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Improving Type 2 Diabetes Therapy Adherence and Persistence in the United States

How to Address Avoidable Economic and Societal Burden

PATIENT
ACTIVATION

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. The U.S. reflects this trend, facing a rising prevalence of T2D in the Medicare population[1] with about 400,000 seniors diagnosed with T2D every year and 17.2 million seniors expected to live with the condition by 2025. 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 burden of T2D and its complications the U.S. Medicare population, national initiatives in place to address this issue, and opportunities in relation to therapy adherence and persistence improvement strategies. A range of validated, U.S. Medicare-specific recommendations to address sub-optimal T2D therapy adherence and persistence are put forth for action by government stakeholders, insurers and healthcare administrators and focus on three broad phases of a patient journey toward optimal adherence and persistence, (i) identify and profile, (ii) activate and, (iii) sustain. These are all designed to improve T2D therapy adherence and persistence in the Medicare 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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Overview of T2D and its complications

Type 2 Diabetes (T2D) is a chronic disease 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.[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 the U.S., it is estimated that 27% of people 65 and older have diabetes (diagnosed and undiagnosed) and an additional 50% have pre-diabetes.[1] About 400,000 seniors are diagnosed with T2D every year[3] and the total figure of those seniors with diagnosed and undiagnosed T2D is predicted to rise to 17.2 million by 2025.[1] Furthermore, there are racial and ethnic differences in diagnosed PwD as T2D disproportionately impacts Hispanics and African Americans.[3] 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 drugs,[4] this condition is not well controlled in many PwD.[5]

This high prevalence, combined with poor control, translates into diabetes being the seventh leading cause of death in the U.S.[3] However, diabetes is likely underreported as a cause of death. Indeed, studies have found that diabetes is listed on the death certificate of only 35–40% of deceased PwD and listed as the underlying cause of death on the death certificate of a mere 10–15% of deceased PwD.[3] It has also been shown that rates of death from all causes are approximately 1.5 times higher among adults with diabetes than among adults without diabetes.[3] Furthermore, in 2010, 1.7 million U.S. seniors had visual impairment, 20,250 developed kidney failure, and 27,180 had a leg amputation as a result of their diabetes.[1]

Economically, it was previously estimated that diagnosed T2D cost the U.S. healthcare system $176 billion in 2012,[6] approximately 59% of which is from those aged 65 or older, the majority of these PwD being enrolled on Medicare.[6] Furthermore, approximately 61% of the cost was due to diabetes-related

complications.[6] 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

There is a general consensus at a policy-making level that diabetes is a real problem in the U.S. and, in light of this, there have been a number of interventions and policies to address the growing burden of diabetes in the U.S. and the U.S. Medicare population.

One of the largest changes in the U.S. healthcare landscape is the shift from the traditional "fee-for-service" reimbursement model towards a "value-based" reimbursement model. As an example, Accountable Care Organizations (ACOs) and patient-centered medical homes aim to improve care management by integrating HCPs across institutions to provide coordinated, high quality care while reducing overall costs. This new model also incorporates enhanced performance measurements and establishes financial incentives through shared savings programs. Quality metrics such as Healthcare Effectiveness Data and Information Set (HEDIS) and Medicare star ratings are used across a variety of metrics to quantify and promote quality of care. HEDIS is used by the majority of healthcare plans to quantify performance on various dimensions of service and care (including HbA1c levels); HEDIS measures enable consumers to compare healthcare plans, and they are also used to track annual performance of healthcare plans. These measures also function to improve adherence and persistence in Medicare PwD. The star rating system enables Medicare beneficiaries to evaluate and compare healthcare plans. This system measures a range of metrics related to quality of treatment and customer satisfaction, and also incorporates HEDIS measures. The aim of this rating system is to provide financial incentives for payers and HCPs who reduce costs and improve quality metrics.

Effective use of medications is another essential component for reducing overall healthcare costs. This is especially important for Medicare PwD, as they typically manage several medications for co-morbidities. The Medicare Medication Therapy Management (MTM) program was established to improve medicine use. Under the MTM program, a pharmacist (or other healthcare professional) provides a comprehensive medication review for people with multiple chronic health conditions (including T2D) to ensure they are taking the right treatments and that they understand why each drug is necessary. Importantly, this program also identifies potential problems or barriers that may prevent people from regularly taking medications. An action plan is subsequently established, which details specific actions for resolving these issues and optimizing the overall patient medication regimen. The new enhanced Medicare MTM program takes this a step further by establishing financial incentives for payers to identify the underlying reasons for non-adherence (and solutions for overcoming these barriers) for individual patients.

These interventions mainly focus on promoting quality of care through improving integration, medication therapy management, and realigning incentives, but are not comprehensive and do not encompass all aspects of T2D management. These could be augmented by other, more targeted strategies that focus on current PwD to help them manage their condition and reduce the rate of diabetes-related complications.

