Chinese clinical guidelines for continuous glucose monitoring (2018 edition)

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1 | BACKGROUND

Blood glucose monitoring is an important part of diabetes management. The results of glucose monitoring are crucial for glycemic status assessment, prescription of the optimal treatment regimen, follow-up of patients’ glucose status, and timely therapy adjustment. Self-monitoring of blood glucose (SMBG) is the basic form of blood glucose monitoring, whereas HbA1c is known as the gold standard for assessing long-term glycemic control.\(^1\) However, both HbA1c and SMBG have limitations. HbA1c reflects the average glucose levels over the previous 2 to 3 months and, thus, does not capture important short-term aspects of glycemic control, such as the time in the target range or the severity, frequency, and duration of hyper- and hypoglycemia. In addition, there is a “delayed effect” when using it to guide therapy adjustments. Moreover, SMBG cannot capture fluctuations in blood glucose throughout the day and night because of practical limitations on the number and timing of finger sticks. Instead, continuous glucose monitoring (CGM) technology demonstrates clinical details that cannot be disclosed by conventional fasting plasma glucose and HbA1c\(^2\) and has been widely applied in clinical practice. More importantly, innovative technologies related to CGM, such as wearables, implants, mobile applications, and cloud technology with professional medical intervention, are emerging, which is promising in changing diabetic patients’ lives dramatically.\(^3\)

To take maximum advantage of CGM technology, the indications for its use, requisite accuracy of the data that are generated, interpretation of the results, and how those results should guide clinical practice must be standardized. In December 2009, the Chinese Diabetes Society (CDS) drafted and published the first Chinese Clinical Guideline for Continuous Glucose Monitoring (2009 edition),\(^4\) providing a basis for the standardization of CGM in clinical application. Over the next 3 years, real-time CGM technology began to be applied in clinical practice, and domestic scholars published a few clinically significant, peer-reviewed research reports. Therefore, the guideline was updated in 2012 as the Chinese Clinical Guideline for Continuous Glucose Monitoring (2012 edition).\(^5\) The 2012 edition of the CGM guidelines added the latest evidence from retrospective and real-time CGM in the Chinese population and highlighted the need for an accurate clinical diagnosis and rigorous indications when using CGM technology. The guideline also emphasized that the monitoring results should be presented as a formal, standardized report, and the report should be used to guide clinical practice. The publication and revision of all the guidelines have effectively promoted the standardized application and clinical research of CGM technology in China.

In October 2010, the American Association of Clinical Endocrinologists (AACE) released an expert consensus statement on CGM technology.\(^6\) Subsequently, in October 2011, the Endocrine Society (ES), together with the European Society of Endocrinology (ESE), published Continuous Glucose Monitoring: an Endocrine Society Clinical Practice Guideline.\(^7\) As more CGM-related clinical evidence emerged, international guidelines and consensus statements have been continually updated, such as the Continuous Glucose Monitoring: a Consensus Conference of the American Association of Clinical Endocrinologists and American College of Endocrinology\(^8\) and American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement\(^9\) in February 2016. Subsequently, the Diabetes Technology-Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline\(^10\) was issued by the ES and ESE in November 2016. Finally, an international panel issued International
Consensus on Use of Continuous Glucose Monitoring in December 2017 following a multinational conference at the Advances in Technology and Therapy of Diabetes (ATTD) meeting in February 2017. Therefore, based on the updates of international guidelines and the increasing evidence of domestic studies, it is necessary to revise the CGM guidelines in China so that the latest clinical evidence can be effectively translated into clinical benefit for our patients. To this end, the CDS revised the Chinese Clinical Guideline for Continuous Glucose Monitoring (2012 Edition) based on the most recent evidence from international and domestic studies.

