst this can now get because now you're having to take insulin. (London, UK)

I took Metformin for a long time and my disease state was such that I thought to myself, you aren't really that sick, you can deal with it and the change to insulin will make me think that I am very sick, just the knowledge of once you start, you have to stick with it. (Munich, Germany)

These sentiments led to the creation of the tool question “I don't think I need insulin because I'm not really that sick. Can't I put it off until the diabetes gets worse?”

3.2.2 *Insulin as Evidence of Personal Failure to Self-Manage Diabetes*

Participants from all countries thought that the need to use insulin was evidence of a personal failure to manage their

diabetes (16.1 %, $n = 14$) and felt their physician used insulin treatment as a threat related to trying to have the patient keep their diabetes in good control through lifestyle and medication management strategies (14.9 %, $n = 13$).

If I have to take insulin, I probably haven't looked after myself. It's the last option. (Stockholm, Sweden)

Yes, a failure. Yes, you feel bad about yourself. (Rotterdam, The Netherlands)

It's one step backwards. I was fine, I did everything I could, but maybe I didn't do enough. (Rotterdam, The Netherlands)

These sentiments led to the creation of the tool question “Does needing to go on insulin mean that I've failed to manage my diabetes?”

3.2.3 *Risk of Long-Term Complications from Insulin*

Some individuals believed that insulin treatment directly caused long-term complications such as amputation or vision loss ($n = 6$; 6.9 %) or that insulin treatment damages the pancreas or causes it to shut down ($n = 5$; 5.7 %). These fears were sometimes the result of watching family members treat themselves with insulin ($n = 7$; 8.0 %), and were predominately expressed in the USA:

Well, he was going through insulin. And I was—since I was young. He wound up losing a leg. And he wound up losing his eyesight from one eye. And he passed away. He was, you know, he had cardiac arrest. But it was, it was from complications and stuff. I know the insulin was there to help him and everything. But just in my head, when I was young, growing up—yeah I—that's what I associated it with. (New York, USA)

So then I did some research on the internet and everything that I read about it says that if you are [INAUDIBLE] and you go onto insulin, that's definitely default for insulin for the rest of your life because your body is still producing—the pancreas is still producing insulin and you start going on insulin and you don't need it, it can kill your pancreas. That's what I read a lot on the internet. I did some research on that. (Los Angeles, USA)

These sentiments led to the creation of the following two tool questions: “Doesn't insulin cause the pancreas to stop working, which means I'll need to keep taking more and more insulin over time?” and “After my grandmother went on insulin, she suffered from all sorts of complications and health problems like amputations. I am afraid of the same thing happening to me”

Table 1 Sample description patient focus groups

Sample size	Value ^a (n = 87)	
	n (or mean)	% (or range)
Gender		
Female	37	42.5
Male	50	57.5
Age [years; mean (range)]	52.9	(20–82)
Marital status		
Married	44	50.6
Single	27	31.0
Partnered	7	8.0
Divorced	4	4.6
Widowed	5	5.8
Living with others		
Yes	58	66.7
No	20	23.0
Missing	9	10.3
Ethnicity ^b		
Caucasian/white	55	63.2
African American/black	7	8.1
Latino	4	4.6
Asian	4	4.6
Mixed race/other not listed	6	6.9
Missing	11	12.6
Employment status		
Full time for pay	42	48.3
Part time for pay	8	9.2
Not working for pay	31	35.6
Student	2	2.3
Missing	4	4.6
Highest level of education completed		
<High school/secondary	6	6.9
High school/secondary	36	41.4
College/undergraduate	30	34.5
Graduate (or higher)	14	16.1
Missing	1	1.1
Combined yearly household income (US\$) ^c		
<40,000	37	42.5
40,000–60,000	9	10.3
>60,000	31	35.6
Missing response	10	11.5
Age [years; mean (range)] at diabetes diagnosis	45.5	(15–74)
How long ago did you decide to add/not add insulin?		
1 month ago or less/current	14	16.1
2–4 months ago	27	31.0
5–6 months ago	32	36.8
>6 months ago	8	9.2
Missing	6	6.9

Table 1 continued

Sample size	Value ^a (n = 87)	
	n (or mean)	% (or range)
Current treatment		
Not on insulin	49	56.3
On Insulin	38	43.7
How well controlled is your diabetes?		
Very poorly	0	0
Poorly	10	11.5
Moderately	37	42.5
Well	31	35.6
Very well	9	10.3
General health		
Poor	3	3.4
Fair	21	24.1
Good	46	52.9
Very good	10	11.5
Excellent	5	5.7
Missing	2	2.3
Number of current comorbid conditions		
None	20	23.0
1	19	21.8
2–3	35	40.2
>3	7	8.0
Missing response	6	6.9

^a Values are number and percentage unless otherwise stated

^b In Europe, the majority (86.6 %) of respondents in Sweden and Germany were self-reported as white or left the item blank/not applicable (13.3 %). In The Netherlands, about two-thirds (64.3 %) of respondents left the item blank, and the remaining 35.7 % self-reported as white

^c To aggregate income data, European incomes were converted to US dollars (US\$) on the basis of average currency rates in January 2011, when focus groups were held, and thus groupings were collapsed into three categories (<40,000; 40,000–60,000; and >60,000) across all countries; the majority of missing responses were from The Netherlands (8/10)