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

Adherence and persistence defined

There is improvement to be made on the current strategies to improve T2D outcomes with respect to tackling sub-optimal T2D therapy adherence and persistence among PwD in the U.S. Medicare population.

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"[7]

Therapy persistence

"The duration of time from initiation to [healthcare professional (HCP) recommended] discontinuation of therapy"[7]

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 in the Medicare population

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,[8,9,10] 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%.[10] In the U.S. Medicare population specifically, GPs estimated that the proportion of PwD with sub-optimal therapy adherence was approximately 36%,[11] while another study based on medical records reported this to be 37%.[5] Finally, analysis of recent Medicare PwD medical records indicated that this proportion stood at 46%.[12]

Despite these significant values, the actual rates of sub–optimal adherence and persistence to T2D therapy in the U.S. Medicare population 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 the U.S.[13] 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

Recognizing that sub–optimal T2D therapy adherence and persistence causes persistently elevated blood glucose levels,[14,15] leading to increased risk of complications[16] and subsequently costs,[17] the extent of this contribution to complication–related costs was estimated. To do this, the CORE Diabetes Model, a validated health economics model,[18,19] was customized to the U.S. Medicare population in order to provide guidance on potential healthcare system savings if the issue of sub–optimal T2D therapy adherence and persistence was addressed among the U.S. Medicare population.

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.[18, 19] The model has been customized to the U.S. Medicare population 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 U.S. Medicare specific data points:

1. The percentage of Medicare PwD with sub-optimal levels of therapy adherence and persistence
   • Estimated to be 46% according to Medicare medical records of PwD from 2014[12]

2. The relationship between sub-optimal therapy adherence and HbA1c in Medicare PwD as estimated by physicians
   • 17% increase in HbA1c due to sub-optimal adherence[11] (similar to results in a widely-cited scientific study in the U.S.[15])
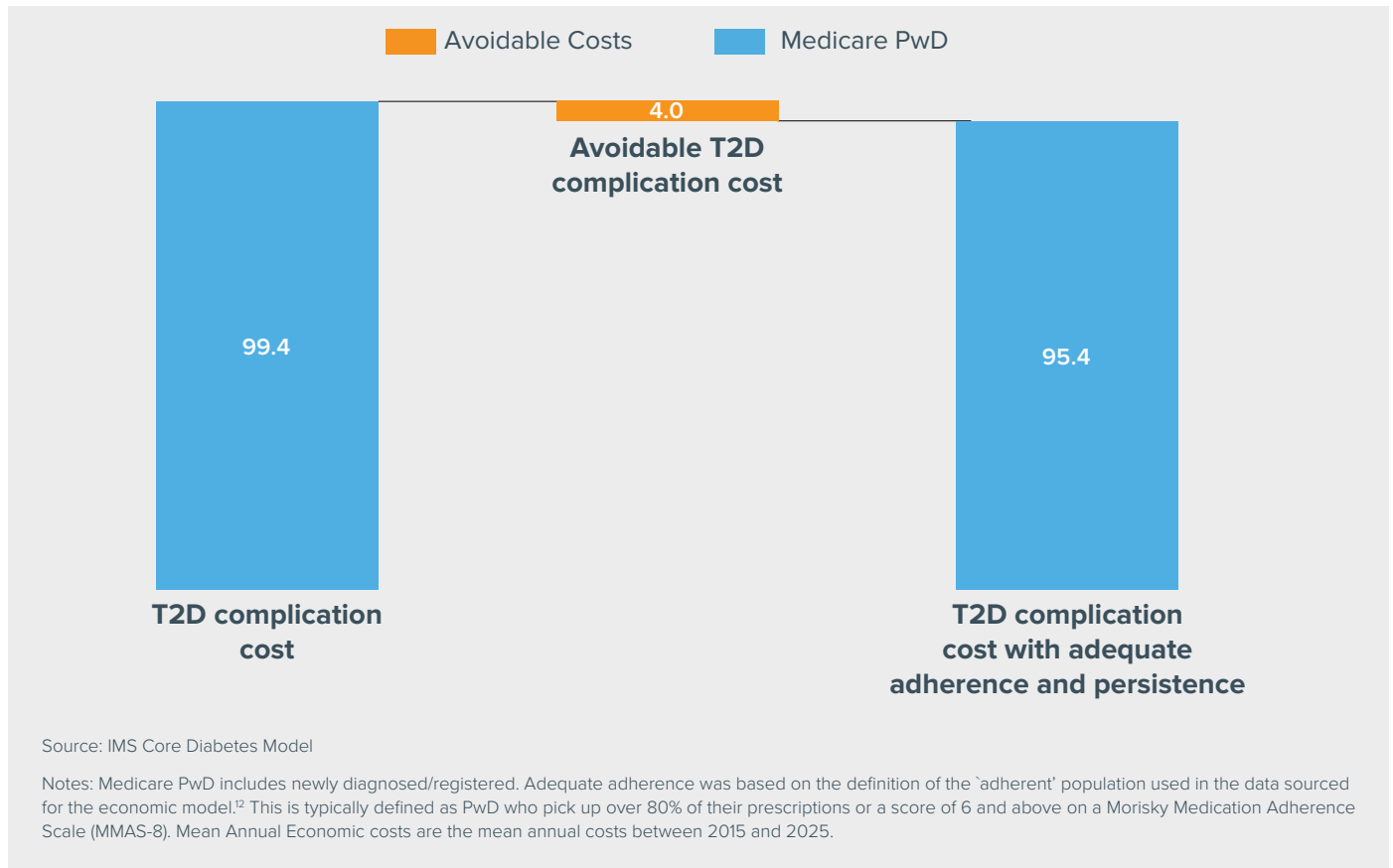
What are HbA1c levels?

