

July 2016

Improving Type 2 Diabetes Therapy Compliance and Persistence in Brazil

How to Address Avoidable Economic and
Societal Burden



Introduction

As the prevalence of type 2 diabetes (T2D) increases globally, the condition and its associated complications are generating considerable—and growing—economic burden on healthcare systems and societies. Brazil reflects this trend, facing a rising prevalence of T2D,^{1,2} with over 11.5 million people living with the condition, and this figure expected to double by 2040. The potential consequences that diabetes could generate on the nation, both in the present and future setting, are a major challenge for all stakeholders. Despite improved diagnosis and advances in treatment options for individuals with T2D, sub-optimal therapy compliance and persistence limit the benefits derived from these and contribute to avoidable economic and social burden.

This report is part of a publication series examining six countries and their differing stages of recognition of T2D as a public health priority. It examines the Brazil-specific burden of T2D and its complications, and opportunities in relation to therapy compliance and persistence improvement strategies. A range of validated, Brazil-specific recommendations to address sub-optimal T2D therapy compliance and persistence are put forth for action by government stakeholders, payers, healthcare providers and healthcare administrators and focus on three broad phases of a patient journey toward optimal compliance and persistence, (i) identify and profile, (ii) activate and, (iii) sustain. These are all designed to improve T2D therapy compliance and persistence in the Brazilian population, and consequently decrease significant and avoidable economic and societal costs, and improve quality of life for people living with the condition.

This study is based on research and analysis undertaken by the IMS Consulting Group with support from Lilly Diabetes. The contributions to this report of Andre Fabre Ballalai Ferraz, Andreas Duva, Daniel Houslay, Peter Thomas, Graham Lewis, Adam Collier, Mark Lamotte, Volker Foos, Phil McEwan, Raf De Moor and others at IMS Health are gratefully acknowledged.

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Burden of T2D

Overview of T2D and its complications

Type 2 Diabetes (T2D) is a chronic condition characterized by both insulin resistance and the progressive dysfunction of insulin producing pancreatic beta-cells. Consequently, person(s) with T2D (henceforth referred to as PwD in this paper) suffer from elevated blood glucose and lipid levels as well as elevated blood pressure, which can result in long-term vascular complications.³

Undetected or poorly managed T2D with persistently elevated levels of blood glucose increases the risk of long-term debilitating and life-threatening complications due to macrovascular damage (e.g. stroke, myocardial infarction) and microvascular damage (e.g. nephropathy, foot ulcers leading to amputations, retinopathy leading to blindness) as well as short-term complications such as lethargy, poor wound healing and propensity for opportunistic infections. All of these complications can vastly decrease quality of life, productivity and life expectancy of PwD.

A major public health concern with significant economic and societal burden

T2D is caused by a combination of factors, including genetic susceptibility, obesity, and physical inactivity. In parallel with population aging, several other factors associated with modern lifestyle have contributed to the increased trend in prevalence of T2D over recent decades.⁴

Globally, Brazil has the fourth highest number of PwD.² Diabetes prevalence is estimated at approximately 6.9% of the population, totaling more than 13 million PwD,⁵ of whom close to 90% suffer from T2D.⁶ Age is a defining factor of T2D prevalence in Brazil, as prevalence ranges from 2.7% in individuals aged 30–59 up to 17.4% in people aged 60–69.⁷ The same is true for the rate of undiagnosed PwD, which scales from approximately 2% in individuals aged 40–44 to approximately 4.6% in individuals aged 75 and over.⁸

Governmental epidemiological data demonstrate a trend toward increasing T2D prevalence rates, which grew from 5.5% in 2006 to 6.9% in 2013.¹ Indeed, it is projected that the diabetes population in Brazil will reach 23.3 million by 2040.² These trends are in line with the increasing rates of overweight (46.6% of the population in 2009) and obesity (13.9% of the population in 2009),⁹ as well as the aging Brazilian population.⁸

Diabetes currently costs the Brazilian healthcare system BRL 66 billion (USD 22 billion)¹⁰ per year and has been predicted to increase to BRL 108 billion (USD 36 billion) by 2040.² Furthermore, the World Health Organization (WHO) predicted that, in Brazil, diabetes and cardiovascular diseases cause a net loss in national income of 49.2 billion International Dollars.¹¹ Between 1999 and 2001, approximately 7.4% of all non-pregnancy related hospital admissions and 9.3% of all hospital costs in Brazil were attributable to diabetes (all types).⁷ Diabetes is also linked to 278,778 years of potential life lost for every 100,000 people.⁷ As such, diabetes places a significant strain on the healthcare system and society, which, in light of the epidemiology trends in the country, will rapidly escalate.

Challenges managing T2D in the Brazilian healthcare system today

Even though governmental data indicate a growing prevalence of T2D in Brazil,¹ which will inevitably cause an increase in the associated economic burden, there is no official government plan aimed at controlling or preventing the condition. The only public sector sponsored, country-wide initiative currently available is the free provision of diabetes medication and related supplies to registered PwD.¹²

As it stands, the biggest obstacle for the implementation of any T2D management solution in Brazil is the complexity and fragmentation of the healthcare system. Brazil is a large and highly populated country, with a complex federal system and precarious income distribution where public and private healthcare systems co-exist with little integration. On the one hand, the public system offers provision of care, funded majorly through SUS (Unified Healthcare System), a tripartite fund based on contributions from the federation, states and municipalities. Of a population of 205 million, approximately three quarters of people depend on public healthcare.¹³ On the other hand, the private system, which covers almost 49 million people,¹⁴ comprises both out-of-pocket financing and private insurance, which is largely employment related. Although regulated in terms of minimal provision, the private system is fragmented, autonomous and heterogeneous. As a result, PwD can be covered under both the public and private sectors. Actions towards better T2D management may depend on the coordination of different agents, which is not always feasible.

