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Glucometers, insulin pumps, and Continuous Glucose Meters (CGMs): Role of pharmacists-an updated review

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***Abstract*---Background**: Effective insulin therapy is crucial for managing diabetes, with recent advancements in glucose monitoring technologies significantly enhancing patient outcomes. Continuous glucose meters (CGMs), insulin pumps, and glucometers play vital roles in improving glycemic control, thereby enhancing the quality of life for individuals with diabetes. **Aim**: This review aims to evaluate the role of pharmacists in managing diabetes through the application of CGMs, insulin pumps, and glucometers, highlighting innovations in technology and their impact on patient care. **Methods**: A comprehensive literature review was conducted to analyze the efficacy of various glucose monitoring systems, including real-time continuous glucose monitoring (RT-CGM) and self-monitoring of blood glucose (SMBG) devices. Clinical trials and recent advancements in diabetes management technologies were examined. **Results**: The review found that RT-CGM devices significantly reduced HbA1c levels and the incidence of hypoglycemia compared to traditional SMBG methods. Long-term CGM use improved glycemic control, patient satisfaction, and quality of life, with evidence supporting its effectiveness across diverse patient populations. Pharmacists play an essential role in educating patients about these technologies and optimizing diabetes management strategies. **Conclusion**: The integration of advanced glucose monitoring technologies into diabetes management represents a substantial improvement in patient care. Pharmacists are crucial in

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facilitating access to these technologies and educating patients, ultimately enhancing glycemic control and overall health outcomes in diabetes care.

***Keywords*---**Diabetes management, Continuous Glucose Monitoring, Self-Monitoring of Blood Glucose, Pharmacists, Insulin therapy.

Introduction

A key objective of insulin therapy in diabetes management is to enhance glycemic control by mimicking the physiological insulin secretion observed in response to glucose and other stimuli when pancreatic islets function normally. Recent advancements in glucose monitoring, insulin delivery systems, algorithms linking these processes, and data management software that reveal glycemic trends have demonstrated the potential to significantly enhance the quality of life for individuals with diabetes. This chapter examines the current state of these innovations and their application in managing insulin-dependent diabetes.

Self-monitoring of blood glucose (SMBG) has been regarded as a critical element in managing type 1 diabetes mellitus (T1DM) since the Diabetes Control and Complications Trial [1]. SMBG is also recommended for individuals with type 2 diabetes mellitus (T2DM) undergoing insulin therapy and can be beneficial for other T2DM patients when integrated into a broader educational framework to guide treatment choices or self-management practices [2,3]. However, the accuracy of SMBG technology has come under scrutiny [4]. Due to concerns regarding the precision of monitoring systems, the ISO standard for these systems was revised in 2013 [5]. The previous 2003 standard mandated that 95% of values fall within 20% of a reference standard (or, for glucose levels under 100 mg/dL [5.6 mmol/L], within 20 mg/dL [1.1 mmol/L] of the reference value). The updated standard requires 95% of values to be within 15% of a reference value (or within 15 mg/dL [0.8 mmol/L] for values under 100 mg/dL). In 2014, the U.S. Food and Drug Administration (FDA) proposed even stricter guidelines, requiring that 95% of all values within the system's measuring range be within 15% of the reference value and that 99% fall within 20% of the reference [6]. The FDA acknowledges that some systems may struggle to meet this standard, especially in lower glucose ranges, and the proposed guideline suggests that manufacturers might need to adjust the lower end of the measuring range. It is expected that devices will demonstrate accuracy in the 50–400 mg/dL range [7]. However, this standard has not yet been fully implemented.