3.2.4 Side Effects of Insulin

Participants reported concern about side effects of insulin treatment and their impact, particularly hypoglycemia. Thirty-three participants (37.9 %) spoke about side effects, and of these, 20 were concerned about the potential for hypoglycemia while on insulin (60.6 % of the 33 participants concerned with side effects and 23.0 % of all participants in the study). Participants from all countries expressed these concerns:

Well, the cons are you have to be worried about low blood sugar levels, especially if you're recently... if your dosage has gone up and also I think it's... It's

been emphasized to me how important it is now to monitor my blood sugar levels with my meter since I've started insulin. (London, UK)

If it gets too low, so that you faint. That's why I don't want it. Because I don't have anyone to look out for me, since I live on my own. (Stockholm, Sweden)

My head said do it. Emotionally I was never sure, one hears so many stories about hypoglycemia. When I eventually did switch, the first few days I couldn't sleep because I was afraid I'd oversleep but after a week I was a new person. Then I thought why didn't you switch years ago? (Munich, Germany)

These concerns led to the creation of the following tool question: "Doesn't insulin cause low blood sugar (hypoglycemia)?"

3.2.5 Treatment Convenience

Participants also reported perceptions of the inconvenience of insulin management as an obstacle to initiating treatment ($n = 17$; 19.5 %). Participants were concerned about difficulties in scheduling/arranging to inject insulin during the course of their day and around meals ($n = 14$, 16.1 %), difficulty traveling with insulin ($n = 14$, 16.1 %), and inconvenience associated with carrying insulin around during the course of their day ($n = 12$; 13.8 %). Ten participants (11.5 %) talked about embarrassment and general difficulty administering insulin in public. Eight participants (9.2 %) believed that their insulin needed to be refrigerated and viewed this as a burden. Participants from all countries shared these concerns:

I just—the whole idea of having to give myself a shot, having to make sure I'm doing it a certain amount of time before meals and things like that. I don't want to—the oral medication, I take it in the morning and then I don't think about it for the rest of the day until I take my pill again at night. I don't have to worry about doing it if I'm on the run or outdoors, or doing something like, "I can't eat yet. I have to take my shot," and those types of things. (Los Angeles, USA)

It's also the inconvenience on it. [...] I know but then I travel a lot and you need fridges. I also visit hot places and I use solar energy where I am. So, there were a lot of things. (London, UK)

Well, if they take my blood, I've got no problems, but shooting yourself is a bit of an awkward thing to do. It's a hassle, too, bringing it along, always. But, yes, it, it's going to happen in the near future, but I'm a little reluctant; but if it's better for my, for me, then I will. (Rotterdam, The Netherlands)

These sentiments led to the creation of the tool questions "If I choose to be on insulin, how much will it affect my daily life?" and "Isn't oral (pill) medication an easier way of treating my diabetes?"

It is of note that for those who made the decision to initiate insulin treatment, the management was often described as generally easy and not much of a burden at all ($n = 27$; 31.0 % of total sample and 71.1 % of those on insulin). Furthermore, many stated that they were happy with their improved blood glucose levels and that they were generally feeling better ($n = 24$; 27.6 % of total sample and 63.2 % of those on insulin). This suggests that while the transition to insulin initiation poses strong challenges, once insulin is initiated, it is perceived as easy to manage, or at least easier than was once thought.

3.2.6 Needles and Injections

Fear of needles and apprehension about injecting were also prominent among respondents ($n = 38$; 43.7 %); examples of quotes regarding this concern include:

Yes, I can understand phobias because it's exactly the same with me. If I see a needle, it doesn't matter where, even at the dentist, it is hell for me. If possible, I would try to avoid it forever. (Munich, Germany)

I was afraid it was going to hurt to shoot the needle, but after a couple weeks, it's nothing. It's actually nothing. (Los Angeles, USA)

These sentiments led to the creation of the tool question "If I give myself a shot, won't it be painful?"

3.2.7 Weight Gain from Insulin

Finally, concerns about weight gain with diabetes in general and specifically around insulin and oral medications were expressed by half of the respondents ($n = 46$; 53 %); approximately a quarter of these respondents' comments were directly related to concerns about managing their weight with treatments. Concerns regarding weight gain related to treatment were found across all countries:

If you could control it with everything else, he (my doctor) said insulin could cause your weight to go up and stuff like that. (Los Angeles, USA)

I don't think it (insulin) causes it but I don't think it helps. I don't... I think it's harder to lose weight from it. That's what I've been told. That's what I've read. (London, UK)

I've heard that it's insulin that causes weight gain, rather than the tablets. But I'm not sure. That was mentioned at one of the Diabetes Schools I went to.

They mentioned that they're trying to develop insulins that don't affect the weight as much. Because you usually put on weight when you take insulin. (Stockholm, Sweden)

These sentiments led to the creation of the tool question "I hear that insulin causes weight gain? Do diabetes pills also cause weight gain?"

3.3 Patient Ranking of Factors Influencing Decision-Making

Patients self-reported the importance of each factor in influencing their insulin taking decision (Table 2). There were no factors in the rankings that were not also discussed in the focus groups as being relevant.

