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Improving Type 2 Diabetes Therapy Adherence and Persistence in Germany

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. Germany reflects this trend, facing a rising prevalence of T2D,¹ with an estimated 270,000 people diagnosed with T2D annually and 8 million people projected to live with the condition by 2030. Despite improved diagnosis and advances in treatment options for individuals with T2D, sub-optimal therapy adherence 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 Germany-specific burden of T2D and its complications, initiatives in place to address this issue, and opportunities in relation to therapy adherence and persistence improvement strategies. A range of validated, Germany-specific recommendations to address sub-optimal T2D therapy adherence and persistence are put forth for action by government stakeholders, payers and healthcare administrators, among other organizations and focus on three broad phases of a patient journey toward optimal adherence and persistence, (i) profile (ii) activate and, (iii) sustain. These are all designed to improve T2D therapy adherence and persistence in the German population, and consequently decrease significant and avoidable economic and societal costs, and improve quality of life for people living with the condition.

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Contents

- 1 Burden of T2D
 - 1 Overview of T2D and its complications
 - 1 A major public health concern with significant economic and societal burden
- 3 Sub-optimal adherence and persistence is a cause of T2D-related complications
 - 3 Adherence and persistence defined
 - 3 Extent of sub-optimal T2D drug therapy adherence and persistence
 - 4 Economic burden of sub-optimal adherence and persistence on governments and healthcare systems
 - 7 Burden of sub-optimal adherence and persistence on individuals and society
- 8 The path to optimal adherence and persistence relies on effective patient activation
 - 8 Action is needed
 - 8 Effective patient activation
 - 11 The path to optimal adherence and persistence
- 13 Recommended interventions to improve T2D therapy adherence and persistence in Germany
 - 13 Profile
 - 14 Activate
 - 16 Sustain
- 18 Conclusion
- 19 References
- 22 Authors
- 24 About the Institute

Burden of T2D

Overview of T2D and its complications

T2D is a chronic disease characterised 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.²

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 (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

In Germany, prevalence of T2D has risen by nearly 40% since 2000 and with over 5.8 million people diagnosed with the condition (over 7% of the population) and another one to two million undiagnosed, the country is one of the top ten nations worldwide in terms of absolute numbers of affected people.^{1,3,4,5,6,7} Furthermore, with 270,000 new cases annually,⁸ these figures are set to continue rising with predictions of 8 million PwD in Germany by 2030.⁶ These PwD are managed with a combination of lifestyle changes and pharmacotherapy, which includes a range of oral anti-diabetic and injectable drugs. However, despite a variety of effective medications,⁹ this condition is not well controlled in many PwD.¹⁰

This high prevalence, combined with poor control, has resulted in approximately 55,000 German citizens dying each year from diabetes.¹¹ Meanwhile, over 10% of PwD (including type 1) suffer from coronary heart disease while 6.7% suffer from stroke.¹⁰ Additionally, 16% of PwD suffer from retinopathy and 8% suffer from nephropathy.¹²

Economically, it was previously estimated that the direct cost of diabetes-related complications to the German healthcare system was €2,380 per person.¹³ When adjusted for inflation¹⁴ and multiplied by the number of people with T2D in Germany today,^{1,6} this results in a total cost of €18.47 billion to the German healthcare system today,¹³ solely due to T2D-related complications. It is worth noting that these cost estimates do not account for indirect costs such as loss of productivity of the PwD, caregivers and families. In addition, these costs do not reflect the impact of lower quality of life on all of these people. As such, T2D places a significant strain on the healthcare system and society which, in light of increasing prevalence trends in the country, will rapidly escalate.

Current strategies to improve T2D outcomes in Germany

There is yet to be a national programme for PwD in Germany⁸ although there is a national programme to promote healthy living and detect T2D early (“In Form”, supported by the “gesundheitsziele” programme and launched in 2008). Initiatives to improve T2D care are, for now, local in the form of disease management and integrated care programmes, notably as a result of the healthcare system set up, under which the 118 different statutory health insurers¹⁵ individually negotiate contracts with regional associations for ambulatory care provision. Meanwhile, German data protection laws hinder the implementation of pragmatic solutions to improve T2D care as they restrict the sharing of patient data between HCPs and the access to patient data by healthcare insurers. Although, third parties can be enlisted to collect such data, this has the potential to hinder, or at least delay patient care and, at a macro scale, prevents analysis of patient data to develop more effective care.

