



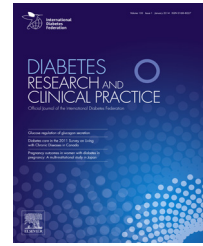
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Time to do more: Addressing clinical inertia in the management of type 2 diabetes mellitus

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ABSTRACT

Aims: Clinical inertia, the tendency to maintain current treatment strategies despite results demanding escalation, is thought to substantially contribute to the disconnect between clinical aspirations for patients with diabetes and targets achieved. We wished to explore potential causes of clinical inertia among physicians and people with diabetes.

Methods: A 20-min online survey of 652 adults with diabetes and 337 treating physicians in six countries explored opinions relating to clinical inertia from both perspectives, in order to correlate perceptions and expectations relating to diagnosis, treatment, diabetes complications and therapeutic escalation.

Results: Physicians had low expectations for their patients, despite the belief that the importance of good glycaemic control through lifestyle and pharmacological interventions had been adequately conveyed. Conversely, people with diabetes had, at best, a rudimentary understanding of the risks of complications and the importance of good control; indeed, only a small proportion believed lifestyle changes were important and the majority did not intend to comply.

Conclusions: The principal findings of this survey suggest that impairments in communication are at the heart of clinical inertia. This manuscript lays out four key principles that we believe are achievable in all environments and can improve the lives of people with diabetes.

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1. Introduction

Although often thought of as a disease of glycaemic regulation, the nature of type 2 diabetes mellitus (T2DM) is more in keeping with a progressive disease characterised by premature cardiovascular morbidity and mortality. In order to arrest this progression, there is clear evidence to support early initiation and intensification of therapy to reduce the risk of *de novo* or worsening of micro- and macro-vascular complications [1]. Maintaining simultaneous control of hypertension, dyslipidaemia and hyperglycaemia is the cornerstone of diabetes care, which requires a holistic approach that addresses the multiple aetiopathogenic mechanisms, and also the psychosocial aspects of the disease.

1.1. Individualised treatment for type 2 diabetes mellitus

Treating and strict adherence to glycaemic targets have become ingrained in the culture of diabetes management, occupying a central role in the standards of medical care for persons with diabetes. National and international guidelines have adopted a stepwise approach to treatment of people with diabetes as their disease progresses. The first step in diabetes treatment should always include education and advice on nutrition and exercise. The latest American Diabetes Association and European Association for the Study of Diabetes (ADA/EASD) guidelines also recommend initiation of a first-line oral antidiabetes drug (OAD) at initial diagnosis [2], while International Diabetes Federation (IDF) Global Guideline for Type 2 Diabetes and national guidelines in some countries such as Japan and Spain do not necessarily recommend use of any OADs at the time of diagnosis [3–5]. These guidelines define good glycaemic control as achieving an HbA1c target of <7.0% (53 mmol/mol) [2,4], whereas other national guidelines apply more aggressive targets in newly diagnosed patients. For example, guidelines from the UK National Institutes for Health and Care Excellence (NICE) and the American Association of Clinical Endocrinology (AACE), last updated in 2009, impose a slightly stricter HbA1c target of <6.5% (48 mmol/mol) [6,7].

Stepwise intensification of therapy is recommended as glycaemic control deteriorates, with the addition of second- and third-line interventions [6]. This rigid approach to intensification of therapy is based on the findings of clinical trials conducted in highly selected groups of people with diabetes, and is increasingly being challenged in clinical practice [2]. This shift towards individualised treatment was underlined in the recent joint position statement of the ADA/EASD [2]. In this statement, treating to an HbA1c target of <7.0% (53 mmol/mol) is endorsed for most people with diabetes, but with greater emphasis placed on patient characteristics such as disease duration, co-morbidities and risk of hypoglycaemia; and also the role of the patient in deciding their own individual targets. Also the recently published IDF Global Guideline for Managing Older People with Type 2 Diabetes and European Diabetes Working Party for Older People (EDWPOP) guideline address the special issues and needs beyond glycaemic control [8,9]. These physical, cognitive and social needs form a platform for shared decision-making which requires physicians and patients to

form a partnership that gives equal weight to the physician's expertise and the patient's needs and preferences. Indeed, in the only study to test the feasibility of individualising treatment, the patients' involvement resulted in 27% of older people with diabetes achieving their individualised targets [10].

1.2. What is clinical inertia?

Clinical inertia may be defined as a failure to initiate or intensify treatment in a timely manner in people with diabetes whose health is likely to improve with this intensification.

A growing body of evidence shows that, despite good intentions, there is often a disconnect between the setting and the achievement of treatment targets. Even with the increasing availability of effective glucose-lowering therapies, there is a failure to achieve established targets in almost half of people with diabetes [11–17].

Clinical inertia is not a new concept, having gained attention in the early 2000s [18–20]. However, increased awareness of the potential for this disconnect in clinical practice does not seem to have translated into improved treatment outcomes [21]. Comparing two retrospective cohort studies using UK general practice data ($n = 14,824$ and $n = 81,573$), the time to intensification of treatment (with combination OADs or insulin) did not significantly improve between the periods 1996–2005 and 2004–2011 (>7.7 years vs. >7.2 years) [21,22]. In the more recent study, for patients on two OADs, median time to treatment intensification actually exceeded the maximum follow-up period of the study [21]. The long delay in stepping up to injectable therapy is reflected in the number of patients with very poor glycaemic control at the time of insulin initiation. In the 1996–2005 UK analysis, mean HbA1c was approximately 10.0% (86 mmol/mol) at insulin initiation [22]. In the later study, HbA1c levels far exceeded the recommended threshold for treatment intensification: 8.7% (72 mmol/mol), 9.1% (76 mmol/mol) and 9.7% (83 mmol/mol) for patients taking one, two and three OADs, respectively [21].