For the group as a total, the top six most important factors were a combination of types of factors: long-term diabetes complications, blood glucose control (treatment efficacy), concerns about diabetes getting worse, ease of taking medication, side effects, and convenience. Overall, the most influential factors in the decision-making process related to efficacy: long-term diabetes complications, blood glucose control (treatment efficacy), and concerns about your diabetes getting worse. This aligned with the 'myths' and concerns heard in the focus groups, such as long-term complications are due to insulin treatment, not diabetes itself, and that the body will become habituated to insulin, leading to less efficacy over time—potentially making the disease worse. The factors ranked next as most influential were related to treatment burden, such as ease of taking medication, convenience, daily injections, and issues of traveling with insulin. These also aligned with themes of inconveniences such as carrying or traveling with insulin and the number of injections per day. However, the spread of importance rankings among the majority of factors (19 out of 24) was attenuated with all ranked as being of moderate or greater importance. Thus, it does not appear that any one factor, such as efficacy or convenience, is the single most important driver for the decision whether or not to start insulin treatment. This suggests that any educational tool designed to help patients make the decision whether or not to initiate insulin treatment should address a range of myths, misconceptions, and clinical realities.

Participants who had decided to begin insulin ranked their top three most important factors as blood glucose control (treatment efficacy), long-term diabetes complications, and concerns about diabetes getting worse. Participants who had decided not to begin insulin overlapped in two of the top three factors, but differed in the ordering, ranking long-term diabetes complications first, ease of

taking medication second, and blood glucose control (treatment efficacy) third.

3.4 Clinical Expert Input

The clinical experts identified one additional barrier, which they believed, based on experience, was an obstacle to initiating insulin that was not directly suggested by the patient data analysis: concerns about adjusting insulin doses. Based on this information, the following question was also included in the tool: "Why do I have to adjust the dose of insulin I am taking?"

3.5 Generation and Formatting of Tool Responses to Questions

In the focus groups, participants were asked their preference for educational material formats, such as printed brochure, patient-hosted video, or online resource center. Their preference was for easy to understand educational materials written from the patient's perspective (testimonials), and including neutral unbiased facts presented by a trusted source such as a health care professional, medical organization or advocacy organization. On the basis of these preferences, the expert panel generated scientifically accurate and factual responses to the questions, which they believed were unbiased and not designed to coerce a patient to initiate insulin. The draft version brochure style tool was created, using the patients' words, as much as possible, to state the myth, misconception, or clinical reality, followed by the physician response to the question.

3.6 Cognitive Debriefing of the Tool

On the basis of the data analysis, the draft tool was generated and cognitively debriefed in the USA to confirm that the language was clear, understandable, inoffensive, and relevant, and that the format was acceptable [41]. Four blocks of two to three cognitive debriefing interviews each were conducted, totaling 11 participants. The inclusion/exclusion criteria used was the same as the focus groups' criteria. Overall, the demographics were similar, though the debriefing sample was more ethnically and racially diverse—six (54.5 %) white, two (18.2 %) Hispanic/Latino, two (18.2 %) African American/black, and one mixed race participant (9.1 %); and a majority (63.6 %) of participants in the debriefing were not working for pay.

Overall, the statements were well received and understood. Feedback from the debriefing interviews resulted in only minor revisions to the text. Consensus was reached by the fourth block of interviews, when no significant issues were raised by participants.

Table 2 The importance of factors influencing decision-making process

On insulin (<i>n</i> = 37)		Not on insulin (<i>n</i> = 50)		Sample total (<i>n</i> = 87)	
Factor	Mean score	Factor	Mean score	Factor	Mean score
Blood glucose control (treatment efficacy)	8.7	Long-term diabetes complications	7.8	Long-term diabetes complications	8.2
Long-term diabetes complications	8.7	Ease of taking medication	7.8	Blood glucose control (treatment efficacy)	8.1
Concerns about your diabetes getting worse	8.6	Blood glucose control (treatment efficacy)	7.7	Concerns about your diabetes getting worse	8.0
Weight change	6.7	Concerns about your diabetes getting worse	7.6	Ease of taking medication	7.2
Side effects	6.5	Side effects	7.3	Side effects	7.0
Convenience	6.5	Daily injections	7.3	Convenience	6.9
Ease of taking medication	6.4	Convenience	7.3	Daily injections	6.8
Daily injections	6.0	Issues of traveling with insulin	6.7	Weight change	6.3
Hypoglycemic events	5.2	Treatment burden	6.6	Issues of traveling with insulin	6.0
Issues of traveling with insulin	5.1	The number of times a day you have to take medication	6.6	Hypoglycemic events	6.0
Psychological impact	4.8	Hypoglycemic events	6.5	Storage of medication	5.8
Storage of medication	4.8	Storage of medication	6.5	The number of times a day you have to take medication	5.7
Ability to exercise or be very physically active	4.8	Lifestyle interference	6.4	Treatment burden	5.7
Management around meals	4.8	Management around meals	6.2	Management around meals	5.6
Pain, discomfort of injections	4.6	Weight change	6.1	Lifestyle interference	5.6
Lifestyle interference	4.5	Psychological impact	5.9	Psychological impact	5.4
The number of times a day you have to take medication	4.4	Feelings of personal failure	5.9	Pain, discomfort of injections	5.3
Treatment burden	4.3	Pain, discomfort of injections	5.7	Ability to exercise or be very physically active	5.2
How you feel about yourself because of your type of treatment	4.3	How you feel about yourself because of your type of treatment	5.6	How you feel about yourself because of your type of treatment	5.1
Fear of needles	3.9	Ability to exercise or be very physically active	5.5	Feelings of personal failure	4.8
Feelings of personal failure	3.3	Fear of needles	5.3	Fear of needles	4.7
Social/personal relationships	3.1	Social/personal relationships	4.7	Social/personal relationships	4.0
Being treated differently by others	2.5	Being treated differently by others	3.5	Being treated differently by others	3.1
Worrying others may think you are a drug addict if you are injecting insulin	1.9	Worrying others may think you are a drug addict if you are injecting insulin	2.8	Worrying others may think you are a drug addict if you are injecting insulin	2.4