Sub-optimal compliance and persistence is a cause of T2D-related complications

Compliance and persistence defined

The challenges in improving T2D care within the Brazilian healthcare system contribute directly or indirectly to sub-optimal T2D therapy compliance and persistence among PwD.

Defining therapy compliance and persistence

There is a lack of consensus in the literature on the exact definitions of therapy compliance (synonym: adherence, referred to as compliance in this paper) and persistence. In this paper, these terms are defined as:

Therapy compliance

“The extent to which a patient acts in accordance with the prescribed interval, and dose of a dosing regimen”¹⁵

Therapy persistence

“The duration of time from initiation to [healthcare professional (HCP) recommended] discontinuation of therapy”¹⁵

Additionally, this paper focuses on the proportion of people who have low therapy compliance, rather than the level of therapy compliance itself.

Extent of sub-optimal T2D drug therapy compliance and persistence

Literature research, database analysis and interviews have indicated that sub-optimal compliance and persistence is a significant issue for PwD globally. At the same time, broadly understanding and resolving issues that impair compliance and persistence do not seem to have been prioritized. This is reflected, although not by a causal relation, in the very limited number of studies that address this issue in Brazil:

- A systematic literature review of Brazilian papers retrieved only two cross sectional studies:¹⁶ The first one evaluated 79 PwD using the Morisky–Green test and reported that 54.5% of PwD were non-compliant;¹⁷ the second one evaluated 31 PwD and reported that 48.4% of them took medication according to the wrong schedule and that 71% of them were classified as not having sufficient knowledge about their prescription.¹⁸

- A cross sectional study conducted in the Brazilian southeast evaluated 423 PwD and reported that 13.6% of them were non-compliant.¹⁹
- A randomized controlled trial conducted in the diabetes outpatient clinic of the Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo evaluated compliance, as measured by the Morisky-Green test, of PwD. At the time of randomization, the proportion of non-compliant PwD was 77.2% (n=70).²⁰
- A transversal study in Brazil based on patient medical records reported that 77% of PwD in the public healthcare setting were non-compliant to their medication.²¹

Compliance rates as reported in local studies vary widely. In our global literature review and market research it has been found that the actual rates of compliance and persistence to T2D therapy may be even lower than many of the estimates stated above as many of these studies fail to grasp all aspects of compliance and persistence. For example, they are unlikely to include rates of primary non-compliance, defined as PwD who have been diagnosed but never initiated therapy. This is significant as rates of primary non-compliance have been shown to be as high as 15% in other countries.²² Additionally, many of these studies will not measure those who started but have since ceased taking their medication. Finally, the studied populations often are small and may not be representative of the different PwD profiles in terms of access to healthcare or age.

Economic burden of sub-optimal compliance and persistence on governments and healthcare systems

Calculating the cost of sub-optimal T2D therapy compliance and persistence with the CORE Diabetes Model

The CORE Diabetes Model is a validated, peer-reviewed model, which simulates clinical outcomes and costs for cohorts of people with either type 1 or type 2 diabetes.^{27,28} The model has been customized to Brazil to calculate the cost of avoidable T2D-related complications as a result of those PwD who struggle with therapy compliance and persistence.

This has been achieved by applying two key Brazilian specific data points:

1. The percentage of Brazilian PwD with sub-optimal levels of therapy compliance and persistence
 - Calculated to be as high as 77%²¹
2. The relationship between sub-optimal compliance and HbA1c as estimated by physicians in Brazilian PHCs and diabetes clinics
 - Approximately 18.3% increase in HbA1c due to sub-optimal compliance^{21,29} (similar to results in a widely-cited scientific study in the US²⁴)

Recognizing that sub-optimal T2D therapy compliance and persistence causes persistently elevated blood glucose levels,^{23,24} leading to increased risk of complications²⁵ and subsequently costs,²⁶ the extent of this contribution to complication-related costs was estimated. To do this, the CORE Diabetes Model, a validated health economics model,^{27,28} was customized to the Brazilian population in order to provide guidance on potential healthcare system savings if the issue of sub-optimal T2D therapy compliance and persistence was addressed in Brazil.

What are HbA1c levels?