HbA1c levels are used to diagnose and monitor diabetes and refer to glycated hemoglobin (HbA1c), reflective of average plasma glucose concentration. HbA1c develops when hemoglobin, an oxygen-carrying red blood cell protein, combines with glucose in the blood, thus becoming glycated.[20]

Measurement of HbA1c reflects average plasma glucose levels over a period of 8-12 weeks. HbA1c tests can be performed at any time of the day and do not require any special preparation such as fasting.[21] 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:[22]

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

Using the IMS CORE Diabetes Model, it has been estimated that T2D–related complications will cost almost $100 billion per year to the U.S. Medicare program (mean annual economic costs between 2015 and 2025, see Exhibit 1). By customizing the CORE Diabetes Model to take into account T2D therapy adherence and persistence levels among Medicare PwD, it has been estimated that as much as 4% of this healthcare system cost, or approximately $4 billion per year, will be driven by complications suffered by those Medicare PwD who are currently struggling to achieve optimal T2D therapy adherence (see Exhibit 1).

Exhibit 1: Mean Annual Economic Costs Associated with Sub-Optimal T2D Drug Therapy Adherence and Persistence among Medicare PwD 2015-2025, US$Bn

Legend: Avoidable Costs | Medicare PwD

4.0 — Avoidable T2D complication cost

99.4 — T2D complication cost

95.4 — T2D complication cost with adequate adherence and persistence

Source: IMS Core Diabetes Model

Notes: Medicare PwD includes newly diagnosed/registered. Adequate adherence was based on the definition of the `adherent' population used in the data sourced for the economic model.[12] This is typically defined as PwD who pick up over 80% of their prescriptions or a score of 6 and above on a Morisky Medication Adherence Scale (MMAS-8). Mean Annual Economic costs are the mean annual costs between 2015 and 2025.

To provide a sense of proportion, $4 billion average annual cost of avoidable complications due to sub-optimal adherence and persistence is equal to ~3.9% of total annual Medicare spend on diabetes[6] and, is approximately 32% of the total annual Medicare spend on diabetes medications and supplies.[6] In summary, the economic cost burden of T2D complications of Medicare 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. 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 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 Medicare individuals 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 Medicare PwD that are sub–optimally adherent and persistent to their T2D therapy (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).[24]

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

Percent increased risk versus adherent PwD	Complication
137%	More likely to have end stage renal disease
10%	More likely to have a heart attack
11%	More likely to have a stroke
20%	More likely to have an amputation
29%	More likely to go blind (severe vision loss)
>$14,500	**Estimated extra cost to the healthcare system over their lifetime**

Source: IMS Core Diabetes Model

Notes: Table 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 the average 65+ year old PwD.

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

Action is needed

Direct diabetes spend is currently exceeding $100 billion among the U.S. senior population, while the U.S. is set to have 17.2 million seniors with T2D by 2025.[1] Additionally, of that $100 billion, it is estimated that $4 billion is being driven by sub-optimal T2D therapy adherence and persistence. Absence of action to tackle this problem now, when prevalence of T2D continues to rise,[1] 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:

- Identifying and profiling Medicare PwD in need of help

- Improving access to and customizing T2D education

- Expanding use of the care team, providing healthcare plan counseling and, addressing the financial burden for Medicare PwD with financial constraints

- Using digital technology to maintain effective disease self-management

These 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.[25] As such, PwD activation relates to the individual's willingness and ability to take independent actions to manage his or her health and care.