The table represents patient self-reported scores of how important each factor was in influencing their decision whether or not to initiate insulin on a scale from 1 (not at all important) to 10 (extremely important). Mean scores are listed in order of most important to least important

3.7 The “Questions about Starting Insulin: Information on the Myths, Misconceptions and Clinical Realities about Insulin” Educational Tool

The tool questions and responses were edited following the cognitive debriefing. After additional clinical review was completed, the “Questions about Starting Insulin: Information on the Myths, Misconceptions and Clinical Realities about Insulin” tool was finalized, as presented in Table 3.

4 Discussion

Barriers to initiating insulin when clinically advisable and in a timely manner can influence people with diabetes in their decision on whether or not to initiate treatment, and ultimately impact the management of their diabetes. Some of these patient concerns are myths and/or misconceptions, while others are realities of insulin treatment that may require further discussion

between patients and their providers to adequately address.

The findings of our study support previously proposed educational materials and toolkits addressing barriers to insulin initiation [44, 48–53] as well as the findings from the Diabetes Attitudes, Wishes and Needs (DAWN) international survey study, which demonstrated that patient resistance is the most significant barrier to the timely initiation of insulin therapy, and that physicians may also present barriers to insulin initiation, preferring to initiate insulin only when “absolutely necessary” and using it as a threat to motivate their patients [17, 25, 54–56].

On the basis of the findings of factors influencing patients’ decision to initiate insulin and in order to accommodate the need for educational information, we developed this tool. The questions and responses in the tool are based on what is important to patients and clinicians in discussing the initiation of insulin treatment and are presented in lay person terminology, using the language patients used in the focus groups. The tool is designed to serve a twofold purpose: first, to help educate patients who are making the decision about whether or not to initiate insulin; and second, to serve as a tool in health care professionals’ dialog with their patients. Participants for this study were selected because they had recently been at the critical junction of deciding whether or not to initiate insulin treatment. Some participants were not aware that early initiation of insulin can potentially lead to better control and that they may feel better once they are on insulin (for example, they will have more energy), or that insulin is a “natural” physiological replacement treatment for diabetes (data not shown). Additionally, the study shows that most beliefs and concerns were consistent amongst the five participating countries despite other socio-cultural differences that may exist.

It is important to understand patients’ beliefs about barriers to insulin initiation as early as possible in the disease process. By understanding these factors early, and using targeted, scientifically correct information to counter negative or incorrect impressions, health care practitioners may be able to appropriately influence patients to initiate insulin therapy sooner. Once on insulin, there is then the potential to reduce patients’ negative opinions of insulin treatment [57] and to improve their treatment satisfaction. Improving treatment satisfaction is of special importance given the positive association between treatment satisfaction and medication compliance [58–62]. Interestingly, the top ranked factors important in making the decision on whether or not to start insulin appear to mirror the three important factors of treatment satisfaction—burden, efficacy, and symptoms—with efficacy usually being the most important driver of patient satisfaction [63]. Thus the factors that influence whether or not to initiate insulin seem to be the same factors that influence treatment satisfaction.

A challenge for health care providers is that some people who hold myths and misconceptions about initiating insulin treatment may have difficulty changing their opinions, particularly when these are influenced by their family members’ experience with diabetes (often attributed to insulin use). Additionally, people with preconceived notions and fears about insulin therapy can be steadfast in their decision to delay or not start treatment. These patients require special attention from providers, who need to recognize these barriers to treatment and proactively identify and address proper insulin initiation and optimization to reduce future disease burden. Most patients reported that their health care providers discussed issues of efficacy with them and that they trusted their provider, though many still chose not to initiate insulin treatment. Thus, it appears that for some patients, their internal fears and beliefs were stronger than their health care provider’s advice. Health care providers may have to be especially proactive in eliciting and discussing the concerns raised by these patients, and possibly refer them to qualified diabetes educators if they themselves lack the time to address informational gaps. Further, while the purpose of the project was to develop a tool for patients, it is recognized that a tool for health care providers to assess what is important to a given individual patient would also be of benefit.

There are methodological limits to this study, and as is often the case with qualitative research, generalizability to larger populations is a fundamental issue. First, there are interpretive challenges due to the condition of the transcripts and translations in countries where English is not the first language. Further, not all respondents had the opportunity to respond to every discussion point during the focus group and may have only responded to what others brought up with a head shake or other non-codable action. Further, the initial focus groups were conducted in the USA and a preliminary analysis resulted in draft measure statements that were then tested in subsequent focus groups in Europe. Together, these considerations made it difficult to get precise counts of participants who supported each of the tool questions. It relies on the experience of the moderator and analyst to interpret the transcripts and identify key themes given these limitations. Those involved in this study have more than 55 combined years of experience conducting and analyzing focus group transcripts, and we hope this experience has mitigated some of this limitation.