Clinical inertia is a global problem. In the USA, an observational study in 3891 people with diabetes, who were registered with a health maintenance organisation, reported a delay of almost three years in patients with consistently elevated HbA1c levels despite dual OAD therapy (metformin and sulphonylurea) [23]. Further, a multinational, 26-week observational study reported an HbA1c level of 8.9% (74 mmol/mol) at insulin initiation [17]. A Japanese study also revealed that physicians are strongly resistant to initiating insulin in individuals with type 2 diabetes, resulting in high levels of HbA1c (9.6%; 81 mmol/mol) at the time of recommending insulin to patients [24]. Furthermore, the same study demonstrated that differences in physician and patient perceptions of diabetes therapies could deter patients from accepting insulin therapy [25]. These findings confirm previous results of a Canadian study in adults with diabetes aged ≥ 65 years ($n = 2502$), which found that, although diabetologists are more likely to initiate insulin based on poor glycaemic control [HbA1c >8.0% (64 mmol/mol)], only 45% intensified treatment overall [20]. The corresponding proportion of primary care physicians (PCPs) was 37%.

1.3. What causes clinical inertia?

Clinical inertia has been identified at several stages in the diabetes management pathway [26]. In early-stage disease, PCPs may not be aware that many patients will benefit from combination therapy. Among patients on OAD monotherapy, physicians may be reluctant to move beyond monotherapy in patients who are asymptomatic. A lack of confidence with newer therapies and insulin initiation amongst practitioners may be a barrier to better care [26]. Additional reasons may include a lack of infrastructure to help physicians monitor and achieve treatment goals, and the adoption of a 'wait until next visit' approach in response to soft rationalisations by patients to avoid treatment intensification [18].

The causes of clinical inertia do not lie solely with physicians. Non-adherence to lifestyle modifications and prescribed drug treatments is prevalent among people with diabetes, with estimates ranging from around one-third of patients to nearly 100% [27]. The underlying reasons for this are unclear. Interestingly, social and environmental pressure maybe the strongest modulators for 'required' lifestyle changes in the management of the disease. The importance of socio-economic factors in determining diabetes outcomes has recently been demonstrated in a population-wide analysis of the consequences of weight loss and regain driven by an economic crisis in Cuba [28]. In this survey, an average population-wide weight loss of ~5.5 kg was associated with rapid, significant decline in diabetes and heart disease prevalence, whereas a weight regain led to a diabetes prevalence that exceeded pre-crisis levels [28].

Patients' understanding of, and engagement with, their treatment can be a crucial determinant of how likely they are to adhere to it [13,29]. Adherence may be influenced by exposure to negative media coverage of topics related to diabetes, and misperception of the disease may affect motivation and compliance [30,31]. The fear of hypoglycaemic episodes and insulin-associated weight gain can make people with diabetes reluctant to comply with insulin therapy [26]. Paradoxically, the dialogue prior to insulin initiation often vilifies the therapy itself. Statements such as 'if you don't comply with the exercise regimen you will need to inject yourself' serve to present the insulin as a punishment rather than a necessary part of the management of this progressive condition. In making such statements, physicians can be the root cause of non-adherence to their own prescriptions [13]. This is clearly at the forefront of many physicians' minds; indeed, the recently published results of the second international Diabetes Attitudes, Wishes and Needs (DAWN) second study indicate that approximately two-thirds of physicians believe that more can be done to improve earlier diagnosis and treatment [32].

1.4. T2DM: Time to do more?

It is increasingly clear that, despite a strong evidence base and an array of well-tolerated treatment alternatives, optimal therapeutic targets are not being met. Overcoming the multidimensional nature of clinical inertia will require a unified approach between physicians, people with diabetes and their support networks in order to reduce the potential

adverse consequences of diabetes. To facilitate this, a more complete understanding of the impediments to better diabetes care is therefore essential.

2. Methods

2.1. Understanding clinical inertia – a survey mapping its dimensions

Individuals from six countries (Brazil, India, Japan, Spain, UK, USA) were randomly selected from the Kantar Health panel of over 2500 physicians and 118,000 patients who have agreed to be contacted for research purposes. They were invited to participate in an online survey (Supplementary Table 1) with the following objectives:

- To identify barriers in improving the treatment of T2DM and understand the ways in which these can be overcome.
- To understand clinical inertia and to what extent it constitutes a barrier to improving care in T2DM
- To explore perceptions on treating earlier and more aggressively.
- To identify areas of unmet need.

2.2. Survey design

The survey was carried out between November 2012 and January 2013. Individuals were included in order to achieve pre-assigned quotas. The questions were designed (Supplementary Table 1) to capture patient and physician perceptions on the following elements of the diabetes management pathway: initial consultation (diagnosis) and the topics discussed (especially lifestyle modifications, such as diet and exercise, and complications); follow-up consultations; attitudes towards complications; adequate disease management; and likelihood of achieving treatment targets. The survey was also designed to assess the treatment algorithms used, including time taken to initiate medication (monotherapy or combination therapy); drug treatments prescribed in certain patient groups (50-year-old and 80-year-old patients, or those with renal impairment); and time to switch or add-on therapy.

To be eligible for the survey, physicians were required to have been in practice for 3–35 years, to be responsible for choosing and prescribing oral and/or injectable diabetes medications, and to spend at least 70% of their time each month in clinical practice attending any patients. During this time PCPs had to treat a minimum of 50 people with diabetes whilst specialist were required to attend a least 100 people with diabetes. Adults with a confirmed diagnosis of type 2 diabetes were invited to participate in order to fill prespecified age, sex and nationality quotas (Supplementary Table 2). This was to address the fact that, while the recruitment process was random, online respondent populations can be more representative of younger individuals, and of those with higher levels of education and/or income.

Statistical tests were run for all variables to assess the existence of differences in score between a number of specific respondent groups (Supplementary Table 3).

Depending on the type/scale of each individual variable, statistical tests were performed based on (1) a t-test between two means from two independent samples or (2) a t-test between two percentages from two independent samples. These tests were used to detect a difference in two means or proportions estimates associated with two independent samples or groups of respondents. The null hypothesis in these tests is that the difference in the two means/proportions estimates is zero. A *p*-value of <0.05 was regarded as significant.

3. Results

Of 8301 eligible respondents, over half (4314) were excluded because their respective demographic quota was complete. The data collection was terminated when 652 people with diabetes and 337 treating physicians (264 PCPs and 73 specialists) had completed the survey. Table 1 shows the distribution of participants by nationality. The basic demographics of the participants suggest that the demographics of the participants reflect the characteristics of the target population of physicians and people with diabetes in their respective countries.