2 INTRODUCTION OF CGM

Blood flows from the arteries to the capillaries to the veins. Glucose in the capillaries diffuses through the interstitial fluid to the cells of a tissue. The glucose concentration in the interstitial fluid accurately reflects the capillary glucose concentration in patients with diabetes mellitus. Understanding the intraday and interday interstitial fluid glucose patterns is extremely important for studying the pathogenesis of short-term and long-term diabetes complications. Therefore, accurately and continuously measuring interstitial fluid glucose concentrations is a milestone representing the ability to closely monitor glycemic control in patients with diabetes. CGM monitors the glucose concentrations in subcutaneous interstitial fluid through a glucose sensor. Compared with SMBG, CGM systems can provide continuous and comprehensive all-day glucose profiles, thereby allowing an understanding of trends in blood glucose fluctuations and the detection of occult hyper- and hypoglycemia that cannot be detected by traditional blood glucose monitoring methods (Table 1). In 1999, the first CGM system was approved by the US Food and Drug Administration (FDA) and it was later approved by the China Food and Drug Administration (CFDA) in 2001 for clinical application and research. CGM systems mainly consist of a glucose sensor, a data transmitter, a data receiver/display, a sensor introducer device, and analysis software. Different CGM systems have different monitoring principles. Currently, most glucose sensors are designed based on an electrochemical principle. The sensor is implanted into the subcutaneous tissue, and an enzyme on the sensor, such as glucose oxidase, interacts with the interstitial fluid glucose to generate electrical signals. These signals are converted into glucose concentrations through the CGM data receiver/display after calculation by a specific algorithm resulting in interstitial glucose levels that can be displayed analytically and graphically.

CGM technology can be divided into retrospective and real-time CGM according to whether the user is able to see the data as it is being collected. Retrospective CGM is the equivalent of "Holter"-style glucose monitoring, and the results can be obtained after the completion of CGM monitoring. Patients are "blinded" to the data and cannot obtain the results until the end of the monitoring period. Thus, it can more objectively record the glucose patterns and reflect the actual effect of intervention treatment.

Compared with retrospective CGM, real-time CGM provides immediate blood glucose readings as well as glucose alarms and predictive alerts, facilitating immediate glucose adjustment. However, the blood glucose should be rechecked with a glucose meter prior to decision making on treatment adjustment. The existing evidence has suggested that patients can achieve better hypoglycemic management under the guidance of a real-time CGM system. Moreover, the improvement in HbA1c level was found to be positively correlated with the frequency of sensor use, which suggests that better control of blood glucose is related to the frequent use of CGM. Retrospective CGM and real-time CGM both exhibit their own features in clinical application (Table 2).

Personal real-time CGM was originally accepted only for adjunctive use, meaning the results must be verified by glucose meters before acting. In 2016, a kind of CGM device was accepted and recommended by FDA for nonadjunctive use. In China, the CFDA approved a flash glucose monitoring system in 2016, which consists of a sensor, scanner, and analysis software and combines the functions of the retrospective and real-time CGM systems with a glucose sensor.

| TABLE 1 | Comparison of the characteristics of self-monitoring of blood glucose (SMBG) and continuous glucose monitoring (CGM) in terms of performance, features, and measurement methods |
| SMBG | CGM |
| **Performance** | 1. Glucose detection using disposable test strips  
2. Some glucose analyzers have data storage function, and the glycemic data can be uploaded to a computer through software | 1. Continuous 24-h monitoring through implantation of a glucose sensor  
2. Data can be read through a CGM data display, and glycemic profiles can be downloaded through a computer |
| **Features** | 1. Reflects glucose value at a certain time point, like a "snapshot"  
2. Sporadic glycemic data, partially reflecting glycemic changes with diet, drugs, exercise, etc.  
3. Retrospective analysis based on the output of sporadic glucose values | 1. Reflects continuous glycemic changes, like a "movie"  
2. Continuous glycemic data, fully reflecting the glycemic changes with diet, drugs, exercise, etc.  
3. Reflects the direction or speed of glucose changes and helps users understand the overall trends and individualized features of glucose changes |
| **Measurement methods** | 1. Measures capillary blood glucose  
2. Uses test strips and a pricker, mostly at the fingertip or other sites | 1. Measures glucose concentration in subcutaneous interstitial fluid  
2. Sensors are mostly implanted in the subcutaneous tissue in the abdomen or arm |
designed to be worn for up to 14 days, during which glucose calibration is not required. By monitoring the interstitial fluid glucose levels, the flash glucose monitoring system can qualitatively and quantitatively reflect the blood glucose levels as well as the characteristics of glucose fluctuations. Currently, there are no data from domestic large-scale clinical trials of this kind of CGM, and its clinical value remains to be further studied.