In the U.S., policy makers at federal and state level are embedding patient activation into legislation in order to reduce health care costs and improve quality.[26] For instance, the Affordable Care Act identifies patient engagement as an integral quality component in ACOs and patient-centered medical homes. Furthermore, Section 3506 of the Act focuses on facilitating Shared Decision-Making (SDM) in clinical practice while Section 3021 tasks the new Center for Medicare and Medicaid Innovation with assessing

how to leverage support tools to improve patients' understanding of their treatment options. The Act also created the Patient-Centered Outcomes Research Institute, tasked with funding research that supports informed health decision making. At state level, California, Massachusetts and Washington have, among others, enacted legislation to promote shared decision making and decision aids.[27]

Research shows that increased degrees of activation are positively correlated with an increase in adherence to therapy and a reduction in healthcare expenditure.[28,29,30] 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.[28]
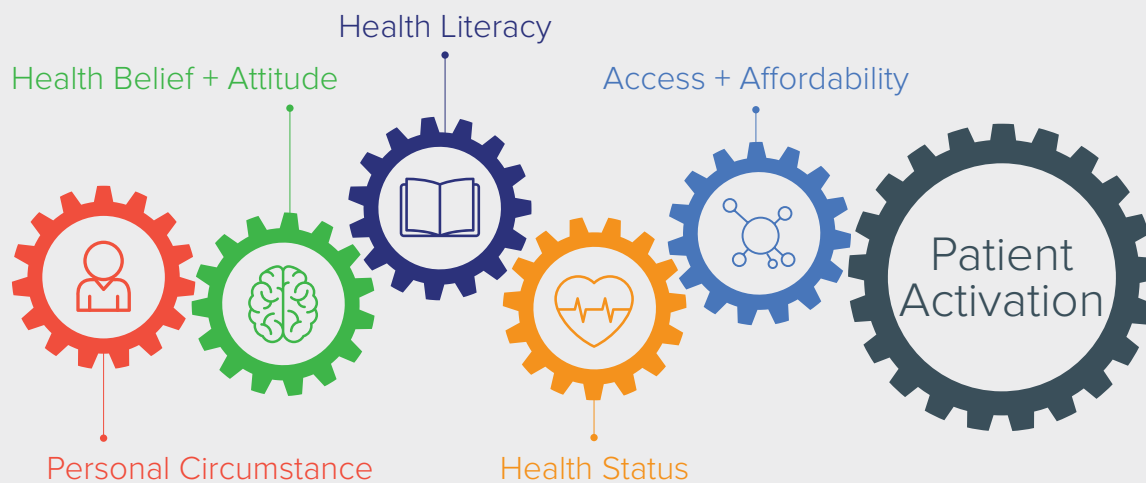
Consequently, T2D therapy adherence and persistence will remain sub-optimal as long as PwD activation remains inadequate. Effective PwD activation is difficult to achieve as it stems from the synergistic impact of multiple underlying drivers and stakeholders. Hence a tailored, individualistic approach 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).[31,32,33,34,35] 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.

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 adherence 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 T2D therapy adherence and persistence and reduce the avoidable T2D complication cost of approximately $4 billion per year associated with this in the U.S. Medicare population (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, socioeconomic factors that have an impact on the individual's health.[31,36,37]

Health beliefs and attitude relate to whether PwD accept their condition and believe in the benefits of their therapy.[32,38,39]

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."[33,40,41,42]

Health status relates to a variety of factors such as diet, exercise, and number of co-morbidities.[34,43,44]

Access and affordability concerns access to and affordability of healthcare, healthy food, and exercise facilities.[35,45,46]