3.1. Initial consultation

The foundations for clinical inertia appear to be established at the visit where the diagnosis is communicated. Both physicians and patients reported a similar time spent on this initial

consultation (23 min for physicians, independent of designation and 27 min for patients), despite the potential for recollection bias on behalf of the patients who may have been diagnosed up to 5 years earlier. The survey identified four key topics that were discussed during the consultation: lifestyle changes, drug treatment, disease aetiology, and risks and complications of T2DM. More than 90% of physicians recalled describing all four key topics. During the visit, most time was spent discussing lifestyle changes and diet, disease aetiology and drug treatment, 10–19% per category depending on physician status.

When prompted, the perceived distribution of time discussing the elements of diabetes was similar between physicians and people with diabetes; however, the order of importance of the elements differed. Although physicians emphasised the importance of cardiovascular disease as a complication of poorly controlled diabetes, the risk of retinopathy and blindness posed greatest concern to the patients. The physicians believed that the risk of premature mortality was discussed with approximately half of the patients in the USA and Brazil; however, this was discussed with 14% of the Japanese population (Supplementary Fig. 1). Approximately three-quarters of the participants in every country felt that the risk of hypoglycaemia was adequately discussed. The people with diabetes, however, did not recall either the risk of premature mortality or hypoglycaemia being discussed in this initial consultation. Further, although emphasised as a reason for optimising treatment by physicians, the majority of people with diabetes regarded the risk of complications as remote.

Table 1 – Patient profile.

	USA (N = 151)	Brazil (N = 100)	UK (N = 100)	Spain (N = 100)	India (N = 100)	Japan (N = 101)
Gender, Male	58%	60%	60%	60%	62%	72%
Mean age, years	60.6	52.4	59.6	53.3	52.3	57.8
Mean BMI, kg/m ²	33.1	33.9	31.0	28.9	24.7	24.9
Employment						
Employed full-time	20%	48%	26%	29%	53%	47%
Employed part-time	7%	22%	18%	13%	13%	7%
Student	–	3%	–	–	1%	–
Not working for health reasons	17%	8%	9%	7%	4%	3%
Not working for other reasons	9%	2%	1%	27%	4%	13%
Retired	47%	17%	46%	24%	25%	31%
Income group						
Low	33%	8%	46%	85%	31%	52%
Middle	48%	23%	28%	3%	30%	35%
High	15%	66%	10%	4%	33%	5%
Prefer not to say	4%	3%	16%	8%	6%	8%
Anti-hyperglycaemic therapy						
Patients treated with an oral agent	88%	80%	92%	88%	81%	96%
Patients treated with an injectable	32%	36%	26%	29%	45%	16%
Patients with diet and exercise recommendations	74%	87%	60%	85%	80%	57%
Take one type of pills	56%	34%	47%	44%	40%	46%
Take two types of pills	45%	66%	52%	55%	60%	53%
Family/personal history						
Mother/father of the patient suffer from diabetes	25%	54%	32%	34%	42%	33%
Brother/sister of the patient suffer from diabetes	24%	25%	15%	20%	27%	15%
Grandparent of the patient suffer from diabetes	14%	21%	12%	13%	19%	4%
Other family member of the patient suffer from diabetes	27%	19%	20%	10%	18%	7%
Friend(s) of the patient suffer from diabetes	21%	7%	22%	10%	22%	5%

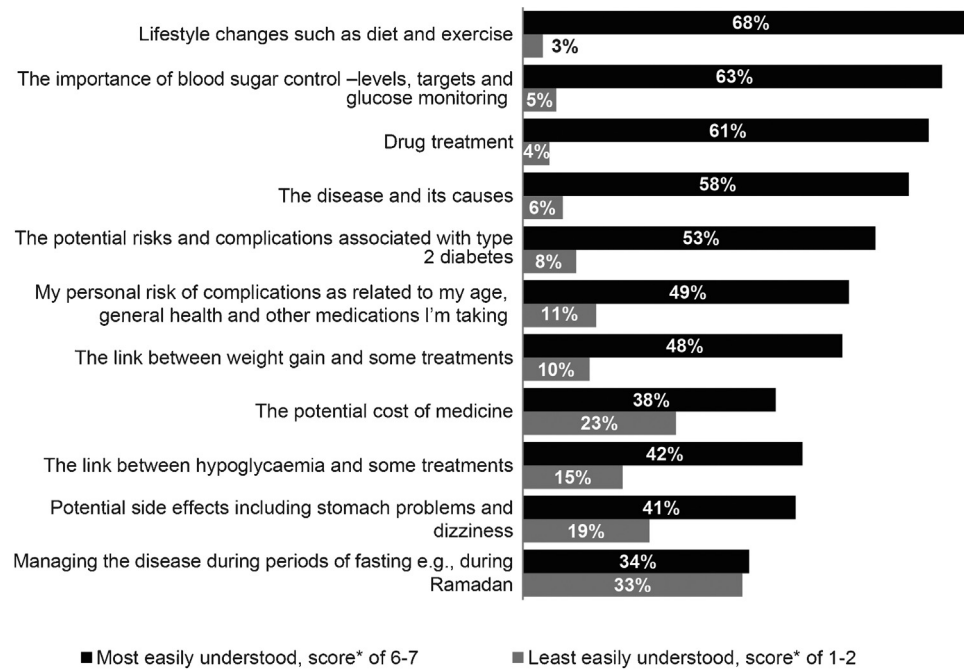


Fig. 1 – Overview of topics most and least easily understood by patients (N = 652) at the diagnosis consultation. Score*, score 1 means ‘did not understand at all’ and 7 means ‘understood very well’.

The majority of the patients (68%) perceived having understood the importance of lifestyle changes and diet (Fig. 1), however, only 37% acknowledged this as a treatment modality. At first consultation, only 23% of the patients were not prescribed any medication (Supplementary Fig. 2).