3 | ACCURACY ASSESSMENT FOR CGM TECHNOLOGY

CGM technology detects the glucose concentration in the interstitial fluid. Both the point and trend accuracy of CGM measurements should be assessed in comparison with those of venous blood glucose values. To determine the point and trend accuracy of a sensor system, frequent venous blood sampling at intervals of 15 minutes for 7 hours should be performed. The samples must be measured on qualified analytical instruments such as a Yellow Springs Instrument (YSI) glucose analyser and paired with the sensor glucose value at the time of sampling. The main indicators for evaluation include consistency analysis of reference values, mean absolute relative difference (MARD), Clarke error grid analysis, and consensus error grid analysis.

4 | CLINICAL INDICATIONS FOR CGM TECHNOLOGY

1. Retrospective CGM is mainly applicable to the following patients or conditions:
   1. type 1 diabetes patients;
   2. type 2 diabetes patients who need intensive insulin therapy (eg. subcutaneous insulin injection three times or more per day or use of an insulin pump);

2. Real-time CGM
   1. Timeliness; real-time glucose monitoring and display
   2. High- and low-glucose alerts
   3. Data storage; retrospective analysis after data download
   4. "Major events" function, records glucose-related events
   5. Integration with subcutaneous continuous insulin infusion system
   6. Not applicable for diabetes patients with depression or anxiety
   7. Requirement of educational background

   1. Good patient adherence
   2. Ability to intervene in rapid blood glucose fluctuations and manage extreme high- and low-glucose levels in a timely manner based on real-time glucose data
   3. Monitor blood glucose as required during use; ability to manage high-/low-glucose alerts
   4. Record life events related to blood glucose fluctuations
   5. For patients using a real-time CGM and insulin pump integration system, if they have experienced large glucose fluctuation or high-/low-glucose alerts, the hypoglycemic regimen should be adjusted under the guidance of a clinician after rechecking patients’ finger-stick glucose level

3. type 2 diabetes patients who use hypoglycemic therapy under the guidance of SMBG but still have one of the following situations:
   - unexplainable severe hypoglycemia or recurrent hypoglycemia, asymptomatic hypoglycemia or nocturnal hypoglycemia;
   - unexplainable hyperglycemia, especially fasting hyperglycemia;
   - dramatic glycemic variability;
   - those patients who deliberately maintain their blood glucose at high levels due to fear of hypoglycemia;

4. gestational diabetes patients and women with diabetes during pregnancy;

5. diabetes education. CGM facilitates the understanding of glucose changes resulting from diet, exercise, drinking, stress, sleep, and hypoglycemic treatment, thus motivating patients to establish a healthy lifestyle, improving patients’ adherence to treatment, and leading to effective communication between clinicians and patients.

6. other clinical situations such as diabetes patients with gastroparesis, special types of diabetes, or endocrine disorders accompanied by dramatic glycemic variability.
2. Real-time CGM is mainly applicable to the following patients or conditions:
   1. children and adolescents with type 1 diabetes whose HbA1c is less than 7%. The use of real-time CGM can help maintain good glycemic control persistently without increasing the risk of hypoglycemia.
   2. children and adolescents with type 1 diabetes whose HbA1c is greater than or equal to 7% and who are capable of using CGM daily.
   3. adult patients with type 1 diabetes who are capable of using CGM daily.
   4. hospitalized patients with type 2 diabetes on insulin therapy in a non-intensive care unit. The use of real-time CGM can reduce glucose fluctuations, allowing rapid and stable achievement of glycemic targets without increasing the risk of hypoglycemia.
   5. perioperative glycemic control in type 2 diabetes patients. The use of real-time CGM can help patients to better control their blood glucose.

CGM technology is widely used in patients with type 1 diabetes. In type 2 diabetes, studies have also suggested that both retrospective and real-time CGM are powerful device to change patients’ lifestyle and to improve their glycemic variability. Women with diabetes during pregnancy and gestational diabetes may also benefit from CGM. On the other hand, CGM is probably not suitable for those who are not interested or willing to learn the basic mechanical skills of the equipment since optimal CGM use requires ongoing education and learning. For inpatient use, using CGM in the intensive care units is not recommended for various reasons. For example, the interstitial fluid glucose in patients who suffer from skin edema might be diluted, which causes inaccurate result. Also, the use of vasoconstrictor drugs decreases blood flow to the skin and results in a slower shift of glucose from capillaries to the interstitial fluid compartment. Some other clinical conditions include hypotension, hypoxemia, and the use of high-dose acetaminophen in intensive care units adversely affect the accuracy of CGM sensors as well.