Source: IMS Consulting Group research and analysis
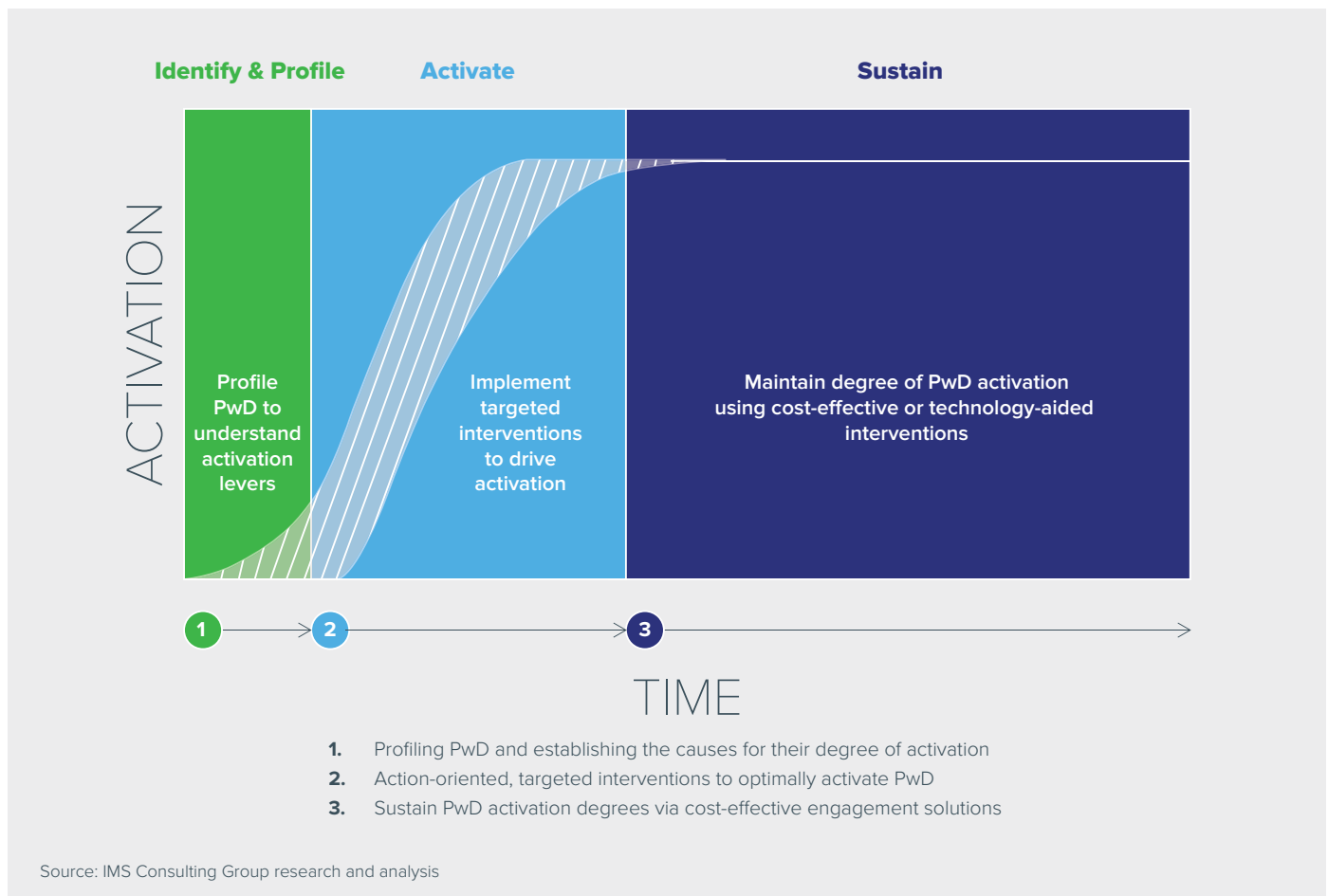
The path to optimal adherence and persistence

PwD activation relates to an individual's willingness and ability to take action to manage their own health and care and is paramount to improving therapy adherence and persistence and, in turn, health outcomes.[48] Through literature research and qualitative interviews with expert stakeholders, it has been determined that effective PwD activation, and therefore a PwD' journey to optimal adherence and persistence, requires progression through three key phases identified as 'identify and profile', 'activate', and 'sustain' (see Exhibit 4).

In the U.S., there are many efforts and innovative thinking to support adherence and persistence.[49] In spite of this, adherence and persistence remains a challenge for Medicare beneficiaries,[50] highlighting substantial challenges in pairing the right intervention with the right person and/or in meeting PwD support needs with existing interventions. Consequently, to effectively activate Medicare PwD and in turn improve adherence and persistence, create efficiencies for insurers, generate savings for the government and improve outcomes for the patients, there is a need to identify what intervention would work for what PwD and, if necessary, develop innovative, scalable solutions in addition to the ones that exist today. Development and scaling up of such solutions will require enabling government polices notably concerning data sharing, data structure requirements, behavioral incentives or fair balance requirements during behavioral discussions.

Effective PwD activation and therefore a PwD' journey to optimal adherence and persistence requires progression through three key phases that are identified as 'identify and profile', 'activate', and 'sustain' (see Exhibit 4).

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 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 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 adherence and persistence can be transitioned to cost-effective T2D management solutions.

Exhibit 4: A PwD Path to Optimal Adherence and Persistence

Source: IMS Consulting Group research and analysis

Customized interventions within each of these phases have been designed to overcome the varied challenges related to activation and support Medicare PwD on the path to optimal adherence and persistence in T2D therapy. However, some recommendations would benefit by enacting policy enablers including a safe harbor allowing for broader organizational engagement in adherence improvement initiatives within Medicare. Policy makers can aid in achieving this by modifying regulations in order for PwD activation to be quantified and built into market–place solutions. Similarly, regulation modifications may be needed to allow for parties to pilot adherence and persistence improvement projects.

To effectively promote and sustain these at the level of the Medicare population, it is essential that interventions are assessed, validated, consolidated and embedded into appropriate administrative, operational and clinical practice architecture, thus requiring alignment between the government, healthcare system and HCPs. 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 the Medicare population, estimated to be $4 billion per year (see Exhibit 1).