3.2. Follow-up visits

Overall, patients were satisfied with the frequency of follow-up visits (approximately five visits per year) although a minority stated that they would like to see the physician more often. Visits were focused on taking history and carrying out monitoring/diagnostic tests, as well as discussing disease management to gauge how well the patient was coping and complying. A few minutes were also allocated to ask about the patient's concerns; however, over a fifth of physicians did not make use of this time to reiterate the risk of complications as the reason for ongoing treatment of the diabetes. Despite the evident knowledge gaps among patients, less than one in four physicians attributed this to a lack of time or not seeing patients regularly.

3.3. Attitudes towards complications

Some important discrepancies were uncovered in terms of patient and physician perceptions of discussions on T2DM complications. While physicians placed similar or greater importance on cardiovascular and renal complications, with one-third of physicians even explaining the potential risk of early death (Fig. 2A), the risk of retinopathy and blindness was of greatest concern to patients (Fig. 2B). Only 25% of patients reported that they were worried about developing T2DM

complications, while the rest were either not concerned or thought the risk was remote (Fig. 2C). Level of concern about risk of developing complications did not decrease from diagnosis to the time of the survey.

3.4. Hypoglycaemia awareness

Two-thirds of physicians believed that patients did not understand the serious consequences of hypoglycaemia and the importance of reporting events (Supplementary Fig. 3). A similar proportion also agreed that patients do not appreciate the potential need to adjust or change their treatment following a hypoglycaemic event (hypo). Only 14% of physicians perceived that patients accurately report hypos, and 82% perceived that hypos are under-reported. When prompted on their knowledge of hypos, 20% of patients said they knew nothing or very little about hypos, and only 33% were aware of at least one symptom to look out for (dizziness 17%, sweating or heavy sweating 8%, feeling tired/weak 6%, unsteadiness/shakiness 5%, feeling faint/lightheaded 5%). More patients in the USA, UK and Japan reported knowing nothing or very little about hypos than patients in India, Spain and Brazil. Only 31% of patients reported telling their healthcare provider each time they had a hypo; 15% said sometimes, 7% said never. Notably, 48% of patients stated that they had never had a hypoglycaemic episode and 20% said that they do not fear them. Only 6% of patients who stated that they feared hypos were aware that a hypo could cause death.

Patients were asked six ‘true or false’ questions about hypos (Fig. 3). An overall mean of 3.2 questions were answered incorrectly, with 97% of patients giving at least one incorrect answer.

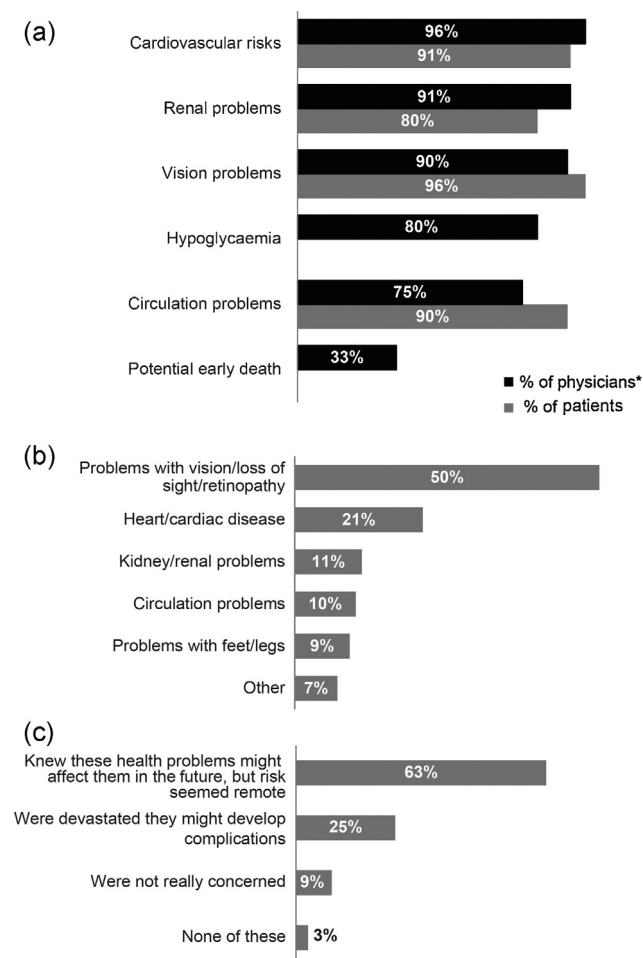


Fig. 2 – (a) Physician and patient recall of explanation of the risks at diagnosis; (b) complications patients were most concerned with at the time of diagnosis; (c) patients' feelings about complications at diagnosis. *, all physicians (N = 337) who participated in the study; **, patients (N = 206) who were explained potential risks and complications of T2D at diagnosis; N = 200 (base value for (b) and (c)), patients who remembered discussing potential complications of T2D with their physicians. T2D, type 2 diabetes.

3.5. Treatments and compliance

Although physicians acknowledged that only about one-third of older patients (age 80+ years) and half of middle-aged patients (50–79 years) would comply with diet and exercise advice, it was the most common first-line prescription independent of age. Indeed, in the UK, 52% of physicians prescribed diet and exercise alone as first-line treatment (as per current NICE guidelines), independent of patient profile or the perceived ability of the patient to follow this regimen. Second-line therapies (after metformin) were also similarly distributed among DPP-4 inhibitor and sulphonylurea use, independent of age (Supplementary Fig. 2). Physicians expected around one-third of 80+ year-olds and half of 50–79 year-olds to take their medications as prescribed. They

attributed the majority of the non-compliance to ‘forgetfulness’ and too many tablets in older adults; whereas they felt younger patients would not take their medication because they did not like it. Adverse treatment-emergent effects were listed as a compliance issue in both age groups. The most common adverse effect that triggered a switch in medication was hypoglycaemia. Physicians expected approximately half the patients to achieve target HbA1c independent of age.

The majority of patients (68%) perceived having understood the importance of lifestyle changes and diet (Fig. 1); however, only 37% acknowledged this as a form of treatment. Overall, patients were more likely to follow dietary than exercise advice. Health problems were quoted as the main reason for not exercising. A key concern following diagnosis, expressed by approximately half of the people with T2DM, was the need to use injectable medications in the near future. Physicians did not recall this as being a topic of the consultation, suggesting that this was a pre-conceived perception of the disease.