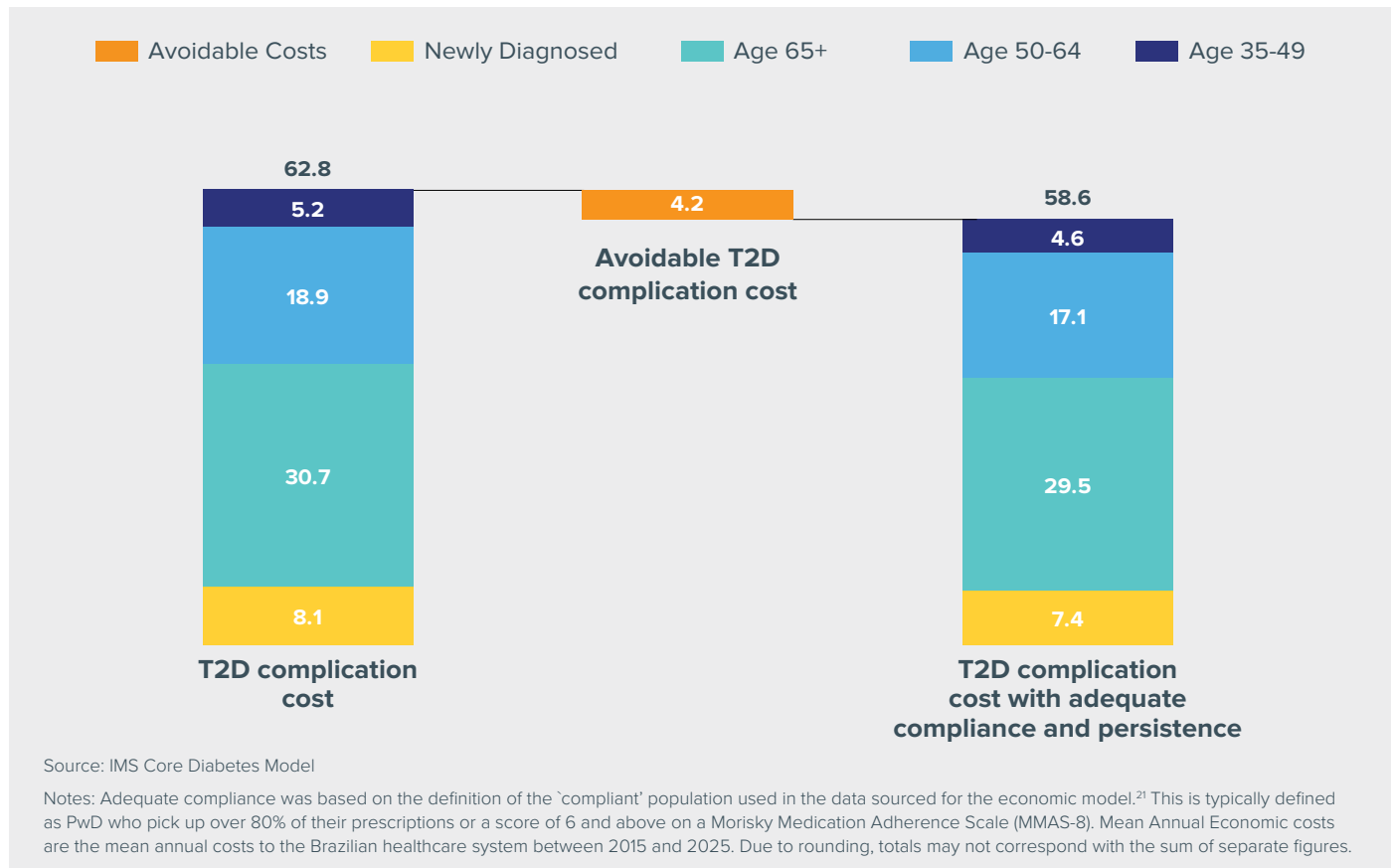
HbA1c levels are used to diagnose and monitor diabetes and refer to glycated hemoglobin (HbA1c), otherwise known as average plasma glucose concentration. HbA1c develops when hemoglobin, an oxygen-carrying red blood cell protein, combines with glucose in the blood, thus becoming glycated.³⁰

Measurement of HbA1c reflects average plasma glucose levels over a period of 8-12 weeks. It can be performed at any time of the day and does not require any special preparation such as fasting.³¹ These properties have made it the preferred test for both diagnosing diabetes and assessing glycemic control in PwD. The higher the HbA1c level, the higher the increase in risk of diabetes-related complications. Normal, pre-diabetic and diabetic HbA1c ranges are provided below:³²

HbA1c Level	Indication
<5.7%	Normal range
5.7% – 6.4%	Pre-diabetes
≥ 6.5%	Diabetes

Using the CORE Diabetes Model, it has been estimated that T2D-related complications will cost BRL 62.8 billion (USD 20.9 billion) per year to the Brazilian healthcare system (mean of next 10 years, see Exhibit 1). By customizing the CORE Diabetes Model to take into account T2D therapy compliance and persistence levels in Brazil, it has been estimated that as much as 6.7% of this healthcare system cost, or approximately BRL 4.2 billion (USD 1.4 billion) per year, will be driven by complications suffered by those PwD who are currently struggling to achieve optimal T2D therapy compliance and persistence (see Exhibit 1).

Exhibit 1: Mean Annual Economic Costs Associated With Sub-Optimal T2D Drug Therapy Compliance and Persistence in Brazil 2015–2025, BRL Bn



To provide a sense of proportion, BRL 4.2 billion (USD 1.4 billion) annual cost of avoidable complications due to sub-optimal compliance and persistence is equal to 1.45 times the total amount spent on diabetes medications annually.³³ In summary, the economic cost burden of T2D complications of Brazilian PwD who are struggling to achieve optimal T2D therapy compliance and persistence is significant and, most importantly, avoidable.

Furthermore, this unnecessary spend and economic wastage is only one dimension of the overall cost of sub-optimal T2D therapy compliance and persistence as it only pertains to the costs associated with avoidable complications of T2D and does not include indirect costs related to lost work days for working-age PwD and their family members. Additionally, spending and investment related to HCP training, T2D screening, diagnosis and PwD education, regular GP or hospital appointments, medication dispensing and medicine costs are all sub-optimized if PwD are unable to comply and persist with their therapy or make the necessary changes to their lifestyle.

Moreover, these costs may be underestimated due to the difficulty in accurately measuring the full extent of sub-optimal therapy compliance and persistence. Separately, due to the long-term nature of the condition and the ever-increasing prevalence, the costs linked to sub-optimal compliance and persistence in T2D therapy are only set to escalate in the short-to-medium term.

Burden of sub-optimal compliance and persistence on persons with T2D and society

The CORE Diabetes Model has also estimated the extent of increased risk for debilitating and life-threatening complications such as coronary artery disease and myocardial infarction, cerebrovascular disease and stroke, renal failure, diabetic retinopathy and blindness, diabetic peripheral neuropathy and diabetic ulcers and lower limb amputations in PwD that are sub-optimally compliant and persistent to their T2D therapy in Brazil (see Exhibit 2). It must be noted that the particularly large increase in risk of end-stage renal disease is, at least in part, due to elevated HbA1c levels having a greater impact on microvascular complications in comparison to macrovascular complications with diabetes being the single most common cause of end-stage renal disease in the developed world. Therefore, poor diabetes control will create a much stronger impact on increasing the risk of these diabetes specific microvascular complications when compared to those with multiple other risk factors (i.e. stroke and heart attack).³⁴

Exhibit 2: Increased Risk of Complications and Healthcare Costs Over the Lifetime of a Non-Compliant PwD

Percent increased risk versus compliant PwD	Complication
303%	More likely to have end stage renal disease
14%	More likely to have a heart attack
15%	More likely to have a stroke
26%	More likely to have an amputation
71%	More likely to go blind (severe vision loss)
>BRL 28,500 (USD 9,500)	Extra cost to the healthcare system over their lifetime