SMBG data can be utilized in various ways. For patients on multiple daily insulin (MDI) therapy, individual readings are used to determine the next insulin dose and to educate patients on the impact of specific foods, exercise, and other activities on their blood glucose levels. For individuals in other treatment regimens, physicians can use SMBG data to inform treatment decisions based on overall patterns. Given the large volume of data and the often inconsistent record-keeping by patients, identifying glycemic patterns can be challenging. To address this, there has been a push to integrate new technologies to simplify and improve accuracy in recognizing these patterns. Innovations have emerged from blood glucose monitoring system manufacturers, mobile phone suppliers, telemedicine platforms, and start-up companies. Many of these advancements were highlighted in a recent review [8]. Mobile applications (apps) for downloading SMBG data are widely available on iOS and Android platforms, though many lack definitive studies demonstrating their safety or effectiveness in improving glycemic control. In the Mobile Diabetes Intervention Study, a mobile diabetes app was used to input glucose readings, carbohydrate intake, medication, and other relevant data. Participants received automated real-time educational, behavioral, and motivational messages tailored to their entered information. A web portal supplemented this with a secure messaging service and additional data, including a personal health record. In one group, healthcare providers had access to a decision support system based on analyzed patient data linked to care standards and evidence-based guidelines, while in another group, providers had access only to unanalyzed data. After 12 months, participants receiving usual care experienced an average reduction in HbA1c of 0.7%, while those using mobile technology without decision support saw a decline of 1.2%, and those with decision support experienced a 1.9% reduction [9]. Telemedicine diabetes support systems have also been shown to enhance quality of life [10] and increase satisfaction among both patients and healthcare providers [11].

Additionally, systems for creating graphical depictions of glucose patterns have been developed; these systems have been demonstrated to improve glucose control. These graphical outputs can be seen immediately on the meter [12] or by downloading SMBG data from the meter using software [13]. An example of such software and can help uncover patterns, like hypoglycemia episodes, that may be harder or need more time to find by looking through a handwritten logbook. Abbott Diabetes Care has released a revolutionary approach to episodic glucose monitoring [14]. According to Abbott, the device, known as the FreeStyle Libre Flash® glucose monitoring system, has an arm-worn sensor that may be used for up to 14 days without the user having to calibrate it. A reader scans the sensor to determine the glucose levels. This gadget monitors the amount of glucose in subcutaneous fluid, as opposed to capillary blood glucose, which is measured using classic meters and strip methods. The system was not yet available in the United States, but it was available in Europe at the time of its release. Though essentially identical to continuous glucose monitors, it does not offer glucose trend data and is only intended for episodic glucose monitoring.

Real Time Glucose Monitoring

Several real-time continuous glucose monitoring (RT-CGM) devices are currently available, including the Medtronic Guardian® REAL-time CGM System and the Dexcom G4 Platinum. The components of a standard CGM system, which typically includes a subcutaneous sensor containing glucose detection chemistry, a receiver that analyzes and displays the results, and a transmitter that sends data from the sensor to the receiver. These devices use a transcutaneous glucose oxidase-based electrochemical sensor to measure glucose levels every minute, smooth the data, and display glucose concentrations in the interstitial fluid every five minutes. The data can also be downloaded into a graphical format. However, there can be a delay between changes in blood glucose levels and when the CGM detects the new concentration. This lag has three components: a physiological lag influenced by blood flow to the skin, a sensor reaction time for data acquisition, and a processing lag for signal analysis and data smoothing. The total lag time can range from as short as 5 minutes to as long as 15 minutes during rapid glucose fluctuations. Due to accuracy limitations [15,16], the current generation of CGM devices is not approved for use as stand-alone devices, and users are still required to perform capillary blood glucose measurements. Nevertheless, this limitation is offset by the detailed information provided by the CGM, including glucose patterns, the rate and direction of glucose changes, and adjustable alarms for both hyperglycemia and hypoglycemia [17].

Clinical Efficacy of CGMs

Several randomized controlled trials have evaluated the clinical efficacy of real-time continuous glucose monitoring (RT-CGM) systems. Early studies of short duration demonstrated that RT-CGM reduced both hyper- and hypoglycemic episodes, leading to more time spent in the target glucose range [18,19]. One of the first longer-term studies, the **GuardControl trial**, involved 156 individuals with type 1 diabetes mellitus (T1DM) and showed a significant reduction in HbA1c after three months in the RT-CGM group compared to the control group ($1.0 \pm 1.1\%$ vs. $0.4 \pm 1.0\%$) [20].