Despite acknowledging differences in compliance, tolerability and the overall disease between middle age and older people with diabetes, the treatment protocols applied to both age groups appeared very similar, suggesting that, despite fundamental differences in the physiology and the nature of disease, all people with diabetes were treated the same.

4. Discussion

4.1. Time 2 do more: a roadmap for improving diabetes care in clinical practice

We have demonstrated a clear disconnect in communication between healthcare providers and people with diabetes. This apparent insufficiency of communication is reflected in the variance of recollection demonstrated from initial consultation and subsequent visits, even if communication-related aspects were never addressed *per se*. Given that people with diabetes and their family members provide the majority of diabetes care, interactions with health care professionals (HCPs) should be ‘patient-centred’ and reflect the need for people with T2DM to feel equally able to take responsibility for their disease [33]. To succeed, however, this approach relies on both parties reaching an agreement for a realistic shared outcome with an acceptance of responsibilities on both sides – a patient-physician contract. The concept of clinical inertia arises when this contract falls short of its ambitions. Thus, we signpost the following roadmap that to facilitate reducing clinical inertia and thereby hopefully improving quality of life for people with diabetes.

Key principle 1: The health outcomes for people with diabetes are a function of the communication between the HCPs and people with diabetes acting as a team.

Behavioural change cannot be easily induced in people with diabetes, nor is their understanding of the disease and its treatment easily influenced. Clinical trials have provided some evidence about the efficacy of education programmes related to knowledge and self-management. However, the evidence is much weaker for their efficacy in relation to biomedical and

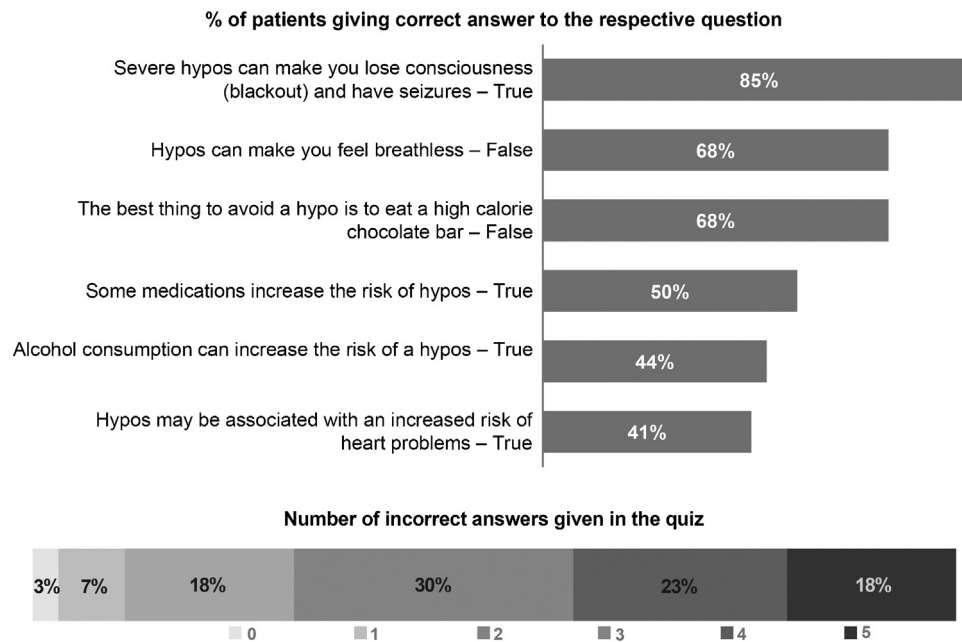


Fig. 3 – Patient responses to a six-item hypoglycaemia quiz. N, all patients (N = 652); mean number of incorrect answers was 3.2.

lifestyle outcomes [34–37]. Furthermore, the evidence for their long-term efficiency in real-world clinical practice, away from the inherent rigours of clinical trials, is scarce. The cause of this discrepancy may lie in the fact that participants in clinical trials are likely to be engaged with their treatment, which may not be the case in real life. This suggests that it is time to do more to engage people with diabetes in their routine clinical care.

Physicians often perceive people with diabetes only as patients, and indeed they often misuse the adjective ‘diabetic’ as a noun. This patient-physician relationship will only change once it is regarded as a partnership of equals. Then, a realistic ‘contract’ may be established. Patient-centred communication can optimise the patient-physician relationship without significantly prolonging office visits. This requires talking and listening by the physician, and this communication needs to be individualised.

There is an equal obligation on the person with diabetes to be accountable for their disease. They need to accept responsibility when attending consultations for providing the necessary information and establish any needs for clarification prior to arrival. They should be encouraged to bring their own clear agenda to the meeting in order to facilitate the answering of any queries within the allotted time constraints. The accessibility and quality of diabetes self-management education is crucial for facilitating these discussions. Indeed, only the knowledge attained from these programmes can empower people with diabetes to feel engaged with and involved in their treatment. Self-management is not just a matter of educating patients in the first place about diabetes, but of providing ongoing support in order to sustain any improvements made through patient education [38,39].

In line with earlier studies, our survey illustrated the wide spectrum of knowledge that people with diabetes have about their disease; some may be well-informed, while others may not have any knowledge of the disease or treatment modalities. A multidisciplinary healthcare team is required to provide appropriate follow-up tailored to each patient’s needs. Just as importantly, the patient’s family, caregivers or other support system also need to be involved in helping the patient to educate themselves and self-manage their disease, provided that the patient consents to their involvement.

Key Principle 2: It is the duty of that team to establish realistic shared goals and a contract in order to achieve these objectives.

Suitable treatment goals should be clearly defined for all people with diabetes, not just for the elderly or those with other limitations to their ability to achieve conventional targets. These goals should not necessarily be limited to glycaemic targets, but also include realistic targets for exercise and dietary changes to be accomplished. Although standard targets for weight or waist circumference reductions have been demonstrated to be beneficial in terms of health outcomes in the pragmatic setting of clinical practice, these are rarely achieved without the benefit of the support provided in controlled trials. Often, simpler targets such as modest changes to diet or practical suggestions for lifestyle modification may be realised with benefits beyond that of the simple health benefits. The sense of control over the disease results in better compliance with future interventions and goal setting.

