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COMMENTARY

# Clinical Inertia in Individualising Care for Diabetes: Is There Time to do More in Type 2 Diabetes?

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## ABSTRACT

Clinical inertia is defined as the failure to establish appropriate targets and escalate treatment to achieve treatment goals. It accounts for a significant proportion of failure to achieve targets in the management of diabetes and contributes to up to 200,000 adverse diabetes- related outcomes per year. Despite a growing awareness of the phenomenon, and newer, better-tolerated agents for the control of diabetes, there has been little improvement over the last decade in the prevalence of clinical inertia. Although common-place in clinical practice, clinical inertia does not appear to affect clinical trials. There are lessons that may be translated from these randomised controlled trials to clinical practice, which that may improve the care for those with diabetes. Key amongst these interventions are good education, clear treatment strategy and more time for interaction between physician and patients, all of which appears to reduce clinical inertia as evidenced by the "placebo effect" of clinical trials. We plan to review here, the lessons that can be learnt from clinical trials and how these may translate to better care for people with diabetes.

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## INTRODUCTION

Clinical inertia, the failure to establish appropriate targets and escalate treatment to achieve treatment goals, is responsible for substantial preventable complications of diabetes with the associated excess in direct and indirect health care costs. If "clinical inertia" was an intervention associated with this increased risk of complications, it would

rapidly be withdrawn pending safety analyses. However, the lack of appropriate escalation of treatment is accepted in every day practice. The concept of clinical inertia is not new. Despite the availability of effective glucose-lowering therapies with low risk of hypoglycaemia and weight gain, there is a persistent failure to achieve the established targets in almost half of people with diabetes.

## PREVALENCE OF CLINICAL INERTIA

Clinical inertia is a worldwide phenomenon, particularly when considering initiation of insulin in persons with type 2 diabetes. In the United States, for example, an observational study in 3,891 persons with diabetes registered with a health maintenance organisation reported a delay of almost 3 years in patients with consistently elevated glycosylated haemoglobin (HbA1c) levels despite dual once a day (OAD) therapy (metformin and sulfonylurea) [1, 2]. Further, a multinational, 26-week observational study reported an HbA1c level of 8.9% (74 mmol/mol) at insulin initiation [3]. A Canadian study in adults with diabetes aged ≥65 years ($n = 2,502$) found that, although diabetologists are more likely to initiate insulin based on poor glycaemic control (HbA1c >8%), only 45% intensified treatment overall compared with 37% of primary care physicians [1]. Unfortunately, this reluctance influences the patient perceptions of diabetes therapies and may deter them from accepting insulin therapy [1, 4, 5]. The fear of side effects can cause hesitancy to comply with insulin therapy [6]. Paradoxically, the dialogue prior to insulin initiation often vilifies the therapy itself. Insulin may also be perceived as a punishment rather than a necessary part of the management of this progressive condition. In doing so, physicians can be the root cause of non-adherence to their own prescriptions [7].

There is also reluctance to initiate combination therapies in early-stage disease; movement beyond monotherapy in patients who are asymptomatic is often slow, particularly when faced with a lack of confidence or experience with newer therapies. Once therapy is initiated, there is also a lack of organisational mechanisms to help physicians monitor response to therapy. Guidelines indicate that the benefits, or otherwise, of therapy should be monitored and if target is not achieved, therapy adjusted. This, however, very rarely takes place, particularly with the generic familiar treatments, such as sulphonylureas. In the absence of good mechanisms to monitor response to therapy prior to review, further unnecessary delays often occur prior to any changes in therapy. In these settings, a 'wait until next visit' approach is often adopted, particularly when faced with soft rationalisations by patients to avoid treatment intensification [7]. Yet, the increased awareness and methods of quantification have done little to improve outcomes. Time to intensification of treatment has not significantly improved since 1990s to date [2].

## THE COST OF CLINICAL INERTIA

Part of the rationalisation of clinical inertia is embedded in the "first do no harm" principle. This results in the perception that non-intervention is better than risking the side effects of treatment. Herein lies one of the major difficulties in preventative medicine; for the event, such as the stroke, deterioration in vision or foot ulcer that has been prevented is never visible, whereas the complications of

treatment, such as hypoglycaemia or weight gain, are all too apparent. Epidemiological data, however, suggest that for every 20 people with type 2 diabetes with an HbA1c value 1% above the 7% target, one will suffer a microvascular complication within 5 years. A low-density lipoprotein (LDL) cholesterol level 30 mg/dl above goal will result in a myocardial infarction or stroke, and for every 20 patients with a blood pressure 10 mmHg above target, one will suffer a myocardial infarction or stroke and one will progress their microvascular disease within the same 5-year period. Analysis of National Health and Nutrition Examination Survey (NHANES) data suggests that only approximately 20% of people with diabetes are achieving all of these targets [8]. Therefore, in North America alone, where there are approximately 36.7 million people with diabetes, this equates to nearly 30 million people who are inadequately controlled. This is responsible for an excess of at least 200,000 avoidable diabetes-related complications per year, which in turn is responsible for billions of dollars in excess health care charges and tens of thousands of premature deaths. If these events were occurring as a result of inaccurate or inappropriate prescriptions it would be regarded as an unacceptable prescribing error, likely to engender public outrage. Paradoxically, there is an acceptance of this inertia where the problem is a lack of appropriate prescription rather than administering inappropriate medication.