Larger multicenter trials, such as the **STAR-1 trial** and the **Juvenile Diabetes Research Foundation (JDRF) CGM trial**, have provided further evidence. In the STAR-1 trial, which enrolled 146 participants using insulin pumps, the RT-CGM group did not achieve a significant difference in HbA1c reduction compared to the control group over six months. However, the RT-CGM group achieved improved glycemic control without increasing biochemical hypoglycemia [21]. Notably, more severe hypoglycemic events occurred in the RT-CGM group, often due to user errors such as ignoring alarm warnings or stacking insulin doses. The **JDRF CGM trial**, which involved 451 participants, demonstrated that for those with baseline HbA1c <7.0% (53 mmol/mol), the RT-CGM group spent less time in biochemical hypoglycemia compared to the control group, though this was not statistically significant. For participants with baseline HbA1c between 7.0% and 10.0%, the RT-CGM group saw a significant reduction in HbA1c in those aged 25 years and older (mean difference of 0.53%, $p < 0.001$). Furthermore, the frequency of achieving an HbA1c of <7.0% without severe hypoglycemia was higher in the RT-CGM group [22,23,24]. A 12-month extension of the JDRF study showed sustained HbA1c reduction and a decrease in severe hypoglycemic events, underscoring the benefits of RT-CGM for improving glycemic control without increasing hypoglycemia risk [25]. In its clinical guidelines, the **American Diabetes Association** supports RT-CGM as an effective tool to lower HbA1c in adults aged 25 and older with T1DM, with potential benefits for younger adults and children, depending on device adherence [26].

Long-Term CGMs Benefits

Long-term use of continuous glucose monitoring (CGM) has demonstrated several significant benefits for individuals with diabetes, particularly those with type 1 diabetes mellitus (T1DM). Key advantages observed in various studies include:

1. **Improved Glycemic Control**: Long-term CGM use has been shown to significantly reduce HbA1c levels. For example, in a follow-up to the Juvenile Diabetes Research Foundation (JDRF) CGM trial, participants using CGM over 12 months saw sustained reductions in HbA1c, with reductions of about 0.4% persisting over timeg lower HbA1c levels without increasing the risk of hypoglycemia is a major goal of intensive diabetes management.
2. **Reduction in Hypoglycemia**: One of the primary benefits of CGM is its ability to detect and alert users to both hyperglycemia and hypoglycemia in real time. This helps reduce the risk of severe hypoglycemia by providing early warnings through alarms. Long-term studies have demonstrated that individuals using CGM spend less time in hypoglycemia compared to those using traditional self-monitoring of blood glucose (SMBG). The incidence of severe hypoglycemic events has been shown to decrease significantly with prolonged CGM use .
3. **Bty of Life and Patient Satisfaction**: Long-term CGM use improves quality of life for patients, offering more freedom and flexibility in managing their glucose levels. Studies have reported higher patient satisfaction, as CGM reduces the need for frequent fingerstick measurements and provides continuous feedback. This can decrease the anxiety surrounding both hyper- and hypoglycemic events and reduce the mental burden associated with diabetes management .
4. **Reduction y**: CGM helps users better understand glucose trends, including the direction and rate of change, which allows for more timely and appropriate adjustments to insulin dosing, diet, and activity. This leads to a reduction in glycemic variability, which is important for long-term cardiovascular and overall health in people with diabetes .
5. **Sustained Benefits Across Diffeoups**: Long-term benefits of CGM are seen not only in adults but also in children and adolescents, though adherence can be more challenging in younger populations. Studies have shown that when used consistently, CGM can lead to significant improvements in glycemic outcomes in all age groups .
6. **Fewer Diabetes-Related Complications**: ving glycemic control and reducing both hyperglycemia and hypoglycemia over the long term, CGM can help mitigate the risk of diabetes-related complications, such as retinopathy, neuropathy, and cardiovascular disease. Although studies on long-term complications are still ongoing, the benefits in reducing HbA1c and glycemic excursions suggest a positive impact on long-term health outcomes.