Clearly defined expectations, for the physician and person with diabetes, allow evaluation of progress. This will help to establish the true prevalence of clinical inertia. It is important these expectations are clearly documented *a priori* in order to

eliminate false claims of having met less aggressive clinical goals while ignoring individual assessment of the patients.

This is particularly applicable in elderly people with diabetes, who have multiple co-morbidities and are typically being treated with multiple medications. There is a perception, as demonstrated in our survey, that these individuals are likely to be poorly compliant with lifestyle changes, yet, according to several studies, respond well to non-pharmacological regimens. In our survey, the physicians believed that elderly patients were less likely to comply with advice, lifestyle changes or pharmacotherapy than younger patients. However, they implement age-independent approaches to treatment strategies. This disconnect requires further evaluation, particularly in the current environment of guidelines specifically indicating individualising therapeutic approaches for these individuals [9,40]. Other studies have demonstrated a remarkable response to simply engaging in an age-appropriate manner and establishing individualised treatment targets with these individuals. Indeed, in one study, the establishment of individualised targets for older people with diabetes resulted in over a quarter achieving their targets when treated with placebo [10]. Prospective work is still required to explore the low expectations and establish an appropriate glycaemic target and treatment algorithm for older adults.

Key Principle 3: Individualising care needs to be personalised to all aspects of the needs of the person with diabetes, not simply chasing glycaemic, blood pressure, or lipid targets.

A paradigm shift is already occurring as diabetes management begins to move away from universal algorithms where one pathway was expected to govern treatment strategies for all patients irrespective of their baseline characteristics (i.e. the one size fits all approach). However, at the core of even the newer individualisation of care remain the HbA1c, fasting blood glucose, arterial hypertension and lipid profile. For people with diabetes, this disregards a number of their priorities. Elements such as changes in weight, exercise tolerance, depression, risk of losing one's job due to insulin initiation and overall quality of life are rarely discussed as a target, but rather as a by-product of meeting these conventional numerical outcomes. This lack of integration of more personalised priorities, however, may be detrimental to the capacity to attain more conventional targets.

Several studies have shown that psychological resistance to the use of insulin is, strikingly, identical from the perspective of the physician and the patient – both groups express denial, wishful thinking, avoidance and procrastination, or fear of hypoglycaemia when initiating or avoiding initiation of insulin therapy. Very little emphasis is placed on the potential for insulin therapy to improve quality of life, exercise tolerability, and, when used appropriately in combination with other agents, to do so without adversely affecting other relevant markers. However, fear of hypoglycaemia has become an outdated and unacceptable excuse for inertia. In the era of DPP-4 inhibitors, SGLT-2 inhibitors and GLP-1 analogues, the risk of hypoglycaemia should not be a reason for not acting earlier to improve diabetes control.

The need to consider all aspects of clinical care is highlighted in the joint ADA/EASD and IDF Global Guideline for Managing Older People with Type 2 Diabetes [2,8]. These guidelines have been criticised by many for not indicating a clear management strategy beyond diet, exercise and metformin. These guidelines, however, emphasise the clear proven benefit of diet, exercise and metformin in all who can tolerate it, before actively encouraging communication and evaluation of the priorities for the person with diabetes. They also detail the relative benefits and potential cautions of all available therapies, and ask for a joint decision between practitioner and person with diabetes as to whether the priority should be to avoid weight gain, treat elements of the metabolic syndrome, consider fracture risk, and also consider the potential lifetime exposure to drugs and glycaemia. Other guidelines that adopt a more didactic approach [6,7], are often better received by practitioners, but these paradoxically dissuade engagement with the person with diabetes as there is little manoeuvrability within them, thereby rendering discussion of shared goals irrelevant.

Key Principle 4: Purchasers and providers should incentivise good management in early disease in order to optimise quality of life for those people with diabetes.

Policy-makers should focus strategies on prevention and early diagnosis/intervention. The demonstration of a legacy effect of early intervention with intensive glucose-lowering therapies, based on long-term follow-up to the UK Prospective Diabetes Study (UKPDS), puts forth a compelling argument for early and aggressive treatment in persons with diabetes [1]. Compared with conventional anti-diabetes therapies, early and intensive glucose-lowering therapy resulted in a significant reduction in the risk of micro- and macrovascular complications of T2DM, with the benefits apparent even at 10 years after patients stopped receiving their randomised treatment. More recent studies have demonstrated that delaying this intervention does not reap the same rewards. Indeed, studies such as ACCORD, ADVANCE and VADT demonstrate that although aggressive glucose-lowering strategies improve microvascular disease outcomes, similar benefits may not be seen in reducing major cardiovascular events [41–44]. In simple terms, maintaining health is achievable and is rewarded with long-term wellbeing; but once our patients are broken, it is unlikely they can be fixed.

Outcomes-based incentives may benefit both patients and physicians to achieve targets. Financial incentives may be practical for physicians, and the achievement of treatment goals can be celebrated as personal victories by the patients. However, the principal problem with this is that it paradoxically discourages individualised care. Rewarding targets achieved may encourage either universal target setting, such as has been used to the detriment of many elderly patients in the UK [6], or self-serving 'easy' target setting in order to receive reward and recognition, rather than acting in the best interest of the person with diabetes. Neither of these options addresses the underlying problem of clinical inertia. We believe that all practitioners have the welfare of their patients at heart, and therefore do not require further incentivisation to act in their best interest. Rather, we believe that the single

biggest cause of failure in the optimisation of care is a lack of time to have the open communications required to explain the nature of the disease in a manner understandable to all, to ascertain the principal goals for the person with diabetes, to determine the most appropriate targets and to work with the person with diabetes and their supporters to achieve the best possible quality of life. Therefore, we call upon the research community to collect evidence on the effectiveness of thorough and longer communication, and purchasers and providers to recognise the importance of the single most important element lacking in the management plans for a person with diabetes: time.

