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Advances in the understanding of treatment pathways for diabetes

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ABSTRACT. *As China's medical system reform continues to deepen and develop, treatment pathways have gradually become a common and effective model of medical behavior and practice in China. The Notice of the General Office of the State Council on the Issuance of the National Health Plan for the 14th Five-Year Plan (Published by the General Office of the State Council, PRC [2022] No. 11, hereinafter referred to as "the Plan") points out that the medical service model should be optimized and the integration of medical care and prevention should be strengthened. Relying on the national basic public health service programs, hypertension and type II diabetes are used as entry points to promote the organic linkage of prevention, treatment, care, and rehabilitation, forming an integrated health management service of "active prevention before illness, scientific management after illness, and uninterrupted follow-up services". During the clinical treatment of diabetes, it is necessary to obtain first-hand information through effective treatment pathways, so it is especially important to strengthen the clinical treatment pathways of diabetes. This paper reviews the existing research literature on the diagnosis and clinical pathway of diabetes as the research object, in order to provide some help for the clinical treatment of diabetic patients.*

Keywords: diabetes; treatment pathways; continuity of health education; research progress

1. **Introduction.** According to the data released by the International Diabetes Federation (IDF), as of the end of 2019, the total number of patients with diabetes in China is about 116.4 million among people aged 20 to 79, and the proportion of deaths due to diabetes and its complications reached 2% of all deaths, which shows that diabetes has become a serious disease that threatens the life safety of the public in China.Therefore, it is crucial to strengthen its clinical treatment[1] . The incidence of diabetes mellitus (DM) has been growing and has become a rising threat in youth, especially in today's society where the standard of living is constantly improving. Overall, it is a serious chronic disease that endangers the physical and mental health of the public [2].

2. **Overview of diabetes mellitus.** Diabetes mellitus is a group of metabolic diseases caused by defective insulin secretion and/or defective insulin action and characterized

by elevated plasma glucose (referred to as blood glucose) levels with impaired metabolism of carbohydrates, fats and proteins. Diabetes can cause chronic damage, dysfunction, and failure of many organs, including the eyes, kidneys, heart, and blood vessels. Characteristic symptoms such as excessive drinking, polyuria, blurred vision, weight loss and polyphagia can occur with markedly elevated blood glucose and, in severe cases, ketoacidosis or non-ketotic hyperosmolar states, even leading to death. The prevalence of diabetes is increasing rapidly worldwide, and China has become the country with the largest number of diabetics in the world[1].

3. **Staging and classification of diabetes mellitus.**

Western medicine classification 3.1. The American Diabetes Association (ADA) in 1997 and the World Health Organization (WHO) in 1999 classified diabetes mellitus into four types based on etiological typing: type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), specific types of diabetes mellitus, and gestational diabetes mellitus (GDM).[4-5] However, with the rapid development of genetic sequencing and other analytical testing technologies, genetic subtypes have been added to the diabetes typing system, combining genomics, proteomics, epigenetics, and environmental factors to classify patients' clinical phenotypes from the etiological and functional perspectives, and taking into account the patient's disease progression and response to medication, which can improve the accuracy of diabetes typing and the effectiveness of interventions.[6] In 2019, WHO updated its recommendations for the staging and diagnosis of diabetes mellitus, aiming to facilitate initial clinical diagnosis and management by classifying occult autoimmune diabetes mellitus (LADA) and keto-prone T2DM in adults as "mixed diabetes mellitus" and adding "unclassified diabetes mellitus" to the four types mentioned above. The addition of "unclassified diabetes mellitus" has led to the classification of 6 types of diabetes mellitus.[7] The addition of "unclassified diabetes" led to the classification of diabetes into 6 types.

Chinese medicine classification3.1. The ancient concept of "thirst" in Chinese medicine is interrelated with modern diabetes mellitus, which is characterized by the symptoms of excessive drinking, excessive eating, excessive urination and weight loss. According to the location of the disease, diabetes is divided into three types of symptoms, namely, upper, middle and lower extinction, and five types of symptoms, namely, lung heat and fluid injury, stomach heat and incandescence, Qi and Yin Deficiency, Kidney Yin Deficiency and Yin and Yang deficiency.