GCMs and SMBG Devices

Continuous Glucose Monitoring (CGM) and **Self-Monitoring of Blood Glucose (SMBG)** are two key methods for monitoring blood glucose levels in diabetes management, but they differ significantly in functionality, benefits, and impact on clinical outcomes. Here's a comparison of the two:

1. Frequency and Continuity of Data

- **CGM**: Provides continuous, real-time glucose readings throughout the day and night, typically every 1-5 minutes. CGM tracks glucose trends and variability, offering a comprehensive picture of glucose levels over time.

- **SMBG**: Involves episodic fingerstick testing to measure blood glucose levels at specific points in time. Most patients perform SMBG several times a day, usually before meals and bedtime, which only gives snapshots of glucose levels and misses trends or fluctuations.

Advantage: CGM provides a more complete and continuous understanding of glucose patterns, especially for detecting nocturnal hypoglycemia or rapid glucose swings that SMBG might miss.

2. Hypoglycemia Detection and Alerts

- **CGM**: Provides real-time alerts for impending hypoglycemia or hyperglycemia, allowing users to take immediate action to prevent dangerous blood sugar excursions. This is particularly important for individuals with hypoglycemia unawareness.
- **SMBG**: Requires the individual to actively perform a blood glucose test, which means hypoglycemia or hyperglycemia may go undetected between tests, especially at night or during periods of inactivity.

Advantage: CGM improves safety by detecting and alerting users to low or high glucose levels in real time.

3. Impact on Glycemic Control (HbA1c Reduction)

- **CGM**: Studies have shown that CGM use leads to significant reductions in HbA1c, particularly for individuals with type 1 diabetes mellitus (T1DM) and those on intensive insulin therapy. It helps users stay within their target glucose range by providing more data and insights on trends.
- **SMBG**: While SMBG can help improve HbA1c by guiding treatment decisions, it is less effective in detecting trends or preventing hyperglycemic and hypoglycemic excursions compared to CGM.

Advantage: CGM, due to its real-time feedback, typically results in better HbA1c reductions and more time spent in the target glucose range.

4. User Convenience and Lifestyle Impact

- **CGM**: Requires a sensor worn on the skin (usually changed every 7 to 14 days), which continuously measures glucose levels. Although the sensor must be calibrated (for some models), it reduces the need for frequent fingersticks. However, wearing a device can be seen as cumbersome by some users.
- **SMBG**: Requires frequent fingersticks, which can be painful and inconvenient, especially for those needing multiple daily measurements. It is less intrusive than wearing a CGM sensor but requires more active participation.

Advantage: CGM, despite the need to wear a sensor, reduces the frequency of fingersticks, which many patients find more convenient in the long run.

5. Detection of Glucose Trends and Variability

- **CGM**: Provides detailed information on glucose trends, including the direction and rate of change, allowing for more informed decision-making. Users can see whether their glucose is rising, falling, or stable, and make timely adjustments to insulin, diet, or activity.

- **SMBG**: Only provides glucose data at specific points in time, making it difficult to detect trends or predict future glucose changes. As a result, patients may be unaware of rapid changes or nocturnal hypoglycemia.

Advantage: CGM offers insights into glucose trends, helping users make proactive adjustments.

6. Clinical Evidence and Outcomes

- **CGM**: Numerous studies have shown that CGM use improves glycemic control, reduces hypoglycemia, and enhances overall quality of life. The continuous data provided by CGM helps patients make more precise insulin adjustments, which can reduce the risk of long-term complications.
- **SMBG**: While SMBG is effective for guiding day-to-day treatment, its limited data can result in less precise adjustments to insulin doses and a higher risk of glycemic variability, which is associated with long-term complications.