Recommended interventions to improve T2D therapy adherence and persistence in the Medicare population

Identify and profile

Recommendation 1

Use predictive analytics to identify PwD at risk for low adherence and persistence

Due to the American Reinvestment and Recovery Act (ARRA), which requires health care providers to implement IT capabilities such as electronic health records (EHRs) and computerized–physician–order–entry (CPOE) systems, there is now an abundance of healthcare data in the U.S.

This wealth of data provides a significant opportunity to perform "predictive analytics", a process whereby software algorithms mine compiled data based on set criteria. There are already cases of big data being leveraged through the use of predictive analytics in the U.S. healthcare system today. For example, Parkland Health and Hospital System in Dallas, Texas, predicts readmission risk in patients with heart failure using a validated EHR–based algorithm. High risk patients are then targeted with various interventions including education and telephone support to ensure therapy adherence, which has resulted in a 26% reduction in readmissions.[51] The Community Care of North Carolina (CCNC) also leverages predictive analytics through electronic data exchange infrastructure, which allows for the identification of individuals in need of care coordination. The program aims notably to facilitate population management and pharmacy management initiatives, enable communication of health information across settings of care; monitor cost and utilization outcomes and provide performance feedback at the patient, practice, and network level.[52] Additionally, significant investment in IT systems and data collection by the Veterans' Health Association (VHA) has allowed for a variety of predictive analytics techniques and has resulted in a net return on EHR investment of over $3 billion.[53]

However, full leverage of the data in the whole of the U.S. and the Medicare population has yet to be realized and there are still significant opportunities for predictive analytics within T2D to improve therapy adherence and persistence. The U.S. health and government leadership could escalate and develop further partnerships with organizations such as those mentioned above to allow full leverage of the benefits of predictive analytics for reducing sub-optimal adherence and persistence in Medicare PwD. As the largest portion of healthcare costs come from high-risk patients, it is critical to leverage predictive analytics to identify the individuals to focus on for further profiling and interventions. Success of further escalation of predictive analytics with Medicare PwD could also pave the way for further leverage of predictive analytics in other medical areas in the U.S., such as other chronic conditions.

Recommendation 2

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

Once Medicare PwD have been identified as being at risk of low therapy adherence and persistence, they can then be profiled using psychometric assessment tools to determine their actual degree of activation and the underlying drivers of this. This would act as a prerequisite to setting realistic goals and actions and put PwD on the path to optimal therapy adherence and persistence (see Exhibit 4). In the U.S., psychometric assessment tools are already used to quantify an individual's degree of activation, although their uptake would benefit from wider awareness and payer buy-in. Such tools have been shown to increase adherence to therapy, reduce healthcare expenditure[28] and predict costs and outcomes for PwD.[29,30] 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 adherence to medicine and a 2% decrease in hospital admissions and readmissions.[54]

However, existing psychometric assessment tools may not sufficiently quantify the underlying drivers of activation that are specific to Medicare PwD nor do they provide effective insights into these particular individuals' attitudes, motivations, behaviors, logistical and financial challenges. The adaptation or development of a Medicare PwD-specific psychometric assessment could be incorporated into the enhanced Medicare MTM program and become a quality and performance assessment metric in the star rating system.[55,56] In the longer-term, an analysis of dispensing data, including refill rates and punctuality of refills, could be used to validate the tool's ability to predict adherence and persistence to medicines in this population.

Recommendation 3
Sponsor further research to improve understanding of Medicare PwD
primary life barriers

Despite a myriad of existing interventions, adherence and persistence remains a significant unmet need for Medicare beneficiaries[50] as there is still a lack of understanding of PwD primary life barriers and support needs. Further research is therefore required to better understand these barriers and needs and allow for the optimal pairing of existing interventions with the PwD or the development of new interventions to address unrevealed adherence and persistence challenges.

Further research could take the form of:

- **Ethnographic studies/conversation analysis** whereby researchers would collect and analyze data on PwD day-to-day experience with diabetes.
- **Behavioral economics** whereby researchers would explore the psychological, social, cognitive and emotional factors linked to the economic decision-making process in Medicare PwD and understand their motivational factors.
- **Lean six-sigma quality review** to identify the root causes of sub-optimal adherence and persistence.

With the view of understanding the underlying reason(s) for low activation and tailoring/devising interventions against the main ones. Indeed, existing interventions may not be considering or solving the most important challenges; for instance, promoting physical activity in Medicare PwD may require a change to the urban environment to make it easier to exercise.