Diabetic complications3.2. Diabetic complications are systemic diseases that occur after having diabetes for a number of years, for the unsatisfactory blood glucose control ot diabetes patients. According to the diagnostic criteria of the American Diabetes Association (ADA), the total prevalence of diabetes among Chinese adults is 12.8%, and the total number of people with diabetes is about 129.8 million (70.4 million men

and 59.4 million women); the prevalence of pre-diabetes is 35.2%. In terms of prevalence characteristics, the prevalence of diagnosed diabetes in China is 6.0% and that of newly diagnosed diabetes is 6.8%, with a higher proportion in men than in women, and increases with age. Diabetes awareness rate was 43.3%, treatment rate was 49.0% and control rate was 49.4%[21]. Patients with untreated diabetes are at great potential risk and can be seen with hypoglycemic crisis as the first symptom, which can even be life-threatening. Further data show that about 834,000 people die each year in China from various complications caused by diabetes.

Diabetic complication classification3.2. Diabetic complications are mainly classified as acute and chronic complications. Acute complications of diabetes include diabetic ketoacidosis (DKA), hyperglycemic hyperosmolar status (HHS), hypoglycemia, and lactic acidosis (LA). Diabetic ketoacidosis and hyperglycemic hyperosmolar status syndrome are the most common, both of which can increase the risk of edema and death. Chronic complications of diabetes are divided into macrovascular complications and microvascular complications. cerebrovascular, and peripheral arterial disease can occur in the macrovascular area, and in severe cases, coronary artery disease, myocardial infarction, cerebral infarction, and diabetic foot disease. Microvascular complications include diabetic nephropathy (DN), diabetic peripheral neuropathy (DPN), and diabetic retinopathy (DR),corresponding patients will appear lower limb edema, foam urine, limb numbness, pain, tingling sensation and blurred vision and other symptoms, The Diabetes Control and Complications Trial (DCCT)[22] in T1DM and the United Kingdom Prospective Diabetes Study (UKPDS) in T2DM were conducted in patients with lower limb swelling, foamy urine, numbness, pain, pins and needles, and blurred vision. The results of the Prospective Diabetes Study (UKPDS)[23] in T2DM confirm that intensive blood glucose control can reduce the risk of diabetes complications. The latest ADA guidelines and the Chinese Diabetes Prevention and Control Guidelines also suggest that patients with diabetes should be evaluated regularly for metabolic control status and complications in order to reduce the risks is enhanced quality of life.

4. **History of the development of diabetes pathways.** In order to promote the standardized treatment of diabetes, the American Diabetes Association (ADA) began publishing the Standards for the Treatment of Diabetes (ADA Guidelines) in 1988, and the European Association for the Study of Diabetes (EASD) and the ADA continue to update the standards based on the latest research evidence. The European Association for the Study of Diabetes (EASD) and the ADA continue to update the standards based on the latest research evidence. The Chinese Medical Diabetes Association assisted the Ministry of Health in the development of the Ninth Five-Year National Diabetes Prevention and Control Program in 1995, and has since updated the standards in ongoing research and has been widely influential in diabetes research. The 2020 edition of the guideline also optimizes a simple pathway for the treatment of hyperglycemia in

patients with type 2 diabetes: glycosylated hemoglobin (HbA1c) <7.0% is the control target, and the treatment is divided into monotherapy, bigeminal therapy, triple therapy and multiple insulin injections. Lifestyle interventions are emphasized as basic therapeutic measures and should be utilized throughout the treatment. At the same time, it also increased the application of artificial intelligence in screening and grading diagnosis of diabetic retinopathy, and improved the important role of electronic diagnosis and treatment of diabetes in medical institutions.