Source: IMS Core Diabetes Model

Notes: Increased lifetime risk of various complications and healthcare costs calculated over the lifetime of a non-compliant PwD in comparison to a compliant PwD, based on the average 50-64 year old PwD

The path to optimal compliance and persistence relies on effective patient activation

Action is needed

Between 2006 and 2013, T2D prevalence in Brazil has risen by 1.4 percentage point,¹ and by 2040 there could be 23.3 million individuals with diabetes in Brazil.² In 2015, direct costs for diabetes (all types) in Brazil were estimated to be approximately BRL 66 billion (USD 22 billion),² which could increase to as much as BRL 108 billion (USD 36 billion) in 2040.² Of this, it is estimated that approximately 6.7% (BRL 4.2 billion) is being driven by sub-optimal T2D therapy compliance and persistence.³⁵ Absence of action to tackle this problem now, when prevalence continues to rise and considerable challenges to optimal T2D management still exist in the public healthcare system, will result in a growing build-up of costs. A set of practical and action-oriented recommendations has been proposed in this paper to raise levels of compliance and persistence in T2D therapy, including diet, exercise and glucose-lowering medicines, by:

- Identifying and profiling PwD in need of help
- Improving access to and customizing T2D education
- Optimizing the physician capacity/capability balance in the public sector
- Using digital technology to maintain effective condition self-management

These recommendations are presented to inspire collaborative discussion and health outcome-oriented pilots that, if found successful, should be expanded to improve treatment outcomes and help reduce the significant cost burden of sub-optimal T2D therapy compliance and persistence.

Effective patient activation

What is patient activation?

Activation is defined as how well a person understands his or her role in the care process, and whether that person has the knowledge, skills, capacity, and confidence to follow through with this role.³⁶ As such, PwD activation relates to an individual's willingness and ability to take independent actions to manage his or her health and care.

Research shows that increased degrees of activation are positively correlated with an increase in compliance to therapy and a reduction in healthcare expenditure and.^{37,38,39} For example, one study, which considers T2D among other conditions, found that patients with lowest activation levels were predicted to cost 21% more than highly activated patients.³⁷

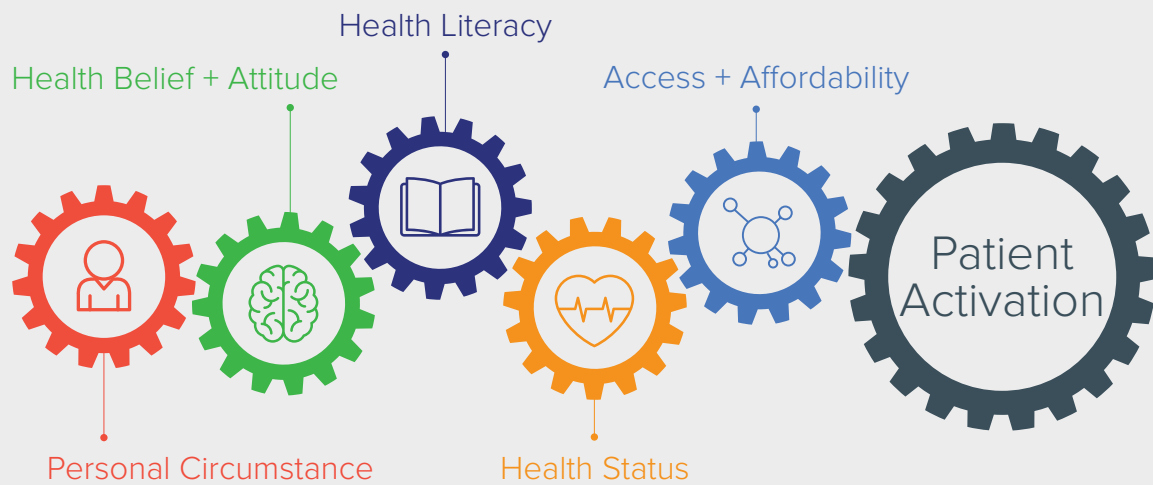
Consequently, T2D therapy compliance and persistence will remain sub-optimal as long as PwD activation remains inadequate. Effective PwD activation is difficult to achieve as it stems from the synergistic impact of multiple underlying drivers and stakeholders, hence a tailored, individualistic approach is needed to improve compliance.

Based on literature and extensive qualitative expert interviews, ‘health beliefs and attitude’, ‘personal circumstances’, ‘health status’, ‘health literacy’ and ‘access and affordability’ have been identified as the five key drivers of PwD activation (see Exhibit 3).^{40,41,42,43,44} While these five distinct drivers work in concert to influence overall degree of PwD activation, they also are intertwined such that changes in one driver impact others (see Exhibit 3). For example, improving health literacy may positively impact health beliefs and attitude, thus enabling PwD to identify opportunities for overcoming burdens associated with barriers to access and affordability.

Effective PwD activation also requires multi-stakeholder involvement, including policy makers, payers, healthcare providers, caregivers, family, and PwD themselves. All of these stakeholders influence PwD activation and can promote T2D therapy compliance and persistence. Policy makers, for instance, play key roles in improving access, health literacy, health beliefs and attitude by addressing barriers in integration and provision of care.

PwD activation is therefore the sum of personal circumstances, attitudes, behaviors, and motivations, which are themselves influenced by a variety of stakeholders. The combination of these factors results in a spectrum of PwD activation degrees that stem from different root causes. As a result, it is critical to not only quantify PwD activation but also identify its associated underlying causes. This will enable HCPs to address an individual’s specific support and information needs and develop a customized, PwD-centric approach that positively impacts compliance and persistence in T2D therapy and reduce the avoidable T2D complication cost of approximately BRL 4.2 billion (USD 1.4 billion) associated with this (see Exhibit 1).