Also, although all participants had been faced with a decision to initiate insulin in the 6 months prior to the interview, some had chosen insulin and others had not. Given that those who had chosen insulin often felt better and more in control as a result of their insulin treatment, their discussion of factors they took into consideration in making their decision may have been somewhat skewed. However, since it was not the purpose of the study to

Table 3 Questions about starting insulin: information on the myths, misconceptions and clinical realities about insulin

Here are some of the questions and fears people with diabetes often have when changing their medicines:

“Isn’t oral (pill) medication an easier way of treating my diabetes?”

Pills are simple and easy to swallow, but they rely on the insulin in your body to work. As your diabetes progresses and your body makes less insulin, pills may not work as well to keep your blood sugar at your target level [42, 43]

“After my grandmother went on insulin, she suffered from all sorts of complications and health problems like amputations. I am afraid of the same thing happening to me”

Although the problems your grandmother faced might have started around the time she started insulin, these problems were not caused by insulin. They were caused by the diabetes [44]. These problems are known to be related to high blood sugar levels, and not insulin. It is very possible that if your grandmother had started using insulin sooner, she might have delayed or prevented these serious complications of diabetes by having better control of her blood sugar over the years [25]. We now know that starting insulin earlier in the course of diabetes helps to delay or prevent the serious complications and health problems that can be caused by long periods with high blood sugar levels [42, 43]

“I don’t think I need insulin because I’m not really that sick. Can’t I put it off until the diabetes gets worse?”

Although many people think of insulin as a “treatment of last resort,” that really is not true. Even though you don’t feel sick or have complications, your high blood sugar levels are taking a toll on your body [42]. Starting insulin does not mean that your diabetes is worse. It is just the opposite—insulin can help you stay healthier by keeping your blood sugar level on target [42, 43]

“I hear that insulin causes weight gain? Do diabetes pills also cause weight gain?”

It is true that some people who begin taking insulin do gain weight [44]. Insulin helps you to use food more efficiently, so even if you eat the same amount as before, you may gain some weight [45]—somewhere between 4 and 9 pounds [4]. If this is a concern for you, talk with your doctor about it and ask for a referral to an educator or dietitian. You can help prevent the weight gain by becoming more active or making some changes in your eating habits [42, 43]. While some of the pills used to treat diabetes can make you gain weight, others (such as metformin) do not usually affect your weight

“Does needing to go on insulin mean that I’ve failed to manage my diabetes?”

Needing insulin does not mean that you have failed or that you have not tried hard enough [46]. Over time, your pancreas makes less insulin and your body needs more help to keep your blood sugar on target [42, 43]. This will likely happen, no matter what steps you’ve taken, or how hard you’ve tried to manage your diabetes [44]. So the insulin you take is just replacing the insulin that your body is no longer making [42, 43]

“Doesn’t insulin cause the pancreas to stop working, which means I’ll need to keep taking more and more insulin over time?”

No, this is not true. Insulin helps by adding to the natural insulin that your body makes [42, 43]. It doesn’t damage or slow down the pancreas, where your own insulin is made [10, 47]. In some cases it may even give your pancreas a rest from the stress of high blood sugars

“Why do I have to adjust the dose of insulin I am taking?”

It is likely that it will take some time to find the best dose of insulin for you, and your dose will likely change over time. This does not mean your diabetes is worse, it just means you need more or less insulin to keep your blood sugar level on target [42, 43]. Your dose may also be adjusted depending on what you eat, how active you are and how much you weigh [42, 43]. Your blood sugar monitoring levels will help you and your health care provider to decide how to adjust your dose

“Doesn’t insulin cause low blood sugar (hypoglycemia)?”

It is true that insulin is more likely to cause a low blood sugar reaction than diabetes pills [42, 43]. However, with modern, longer-acting insulins (insulins that work slowly and for a longer period of time in your body), low blood sugar or “hypos” are less likely to happen than with the fast-acting insulins—but it can still happen [42, 43]. This is one of the reasons insulin dose is adjusted. When you learn how to take insulin, you will also learn how to prevent low blood sugar, how to know when it is happening, and what to do if it happens [42, 43]

“If I choose to be on insulin, how much will it affect my daily life?”

Using insulin does mean that you will have to give yourself shots, but they can be done in privacy, and most people find that it is easy to do once they learn how to do it. It also means you may need to check your blood sugar more often than you are doing now [42, 43]. Many studies have shown that when insulin is started, people find that they have more energy, have more flexibility in planning their day-to-day lives and feel better about themselves due to the improvement in blood sugar control [25, 44]

“If I give myself a shot, won’t it be painful?”

Most people are surprised at how little an insulin shot hurts [25, 44]. Most people find the pain level from an insulin shot to be less than that of a finger-stick for routine blood sugar monitoring [44]

identify how those who decide to initiate insulin differ from those who do not, we do not believe the identification of major issues considered by both groups when thinking about initiating insulin was hindered. A barrier to initiation does not assume that it is an insurmountable obstacle as some respondents with the same concerns chose to start

treatment while other did not. This conclusion is supported by the fact that both groups quantifiably identified two of the same top three factors that they considered when thinking about the issue.