Status of domestic and international research on diabetes treatment pathways.4.1. The essence of clinical pathway is the standard of single disease diagnosis and treatment services, which contains the admission pathway patient criteria, diagnosis, treatment, care and related charges after admission and other processes, such as examination items, care level, frequency of care, etc.[8] The standardized treatment for a single disease dispenses with redundant examinations and medications, standardizes physician operations, shortens hospitalization days, improves bed rotation efficiency, and achieves the purpose of ensuring medical quality and reducing medical costs.

Status of foreign research.4.1. Since 2006, the ADA/EASD hyperglycemia pathway has been continuously updated, from the development of the two main causes of diabetes: insulin insufficiency and insulin resistance, with the current support of lifestyle enhancement and metformin use as cornerstones of type 2 diabetes treatment. The use of medications and the cost of glucose-lowering drugs in the treatment pathway have been the focus of research, and the quality of medical resulting from the application of the treatment pathway has been continuously explored. M. Panella, S. Marchisio, F [9] and others believed that diagnosis and treatment path could improve the quality of modern medicine after analysis and comparison of clinical data; Feisul IM, Azmi S, Mohd Rizal AM[10] and others found that the high cost of state investment in diabetes care pathways can guarantee the quality of diabetes care; Kalra S, Thai HQ, Deerochanawong C[11] et al. research results show the importance and use of premixed or dual-action insulin in diabetes care pathways in Southeast Asian countries.

Current status of domestic research4.1. Since the concept of "clinical pathway" was proposed in the United States in the 1980s and introduced into China in the mid-1990s, China's first Diabetes Prevention and Treatment Guidelines was released in 2004, and "standardized diagnosis and treatment behavior" was mentioned in the Opinions of the CPC Central Committee and The State Council on Deepening the Reform of the Medical and Health System in 2009. Compared with foreign clinical path application from hospitals to communities to rehabilitation institutions on a wide range of multi-level, our start is relatively late and the focus of overall medical information construction is still limited in big cities. Along with the application of clinical pathways, related research gradually deepened. The diagnosis and treatment pathways of diabetes are also gradually moving forward, since the emergence of related research in 2004 to 2022 reached the hottest so far with a total of 1380 related papers published. Its research on clinical medicine, public health and prevention, and the integration of

Chinese and Western medicine have promoted the effect, especially hospital management and quality of care have been the focus of research. Liang Wannian, Cao Hongxia[12] et al. believe that the clinical pathway for the diagnosis and treatment of type 2 diabetes is guided by evidence-based medicine, and highlights the characteristics of continuity of care in general medicine while emphasizing the standardization of treatment services. Dai, Hui-Min, Cheng-Yuan[13] et al. showed that the clinical pathway combined with the graded diagnosis and treatment of diabetes mellitus could further restrain the behavior of general practitioners, specialists and patients, promote the formation of an orderly pattern of medical care, and effectively promote graded diagnosis and treatment. Li Mei[14] believed that the implementation of the clinical pathway improved the cognitive ability and self-management ability of diabetic patients, improved the effect of health education, and achieved good control of blood glucose.

5. **Analysis of common clinical pathways for diabetes.**

General diagnostic pathway.5.1. The diagnostic pathway is to set up a set of standardized clinical treatment patterns and procedures for a disease based on medical evidence and guidelines, with the ultimate goal of regulating medical behavior, delaying the occurrence of complications, and improving patients' quality of life. The general diagnostic pathway is mainly to understand and obtain information about the patient's disease through sensory involvement without the use of special instruments and equipment, and to make preliminary judgments by combining the clinical diagnostic criteria and regulations for diabetes. The main clinical symptoms of diabetes mellitus can be summarized as "three more and one less", i.e. excessive eating, excessive drinking, excessive urination, and weight loss. The initial diagnosis of diabetes can be taken by observing the presence of these symptoms in the clinical setting.