Exhibit 3: The Five Drivers of Patient Activation and Their Definition



Personal circumstances constitute the social factors, including age, gender, social network, socio economic factors, that have an impact on the individual’s health.^{40,45,46}



Health beliefs and attitude relate to whether PwD accept their condition and believe in the benefits of their overall therapy.^{41,47,48}



Health literacy relates to the extent “to which individuals have the capacity to obtain, process, and understand basic information and services needed to make appropriate decisions regarding their health.”^{42,49,50,51}



Health status relates to a variety of factors such as diet, exercise, and number of co-morbidities.^{43,52,53}



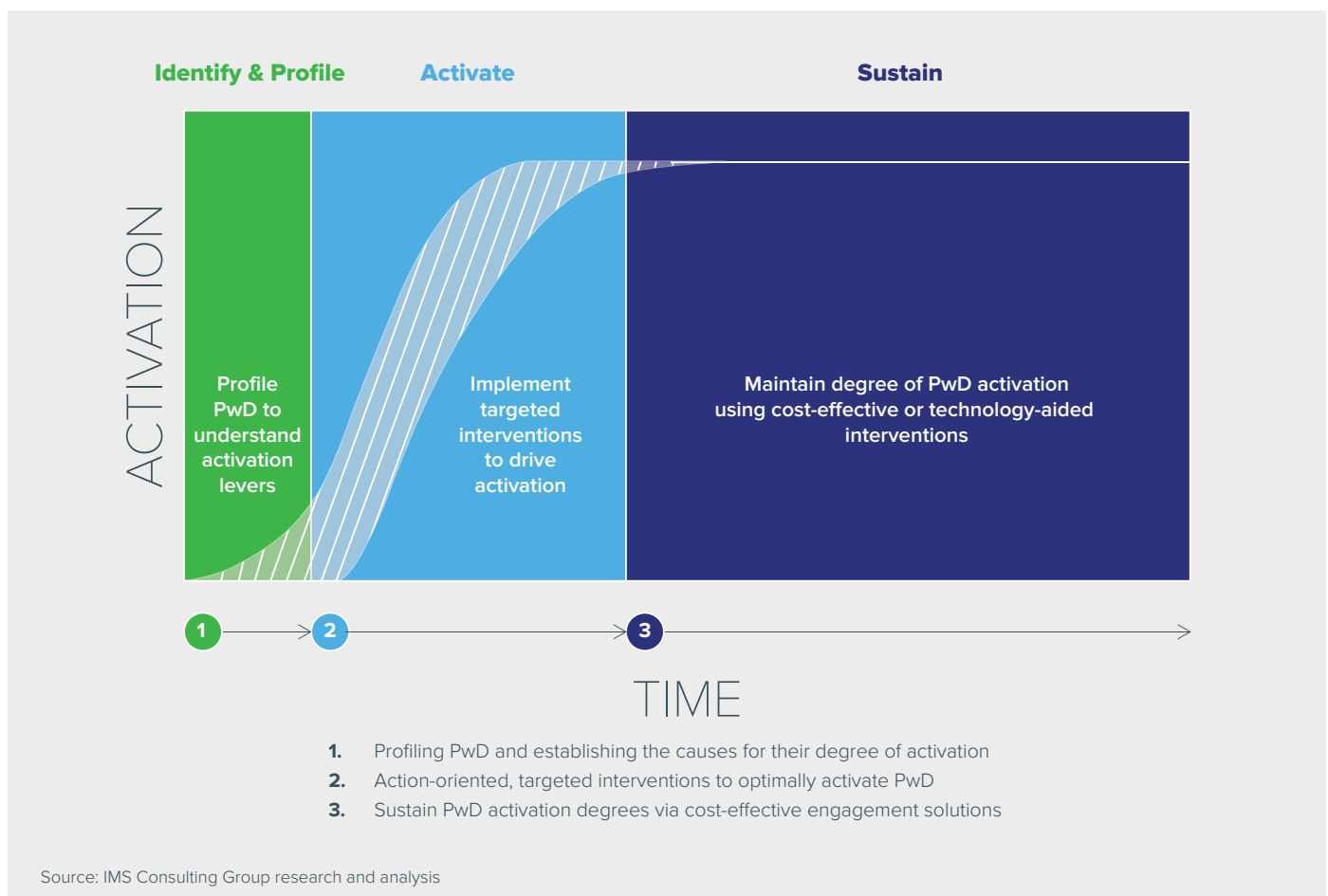
Access and affordability concerns access to and affordability of healthcare, healthy food, and exercise facilities.^{44,54,55}

Source: IMS Consulting Group research and analysis

The path to optimal compliance and persistence

PwD activation relates to an individual's willingness and ability to take independent actions to manage their own health and care. It is therefore paramount to improving therapy compliance and persistence and, in turn, health outcomes.⁵⁶ Through literature research and qualitative interviews with expert stakeholders, it has been determined that effective PwD activation, and therefore a PwD' journey to optimal compliance and persistence, requires progression through three key phases identified as 'identify and profile', 'activate', and 'sustain' (see Exhibit 4).

Exhibit 4: A PwD Path to Optimal Compliance and Persistence



In the 'identify and profile' phase, PwD need to be assessed by HCPs to determine their degree of activation as well as the health-related attributes (including attitudes, motivations, behaviors, logistical and financial challenges) that lead to this degree of activation. In the 'activate' phase, to effectively improve activation and successfully set PwD on the path to optimal compliance and persistence, interventions, goals and action steps need to be customized based on the individual's degree of activation. Finally, in the 'sustain' phase, PwD who have reached high degrees of activation and therefore proficient self-management behaviors in therapy compliance and persistence can be transitioned to cost-effective T2D management solutions.