5. Summary

Clinical inertia is, at least in part, responsible for delays in the initiation and escalation of therapy in the treatment of type 2 diabetes. There is impairment in communication between physicians and people with diabetes that, we believe, plays a significant modifiable part in this clinical inertia. Implementation of the principles described here, necessarily requiring appropriate recognition, will improve understanding and collaboration between all parties and consequently improve outcomes for people with diabetes.

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Conflict of interest statement

The study was funded by Novartis and all authors are members of a steering committee for the Time2DoMore™ program initiated based on this survey. WDS reports personal fees from Novartis, Boehringer-Ingelheim, Pfizer, grants and personal fees from Novo-Nordisk. MH, DY, SV declare no conflict of interest. XC is a consultant with Novo-Nordisk, Novartis, Saonfi, Boehringer Ingelheim and has received speaker honoraria from AstraZeneca, Bristol-Mayer Squibb, Lily, Novartis, Novo-Nordisk, Sanofi and has also been involved in clinical trials for Novartis and observational international study for Lily. ZV has received consultancy fees from pharmaceutical companies. VM has received research or educational grants from MSD, Novartis, Novo Nordisk, Eli Lilly, USV, Lifescan, Johnson & Johnson, Sanofi Aventis, Merck and from several Indian pharmaceutical companies. MB reports grants and personal fees from Bayer, Boehringer-Ingelheim, Novartis, Novo Nordisk; grants from Riemser; personal fees from Sanofi Aventis, Lilly, Bristol-Myers Squibb, Roche, AstraZeneca, MSD, Daiichi-Sankyo, Ipsen, Johnson & Johnson, Pfizer, Takeda. PMP is employed by and own shares in Novartis. Time2DoMore™ is a trademark owned by Novartis AG.

Previous presentations

Parts of the data were presented as a poster (P-1744, P-1593) and an oral presentation (OP-0461) at World Diabetes

Congress, International Diabetes Federation 2013, Melbourne, Australia, December 2–6, 2013.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.diabres.2014.05.005>.

REFERENCES

- [1] Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HA. 10-Year follow-up of intensive glucose control in type 2 diabetes. *N Engl J Med* 2008;359:1577–89.
- [2] Inzucchi SE, Bergenstal RM, Buse JB, Diamant M, Ferrannini E, Nauck M, et al. Management of hyperglycaemia in type 2 diabetes: a patient-centered approach. Position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetologia* 2012;55:1577–96.
- [3] International Diabetes Federation. Global guideline for type 2 diabetes. *Diabetes Res Clin Pract* 2014. <http://dx.doi.org/10.1016/j.diabres.2012.10.001>.
- [4] Japan Diabetes Society (JDS). Treatment guide for diabetes 2012–2013, Bunkodo; 2013, available from: http://www.jds.or.jp/common/fckeditor/editor/filemanager/connectors/php/transfer.php?file=/uid000025_54726561746D656E745F47756964655F666F725F44696162657465735F323031322D323031332E706466 [accessed 17.12.13].
- [5] Menéndez Torre E, Lafita Tejedor J, Artola Menéndez S, Milán Núñez-Cortés J, Alonso García A, Puig Domingo M, et al. Recommendations for the pharmacologic treatment of hyperglycemia in type 2 diabetes. Consensus document. *Nefrología* 2011;31:17–26.
- [6] National Collaborating Centre for Chronic Conditions. NICE clinical guideline 66. In: Type 2 diabetes: national