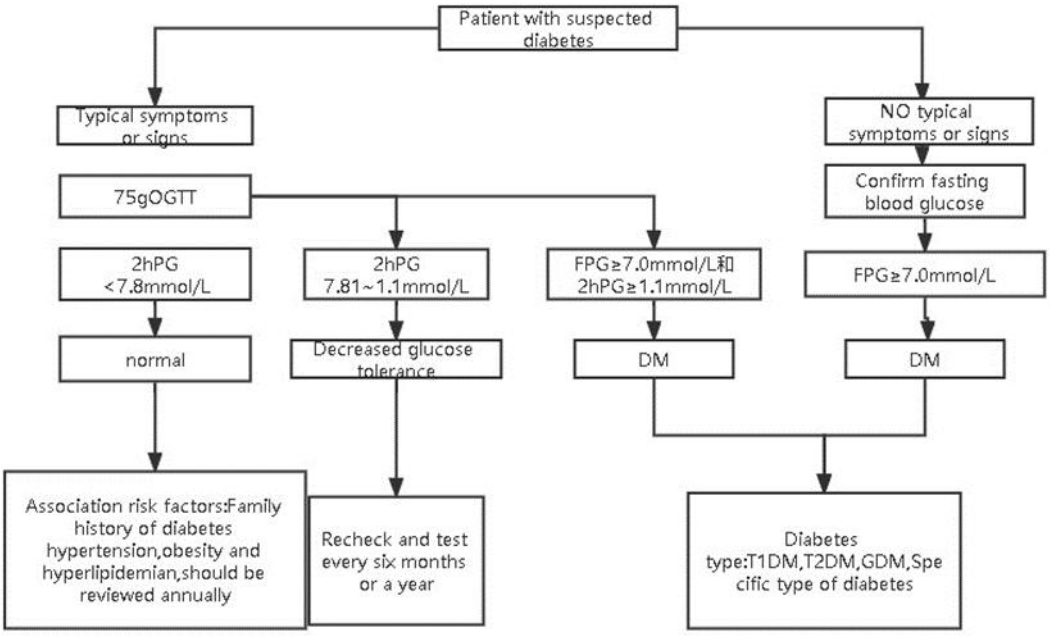

FIGURE 1. Diabetes treatment pathway

Zhang Yuan[15] analyzed the early clinical symptoms of diabetes mellitus and pointed out that early detection and early treatment can be achieved by identifying the typical early disease symptoms such as "three more and one less". Therefore, during the clinical diagnosis of diabetic patients, the clinical symptoms of patients can be observed and analyzed without the help of professional testing equipment and instruments, which can be an important path for the early clinical diagnosis and treatment of diabetic diseases and can greatly improve the efficiency of clinical diagnosis and treatment.

Screening and diagnosis of diabetes mellitus.5.2. There are currently four diagnostic criteria for diabetes: (1) HbAlc ⩾6.5% with a clear diagnosis; (2) FPG ⩾7.0 mmol/L with fasting meaning 8h fasting; (3) 2h glucose concentration ⩾ 11.1 mmol/L in OGTT test (75g anhydrous glucose dissolved in water); (4) patient with hyperblood glucose symptoms or hyperblood glucose crisis and random glucose concentration ⩾ 11.1 mmol/L. In general, FPG, 2hPG in 75 g OGTT, and HbA1c are equally suitable for diagnostic screening. Xianghai Zhou and Linong Ji[24] in their study similarly stated that further OGTT should be performed when F P G is above 6.2 m mol /L or HbA1c is above 6.2% to clarify the presence or absence of DM; Xie Qiuqiu and Bao Chunhua[25] et al. study illustrated the significant advantages of HbAlc for diabetes diagnosis, which can provide a scientific reference basis for the development of subsequent treatment plans, assessment of treatment effects and risk of complications in diabetic patients. If the test result of the patient is close to the critical value of the diagnostic threshold, the doctor should discuss the symptoms and signs with the patient, and urge him to recheck within half a year.