5 | OPERATION SPECIFICATIONS FOR CGM

The quality of CGM monitoring results is influenced by many factors (eg, the effectiveness of the sensor, aseptic operation or not, instrument failure, etc) in actual practice. Therefore, CGM systems should be managed by specialized staff during operation and nursing. Medical personnel should apply CGM in accordance with standard operation specifications and eliminate various alarms in a timely manner to ensure the accuracy and validity of CGM results.

1. Capillary blood glucose monitoring during CGM

At present, most CGM systems require at least 1 to 4 capillary blood glucose measurements for calibration daily. The following points should be noted:

   1. Blood glucose concentration should be obtained using the same glucose meter and same batch of test strips.
   2. Capillary blood glucose concentrations should be obtained at different time points throughout the day, preferably during a period when blood glucose is relatively stable (such as before meals and before bedtime).
   3. When using a CGM system that requires the input of a capillary blood glucose concentration for calibration, the glucose value should be entered immediately after the result is displayed on the meter.
   4. If the user incorrectly enters the blood glucose value for calibration, one should re-enter the correct glucose value as soon as possible.

2. Recording diet and glucose-related events

   During CGM monitoring, diet, exercise, medication, and other events should be recorded in detail.

3. Daily device maintenance

   When wearing a CGM system, the patient should avoid exposure to any strong magnetic field and imaging examinations such as magnetic resonance imaging (MRI). In addition, conventional X-ray imaging and Computed Tomography (CT) scanning should be avoided. Some types of CGM devices are not water-resistant. The use of a mobile phone does not affect the CGM device.

4. Criteria for assessing the validation of real-time CGM data

   1. The real-time CGM system should have been worn for at least 12 hours, since it is sometimes inaccurate during the initial 12 hours.
   2. The real-time CGM system should have been adequately calibrated, with a good match between the most recent CGM sensor glucose value and the meter glucose value (difference < 15%).
   3. The real-time CGM readings have no false alarms.

6 | METHODS FOR INTERPRETING CGM GRAPHS

The following points should be noted for interpreting CGM graphs:

   1. CGM data can be used to guide treatment regimens when they are accurate. Clinicians should interpret CGM results by illustrating statistical reports or charts, which facilitates optimal communication between clinicians and patients.
   2. Downloading CGM data before each follow-up visit is time-saving. In addition, it is necessary to confirm that the time on the recorder is correct. If the time is not correct, the downloaded results will be wrong, especially for postprandial blood glucose data judged based on a “meal event” icon on the report.
3. Through the interpretation of CGM graphs, clinicians and patients should communicate and analyse the short-term glycemic profiles together. The interpretation should focus on the trend and regularity of glucose fluctuations rather than on a single, specific glucose value. The discussion between the patient and physician should identify factors that cause abnormal glucose fluctuations, such as the relationship between fasting hyperglycemia and snacks or between hypoglycemia and excessive exercise.

4. For beginners, the practical method to interpret CGM graphs and profiles is “three-step method.” For 3-day CGM data, the first step is to analyse the nocturnal blood glucose; the second step is to analyse the preprandial glucose levels; and the third step is to analyse the postprandial glucose levels. In each step, hypoglycemia should be noted first, followed by hyperglycemia, and then the underlying reasons causing abnormal glucose should be identified to guide treatment adjustment. For 14-day CGM data, the first step is to analyse the time interval to achieve the target; the second step is to analyse glucose fluctuations; and the third step is to analyse the risk of hypoglycemia.

5. On the real-time CGM display, the user can view 3, 12, and 24-hour trends in glucose changes. The 3-hour trend graph is used for the analysis of preprandial and postprandial glucose levels, the 12-hour trend graph is for the analysis of night-time glucose levels, and the 24-h trend graph is for the analysis of a full day of glucose levels.