Advantage: CGM is more effective in improving long-term glycemic outcomes and reducing variability.

7. Cost and Accessibility

- **CGM**: Generally more expensive than SMBG, as it involves the cost of sensors, transmitters, and receivers. Insurance coverage for CGM varies, though coverage has expanded in recent years. Despite the cost, CGM's clinical benefits may justify the expense for many patients.
- **SMBG**: Cheaper than CGM and more widely available. Test strips are generally affordable and covered by most insurance plans. However, the cumulative cost of frequent SMBG testing can add up, especially for patients on intensive insulin therapy.

Advantage: SMBG is more accessible and affordable, though CGM's long-term benefits may outweigh the upfront cost for some patients.

8. Accuracy

- **CGM**: There is a slight delay between real-time blood glucose and the glucose measured in interstitial fluid (about 5-15 minutes). Some CGM models still require occasional calibration with a fingerstick glucose measurement. Newer CGM systems have improved accuracy, especially in the low glucose range.
- **SMBG**: Fingerstick measurements are considered highly accurate when properly performed, as they directly measure capillary blood glucose. However, accuracy can vary depending on user technique and the quality of the device.

Advantage: SMBG is slightly more accurate for individual point measurements, though CGM accuracy has improved significantly with newer models.

Conclusion:

- **CGM** is the superior tool for individuals who need continuous monitoring, early detection of glucose excursions, and better glycemic control. It is especially valuable for patients with T1DM or those on intensive insulin therapy, providing more comprehensive data and reducing the risk of severe hypoglycemia.

- **SMBG** remains a practical and affordable option for many people, particularly those with type 2 diabetes mellitus (T2DM) not on intensive insulin therapy. However, it lacks the continuous, proactive feedback that CGM offers.

Ultimately, the choice between CGM and SMBG depends on individual needs, the intensity of diabetes management, and financial considerations.

Practical Issues of CGMs:

1. **User Engagement and Diabetes Self-Care**: RT-CGM benefits are often seen in individuals highly engaged in their diabetes self-management. Advanced diabetes management skills are required for successful use (JDRF trial).
2. **Physiological Lag**: A delay exists between blood glucose (measured by capillary blood glucose devices) and interstitial glucose (measured by CGM), which can cause practical challenges. This lag is important when calibrating devices, which should only occur during stable glucose levels, typically pre-meal or after a 3-hour period following a bolus [27], [28].
3. **Impact on Hypoglycemia Detection**: During rapid glucose drops, the CGM sensor may display normal levels while blood glucose is already low due to the lag. Individuals should confirm low glucose readings via fingerstick before driving or if glucose levels are falling rapidly [29].
4. **Hypoglycemia Recovery**: After treating hypoglycemia, interstitial glucose may remain low even after blood glucose normalizes. It is essential to confirm recovery with fingerstick measurements, as relying on CGM readings can lead to overconsumption of glucose [31].
5. **Setting Alarms**: Alarms for hypo- and hyperglycemia are a crucial feature of CGMs. Alarm thresholds should be tailored based on individual needs. For individuals with hypoglycemia unawareness, alarms should be set at higher levels (4.5 mmol/L or above). For others, lower thresholds can be set initially to reduce alarm fatigue [32], [33].
6. **Alarm Fatigue**: Frequent false alarms can cause individuals to ignore important alerts. Alarm thresholds should be adjusted step-by-step to minimize irritation and improve glucose control. Predictive alarms, which alert users before glucose reaches dangerous levels, can be helpful [33-34].