- clinical guideline for management in primary and second care (update). London: Royal College of Physicians; 2008 .
- [7] Handelsman Y, Mechanick JI, Blonde L, Grunberger G, Bloomgarden ZT, Bray GA, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for developing a diabetes mellitus comprehensive care plan. *Endocr Pract* 2011;17(Suppl. 2):1–53.
- [8] International Diabetes Federation. Global guideline for managing older people with type 2 diabetes. Brussels, Belgium: International Diabetes Federation; 2013, available from: <http://www.idf.org/guidelines/managing-older-people-type-2-diabetes> [accessed 05.01.14].
- [9] Sinclair A, Morley JE, Rodriguez-Mañas L, Paolisso G, Bayer T, Zeyfang A, et al. Diabetes mellitus in older people: position statement on behalf of the International Association of Gerontology and Geriatrics (IAGG), the European Diabetes Working Party for Older People (EDWPOP), and the International Task Force of Experts in Diabetes. *J Am Med Dir Assoc* 2012;13:497–502.
- [10] Strain WD, Lukashevich V, Kothny W, Hoellinger MJ, Paldánus PM. Individualised treatment targets for elderly patients with type 2 diabetes using vildagliptin add-on or lone therapy (INTERVAL): a 24 week, randomised, double-blind, placebo-controlled study. *Lancet* 2013;382:409–16.
- [11] Hoerger TJ, Segel JE, Gregg EW, Saaddine JB. Is glycemic control improving in US adults? *Diabetes Care* 2008;31:81–6.
- [12] Braga M, Casanova A, Teoh H, Dawson KC, Gerstein HC, Fitchett DH, et al. Treatment gaps in the management of cardiovascular risk factors in patients with type 2 diabetes in Canada. *Can J Cardiol* 2010;26:297–302.
- [13] Avignon A, Attali C, Sultan A, Ferrat E, Le Breton J. Clinical inertia: viewpoints of general practitioners and diabetologists. *Diabetes Metab* 2012;38:S53–8.
- [14] Ross SA. Breaking down patient and physician barriers to optimize glycemic control in type 2 diabetes. *Am J Med* 2013;126:S38–48.
- [15] Valensi P, Benroubi M, Borzi V, Gumprecht J, Kawamori R, Shaban J, et al. The IMPROVE study – a multinational, observational study in type 2 diabetes: baseline characteristics from eight national cohorts. *Int J Clin Pract* 2008;62:1809–19.
- [16] Sreenan S, Virkamäki A, Zhang K, Hansen JB, PREDICTIVE study group. Switching from NPH insulin to once-daily insulin detemir in basal bolus-treated patients with diabetes mellitus: data from the European cohort of the PREDICTIVE study. *Int J Clin Pract* 2008;62:1971–80.
- [17] Home P, Naggar NE, Khamseh M, Gonzalez-Galvez G, Shen C, Chakkarwar P, et al. An observational non-interventional study of people with diabetes beginning or changed to insulin analogue therapy in non-Western countries: the A1chieve study. *Diabetes Res Clin Pract* 2011;94:352–63.
- [18] Phillips LS, Branch WT, Cook CB, Doyle JP, El-kebbi IM, Gallina DL, et al. Clinical inertia. *Ann Intern Med* 2001;135:825–34.
- [19] Grant RW, Cagliero E, Dubey AK, Glidesgame C, Chueh HC, Barry MJ, et al. Clinical inertia in the management of type 2 diabetes metabolic risk factors. *Diabet Med* 2004;21:150–5.
- [20] Shah Br Hux JE, Laupacis A, Zinman B, Van Walvaren C. Clinical inertia in response to inadequate glycemic control: do specialists differ from primary care physicians? *Diabetes Care* 2005;28:600–6.
- [21] Khunti K, Wolden ML, Thorsted BL, Andersan M, Davies MJ. Clinical Inertia in people with type 2 diabetes: a retrospective cohort study of more than 80,000 people. *Diabetes Care* 2013;36:3411–7.
- [22] Calvert MJ, McManus RJ, Freemantle N. Management of type 2 diabetes with multiple oral hypoglycaemic agents or insulin in primary care: retrospective cohort study. *Br J Gen Pract* 2007;57:455–60.
- [23] Nichols GA, Koo YH, Shah SN. Delay of insulin addition to oral combination therapy despite inadequate glycemic control: delay of insulin therapy. *J Gen Intern Med* 2007;22:453–8.
- [24] 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(6):e36361.
- [25] Yoshioka N, Ishii H, Tajima N, Iwamoto Y, The DAWN Japan group. Differences in physician and patient perceptions about insulin therapy for management of type 2 diabetes: the DAWN Japan study. *Curr Med Res Opin* 2013;1–7.
- [26] Lovshin JA, Zinman B. Diabetes Clinical inertia – a barrier to effective management of T2DM. *Nat Rev Endocrinol* 2013;9:635–6.
- [27] Cramer JA. A systematic review of adherence with medications for diabetes. *Diabetes Care* 2004;27:1218–24.
- [28] Franco M, Bilal U, Orduñez P, Benet M, Morejón A, Caballero B, et al. Population-wide weight loss and regain in relation to diabetes burden and cardiovascular mortality in Cuba 1980–2010: repeated cross sectional surveys and ecological comparison of secular trends. *BMJ* 2013;346:f1515.
- [29] Handelsman Y, Jellinger PS. Overcoming obstacles in risk factor management in type 2 diabetes mellitus. *J Clin Hypertens* 2011;13:613–20.
- [30] Broadbent E, Donkin L, Stroh JC. Illness and treatment perceptions are associated with adherence to medications, diet, and exercise in diabetic patients. *Diabetes Care* 2011;34:338–40.
- [31] García-Pérez LE, Alvarez M, Dilla T, Gil-Guillén V, Orozco-Beltrán D. Adherence to therapies in patients with type 2 diabetes. *Diabetes Ther* 2013;4:175–94.
- [32] Holt RI, Nicoluci A, Kovacs Burns K, Escalante M, Forbes A, Hermanns N, et al. Diabetes Attitudes, Wishes and Needs second study (DAWN2): cross-national comparisons on barriers and resources for optimal care—healthcare professional perspective. *Diabet Med* 2013;30:789–98.
- [33] Funnell M. Beyond the data: moving towards a new DAWN in diabetes. *Diabet Med* 2013;30:765–6.
- [34] Steinsbekk A, Rygg LØ, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. *BMC Health Serv Res* 2012;12:213.
- [35] Rosenbek Minet LK, Wagner L, Lønving EM, Hjelmberg J, Henriksen JE. The effect of motivational interviewing on glycaemic control and perceived competence of diabetes self-management in patients with type 1 and type 2 diabetes mellitus after attending a group education programme: a randomised controlled trial. *Diabetologia* 2011;54:1620–9.
- [36] Khunti K, Gray LJ, Skinner T, Carey ME, Realf K, Dallosso H, et al. Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus: three year follow-up of a cluster randomised controlled trial in primary care. *BMJ* 2012;344:e2333.
- [37] Scain SF, Friedman R, Gross JL. A structured educational program improves metabolic control in patients with type 2 diabetes: a randomized controlled trial. *Diabetes Educ* 2009;35:603–11.
- [38] International Diabetes Federation. International Standards for Diabetes Education. 3rd ed. Brussels, Belgium: International Diabetes Federation; 2009, available from: <http://www.idf.org/files/docs/INTNL-STANDARDS-EN.pdf> [accessed 05.01.14].
- [39] Haas L, Maryniuk M, Beck J, Cox CE, Duker P, Edwards L, et al. National standards for diabetes self-management education and support. *Diabetes Care* 2013;36(Suppl. 1): S100–8.

- [40] Virkamäki A, Saltevo J. Finnish Current Care Guideline for Diabetes: interactive approach to improve individualised treatment. *Diabetologia* 2011;54:1264–5.
- [41] ADVANCE Collaborative Group, Patel A, MacMahon S, Chalmers J, Neal B, Billot L, et al. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. *N Engl J Med* 2008;358:2560–72.
- [42] Bonds DE, Miller ME, Bergenstal RM, Buse JB, Byington RP, Cutler JA, et al. The association between symptomatic, severe hypoglycaemia and mortality in type 2 diabetes: retrospective epidemiological analysis of the ACCORD study. *BMJ* 2010;340:b4909.
- [43] Ismail-Beigi F, Craven T, Banerji MA, Basile J, Calles J, Cohen RM, et al. Effect of intensive treatment of hyperglycaemia on microvascular outcomes in type 2 diabetes: an analysis of the ACCORD randomised trial. *Lancet* 2010;376:419–30.
- [44] Duckworth W, Abaira C, Moritz T, Reda D, Emanuele N, Reaven PD, et al. Glucose control and vascular complications in veterans with type 2 diabetes. *N Engl J Med* 2009;360:129–39.