As alluded to above, initiatives to improve T2D care exist under the realm of regional disease management programmes (DMPs), of which there are over 3,000 approved by the Federal Insurance Agency for PwD.¹⁶ The success of these interventions has been difficult to measure but data has shown that approximately 75% of primary-care physicians are participating with DMPs for diabetes,^{17,18,19} while studies have shown that they improve quality of care and reduce costs.^{20,21} However, one of the most recent studies suggests there is still room for improvement for diabetes care in Germany, particularly regarding prevention measures and diabetes self-management.²²

In addition, the integrated care (Integrierte Versorgung) model of service provision aims to improve cooperation between outpatient and inpatient care, notably in the management of T2D. Under this model of care, healthcare providers can enter service provision contracts with health insurers. PwD enrollment into an integrated care programme is strictly voluntary. In T2D, integrated care programmes put significant emphasis on disease self-management with the overarching objective of improving PwD health and quality of life.²³

Although these interventions and policies have led Germany to claim plaudits in some other countries²⁴ and have coincided in the relative reduction of incidence of complications in PwD when compared to the general population,^{3,25,26,27} they are yet to be fully comprehensive and do not encompass all aspects of T2D management.⁸ In order to more effectively tackle T2D, they could be augmented by other, more targeted strategies that focus on helping PwD adhere to therapy and reduce the rate of diabetes-related complications.

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

Adherence and persistence defined

The current strategies to improve T2D outcomes are not directly focused on addressing sub-optimal T2D therapy adherence and persistence among PwD.

Defining therapy adherence and persistence

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

Therapy Adherence

“The extent to which a patient acts in accordance with the prescribed interval, and dose of a dosing regimen”²⁸

Therapy Persistence

“The duration of time from initiation to healthcare professional (HCP) recommended discontinuation of therapy”²⁸

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

Extent of sub-optimal T2D drug therapy adherence and persistence

Literature research and interviews have indicated that sub-optimal adherence and persistence is a significant issue for PwD, globally. A number of systematic reviews and meta-analyses on diabetes therapy adherence around the world have been conducted,^{29,30,31} the most recent of which identified 27 studies and found that the proportion of PwD who are non-adherent to therapy ranges from 6.9% to 61.5%, with a mean value of 37.7%.³¹ In Germany specifically, GPs estimated that the proportion of PwD non-adherent to therapy was approximately 37.4%,³² while a German study based on a large retrospective claims dataset (n=1,627) reported this to be 19.9% during continued therapy but, 36.4% of PwD in this dataset ended up discontinuing therapy with a treatment gap of over 90 days.³³ Further studies in Germany, which used self-reported measures of adherence among study populations of 938 and 1,142, reported that 28.2% and 23.5% of PwD were non-adherent, respectively.^{34,35}

Despite these significant values, the actual rates of sub-optimal adherence and persistence to T2D therapy in Germany may be even higher than the estimates stated above because many of these studies fail to grasp all aspects of adherence and persistence. For example, they are unlikely to include rates of primary non-adherence, defined as PwD who have been diagnosed but never initiated therapy. This is significant as rates of primary non-adherence have been shown to be as high as 15% in countries outside of Germany.³⁶ Additionally, many of these studies will not measure those who started but have since ceased taking their medications or, those who pick up their medication but do not take them at the recommended time or dose, i.e. poor concordance with dosing instructions.

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

Recognising that sub-optimal T2D therapy adherence and persistence causes persistently elevated blood glucose levels,^{37,38} leading to increased risk of complications³⁹ and subsequently costs,⁴⁰ the extent of this contribution to complication-related costs was estimated. To do this, the CORE Diabetes Model (CDM), a validated health economics model that has been used for updating diabetes guidelines in other countries,^{41,42,43,44} was customised to Germany in order to provide guidance on potential healthcare system savings if the issue of sub-optimal T2D therapy adherence and persistence was addressed in Germany.

Calculating the cost of sub-optimal T2D therapy adherence 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.^{41,42} The model has been customised to Germany to calculate the cost of avoidable T2D-related complications as a result of those PwD who struggle with therapy adherence and persistence.