In 2009, an international expert committee added HbA1c to the diagnostic criteria with the aim of increasing the detection rate of screening; in China, the 2020 edition of the Chinese Guidelines for the Prevention and Treatment of Type 2 Diabetes also included HbA1c in the diagnostic criteria for the first time[26]. It has been confirmed that HbA1c is a golden indicator for long-term (last 3 months) blood glucose control and an important basis for clinical adjustment of the treatment plan.

For screening for diabetes, the 2022 ADA recommends that everyone starts at age 35. The 2020 edition of the Chinese Guidelines for the Prevention and Control of Type 2 Diabetes also states that screening is recommended every three years for people with normal screening results in people at high risk for diabetes, and for people with pre-diabetes, the guidelines specify that annual screening is recommended. Screening[26] The guidelines also state that screening is recommended every three years for those with normal screening results and once a year for those with pre-diabetes. A detailed evaluation should be performed at the time of initial diagnosis to help clarify the clinical type of diabetes, detect complications and complications, and provide appropriate treatment to improve the patient's prognosis.

Blood biochemical tests.5.3. In the clinical diagnosis and treatment of diabetes, blood biochemical testing is a key route to further confirm the diagnosis of diabetes. The so-called blood biochemistry test is a common test method in clinical laboratory testing, which mainly involves taking an appropriate amount of centrifuged plasma, aspirating the upper layer of serum components after a period of resting, and then placing the sample at a specific location in the biochemistry tester for aspiration and testing (to ensure that the biochemistry tester parameters are adjusted), thereby obtaining the relevant index data about the disease. In the case of diabetes, there are numerous blood biochemical tests involved in clinical management, such as fasting glucose, 2h postprandial glucose, glucose tolerance, total cholesterol (TC), triacylglycerol (TG), and glycated hemoglobin (HbA1c), which are all valuable indicators in the diagnosis of DM. In the clinical diagnosis of DM disease, the blood biochemical indicators reflecting DM patients can be tested with the help of special clinical testing equipment, and the actual test data of these indicators can be compared and analyzed with the standard (correct) values to determine whether the patient is diagnosed with DM disease. There are more research results on the application of blood biochemical tests in DM treatment, and typical studies are reproduced below.

In Rantang Lai and Huipu Liang[16]'study, one hundred and fifty patients with type 2 diabetes mellitus who received clinical diagnosis in our hospital were selected and divided into group A (diabetic patients group), group B (patients with impaired glucose tolerance) and group C (glucose tolerance remained normal) according to the patients' glucose tolerance, and the HbA1c levels in the blood of the patients in each group were compared, and it was found that the average level of HbA1c detected in each group showed a gradual decrease, and this change trend There was a positive correlation between it and the blood glucose level in the blood; the corresponding specificity of the diagnosis of DM patients based on HbA1c levels was up to 95% or more. Thus, it can be seen that HbA1c level can served as an important cut-off point for clinical diagnosis of DM patients. Fan Yingxiang and Zeng Shuzhen[17] selected 90 patients with suspected DM who came to the hospital and divided them into DM group, IGR group and NGT group based on the WHO diagnostic criteria for diabetes mellitus, after which oral glucose tolerance test (OGTT) and blood glucose index were measured on them, and the results showed that the specificity and sensitivity of HbA1c as a test for DM disease were found at HbA1c $\geqslant$ 6.5% It can be seen that HbA1c has the advantages of simplicity and accuracy in the clinical diagnosis of DM patients, but if HbA1c is used alone, patients may be missed to a certain extent, so when OGTT is inappropriate or impossible, the HbA1c index can be used in combination with other tests to greatly improve the overall clinical test results. The reliability of the overall clinical test results can be greatly improved by combining other tests. [18]The mean HbA1c level, 2h postprandial blood glucose level (2hPBG level), fasting blood glucose level (FBG level) and GSP level of the two groups of patients were measured afterwards, and it was found that the HbA1c test could accurately reflect the average blood glucose level in the patients' blood within the last 3 months. Therefore, the HbA1c test level can be employed as an important indicator for clinical diagnosis and treatment of DM disease. However, in order to reduce the probability of missing

diagnosis, it is necessary in order to strengthen the combination of the HbA1c test with other testing methods. Wang Chao[19] also used a similar experimental grouping, except that the number of each group was 50 cases, and then their HbA1c levels, 2hPBG levels, and FBG levels were measured, and the results showed that the DM patients were significantly higher than the control group in these indexes. It can be seen that the effective application of the HbA1c index in the process of clinical diagnosis of DM disease can provide a reliable basis for clinical diagnosis of DM patients.