Customized interventions within each of these phases have been designed to overcome the varied challenges related to activation and support Brazilian PwD on the path to optimal compliance and persistence in T2D therapy. To effectively promote and sustain these at a country level, it is essential that any interventions are assessed, validated and embedded appropriately in the healthcare system or governing body. This will require alignment between public stakeholders within the healthcare system and involvement from private stakeholders as well as legislative changes. With this view, it has been suggested that a number of assessment metrics and outcomes could be used to validate each intervention proposed in the paper (see Appendix, Exhibit A). By implementing these interventions, it will be possible to reduce the avoidable complication costs resulting from sub-optimal T2D therapy compliance and persistence in Brazil, estimated to be BRL 4.2 billion (USD 1.4 billion) per year (see Exhibit 1).

Enabling optimal compliance

However, advances would benefit from essential enablers, like coordination of efforts among different stakeholders and country-wide implementation of electronic medical records (EMRs), which currently are not broadly employed. This is an example where tracking information on activation, compliance, interventions and health outcomes would act as a data resource to analyze what interventions are working and where, thus presenting further opportunities to optimize and allocate resources for the most cost-effective results. It is also important to highlight that given the realities of the Brazilian healthcare system, governmental initiatives and support are vital to the implementation and success of national programs.

In line with the heterogeneity of the Brazilian health system, recommendations will refer particularly to:

- Basic/primary assistance in public service
- Reference centers or secondary/tertiary care in public system
- Private system

Recommended interventions to improve T2D therapy compliance and persistence in Brazil

Identify and profile

Recommendation 1

Promote the use of electronic medical records and keep track of compliance and persistence



An important requisite to address compliance and persistence is the existence of EMRs, as to allow both individual and aggregate public health decisions.

In 2015, SUS Basic Attention Department released e-SUS AB, its system and protocol for EMRs.⁵⁷ This was a great advance, however, lack of infrastructure, notably of computers and connectivity at care centers, still exists.^{58,59} Moreover, participation of private healthcare providers in this network, which feeds SISAB (Basic Attention Information System), is completely discretionary and not mentioned in the e-SUS AB regulating legislation.

In general, recording of compliance and persistence in a database must be possible and promoted, allowing for analysis and corrective actions. Moreover EMRs could advance if:

- At basic/primary assistance in public service, infrastructure issues, especially hardware and connection, were dealt with. Also, completion of EMRs must be simple and consume as little time as possible, as time is a precious resource in a high-volume facility. Division of tasks among HCPs is also desirable to alleviate physicians of bureaucratic work.
- At reference centers or secondary/tertiary care in public system, EMRs are introduced or reinforced, with incentives for correct completion. Closed-field forms are desirable as they allow faster data crunching. Data exploration must be fostered in the Academic field, providing scientific advancement that may indirectly benefit compliance and persistence as a consequence of an overall improvement of the healthcare system.
- At private system, utilization of standardized protocols and software created for public service can avoid implementation costs for private providers. Educating private payers about the importance and economic benefits of EMRs should create an incentive for providers to engage in correct logging of information.

Correct utilization of EMRs enables feeding evidence databases, which provide valuable information regarding real-world PwD behavior and outcomes, thus presenting opportunities to better understand the underlying drivers for optimal compliance and persistence.

Recommendation 2

Use predictive analytics to identify PwD at risk of low compliance and persistence



With the improvement of Brazil’s EMRs and healthcare database structure, this information can be analyzed to rapidly identify which PwD have or are at risk of low compliance and persistence. Data can be used to perform “predictive analytics”, a process whereby software algorithms mine compiled data based on set criteria. This would make identification quick and accurate, thus narrowing down the pool of PwD for further profiling and intervention. Although harnessing the full potential of predictive analytics in the Brazilian setting is going to take some time as EMRs and databases have only recently been launched, even a rudimentary application of such techniques could have substantial impact and this impact could have broader benefit than just in the diabetes care space.

There is a growing number of predictive analytic service providers. Brazilian health and government leaderships could explore early discussion and possibilities with such organizations to start a process that allows for the full leverage of the benefits (cost reduction and improved patient care) of predictive analytics.

Recommendation 3

Use validated psychometric assessment models to evaluate identified PwD activation as related to their diabetes care



Once PwD have been identified as having or at risk of low therapy compliance and persistence, they can then be profiled using psychometric assessment tools to determine their actual degree of activation and the underlying drivers of this. However, understanding that full leverage of predictive analytics will take some time, simple criteria could be used in the interim to rapidly implement psychometric assessment models now. For instance, acknowledging that compliance to T2D therapy can be low in newly diagnosed PwD⁶⁰ or in PwD with complex dosing regimen,⁶¹ these subgroups could be preferentially given a psychometric assessment.

Information then garnered from a psychometric assessment tool will reveal the PwD' ability and willingness to take independent action to manage their own health and care. This evaluation step is a prerequisite to setting realistic goals and actions and set PwD onto the path of optimal compliance and persistence. Such tools have been shown to increase compliance to therapy, reduce healthcare expenditure³⁷ and predict costs and outcomes for PwD.^{38,39} The Patient Activation Measure (PAM) Survey, an example of such a tool, assesses beliefs, knowledge and confidence in managing one's condition and assigns individuals to one of four activation levels, ranging from disengaged and overwhelmed (level 1) to maintaining behaviors and pushing further (level 4). On a 100 point scale, each point increase in PAM score translates into a 2% increase in compliance to medicine and a 2% decrease in hospital admissions and readmissions.⁶²

While such patient activation measurement tools need to be adapted to the Brazilian context, other conditions should be prioritized and incentivized, including:

- Integration with EMRs, which are themselves still in their infancy
- Questionnaire completion length to fit within the existing time limitations at a basic care facility
- Definition of accountability for survey among HCPs at basic care, avoiding concentration of tasks on physicians

Indeed, it is important to keep in mind that HCPs face a heavy workload of patient consultations for a number of conditions. Consultations for PwD, regardless of activation degree and other conditions tend to range between 10 and 20 minutes.⁶³ While improvements in consultation length may be implemented, correct application of a psychometric assessment tool may face time constraints. This is especially true at the time of PwD diagnosis or treatment change.