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

1. The percentage of PwD with sub-optimal levels of therapy adherence and persistence in Germany
 - Estimated to be as high as 46.8%, assuming 15% of PwD are primary non-adherent^{32,36}
2. The relationship between sub-optimal therapy adherence and HbA1c as estimated by GPs in Germany
 - 15.5% increase in HbA1c due to sub-optimal adherence³² (similar to results in a widely-cited scientific study in the US)³⁸

What are HbA1c levels?

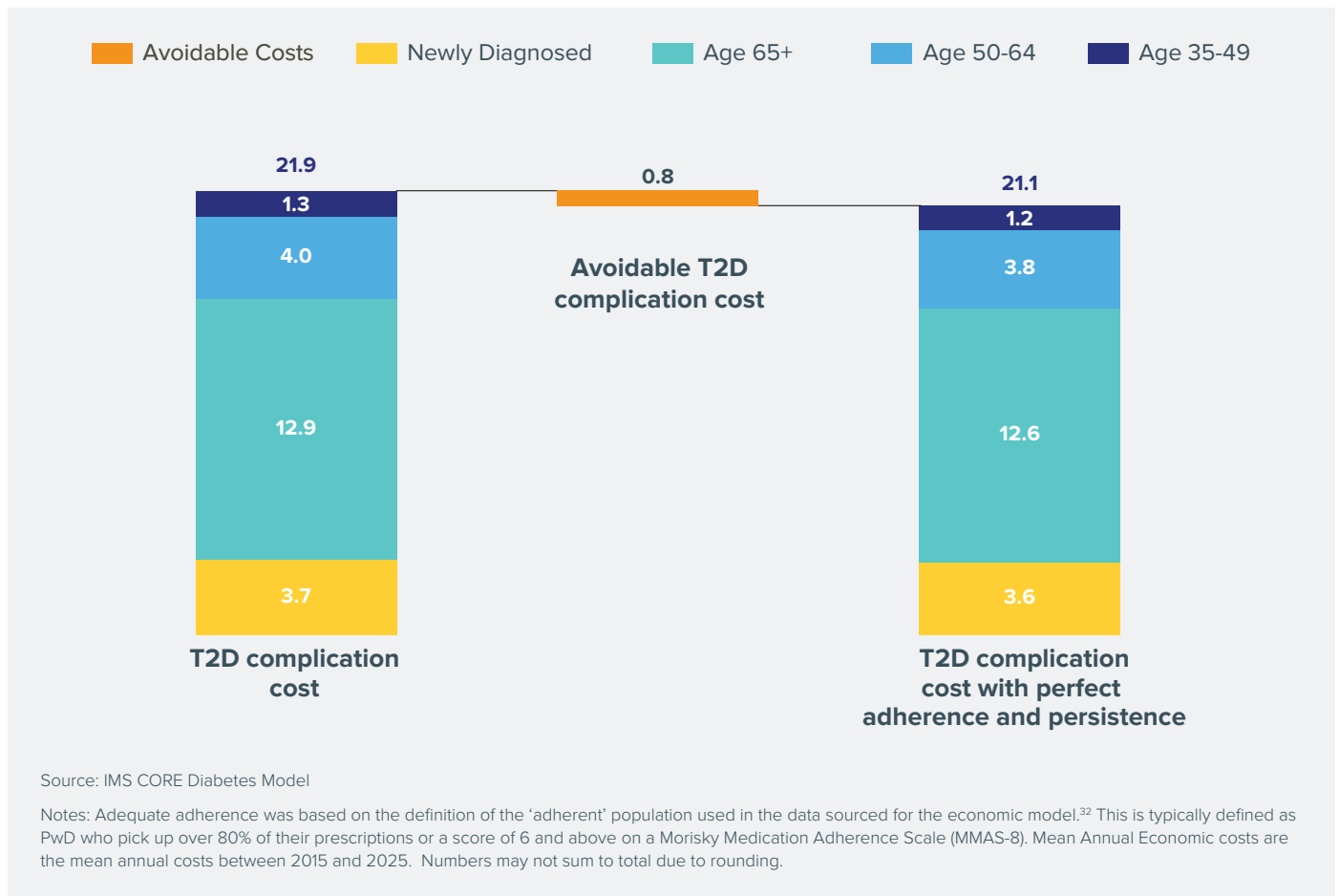
HbA1c levels are used to diagnose and monitor diabetes and refer to glycated haemoglobin (HbA1c), reflective of average plasma glucose concentration. HbA1c develops when haemoglobin, an oxygen-carrying red blood cell protein, combines with glucose in the blood, thus becoming glycated.⁴⁵