## CAUSES OF CLINICAL INERTIA

Part of the acceptance of clinical inertia is because there is no single identifiable fault. Rather, it is a multifactorial condition, with contributory factors from the people with diabetes, the physicians and the system in which they operate.

### Physician Factors

Whereas physicians are able to accurately identify clinical inertia in their peers, they consistently overrate the quality of the care they provide. Additionally, they substantially underestimate the number of their own patients that are not at targets. Physicians are also more prone to making "soft excuses" to avoid intensification; a lack of time to adequately discuss the new strategy, blaming the patient for non-compliance or adopting a paternalistic approach. Finally, many physicians may lack the appropriate support, knowledge or training to manage multiple chronic diseases. This is particularly true in the management of type 2 diabetes, where therapeutic options have expanded considerably in a relatively short time frame mirrored by substantial changes in guidelines. These guidelines further complicate the management strategy of diabetes, as physicians are increasingly recommended to individualise treatment goals. There are, however, no clear recommendations as to how to establish these goals. Paradoxically, therefore, the drive to individualise care actually encourages clinical inertia through lack of clarity.

There are three potential points on the pathway to good control where these can fail—setting the appropriate target, initiating appropriate treatment and modifying the treatment in response to outcomes.

### Establishing Goals

Physicians tend to set targets based on treatment strategies with which they are most familiar, appropriate for the individual or not.

To date there is only one study which has evaluated the feasibility of individualising treatment targets [9]. Despite being provided clear guidance on how to personalise targets, conventional targets of around 7% were still set, demonstrating inertia of a different sort—the reluctance to move away from conventional targets and therefore potentially overtreat certain individuals.

Individualising treatment targets often provides an opportunity for "false reporting" of success, allowing the goal to retrospectively move to meet achieved value. Often this may be appropriate and indeed these goals should be in a permanent state of flux reflecting the complex progressive nature of diabetes. However, in such time-varying processes, goals should reflect the anticipated changes. Such forward planning facilitates realistic target setting with appropriate thresholds for action. Clear documentation and review on a regular basis allows coordination whilst demonstrating the reality of individualising care.

## Systemic Contributors to Clinical Inertia

Older guidelines that promoted universal algorithmic pathways triggered a different type of clinical inertia. When faced with such goals and protocols to achieve them, physicians often feel a sense of futility. Furthermore, this focus on goal-setting pathology management overshadows the need for appropriate action and grossly under-recognises the importance of basic communication between patient, physician and within the multidisciplinary team. This is particularly true in the primary care setting where physicians tend to operate in isolation. The resultant reactive, rather than proactive, approach to management leads to intensification of diabetes treatment, and specialist support is only requested once the glycaemic control has been lost and, in effect, waiting until complications have arisen before appropriate preventative strategies are engaged.

Time constraints further contribute to the delays in appropriate intensification of therapy [10]. Clinical trials offer extended, frequent visits demonstrating a significant "placebo-effect". Unlike quality of life measures, glycaemic control is unlikely to be directly affected by the level of patient/physician contact time. However, increased frequency of visits and engagement may offer other mechanisms for reduction of clinical inertia. Regular scheduled visits encourage shorter-term goal setting with established timelines and planned interventions if these are not met.

Clinical trials have additional transferable features that may further reduce clinical inertia; trial protocols provide decision support that leaves little ambiguity about required interventions. The final, potentially transferable, lesson from clinical trials is the degree of accountability at each visit and introducing clear clinical record forms to facilitate adherence to protocols, requiring a systematic record of results, actions implemented and justifications of any deviations from the protocols.

## Patient Factors Contributing to Clinical Inertia

The causes of clinical inertia do not solely lie with physicians. Non-adherence to lifestyle modifications and prescribed drug treatments is estimated to count up to nearly 100% [11]. The underlying reasons for this are unclear. Interestingly, social and environmental pressure may be the strongest modulators for "required" lifestyle changes. The importance of socio-economic factors for diabetes outcomes has recently been demonstrated by a population

wide analysis of the consequences of weight loss and regain driven by an economic crisis in Cuba [12]. In this survey, an average population wide ~5.5 kg weight loss was associated with rapid significant declines in diabetes and heart disease prevalence, whereas a weight rebound led to a diabetes prevalence that even exceeded pre-crisis levels [12].