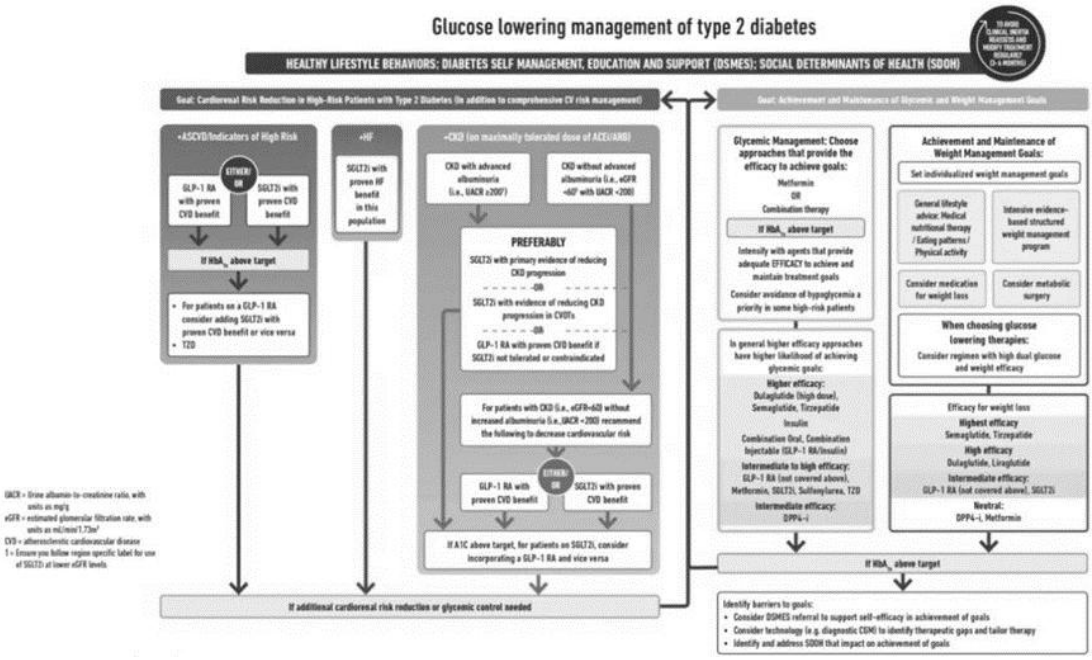

FIGURE 2. Treatment pathway of applying Hb1Ac as a therapeutic index

6. **Status and evaluation of applications related to diabetes pathways.**
History and basic requirements for the development of diabetes management procedures.6.1. A number of diabetes diagnosis and treatment guidelines have pointed out that the vigorous development of telemedicine services based on Internet technology is of great significance in strengthening the health management of patients with chronic diseases and improving the conflict between doctors and patients[20], Internet telemedicine services are new technologies that can help improve diabetes management, and remote diabetes application management programs include at least self-monitoring functions, interactive communication functions, and professional medical functions in terms of basic functions, At present, the application programs and systems of diabetes diagnosis and treatment pathway at home and abroad can be roughly divided into two aspects: remote diabetes management service and the implementation of professional diagnosis and treatment pathway. In terms of remote diabetes management services, in 2010, Welldoc, an American company, launched Diabetes Manager, an application management program for type 2 diabetes management, and in 2016, the first intelligent domestic health management system for diabetes was released in Wuhan. As a result, diabetes management apps are gradually understood and used by diabetes patients at home and abroad. In terms of the