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.⁴⁶ These properties have made it the preferred test for both diagnosing diabetes and assessing glycaemic control in PwD.³¹ The higher the HbA1c level, the higher the increase in risk of diabetes-related complications. Normal, high risk and diabetic HbA1c ranges are provided below:⁴⁷

HbA1c Level	Indication
<5.7% (<39 mmols/mol)	Normal range
5.7%-6.4% (39 – 48 mmols/mol)	Pre-diabetes
>6.5% (≥48 mmols/mol)	Diabetes

Using the CDM, it has been estimated that T2D-related complications will cost €21.9 billion per year to the German healthcare system (mean of next 10 years, see Exhibit 1), which is broadly aligned with the estimate of €18.47 (current year) adapted from well-recognised, past studies on healthcare costs of diabetes in Germany.¹³ By customising the CDM to take into account T2D therapy adherence and persistence levels in Germany, it has been estimated that as much as 3.45% of this healthcare system cost, or approximately €760 million per year, will be driven by complications suffered by those PwD who are currently struggling to achieve optimal T2D therapy adherence and persistence (see Exhibit 1).

Exhibit 1: Mean Annual Economic Costs Associated With Sub-Optimal T2D Drug Therapy Adherence and Persistence in Germany 2015-2025, € BN



To provide a sense of proportion, €760 million average annual cost of avoidable complications due to sub-optimal adherence and persistence is equal to approximately 40% of the total annual spend on diabetes medications in Germany today.⁴⁸ In summary, the economic cost burden of T2D complications of German PwD who are struggling to achieve optimal T2D therapy adherence 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 adherence 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-optimised if PwD are unable to comply and persist with their therapy or make the necessary changes to their lifestyle.

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

Burden of sub-optimal adherence and persistence on individuals and society

The CDM 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 adherent and persistent to their T2D therapy in Germany (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).⁴⁹

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

Percent increased risk versus adherent PwD	Complication
252%	More likely to have end stage renal disease
9%	More likely to have a heart attack
8%	More likely to have a stroke
21%	More likely to have an amputation
24%	More likely to go blind (severe vision loss)
>€14,950	Extra cost to the healthcare system over their lifetime

Source: IMS CORE Diabetes Model

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

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

Action is needed

The direct cost of T2D-related complications is set to amount to €21.9 billion per year in Germany, while the country is expected to have 8 million people with T2D by 2030.⁶ Of that €21.9 billion, it is estimated that around 3.45% (€760 million) is being driven by sub-optimal T2D therapy adherence and persistence.⁵⁰ Absence of action to tackle this problem now, when prevalence of T2D continues to rise,⁶ 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 adherence and persistence in T2D therapy, including diet, exercise and glucose-lowering medicines, by:

- Profiling PwD in need of help
- Allowing pharmacists to act as management partners
- Providing modular, repeatable T2D education to PwD and their primary support person
- Using digital technology to maintain effective disease 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 adherence 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.⁵¹ 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 adherence to therapy and a reduction in healthcare expenditure.^{52,53,54} 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.⁵²