This study was designed to only examine the barriers to initiating insulin for insulin-naïve patients. However,

although patients already receiving insulin have more favorable appraisals of insulin and fewer barriers to intensifying insulin treatment compared with those initiating insulin, many still have concerns about disease progression, hypoglycemia, and weight gain [64–66]. Barriers to continued adherence to insulin or intensification of insulin regimes over time were not examined in this study, and similar work to understand these barriers in the patient voice is warranted. Finally, patients in most health systems are often educated not only by physicians, but also by nurses, diabetes educators, dietitians, and formal diabetes educational program staff. The study guide for these focus groups focused primarily on physicians; consequently, participants spoke most about their relationships and conversations with physicians. Only a few spoke spontaneously about interactions with other health professionals, and did so without analyzable specifics. Further research on the influence of other health professionals who often play a key role in patient care, such as nurse educators, is warranted.

5 Conclusions and Implications

“Questions about Starting Insulin: Information on the Myths, Misconceptions and Clinical Realities about Insulin” is an educational tool for diabetes patients facing the decision of whether or not to start insulin. This tool can assist both patients and clinicians by providing information to be used for patient education and patient–health-care provider interactions. This document was generated following scientifically rigorous principles for the development of PRO measures. It has confirmed content validity (including cross-cultural applications), is written in the patient’s voice, and was designed to be unbiased and clinically relevant. Thus, it is a valuable addition to the currently available materials to help educate patients and promote optimal diabetes management.

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Stephen A. Brunton, MD, Adjunct Clinical Professor, Department of Family Medicine, University of North Carolina, Chapel Hill, USA.

Martha M. Funnell, MS, RN, CDE, Associate Research Scientist, Department of Medical Education, University of Michigan Medical School, USA.

Julio Rosenstock, MD, Director, Dallas Diabetes and Endocrine Center at Medical City and Clinical Professor of Medicine, University of Texas Southwestern Medical School, Dallas, Texas, USA.

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Author contributions Meryl Brod and Suzanne Lessard Aolga conducted all patient interviews, participated in the data analysis, tool development, and manuscript preparation. Luigi Meneghini participated in the tool development and manuscript preparation. Meryl Brod is the guarantor for the overall content of the manuscript.

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References

1. Danaei G, Finucane MM, Lu Y, Singh GM, Cowan MJ, Paciorek CJ, et al. National, regional, and global trends in fasting plasma glucose and diabetes prevalence since 1980: systematic analysis of health examination surveys and epidemiological studies with 370 country-years and 2.7 million participants. *Lancet*. 2011;378(9785):31–40.
2. World Health Organization. Diabetes. Fact Sheet. Number 31 World Health Organization. 2012 <http://www.who.int/media/centre/factsheets/fs312/en/index.html>. Accessed 29 Nov 2012.
3. Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study.” *BMJ*. 2000;321:405–12.
4. Nathan DM, Buse JB, Davidson MB, Ferrannini E, Holman RR, Sherwin R, et al. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*. 2009;32:193–203.
5. Logtenberg SJ, Kleefstra N, Ubink-Veltmaat LJ, Houweling ST, Bilo HJ. Intensification of therapy and no increase in body mass index with longer disease duration in type 2 diabetes mellitus (ZODIAC-5). *Fam Pract*. 2007;24:529–31.
6. de Vegt F, Dekker JM, Ruhe HG, Stehouwer CD, Nijpels G, Bouter LM, et al. Hyperglycaemia is associated with all-cause and cardiovascular mortality in the Hoorn population: the Hoorn study. *Diabetologia*. 1999;42:926–31.
7. Wild SH, Smith FB, Lee AJ, Fowkes FG. Criteria for previously undiagnosed diabetes and risk of mortality: 15-year follow-up of the Edinburgh Artery Study cohort. *Diabet Med*. 2005;22:490–6.
8. Meneghini L. Why and how to use insulin therapy earlier in the management of type 2 diabetes. *South Med J*. 2007;100:164–74.
9. Lingvay I, Kaloyanova PF, Adams-Huet B, Salinas K, Raskin P. Insulin as initial therapy in type 2 diabetes: effective, safe, and well accepted. *J Investig Med*. 2007;55:62–8.
10. UK Prospective Diabetes Study 16. Overview of 6 years’ therapy of type 2 diabetes: a progressive disease. UK Prospective Diabetes Study Group [erratum in *Diabetes*. 1996;45:1655]. *Diabetes*. 1995;44:1249–58.
11. Koro CE, Bowlin SJ, Bourgeois N, Fedder DO. Glycemic control from 1988 to 2000 among U.S. adults diagnosed with type 2 diabetes: a preliminary report. *Diabetes Care*. 2004;27:17–20.
12. Brod M, Kongsø JH, Lessard S, Christensen TL. Psychological insulin resistance: patient beliefs and implications for diabetes management. *Qual Life Res*. 2009;18:23–32.