Activate

Once PwD activation has been evaluated and individual needs identified, there is still a considerable challenge to engage Medicare PwD. However, there are a number of actions that can be taken in order to improve PwD engagement and these revolve around improving access to and customizing T2D education and, expanding use of the care team, providing healthcare plan counseling and addressing the financial burden for Medicare PwD with financial constraints. 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 4

Offer easy-to-access educational content tailored upon PwD activation

One of the most effective interventions to activate PwD and improve health outcomes is T2D education.[57] It is important to note that there is an abundance of T2D educational material currently available in the U.S.[58,59] However, existing educational programs for Medicare PwD do not fully encompass all needs of PwD in both content and format. Additionally, Medicare PwD must overcome barriers to access these courses, including physician preauthorization requirement and transportation to the course. The challenge in the U.S. is therefore to provide the relevant education content to the right PwD at the right time.

To be effective, T2D education should be tailored upon a PwD' degree of activation and its root causes. This is in order to avoid providing information that is not adapted to an individual's level of health knowledge or self-management skills as this results in sub-optimal PwD activation and, in turn, greater healthcare service use and costs. Furthermore, tailored T2D education should be timely and provided within the first 90 days post diagnosis or therapy change to effectively set PwD off to a good start.[60] This is especially important for PwD with low activation as these individuals fundamentally have a low probability of T2D therapy adherence and persistence and are could generate higher costs to the system in the future (see Exhibit 2).

Education should also contain advice on habit formation which, when paired with a 'small changes' approach, has been proven as an effective long-term behavior change strategy.[61,62,63] Habit formation starts with selecting a new behavior (e.g., eat one more fruit a day or walk) and the context in which it will be done and culminates with the establishment of automaticity, which happens on average about 66 days or about 10 weeks after initiation.[64]

More effective and targeted use of T2D education could be achieved via the use of decision aids.[65] The identification of key decision points (i.e. transition of care) along the PwD journey could involve nurses to use motivational interviewing and the teach back method to expand and consolidate learnings[66] or as part of a SDM process, providing physicians (or allied healthcare providers) can be reimbursed for the time dedicated to SDM.[65] Payers and providers could also offer modular, 2-hour courses at community centers or using online format (for computer savvy PwD) in place of non-modular, day-long courses, which require transportation. Indeed, to improve access to T2D education, it is also important to take PwD logistical needs into consideration and for example, offer courses adapted to their schedule or provide transportation.

Additionally, access to T2D education would improve with removal of physician preauthorization requirements for enrolment. Lastly, there is a need to implement policy changes to more widely fund programs like SDM as a means to get PwD more involved in disease management, and establish standards for these guides. This is especially important for Medicare PwD with low activation and low computer literacy, who may also be dependent on others for transportation, as this time with the care team represents the majority of education these PwD receive.

Recommendation 5

For PwD with low activation, expand use of care team and educators to provide support to improve health literacy

In order for Medicare PwD to reach optimal activation and T2D therapy adherence and persistence, HCPs should not only develop tailored education plans based on an individual's degree of activation but also customize engagement by the care team in terms of pace of engagement, logistical support and time allocation, especially within the first 90 days post diagnosis or change in therapy. For example, customized engagement for Medicare PwD with low activation could take the form of regular home visits by nurses and social workers to provide education, counseling, and checkups. Some HCPs are already doing this effectively and seeing cost savings, but this needs to be expanded nationally to really make an impact.[67]

In order to ensure continuity of care and a consistent approach in the event that PwD change plans, the government could develop national standards in relation to this type of care delivery and associated reimbursement. This will also require amendments to existing patient privacy laws in order to allow for linkage between different data systems and drive population–level health change data collection.

Recommendation 6

Incorporate healthcare plan counseling as part of medical appointments

There is confusion among Medicare PwD about differences between available healthcare plans.[68] Yearly changes in formularies further complicate this situation as, under the same healthcare plan, medications may be covered in one year but not the next year. As a result, many PwD select a plan that is not aligned to their healthcare needs, or fail to adapt healthcare plans (or medications) when formularies are updated and existing medications are no longer covered (or become more expensive). The Plain Writing Act of 2010 attempted to improve transparency, but significant challenges remain.[69]

This creates unnecessary financial and logistical barriers to accessing T2D medications. While it is possible to look up healthcare plan formulary information online, some Medicare PwD may be less internet savvy. In addition, these PwD are typically managing several medications for multiple co-morbidities, so this process can become overwhelming. Programs such as Walmart's "Healthcare begins here"[70] have recently been launched to increase healthcare plan transparency during sign-up periods, but these programs do not help PwD adapt to formulary changes, nor are they tailored to suit PwD needs. PwD typically find out at the pharmacy if their medications are no longer covered under the same tier for their healthcare plan, which requires them to go back to physician and switch medications.