7 | CGM PARAMETERS

7.1 | Introduction of CGM parameters

Glycemic variability refers to the unstable state of blood glucose levels fluctuating from peaks to nadirs and is an important aspect of glycemic control in addition to HbA1c. 80-85 Glycemic variability includes short-term glycemic variability such as postprandial hyperglycemia and long-term glycemic variability as assessed by HbA1c variability. Studies have shown that both short-term and long-term glycemic variability may be an important factor in the development of diabetes complications. 86-99 CGM continuously captures patterns of hypoglycemia, hyperglycemia, and the short-term glucose variability. Retrospective analysis of CGM data quantifies the time in target range and the time in hypoglycemia and hyperglycemia. The calculation methods and clinical significance of glycemic parameters are presented in Table 3 and the Supplementary Table. These parameters are mostly used for research, and their clinical significance and role in guiding diabetes treatment are still under investigation.

Among the CGM metrics, time in range (TIR) generally refers to the time spent in a patient’s target glucose range (usually 3.9-10 mmol/L). TIR measurements add valuable information to evaluate the glycemic control and were found to be associated with the prevalence of diabetic complications in type 2 diabetes. 100 In recent years, TIRs are recommended as key metrics of glycemic control for evaluating and comparing different glucose-lowering interventions 11 and were used in domestic clinical trial as well. 101

When assessing hypoglycemia using CGM, the accuracy of the device should be considered first. In the International Consensus on Use of Continuous Glucose Monitoring, 11 the classifications of hypoglycemia are presented as the following: (a) level 1: a hypoglycemia alert glucose value of less than 3.9-3.0 mmol/L with or without symptoms; (b) level 2: a glucose level of less than 3.0 mmol/L with or without symptoms; and (c) level 3: severe hypoglycemia requiring external assistance. A prolonged hypoglycemic event was defined as the CGM levels less than 3.0 mmol/L lasting more than 120 minutes. At

| Variables                      | Calculation Method                                      | Features/Clinical Significance                                                                 |
|-------------------------------|--------------------------------------------------------|------------------------------------------------------------------------------------------------|
| Mean glucose (MG)             | Mean of daily continuous 24-h blood glucose           | Reflects overall blood glucose level                                                          |
| Premeal 1-h MG                | MG within 1-60 min before three meals                   | Reflects the characteristics of preprandial or postprandial glucose, that is, the impact of eating on blood glucose |
| Postmeal 3-h MG               | MG within 1-180 min after three meals                   |                                                                                               |
| Percentage of time            | Percentage of time above, below and within the target range of blood glucose values | Reflects the time characteristics of blood glucose changes; simple and easy to understand, suitable for clinical application |
| Area under the curve          | Area between the target blood glucose curve and CGM measurement curve | Analyzes the time and amplitude of glucose excursions by a comprehensive statistical analysis method |
| Coefficient of variation (CV) | The ratio of SD to MG                                   | Reflects the standardized measure of variation or dispersion from the MG                       |
| Standard deviation (SD)       | The standard deviation of blood glucose                 | Reflects the amount of variation or dispersion of a series of glucose values                   |
| Mean amplitude of glycemic excursion (MAGE) | The average value of all valid glycemic excursions, which are calculated based on the direction of first valid excursion. Valid glycemic excursion is defined as more than 1 SDBG during 24-h CGM | Removes small amplitudes that do not exceed a certain threshold and therefore truly reflects the degree of blood glucose fluctuations rather than discrete features |
this moment, Chinese patients were required to verify the CGM result with a confirmatory fingerstick glucose meter prior to any intervention when experiencing hypoglycemia.

7.2 | Normal reference values for CGM parameters

There has been considerable interest in the study of normal reference values for CGM parameters since the development of CGM technology. Based on the results of a national multicenter study conducted in China, the normal reference ranges of CGM parameters for subjects between 20 and 69 years old in China are shown in Table 4. In addition, a preliminary analysis showed that the 24-hour mean glucose value had a good correlation with HbA1c and that these values could be converted into one another using the following equation: 24-hour mean glucose = 1.198 × HbA1c – 0.582. When HbA1c levels were 6.0%, 6.5%, and 7.0%, the corresponding CGM 24-hour mean glucose levels were 6.6, 7.2, and 7.8 mmol/L, respectively.