13. Larkin ME, Capasso VA, Chen CL, Mahoney EK, Hazard B, Cagliero E, et al. Measuring psychological insulin resistance: barriers to insulin use. *Diabetes Educ.* 2008;34:511–7.
14. Polonsky WH, Fisher L, Guzman S, Villa-Caballero L, Edelman SV. Psychological insulin resistance in patients with type 2 diabetes: the scope of the problem. *Diabetes Care.* 2005;28:2543–5.
15. Wang HF, Yeh MC. Psychological resistance to insulin therapy in adults with type 2 diabetes: mixed-method systematic review. *J Adv Nurs.* 2012;68:743–57.
16. Woudenberg YJ, Lucas C, Latour C, Scholte op Reimer WJ. Acceptance of insulin therapy: a long shot? Psychological insulin resistance in primary care. *Diabet Med.* 2012;29:796–802.
17. Peyrot M, Rubin RR, Lauritzen T, Skovlund SE, Snoek FJ, Matthews DR, et al. Resistance to insulin therapy among patients and providers: results of the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study. *Diabetes Care.* 2005;28:2673–9.
18. Nathan DM. Clinical practice: initial management of glycemia in type 2 diabetes mellitus. *N Engl J Med.* 2002;347:1342–9.
19. Davis SN, Renda SM. Psychological insulin resistance: overcoming barriers to starting insulin therapy. *Diabetes Educ.* 2006;32:146S–52S.
20. Ishii H, Iwamoto Y, Tajima N. An exploration of barriers to insulin initiation for physicians in Japan: findings from the Diabetes Attitudes, Wishes and Needs (DAWN) Japan study. *PLoS One.* 2012;7:e36361.
21. Ratanawongsa N, Crosson JC, Schillinger D, Karter AJ, Saha CK, Marrero DG. Getting under the skin of clinical inertia in insulin initiation: the Translating Research Into Action for Diabetes (TRIAD) Insulin Starts Project. *Diabetes Educ.* 2012;38:94–100.
22. Miller CD, Phillips LS, Ziemer DC, Gallina DL, Cook CB, El-Kebbi IM. Hypoglycemia in patients with type 2 diabetes mellitus. *Arch Intern Med.* 2001;161:1653–9.
23. Riddle MC. The underuse of insulin therapy in North America. *Diabetes Metab Res Rev.* 2002;18(Suppl 3):S42–9.
24. Karter AJ, Subramanian U, Saha C, Crosson JC, Parker MM, Swain BE, et al. Barriers to insulin initiation: the Translating Research Into Action for Diabetes Insulin Starts Project. *Diabetes Care.* 2010;33:733–5.
25. Funnell MM. Overcoming barriers to the initiation of insulin therapy. *Clin Diabetes.* 2007;25:36–8.
26. Lawton J, Peel E, Parry O, Douglas M. Patients' perceptions and experiences of taking oral glucose-lowering agents: a longitudinal qualitative study. *Diabet Med.* 2008;25:491–5.
27. Hinder S, Greenhalgh T. "This does my head in". Ethnographic study of self-management by people with diabetes. *BMC Health Serv Res.* 2012. doi:10.1186/1472-6963-12-83.
28. Gucciardi E, Fortugno M, Senchuk A, Beanlands H, McCay E, Peel EE. Self-monitoring of blood glucose in Black Caribbean and South Asian Canadians with non-insulin treated type 2 diabetes mellitus: a qualitative study of patients' perspectives. *BMC Endocr Disord.* 2013. doi:10.1186/1472-6823-13-46.
29. Hortensius J, Kars MC, Wierenga WS, Kleefstra N, Bilo HJ, van der Bijl JJ. Perspectives of patients with type 1 or insulin-treated type 2 diabetes on self-monitoring of blood glucose: a qualitative study. *BMC Public Health.* 2012. doi:10.1186/1471-2458-12-167.
30. Peel E, Parry O, Douglas M, Lawton J. Blood glucose self-monitoring in non-insulin-treated type 2 diabetes: a qualitative study of patients' perspectives. *Br J Gen Pract.* 2004;54:183–8.
31. Peel E, Douglas M, Lawton J. Self monitoring of blood glucose in type 2 diabetes: longitudinal qualitative study of patients' perspectives. *BMJ.* 2007;335:493.
32. Beverly E, Ritholz M, Brooks K, Hultgren B, Lee Y, Abrahamson M, et al. A qualitative study of perceived responsibility and self-blame in type 2 diabetes: reflections of physicians and patients. *J Gen Intern Med.* 2012;27:1180–7.
33. Carbone ET, Rosal MC, Torres MI, Goins KV, Bermudez OI. Diabetes self-management: perspectives of Latino patients and their health care providers. *Patient Educ Couns.* 2007;66:202–10.
34. Nagelkerk J, Reick K, Meengs L. Perceived barriers and effective strategies to diabetes self-management. *J Adv Nurs.* 2006;54:151–8.
35. Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the Health Belief Model. *Health Educ Q.* 1988;15:175–83.
36. Harvey JN, Lawson VL. The importance of health belief models in determining self-care behaviour in diabetes. *Diabet Med.* 2009;26:5–13.
37. Champion V, Skinner CS. The Health Belief Model. In: Glanz K, Rimer BK, Viswanath K, editors. *Health behavior and health education: theory, research, and practice.* San Francisco: Jossey-Bass; 2008. p. 45–65.
38. Hayden JA. *Introduction to health behavior theory.* 2nd ed. Burlington: Jones & Bartlett Learning; 2014.
39. Brod M, Tesler LE, Christensen T. Qualitative research and content validity: developing best practices based on science and experience. *Qual Life Res.* 2009;18:1263–78.
40. Saldana J. *The coding manual for qualitative researchers.* Los Angeles: Sage; 2010.
41. Frost MH, Reeve BB, Liepa AM, Stauffer JW, Hays RD, Mayo/FDA Patient-Reported Outcomes Consensus Meeting Group. What is sufficient evidence for the reliability and validity of patient-reported outcome measures? *Value Health.* 2007;10:S94–105.
42. National Diabetes Information Clearinghouse (NDIC). <http://diabetes.niddk.nih.gov>. Accessed 6 Dec 2010.
43. American Diabetes Association. <http://www.diabetes.org>. Accessed 6 Dec 2010.
44. American Diabetes Association. Insulin myths and facts. <http://clinical.diabetesjournals.org/content/25/1/39.full>. Accessed 4 Oct 2010.
45. Mayo Clinic.com. <http://www.mayoclinic.com/health/diabetes/DS01121>. Accessed 6 Dec 2010.
46. Joslin Diabetes Center. <http://www.joslin.org/diabetes-information.html>. Accessed 4 Oct 2010.
47. UK Prospective Diabetes (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet.* 1998;352:837–53.
48. Joslin Diabetes Center. Joslin Injection Training Tools: addressing patient concerns. <http://www.bd.com/us/diabetes/hcp/main.aspx?cat=3065&id=63266>. Accessed 14 Mar 2013.
49. American Association of Diabetes Educators (AADE). Strategies for insulin injection therapy in diabetes self-management. http://www.diabeteseducator.org/export/sites/aaede/_resources/pdf/research/AADE_MedEd.pdf. Accessed 14 Mar 2013.
50. Johns Hopkins Medicine. Insulin therapy: friend, not foe. It's time to dispel common myths about insulin treatment for people with type 2 diabetes. *Johns Hopkins Med Lett Health After.* 2011;23:4–5.
51. Minze MG, Dalal K, Irons BK. Removing barriers to insulin use. *J Fam Pract.* 2011;60:577–80.
52. Peyrot M, Rubin RR, Khunit K. Addressing barriers to initiation of insulin in patients with type 2 diabetes. *Prim Care Diabetes.* 2010;4:S11–8.
53. Novo Nordisk. Changing my diabetes—insulin dialogue toolkit. http://www.dawnstudy.com/News_and_activities/insulin_dialogue_toolkit.asp. Accessed 14 Mar 2013.
54. Alberti G. The DAWN (Diabetes Attitudes, Wishes and Needs) study. *Pract Diab Int.* 2002;19:22–4a.
55. Skovlund SE, Peyrot M. The Diabetes Attitudes, Wishes, and Needs (DAWN) program: a new approach to improving outcomes of diabetes care. *Diabetes Spectrum.* 2005;18:136–42.