At basic/primary assistance in public service, psychometric assessments could be used to map activation and direct more complicated cases to reference centers. In public reference centers or secondary/tertiary care, multidisciplinary teams, nurses, nutritionists and social workers could all conduct psychometric assessments. In the private system, pharmacists could carry out psychometric assessments and record results.

Activate

Recommendation 4

Provide education on T2D management, including compliance and persistence



Educational programs are a key factor in the strategy to improve PwD compliance and persistence. Not only does education help PwD and HCPs crystallize knowledge about the importance of compliance and persistence, it is also often a cost-effective measure.^{64,65,66} For example, a recurrent description during interviews with HCPs is that PwD typically come out of consultations feeling confused and without a clear understanding about the nature and consequences of their condition, which negatively impacts their degree of activation and propensity for compliance and persistence. This is consistent with what is reported in the literature: a multivariate correlation analysis of glycemic control in Brazil found that, among other factors, participation in a diabetes health education program and satisfaction with current diabetes treatment improved control itself.⁶⁷ Even though the format and frequency of T2D education may impact its short and long-term results, educational programs could be considered.

Therefore:

- At basic/primary assistance in public service: fundamental education materials, videos, web training and other low-labor-intensive initiatives could be provided independent of infrastructure limitations. Given the importance of diabetes education, an assessment of current tools should be undertaken. Such an assessment should verify impact of diabetes education tools for comprehension, ability to cause positive action by the user, and longevity of the new ability. For low-impact tools, modification for improvement should be made and impact retested or the tool should be dispensed with. Subsequent diabetes education tools should have the same consideration applied.
- At reference centers or secondary/tertiary care in public system: more sophisticated initiatives, although still cost savvy, could be applied. An example is the use of Conversation Maps, a tool that utilizes a diabetes themed map to promote learning and assimilation in an interactive way.⁶⁷
- At private system health centers: leveraging proven public materials would allow standardization of guidance and education throughout the healthcare system. Ultimately, feedback loops amongst delivery levels and systems could be enacted to share learning and aid in periodic diabetes education tool improvement.

There is a lack of integration across initiatives in the country and across segments of care with very few examples of coordination to address the right population with the most effective message. The Federal government has focused on providing treatment through pharmaceutical assistance, but there is a lack of nation-wide programs designed to educate and disseminate information on diabetes. In addition, states and municipalities policy makers act independently according to their understanding of diabetes and compliance and persistence importance. One example from Academia is from Santa Casa de Belo

Horizonte (Minas Gerais), where a strictu sensu master degree was approved in 2011 in the specific area of diabetes education.⁶⁸ The course is designed for Health Professionals, under the assumption that a pragmatic training may improve diabetes control through multidisciplinary teams. From a NGO perspective, Lions Club International supports a funding system for initiatives focused on awareness, education and management of diabetes.⁶⁹

Recommendation 5

Develop follow up programs for PwD tailored to their activation degree



Furthermore, implementation of psychometric assessment tools would provide the data necessary to support tailored, follow-up programs in addition to broader education programs. It is important to note that the correct prediction of behavior calls for distinct activation tactics for distinct people. In that sense, follow-up programs could be tailored according to information provided by IT systems that integrate both EMRs and electronically stored psychometric assessment surveys. Relationship rules can be associated with distinct behavioral clusters, triggering specific actions, necessarily cost-efficient.

The impact of a multi-pronged intervention has already been described in a small-scale study conducted in São Paulo.⁷⁰ The study reports that, within a population of PwD and hypertensive patients, promotion of educative measures, regular follow-ups, reliable drug supply, periodic control and treatment of medical occurrences caused a decrease in glycemic levels. After two years of follow-up, some PwD still had uncontrolled glycemic levels and were submitted to a more intense, tailored strategy, which included a closer monitoring and education.⁷⁰

Although such tailored, multi-pronged programs may not be feasible at a national level, it could make a considerable impact in PwD where there are a series of factors that if not managed promptly and correctly will surely generate more complications. Reference centers are the most feasible starting points for the implementation of this recommendation.

Sustain

The preceding recommendations are designed to activate PwD so that they are empowered to effectively self-manage their condition and comply with their therapy, thus prolonging life and reducing the risk of complications. However, these interventions all involve a high degree of human interaction, which is costly and no longer necessary to the same extent once a PwD exhibits a high degree of activation. Therefore, in order to maintain activation, a sustainable approach can be adopted to reduce human involvement and associated costs.

Recommendation 6

Monitor high PwD activation and repeat or adapt activation strategy for PwD with dropping activation or diabetes control



Even once fully activated, a PwD's degree of activation will vary over time, notably as a result of natural disease progression or a change in the person's external environment that impacts their ability to independently self-manage their condition. Consequently, it is critical to periodically reassess PwD activation and take appropriate actions with these PwD that are experiencing a temporary decrease in their degree of activation. Similarly, those that are self-managing their condition well by sustaining their degree of activation need positive reinforcement that what they are doing is having a beneficial impact on their health.

Clinical outcomes could be used to cost-effectively identify PwD experiencing a temporary setback in activation. For instance, highly activated PwD who move outside the normal range for HbA1c levels, number of hypoglycemic events, and number of hospitalizations and/or infection rates should be offered to retake a psychometric assessment to re-quantify their degree of activation and identify its associated root causes. Review of clinical outcomes would ideally occur every 90 to 120 days in order to rapidly take action with those PwD who need further support while continuing with the existing strategy and giving continual HCP-led feedback on progress on clinical outcomes for those PwD whose condition remains satisfactorily controlled.