implementation of professional diagnosis and treatment pathways, the current systems involving diabetes diagnosis and treatment pathways at home and abroad are basically based on the guidance set by the ADA Guidelines as the standard. It has improved the diagnosis and treatment speed of frontline medical staff, improved the blood glucose control of patients, and strengthened the self-management of diabetic patients. On September 19, 2022, China Medical Insurance's Smart Medical Insurance Solution Competition launched a new program: Medical Insurance Regulatory Application Practice Based on Medical Big Data Disease Pathway Intelligence Database. The program proposes to take different treatment modalities of a single disease as the core, to gather medical data of the whole process, to promote the standardization of treatment pathways, and to promote the development of value-based medicine, which also indicates that electronic treatment pathways for diabetes will occupy an important position in medical practice and services in the future.

Current status and deficiencies in the application of diabetes management procedures6.2. Diabetes management applications play an indispensable role from in-hospital treatment to discharge self-monitoring. In frontline clinical practice, it is not only efficient in determining whether a patient is transferred to a clinical pathway, but also in regulating medical practices; in the field of diabetes, remote patient monitoring is the most essential part of achieving telemedicine. In the field of diabetes, remote patient monitoring is a key and important part of telemedicine. A diabetes remote application can help improve the self-management of diabetic patients. Thus improving blood glucose control and not adding additional time costs. A nice app should be practical and simple, and easy to operate. Currently, apps on the market have too many functional sections, and pages selling self-branded diabetes management peripherals often take up most of the main page of the app, making it inconvenient for middle-aged and elderly diabetics to use and decreasing patient compliance. Most management programs do not seamlessly connect to the patient's medical system at the hospital where the patient is viewed, thus leaving clinical staff without a true picture of the patient's condition.

Evaluation of diabetes management procedures.6.3. Under the new situation that diabetes is listed as a key disease of concern in the Internet diagnosis and treatment policy, cooperation between medical and health institutions and Internet enterprises to strengthen the integration of regional medical and health information resources is already a must, and It is necessary to carry out clinical and offline diabetes management applications to verify the completeness and flexibility of the diagnosis and treatment path, to promote the hierarchical diagnosis and treatment of diabetes.

7. **Discussion.** In summary, the diagnosis and treatment pathway of diabetes plays a key role in the standardization and scientification of clinical treatment. Two pathways are mainly used in clinical diabetes diagnosis and treatment today, namely the overall diagnosis and treatment pathway (including consultation and visualization) and the biochemical test pathway. The former is appropriate for the preliminary determination of diabetes disease, while the latter is suitable for the precise determination of diabetes disease, and the clinical

diagnosis and treatment of DM disease under the biochemical test pathway involves relatively more reference indicators. In addition to HbA1c levels, several testing indicators such as 2hPBG, FBG and GSP levels were involved, and the differences between the comparative analysis of these indicators in DM patients and healthy physical examiners were very significant. Although the specificity of 2hPBG, FBG, and GSP levels is not as high as that of HbA1c, the diagnosis of DM disease is very apt to be missed if HbA1c is used as a single indicator. At this time, if the 2hPBG, FBG, and GSP indexes can be combined in the application of HbA1c indexes to diagnose DM patients, then the specificity and accuracy of clinical diagnosis of DM disease can be greatly improved, and the rate of missed diagnosis and misdiagnosis can be reduced. It should be noted that, regardless of the final application of the test indicators, it is necessary to ensure the accuracy of the testing method and process of each indicator, so as to maximize the important role of blood biochemical indicators in the diagnosis of DM patients. With the encouragement of developing a sound "Internet+medical health" service system, it is the trend to strengthen the management of diabetes online services and to build an integrated online and offline medical service model covering pre-consultation, consultation and post-consultation, while also paying attention to the variables that occur in Hierarchic Healthcare in order to achieve a truly patient-centered diagnosis and treatment model. The model of integrated online and offline medical services covering pre-consultation, consultation and post-consultation has become a trend.

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