56. Skovlund SE. Diabetes attitudes, wishes and needs. *Diabetes Voice*. 2004;49:4–11.
57. Hermanns N, Mahr M, Kulzer B, Skovlund SE, Haak T. Barriers towards insulin therapy in type 2 diabetic patients: results of an observational longitudinal study. *Health Qual Life Outcomes*. 2010;8:113.
58. Ruiz MA, Pardo A, Martinez de la Casa JM, Polo V, Esquiro J, Soto J. Development of a specific questionnaire measuring patient satisfaction with glaucoma treatment: Glausat. *Ophthalmic Epidemiol*. 2010;17:131–43.
59. Dréno B, Thiboutot D, Gollnick H, Finlay AY, Layton A, Leyden JJ, et al. Large-scale worldwide observational study of adherence with acne therapy. *Int J Dermatol*. 2010;49:448–56.
60. Biderman A, Noff E, Harris SB, Friedman N, Levy A. Treatment satisfaction of diabetic patients: what are the contributing factors? *Fam Pract*. 2009;26:102–8.
61. Testa MA, Simonson DC. Satisfaction and quality of life with premeal inhaled versus injected insulin in adolescents and adults with type 1 diabetes. *Diabetes Care*. 2007;30:1399–405.
62. Brod M, Cobden D, Lammert M, Bushnell D, Raskin P. Examining correlates of treatment satisfaction for injectable insulin in type 2 diabetes: lessons learned from a clinical trial comparing biphasic and basal analogues. *Health Qual Life Outcomes*. 2007;5:8.
63. Brod M, Skovlund SE, Wittrup-Jensen KU. Measuring the impact of diabetes through patient report of treatment satisfaction, productivity and symptom experience. *Qual Life Res*. 2006;15:481–91.
64. Casciano R, Malangone E, Ramachandran A, Gagliardino JJ. A quantitative assessment of patient barriers to insulin. *Int J Clin Pract*. 2011;65:408–14.
65. Martinez L, Consoli SM, Monnier L, Simon D, Wong O, Yomtov B, et al. Studying the Hurdles of Insulin Prescription (SHIP): development, scoring and initial validation of a new self-administered questionnaire. *Health Qual Life Outcomes*. 2007;5:53.
66. Snoek FJ, Skovlund SE, Pouwer F. Development and validation of the Insulin Treatment Appraisal Scale (ITAS) in patients with type 2 diabetes. *Health Qual Life Outcomes*. 2007;20(5):69.