Recommendation 7

Leverage technology and digital offerings to maintain PwD activation



A multi-pronged, structured approach could be used to help HCPs gradually encourage PwD to start adopting technology to help them manage their condition. A variety of communication channels as well as appropriate language should be employed to ensure that the high degree of activation is maintained across different PwD. Such an approach could further leverage technology:

- Internet has a high penetration in Brazil⁷¹ and a significant part of the population uses search engines. There are a variety of health and life style websites, blogs and diabetes-specific online resources, such as patient advocacy and medical societies, available.²⁹ However, most of these resources focus on treatment alternatives, diet and fitness, and side effects management. Compliance and persistence is often mentioned only as a factor in the worsening of diabetes.^{72,73,74,75} More could be done to address improve compliance on these websites, thus presenting an opportunity to bring this topic directly to PwD.
- Social Media is massively popular in Brazil,⁷¹ benefiting from the widespread use of smartphones and apps,⁷¹ with their penetration reaching a great range of profiles.⁷⁶ This is a vital channel in terms of awareness generation and quick advice.

Thus, structured organizations such as medical societies and patient advocacy groups could develop a coordinated approach to bring compliance and persistence to same level of priority as other factors like diet and fitness by incorporating compliance and persistence in websites, blogs, apps and social media ecosystem.

It does not mean however, that going digital guarantees a universal approach in the Brazilian setting. During interviews, a number of physicians have mentioned that for young T1D PwD, this kind of approach might be more successful than for T2D PwD who are older and not necessarily technology savvy. This issue may be even bigger when dealing with the lower income stratum in the public system.

Educational programs can also leverage traditional mass media. One communication channel may not be enough and will probably not be ideal for different PwD activation levels. Radio and public television, which have high penetration in Brazil⁷⁷ and greater reach than newspapers and magazines, could be useful to promote messages regarding timing of medication and dieting tips. Brazil has extensive experience in awareness programs through such media, the latest example being the Aedes Aegypti combat for Zika transmission prevention.^{78,79,80}

Recommendation 8

Engage NGOs and medical societies as to turn them into process and advocacy keepers



In Brazil, awareness efforts are in general disperse.²⁹ Only a few health management organizations and insurers offer this kind of programs; moreover, these companies tend to operate in the private premium segment (i.e. employment-related insurance) and therefore fail to reach the whole population.⁶³ Despite medical societies and key opinion leaders acknowledging that compliance and persistence is key to optimum condition control, it is still not a priority theme and thus, more needs to be done to raise further awareness and bring compliance and persistence to the fore.

Prior to the development of campaigns to communicate the importance of compliance and persistence, the theme must emerge as a real priority for all stakeholders and medical societies that have the influence and capacity to i) engage key opinion leaders to generate compliance and persistence discussion across medical and scientific forums ii) coordinate and facilitate national initiatives to foster compliance and persistence discussion and finally iii) influence policy makers to add compliance and persistence as a priority theme for education within both national and local initiatives.

Once compliance and persistence becomes a priority, the health system will be incentivized to develop and coordinate educational programs, information materials and campaigns addressing the importance and impact of compliance and persistence to PwD and HCPs. As it stands, nation-wide initiatives are mainly focused on pharmaceutical assistance. By using the Farmácia Popular dataset and basic assistance and surveillance information, for instance, central level policy makers would be able not only to promote discussion among all stakeholders but also to synthesize and disseminate compliance and persistence information.

Last but not least, patient advocacy groups should be in charge of engaging patients and society to be part of these initiatives and communicate on the importance of compliance and persistence and the risks of poorly managing the condition.

Conclusion

The economic and societal burden of low T2D therapy compliance and persistence in Brazil is high and rising. It is predicted that over 6.7% of diabetes-related complication costs, estimated to be BRL 4.2 billion (USD 1.4 billion) per year, are due to sub-optimal therapy compliance and persistence (see Exhibit 1).³⁵ With over 13 million Brazilian PwD today, estimated to grow to 23.3 million by 2040,² it is imperative that structured action is taken to improve T2D therapy compliance and persistence.

In light of this, a comprehensive and coordinated set of actions has been laid out in this paper to identify and profile PwD struggling to engage with their condition, activate them, and then sustain that degree of activation. By making steps to pilot these recommendations and measure their benefits, Brazilian healthcare system leaders could make informed decisions on how and what interventions to scale up for successful reduction of significant and avoidable costs of sub-optimal T2D therapy compliance and persistence, as well as improve health of millions of PwD. This could allow Brazil to become a regional, if not global, Center of Excellence in diabetes care.

Additional Information:

For further details on methodology, sources, calculations, and generation of recommendations, please refer to the separate Appendix document.

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About the Institute

The IMS Institute for Healthcare Informatics leverages collaborative relationships in the public and private sectors to strengthen the vital role of information in advancing healthcare globally. Its mission is to provide key policy setters and decision makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved patient care. With access to IMS Health's extensive global data assets and analytics, the Institute works in tandem with a broad set of healthcare stakeholders, including government agencies, academic institutions, the life sciences industry and payers, to drive a research agenda dedicated to addressing today's healthcare challenges.

By collaborating on research of common interest, it builds on a long-standing and extensive tradition of using IMS Health information and expertise to support the advancement of evidence-based healthcare around the world.

Research Agenda

The research agenda for the Institute centers on five areas considered vital to the advancement of healthcare globally:

The effective use of information by healthcare stakeholders globally to improve health outcomes, reduce costs and increase access to available treatments.

Optimizing the performance of medical care through better understanding of disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.

Understanding the future global role for biopharmaceuticals, the dynamics that shape the market and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.

Researching the role of innovation in health system products, processes and delivery systems, and the business and policy systems that drive innovation.

Informing and advancing the healthcare agendas in developing nations through information and analysis.

Guiding Principles

The Institute operates from a set of Guiding Principles:

The advancement of healthcare globally is a vital, continuous process.

Timely, high-quality and relevant information is critical to sound healthcare decision making.

Insights gained from information and analysis should be made widely available to healthcare stakeholders.

Effective use of information is often complex, requiring unique knowledge and expertise.

The ongoing innovation and reform in all aspects of healthcare require a dynamic approach to understanding the entire healthcare system.

Personal health information is confidential and patient privacy must be protected.

The private sector has a valuable role to play in collaborating with the public sector related to the use of healthcare data.

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