As part of a medical visit, a member of the care team could help ensure Medicare PwD understand the available healthcare plans and help them identify the best option. This care team member could also ensure PwD are not affected by yearly changes in formularies; if there is a change in PwD medication coverage that may affect access, the care team member could identify this during the office visit and ensure the PwD is switched to an alternative medication.

EHRs and other healthcare technologies enable this type of program but payers need to establish reimbursement solutions and ensure PwD can receive this educational counseling during a medical appointment. Additionally, payers need to provide training to ensure HCPs understand the nuances of different healthcare options, in order for HCPs to effectively relay this information to PwD.

Recommendation 7

Promote innovative ways to reduce financial burden for Medicare PwD with financial constraints

Affordability can be a hurdle to optimal adherence and persistence for Medicare PwD who often are on multiple treatments.[3] Over the last few decades, although healthcare related costs per dollar have moderately changed, an increasing share of the cost has been shifted onto the patients who have become cost-insurers.[71] As a result, Medicare PwD sometimes "ration medication", prioritize which medications to take, or take half the prescribed dose to extend time covered.[47]

In order to tackle low therapy adherence and persistence amongst Medicare PwD due to financial difficulties, innovative programs could be devised to share responsibility of costs and help address therapy affordability in the Medicare population. For example, value-based contracts could include adherence and persistence measures. Similarly, insurers and pharmacists could offer financial incentives to Medicare PwD who refilled their prescription on time.

Policy changes would be required to incentivize payers to make long-term decisions regarding more favorable co-pay offers for Medicare PwD who are struggling financially. This could be achieved by increasing requirement for payers to focus on retention (e.g., inflicting penalties for low retention).

Sustain

The preceding recommendations are designed to activate Medicare 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 involve 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 reduce unnecessary 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 8

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 suddenly move outside the normal range for HbA1c levels, number of hypoglycemic events, 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. As it stands, quality measures in diabetes rely on care processes (such as HbA1c tests, annual screening for complications) and on clinical outcomes (such as meeting targets for HbA1c, LDL cholesterol, and blood pressure). While these metrics are easily measurable, they fail to address patient safety. Recent literature has suggested using hypoglycemia as a safety-centered, quality of care metric.[72]

Recommendation 9

Better leverage technology and digital offerings to maintain PwD activation

Upon reaching a high degree of activation, Medicare PwD could be transitioned to a cost-effective T2D management program. Such a program could leverage technology for T2D therapy self-tracking, T2D management support, re-assessment of patient action levels, refresher education, and reminders to reduce need for human intervention. These interventions could be tailored based on individual PwD to ensure high activation is sustained. Furthermore, to effectively sustain activation, behavioral incentives should also be considered; this could include a cash or tax rebate for good adherence and persistence.

Specific examples of technology interventions that could be utilized in the sustain phase are GlowCaps (dispenser containing a chip that monitors bottle opening and wirelessly relays alerts when the medicine is not dispensed), near field technology (e.g., passive uploading of results from glucometer to a Smartphone app and automatic transmission to HCPs) and calls/SMS reminders to take and refill medications. GlowCaps-linked calls/SMS reminders could increase in frequency if the behavior remains unchanged and escalate to human intervention (e.g., automated calls at first and a call from a call center, then a pharmacist or other HCP if the behavior remains unchanged). Nanotechnology is another emerging tool that could be leveraged for monitoring adherence, HbA1c levels, complications, diet, and exercise. Finally, apps can be used to track progress between appointments to reduce the frequency of HCP visits, and as a platform for peer-to-peer support programs. Additionally, for older generations who may be less comfortable with digital tools, these could be played on a radio frequency communicated by their doctor, nurse or pharmacist.

All the above recommendations could be initiated as pilot projects, which would allow assessment of outcomes and capture of the learnings. Involvement from relevant stakeholders including government stakeholders, payers and healthcare administrators, among others, will be crucial for the success of such initiatives. Successful pilots could then be scaled up to a national level to fully realize the potential cost savings.

Conclusion

The economic and societal burden of low T2D therapy adherence and persistence to the U.S. Medicare system is high and rising. T2D-related complications are thought to make up 61% of T2D costs to the healthcare system[6] and it is predicted that over 4% of these complication costs, or $4 billion per year, are due to sub-optimal therapy adherence and persistence (see Exhibit 1). With nearly 12 million Medicare PwD in the U.S. today, estimated to grow to 17.2 million by 2025,[1] it is imperative that structured action is taken to improve T2D therapy adherence and persistence on a war footing.

In light of this, a comprehensive and coordinated set of actions has been laid out in this paper to identify and profile Medicare 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, the U.S. government, insurers and providers could make informed decisions on how and what interventions to scale up for successful reduction of significant and unnecessary costs of sub-optimal T2D therapy adherence and persistence, as well as improve health of millions of Medicare 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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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.

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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.

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