7.3 | Glucose management indicator

Modern CGM technology lasting for 10 days or more of CGM data is usually sufficient for an estimate of mean glucose, time in target range, and time in hyperglycemia, while 14 days or more of CGM data provide a better estimate for time in hypoglycemia and glucose variability. Using a standard formula, a value called "estimated HbA1c" was generated from the mean glucose, and the term was later replaced by "glucose management indicator" (GMI). Many patients and clinicians find the GMI to be a helpful educational tool in understanding the CGM-generated glucose profiles and will facilitate optimal diabetes management and the adjustment of anti-diabetic therapy.

### Table 4

| Parameter type | Parameters | Normal Reference Value |
|----------------|------------|------------------------|
| Glycemic level | Mean glucose (MG) | <6.6 mmol/L |
|                | Percentage of time when glucose ≥7.8 mmol/L | <17% (4 h) |
|                | Percentage of time when glucose ≤3.9 mmol/L | <12% (3 h) |
| Glycemic variability | Standard deviation (SD) of blood glucose | <1.4 mmol/L |
|                | Mean amplitude of glycemic excursion (MAGE) | <3.9 mmol/L |

### Table 5

| Items | Normal reference value (24 h) | Month/day | Month/day | Month/day | Month/day |
|-------|-------------------------------|-----------|-----------|-----------|-----------|
| Number of measurements | | | | | |
| Mean glucose (MG, mmol/L) | <6.6 | | | | |
| Standard deviation (SD, mmol/L) | <1.4 | | | | |
| Coefficient of variation (CV, %) | | | | | |
| Maximum glucose (mmol/L) | | | | | |
| Minimum glucose (mmol/L) | | | | | |
| Percentage of time in hyperglycemic ranges (≥13.9 mmol/L) | | | | | |
| Percentage of time in hyperglycemic ranges (≥10.0 mmol/L) | | | | | |
| Percentage of time in hyperglycemic ranges (≥7.8 mmol/L) | | | | | |
| Percentage of time in hypoglycemic ranges (≤3.9 mmol/L) | | | | | |
| Percentage of time in hypoglycemic ranges (≤2.8 mmol/L) | | | | | |
| Percentage of time in target range (3.9-10 mmol/L) | | | | | |

Record: measurements in total:; MG: mmol/L; SD: mmol/L; CV: %; maximum and minimum glucose were mmol/L and mmol/L; percentage of time in target range (3.9-10 mmol/L) was %; Percentage of time in hyperglycemic ranges greater than or equal to 7.8 mmol/L greater than or equal to 10 mmol/L and greater than or equal to 13.9 mmol/L were %, %, and %, respectively; Percentage of time in hypoglycemic ranges less than or equal to 3.9 mmol/L and less than or equal to 2.8 mmol/L were h min (%) and h min (%).
8 | CGM REPORT

The lack of unified content and format of the CGM report limits the clinical interpretation and application of CGM monitoring results. Therefore, standardization of CGM reports is extremely important.114 Currently, CGM monitoring reports generally include three parts: (a) general items: basic information about the subject, clinical diagnosis, inspection date, medical staff signature and date; (b) CGM data; and (c) clinical implications of the results. An example of a CGM report is shown in Table 5. At present, some scholars have developed CGM management software to reduce the clinical workload and to facilitate the optimal management of CGM results.115

Ambulatory Glucose Profile (AGP) is one of the standardized visualization tools of CGM data that are now available.11 Key metrics include target range, glucose exposure, glycemic variability, hypoglycemia, and hyperglycemia. The visual display of the AGP pools glucose data as if the data were recorded during a 24-hour period. The result is a single curve representing average glucose values, with interquartile and interdecile ranges shaded to demonstrate glycemic variability.116 As a standardized report form, AGP is useful in translating glucose data into more actionable information both for clinicians and patients.

In conclusion, to standardize the application of CGM technology in clinical practice, the following elements are required: a clear clinical purpose, strict indications, a standardized reporting system, and appropriate treatment adjustment(s) based on CGM results.

CONFLICT OF INTEREST

No competing financial interests exist.

AUTHOR CONTRIBUTIONS

All authors discussed and drafted the manuscript. WJ, LC and JZ wrote and revised the paper and all authors have read and approved the final manuscript.

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**SUPPORTING INFORMATION**

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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