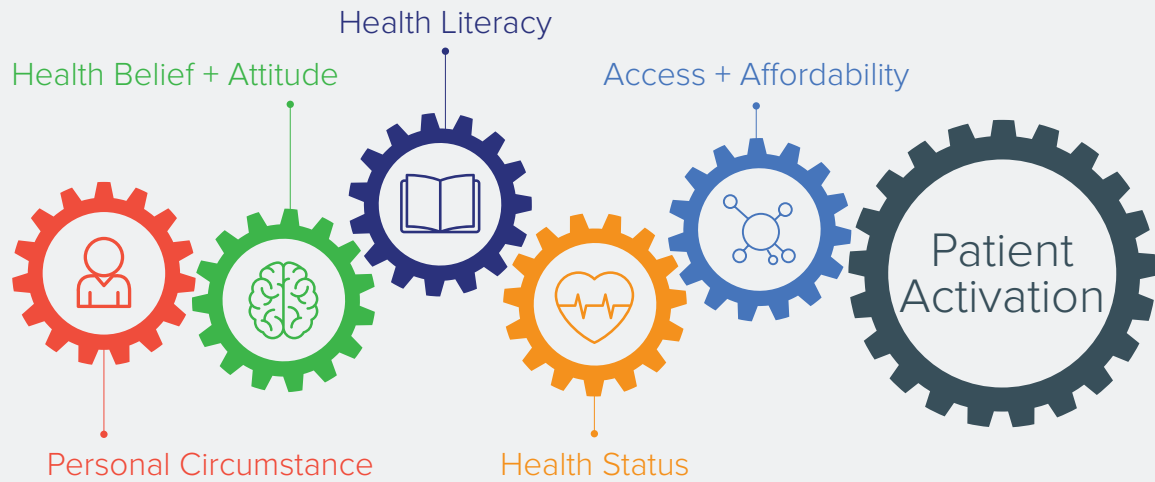
Consequently, T2D therapy adherence and persistence will remain sub-optimal as long as PwD activation remains inadequate. Effective PwD activation is difficult to achieve as it stems from the synergistic impact of multiple underlying drivers and stakeholders. Hence, a tailored, individualistic approach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

Based on literature and 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).^{55,56,57,58,59} While these five distinct drivers work in concert to influence overall degree of PwD activation, they are also 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. In Germany, it will also be important to promote disease awareness and elevate the condition to a health priority issue as existing societal T2D stigmatisation negatively impacts on PwD health beliefs and attitude. Indeed, as opposed to countries such as the U.S. or the U.K. where PwD feel free to discuss and share their experiences regarding their condition, in Germany, PwD avoid to do so.

Effective PwD activation also requires multi-stakeholder involvement, including policy makers, payers, healthcare providers, the private sector, caregivers, family, and PwD themselves. All of these stakeholders influence PwD activation and can promote T2D therapy adherence and persistence.

PwD activation is therefore the sum of personal circumstances, attitudes, behaviours, 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 customised, PwD-centric approach that positively impacts adherence and persistence in T2D therapy and reduce the avoidable T2D complication cost of approximately €760 million per year 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.^{55,60,61}



Health beliefs and attitude relate to whether PwD accept their condition and believe in the benefits of their overall therapy.^{56,62,63}



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.”^{57,64,65,66}



Health status relates to a variety of factors such as diet, exercise, and number of co-morbidities.^{58,67,68}



Access and affordability concern access to and affordability of healthcare, healthy food, and exercise facilities.^{59,69,70}

Source: IMS Consulting Group research and analysis

The path to optimal adherence and persistence

PwD activation relates to an individual's willingness and ability to take action to manage their own health and care. It is therefore paramount to improving therapy adherence and persistence and, in turn, clinical outcomes.⁷¹ Through literature research and qualitative interviews with expert stakeholders, it has been determined that effective PwD activation, and therefore a PwD's journey to optimal adherence and persistence, requires progression through three key phases identified as 'profile', 'activate', and 'sustain' (see Exhibit 4).

Exhibit 4: A PwD Path to Optimal Adherence and Persistence



In the '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, behaviours and logistical 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 adherence and persistence, interventions, goals and action steps need to be customised 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 behaviours in therapy adherence and persistence can be transitioned to cost-effective T2D management solutions.

Customised interventions within each of these phases have been designed to overcome the varied challenges related to activation and support German PwD on the path to optimal T2D therapy adherence and persistence. It must be noted that aspects of the recommendations presented therein have been implemented in local pilot projects, one example being the AOK Hesse Aktiv + Vital initiative, under which participating patients received personalised T2D care and education from participating physicians.⁷² Therefore, to effectively promote and sustain the present recommendations at a country level:

- A top-down approach driven by the Ministry of Health may be required alongside adequate funding for the sick funds and incentives for participating patients and physicians
- Interventions must be assessed, validated, consolidated and embedded appropriately in the healthcare system or governing body, which will require alignment between healthcare and government leaders and involvement from voluntary associations and private stakeholders

Furthermore, some recommendations would also benefit from improvements in information technology (IT) infrastructure to leverage and enable technological interventions. However, it must be noted that the use of analytics is difficult in Germany as strict privacy laws limit data sharing.

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 adherence and persistence in Germany, estimated to be €760 million per year (see Exhibit 1).