Patient understanding of, and engagement with, their treatment can be a crucial determinant of adherence [13] as it may be adversely influenced by attitudes, negative media publicity and resultant misperception [14, 15]. Although no research has demonstrated the role of positive media publicity, a logical extrapolation of this is that positive publicity may encourage a willingness to intensify treatment on behalf of the patient. This approach has been effective in conditions such as erectile dysfunction and stress incontinence and would be expected to reduce clinical inertia, particularly if the positive message is focused on diabetes rather than specific pharmaceutical agents.

## TACKLING CLINICAL INERTIA

Identifying the causes of clinical inertia is only a small step in reducing the excess burden of undertreated diabetes. There have been several studies attempting to address the issue with limited success. One of the limiting factors of these studies is that they have each attempted single interventions to challenge a multifactorial condition. When considering each of the factors to be discussed, we ask the reader to remember how these can only work as part of a combination strategy. Still, prior to developing strategies, a clear definition of clinical inertia is required. Older "one size fits all" protocols are no longer applicable; the lack of an individualised target is the evidence of clinical inertia itself.

The therapeutic goal may be fluid. The reality of patient factors such as forgetfulness and real-world impediments may make previously set targets unachievable despite all good intentions and every effort. In such circumstances, targets should be amended to concede that previous targets are unachievable or inappropriate with available tools. This must be distinguished from retrospective amendment of targets to excuse clinical inertia.

### Accountability Through Incentivisation

Accountability between patient and physician is difficult, particularly as "soft reasoning" resulting in fewer tablets and less intensification is perceived as a positive outcome by the patient. However, considering the implications of chronic, inadequate metabolic control, personal and economic direct and indirect costs, several providers have elected to provide financial incentives for good metabolic control. In 2003, the UK National Health Service (NHS) renegotiated the primary care general practitioners' contract to include a "pay-per-performance" scheme. This quality and outcomes framework (QOF) linked 129 indicators covering different areas including diabetes, and provided a pecuniary reward for achieving targets. Among these, 16 points, each worth £124.60, were awarded for achieving an HbA1c of at <7.5% in at least 50% of people with diabetes. This financial incentivisation of better metabolic control was associated with an increase from 39.7% in 2006 to 52.1% in 2008 of people with diabetes achieving an HbA1c of <7.5% in the UK. Additionally, the number of patients with poor control (i.e. >10%) reduced from 11.8% to 10.1%, suggesting the intervention had also

improved the general approach to diabetes, not just chasing the 50% target to receive the reward. It must be acknowledged that this time period also saw the introduction of the dipeptidyl peptidase-4 (DPP-4) inhibitors, enabling targets to be achieved with less hypoglycaemia and weight gain, thereby making realising targets more acceptable to the people with diabetes. The process of incentivised management, however, did not necessarily provide additional doctor–patient contact time with the population as a whole. Therefore, to achieve these targets, increased time intervening in people with diabetes, may come at a cost of less time available to people with other non-incentivised long-term conditions, potentially to their long-term detriment.

**Increased Direct Patient Contact Time**

Clinical trials usually commence with high-frequency screening visits, followed by a series of more frequent visits to initiate and intensify care, before a stabilised visit regimen approximately 3–4 months apart. These trials usually report good early glycaemic control that is sustained for the duration of the study. There are many reasons why this increased frequency of visits may improve control, beyond the increased opportunity to intensify care and better monitoring of response to therapy. The increased frequency, particularly at the outset of the disease, reinforces the severity of the disease to the persons with diabetes, thereby reducing resistance to escalate intervention. It offers the opportunity for regular educational input, in digestible packages, and allows development of a good rapport. Finally, the patient learns by experience that frequent review and adjustment of therapy is a part of good diabetes care rather than a sign of treatment failure. There are, of course, cost implications of increased frequency of visits, extra investigations and the increased prescribing, however, it would be anticipated that this would be ameliorated in the long-term by the reduced complications.

## IN SUMMARY

The causes of clinical inertia are multifactorial, with contributory elements from people with diabetes, physicians and the system within which they work. One of the key elements appears to be a lack of open communication in both directions allowing the person with diabetes to understand the gravity of their diagnosis and engage them in treatment choices, whilst the patient equally may not express their willingness, nor comply with attempts to escalate therapies to improve their health.

Clinical trials are not affected by clinical inertia, however, these protocols are expensive to run and cannot be generalised into general practice. Yet, there are valuable lessons to be learnt from these trials that may be transferable to daily practice. Further work is required to assess the comparative costs and effectiveness of each individual element of the clinical trial strategies either alone or in combination to reduce the burden of clinical inertia.

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***Compliance with ethics guidelines.*** The analysis in this article is based on previously conducted studies, and does not involve any new studies of human or animal subjects performed by any of the authors.



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