Conclusion

The evolution of glucose monitoring technologies, particularly Continuous Glucose Monitoring (CGM) and Self-Monitoring of Blood Glucose (SMBG) devices, has transformed diabetes management. CGMs provide continuous, real-time glucose data, enabling patients and healthcare providers to recognize trends and make timely interventions. The evidence from various studies illustrates that the implementation of CGMs can lead to significant reductions in HbA1c levels and overall improvement in glycemic control. These technologies not only decrease the frequency of hypoglycemic and hyperglycemic episodes but also enhance patient satisfaction and quality of life. Pharmacists play a pivotal role in the successful integration of these technologies into diabetes care. Their expertise in medication management, coupled with their accessibility to patients, positions them as essential members of the healthcare team. By providing education on the use of

CGMs and SMBG devices, pharmacists can empower patients to take control of their diabetes management. They can also assist in interpreting glucose data, guiding patients in making informed decisions about insulin dosing, dietary choices, and lifestyle modifications. The collaboration between pharmacists, healthcare providers, and patients is vital for optimizing diabetes management. As glucose monitoring technology continues to advance, ongoing education and support from pharmacists will be crucial in maximizing the benefits of these innovations. This approach not only supports individuals with diabetes in achieving better health outcomes but also helps mitigate the long-term complications associated with the disease, thereby improving overall quality of life for patients.

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جهازقياس السكر، مضخات الأنسولين، وأجهزة قياس الجلوكوز المستمر :(CGMs) دور الصيادلة - مراجعة محدثة.

الملخص:

الخلفية :تعتبر العلاج الفعال بالأنسولين أمرًا حيويًا لإدارة مرض السكري، حيث أسهمت التطورات الأخيرة في تقنيات مراقبة الجلوكوز بشكل كبير في تحسين نتائج المرضى. تلعب أجهزة قياس الجلوكوز المستمر (CGMs) ومضخات الأنسولين وأجهزة قياس السكر أدوارًا حيوية في تحسين التحكم في مستوى السكر في الدم، مما يعزز نوعية الحياة للأفراد المصابين بالسكري.

الهدف :تهدف هذه المراجعة إلى تقييم دور الصيادلة في إدارة مرض السكري من خلال استخدام أجهزة CGMs ومضخات الأنسولين وأجهزة قياس السكر، مع تسليط الضوء على الابتكارات في التكنولوجيا وتأثيرها على رعاية المرضى.

الطرق :تم إجراء مراجعة شاملة للأدبيات لتحليل فعالية أنظمة مراقبة الجلوكوز المختلفة، بما في ذلك مراقبة الجلوكوز المستمر في الوقت الحقيقي (RT-CGM)وأجهزة المراقبة الذاتية لمستوى السكر في الدم .(SMBG) تم فحص التجارب السريرية والتطورات الحديثة في تقنيات إدارة مرض السكري.

النتائج :وجدت المراجعة أن أجهزة RT-CGM قد خفضت بشكل كبير مستويات HbA1c ومعدل حدوث نقص السكر في الدم مقارنةً بأساليب SMBG التقليدية. أدى الاستخدام طويل الأمد لأجهزة CGM إلى تحسين التحكم في مستوى السكر في الدم، وزيادة رضا المرضى، وتحسين نوعية الحياة، مع وجود أدلة تدعم فعاليتها عبر مجموعات مرضى متنوعة. يلعب الصيادلة دورًا أساسيًا في تثقيف المرضى حول هذه التقنيات وتحسين استراتيجيات إدارة مرض السكري.

الخاتمة :يمثل دمج تقنيات مراقبة الجلوكوز المتقدمة في إدارة مرض السكري تحسينًا كبيرًا في رعاية المرضى. يُعتبر الصيادلة عنصرًا حيويًا في تسهيل الوصول إلى هذه التقنيات وتثقيف المرضى، مما يعزز في النهاية التحكم في مستوى السكر في الدم والنتائج الصحية العامة في رعاية مرض السكري.

الكلمات المفتاحية :إدارة مرض السكري، مراقبة الجلوكوز المستمر، المراقبة الذاتية لمستوى السكر في الدم، الصيادلة، العلاج بالأنسولين.