Recommended interventions to improve T2D therapy adherence and persistence in Germany

Profile

Recommendation 1

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



Psychometric assessment tools could be used to determine a PwD' degree of activation and the underlying drivers of this. These assessments would act as a pre-requisite to setting realistic goals and actions and put PwD on the path to optimal therapy adherence and persistence (see Exhibit 4). Such tools have been shown to increase adherence to therapy, reduce healthcare expenditure⁵² and predict costs and outcomes for PwD.^{53,54} 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 behaviours and pushing further' (level 4). On a 100 point scale, each point increase in PAM score translates into a 2% increase in adherence to medicine and a 2% decrease in hospital admissions and readmissions.⁷³

Going forward, sick funds could use simple criteria to identify subgroups of PwD to pilot a psychometric assessment tool. For example, newly diagnosed PwD⁷⁴ or PwD with complex dosing regimens³⁰ could be assessed as adherence has previously been found to be lower in these subgroups. This could help physicians in Germany personalise diabetes treatment and improve health outcomes.^{71,73}

Activate

Once PwD activation has been evaluated, there is still a considerable challenge to engage PwD. However, there are a number of actions that can be taken in order to improve PwD engagement and these revolve around further leveraging pharmacists, improving access to T2D education and further involving the PwD social circles in the care process. These interventions could also be tailored to the degree of PwD activation so that goals and action steps are realistic and build towards greater activation.

Recommendation 2

Open conversation to allow pharmacists to act as T2D management partners



Pharmacists are qualified providers of information on therapy, side effects and dosing. Efforts exist to expand the capabilities of pharmacists on a local level,^{75,76} but a more formal framework needs to be put in place to ensure more widespread offerings can succeed. Consequently, opportunities to involve pharmacists as T2D management partners as well as metrics to make pharmacists accountable and responsible for PwD management could be further explored.

Data protection laws currently restrict exchange of patient and prescription information between physicians, pharmacists and the sick funds. To grant pharmacists access to patient data to monitor prescriptions, a contracting system needs to be discussed whereby data could be shared in return for PwD agreeing to be managed exclusively by the contracted pharmacist. Discussions to facilitate this approach would likely have to take place with the DDG (German Diabetes Association) and the DAV (Deutscher Apothekerverband). In addition, the sick funds should be part of the contract to promote fill rates.

Concerns of increased competition would be best addressed by promoting cooperation through clearly defining physician and pharmacist individual roles in the treatment process. To do so, pharmacists should be involved in the “quality circles” that currently include various physicians on a local level and where quality and approaches to treatment and professional activities are discussed.

Utilising pharmacists as trusted partners in PwD engagement and management would benefit all stakeholders involved: pharmacists would gain a competitive advantage in their field by becoming partners in treatment and physicians could rely on pharmacists to monitor the actual filling of prescriptions. Meanwhile, PwD would have increased access to healthcare professionals thereby improving their degree of activation. Such an approach would allow for more efficient PwD care.

Recommendation 3

Improve attendance to education programmes and retention of content by gearing incentives towards repeatable modular education



In Germany, referral into T2D education courses can be challenging due to complex and bureaucratic reimbursement practices. In addition, existing T2D education courses do not optimally address PwD information needs as they are offered as lengthy, block training sessions that cover all aspects of disease progression and management. In order to make T2D education relevant and engaging and to improve information retention, current programmes could be broken down into modules that can be independently and individually repeated and reimbursed (some states such as e.g., Bavaria already offer and reimburse modular education, including in other therapy areas,⁷⁷ however, this is not the case of all states);⁷⁸ furthermore these modules could be tailored to the degree of PwD activation. The DDG and the sick funds would need to sign off on this tailored, modular education. Furthermore, clear protocols and incentives for HCPs to prescribe these courses would need to be developed.

Complementary T2D education courses could also be offered online via social media or novel apps as this would improve access for those PwD who are not able or not willing to attend courses in person. Digital offerings could also be used to help consolidate what has been learned during the face-to-face courses. This would extend the purpose of education from increasing activation to sustaining an optimal degree of activation once achieved (see Recommendation 6). Digital offerings would also help empower PwD and allow them to take greater ownership of their condition.

Recommendation 4

Promote involvement of PwD social circle (primary support person in the first place) in the T2D education and care process



In order to support PwD with the day-to-day management of their condition, it is also important to further involve and educate their primary support person and, economic and human resources allowing, their close social network (for example, caregivers, family and partners). While, as it stands, a PwD' primary support person can take T2D education courses if the PwD agrees to it, more consistent involvement could help address the fact that many PwD in Germany feel as though their condition is not readily discussed and best kept a private or personal issue.

In the U.K. for instance, partners, friends and family can attend T2D education courses along with the PwD.⁷⁹ To implement T2D education specifically targeted at the PwD social network in Germany, educational modules and materials would need to be developed while the SHI could provide funding. Due to the costs involved, participation will need to be rationalised and the additional attendees carefully selected. Furthermore, there should be an evaluation of whether involvement of the PwD social network in T2D education and management has a tangible impact on PwD behaviour and health outcomes (e.g., clinical outcomes such as HbA1c levels, infections rates, hypoglycaemic events).

Broader initiative to involve caregivers, family and partners could come from patient advocacy groups, healthcare providers or education networks. This could be done via awareness campaigns and flyers/posters at healthcare provider practices or clinics.

Sustain

The preceding recommendations are designed to activate PwD so that they are empowered to effectively self-manage their condition and adhere to their therapy, thus prolonging life and reducing the risk of complications. However, these interventions all require a high degree of human involvement, 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 must be adopted to optimise human involvement and associated costs. Technology and digital offerings can be phased in throughout the PwD path to optimal adherence and persistence where, at the point of maximal activation, they will be sufficient to keep PwD engaged at a minimum cost to the healthcare system.

Recommendation 5

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



Even once fully activated, a PwD' 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 on 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 hypoglycaemic events, number of hospitalisations 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. Leveraging the use of e-health cards as they are introduced in Germany would make this quick and easy for HCPs to access this information for each PwD.⁸⁰

Recommendation 6

Leverage technology and digital offerings to maintain PwD activation



Improving the structure and provision of education as previously suggested in this paper, although effective, is likely to present large investments. A sustainable approach to maintain PwD on a high degree of activation, once achieved, would be to leverage technology and digital offerings. These can be phased in throughout the PwD path to adherence and persistence where, at the point of optimal activation, their use will be maximised to keep PwD engaged at a minimum cost to the healthcare system. At this point, the mix of human versus technology interventions also need to be tailored based on individual PwD, to ensure high degree of activation is sustained.

German sick funds could be open to further leveraging digital technology in clinical practice. For instance, e-learning initiatives such as the Structure Geriatric Diabetes Education, a programme developed in collaboration with the DDG, accredited at the national level and reimbursed in Bavaria, Lower-Saxony and Saxony-Anhalt, and under which PwD can take online modular training, could be combined with in-person offerings.⁸¹ As PwD progress towards an optimal degree of activation, they could be transitioned to digital offerings for purposes of monitoring, reporting and self-management. Offerings in this space is expected to expand as additional initiatives are promoting digitalisation of T2D education.⁸²

T2D education apps and websites could also be designed to help keep PwD up-to-date while online forums or Tweet chats could also act as easy knowledge refreshers and ways for peers to connect. For example, diabetes specialist nurses who already run T2D structured group education courses could also hold weekly Tweet chats for their 'graduates'. This would allow people to consolidate contacts created with peers as well as their learning all in an interactive and easy manner. Course content could also be adapted as podcasts for individual offline listening. Trends such as these would reflect the long-term epidemiological direction T2D is taking in Germany, with the incoming generation of PwD will be more versed in mobile communication and technology.

Conclusion

The economic and societal burden of sub-optimal T2D therapy adherence and persistence in Germany is high and rising. It is predicted that over 3.45% of these complication costs, estimated to be €760 million per year and equal to approximately 40% of the total annual spend on diabetes medications in Germany today,⁴⁸ are due to sub-optimal therapy adherence and persistence (see Exhibit 1).⁵⁰ With over almost 6 million PwD in Germany today, estimated to grow to ~8 million by 2030,⁸³ it is imperative that structured action is taken to improve T2D therapy adherence and persistence.

In light of this, a comprehensive and coordinated set of actions has been laid out in this paper to 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 across sick funds, informed decisions could be made on how and what interventions to scale up for successful reduction of significant and avoidable costs of sub-optimal T2D therapy adherence and persistence, as well as improve health of millions of PwD.

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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