

**Washington State Health Care Authority, HTA Program
FINAL Key Questions and Background
Glucose Monitoring**

Introduction

HTA has selected Glucose Monitoring to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input about available evidence. Key questions guide the development of the evidence report. They are posted for public review and comment. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

There are concerns about efficacy, safety, cost, and health impact of glucose monitoring on clinical outcomes among patients with diabetes (and/or subgroups). The role of glucose monitoring is unclear. Intermittent glucose monitoring employs a small quantity of capillary blood obtained by pinprick and placed on a reactive test strip that is read by an electronic meter. Continuous glucose monitoring employs a probe placed under the skin, connected to a monitor that reads glucose levels at frequent intervals, virtually continuously. Important questions remain about its effect on patient outcomes, education regimens, titration schemes, and determining adequacy of an overall treatment plan.

Key Questions

For patients 18 years of age or under with insulin requiring diabetes mellitus:

1. What is the evidence of efficacy and effectiveness of glucose monitoring? Including consideration of:
 - a. Achieving target A1c levels
 - b. Maintaining target A1c levels
 - c. In conjunction with provider specific report cards for target (e.g. under 7/over 9)
 - d. Reduce hospitalizations or acute episodes of diabetic ketoacidosis, hyperglycemia and hypoglycemia
 - e. Reduce microvascular complications (retinopathy, nephropathy, neuropathy)
 - f. Reduce Mortality
 - g. Effect on medication or nutritional management
 - h. Quality of life
2. What is the evidence on optimal or improved efficacy or effectiveness of glucose monitoring based on frequency or mode (continuous versus self monitoring) of testing?
3. What is the evidence of the safety of glucose monitoring? Including consideration of:
 - a. Adverse events type and frequency (mortality, major morbidity, other)
4. What is the evidence that glucose monitoring has differential efficacy or safety issues in sub populations? Including consideration of:
 - a. Gender
 - b. Age (differential within the 18 and under population)
 - c. Psychological or psychosocial co-morbidities

- d. Other patient characteristics or evidence based patient selection criteria
 - e. Provider type, setting or other provider characteristics
 - f. Health care system type, including worker's compensation, Medicaid, state employees
5. What is the evidence of cost implications and cost-effectiveness of glucose monitoring? Including consideration of:
- a. Costs (direct and indirect) in short term and over expected duration of use
 - b. Estimates of costs saved by preventing morbid events

Technology Background

Disease: Diabetes mellitus, or diabetes, is a serious chronic disease without a definitive cure and associated with significant acute and chronic morbidity and mortality. Diabetes is a metabolic disorder caused by defects in insulin secretion, insulin action or both. Type 1, insulin requiring diabetes, refers to cell-mediated autoimmune destruction of the pancreatic beta islet cells, which leads to absolute insulin deficiency.

Technology: Glucose monitoring is a process to assist in managing diabetes by measuring and controlling blood glucose (often measured by HBA1c levels). Monitoring glycemic status is used as a way to evaluate sufficiency of treatment and guide selection of appropriate interventions. Traditionally, glucose monitoring occurs through a combination of testing during office visits and self-monitoring by patients. Self monitoring in patients with diabetes who use insulin may contribute to improved glycemic control and reduced hypoglycemia by allowing for self-adjustments in insulin doses to be made based on meter readings and may also allow for appropriate changes in diet and physical activity to be made.

Although organizations make recommendations and guidelines exist on use of blood glucose monitoring, the effectiveness and optimal frequency of self-monitoring of blood glucose in patients is controversial. Several lines of evidence suggest an association between glucose monitoring and increased discomfort, inconvenience and worsening of depression scores with regular self monitoring, along with a lack of clinically relevant improvement in diabetes-related outcomes in patients who self-test. On the other hand, children and adolescents can be especially at risk for some diabetes related complications (e.g. hypoglycemia, ketoacidosis). Information about the best management strategies for diabetics under 18, including evidence of efficacy and safety and cost; and correlation of frequency (including strip frequency and continuous monitoring) to improved outcomes is needed.

Public Comment and Response

HTA received ten timely public comments, most of which cited evidence supporting the efficacy, effectiveness, safety and cost effectiveness of glucose monitoring. This information will be relayed to the evidence vendor for review. Comments that addressed the key questions and their relevance to guide the development of the evidence report were evaluated along with input from the technology assessment center. HTA reviewed the public comments, consulted clinical committee members and the technology assessment centers, and gathered follow up information from the nominating agencies. A summary of the input and modification to key questions is below.

Overall topic/other information: Several commenters questioned the appropriateness of the topic and population in general and assert that glucose monitoring is a long-standing practice with clear clinical evidence and guidelines.

This topic was prioritized based on agency prioritizing the encouragement of the best chronic care management possible, especially with high impact condition such as diabetes. Concerns initially centered primarily on two areas: the frequency and method of glucose monitoring. The goal is to gather and summarize the current evidence around the safety, efficacy and effectiveness and cost of glucose monitoring so that we can ensure payment policies are aligned to support appropriate utilization of diabetic management technologies.

The key questions reflect our statutory criteria and standard HTA methodology about population, intervention, comparators, and outcomes. Specific to this topic, the core of the glucose monitoring concerns are reflected in key question #2 around evidence about when, what type, and how much. The subpopulation of focus (insulin requiring patients 18 and under) was chosen because there is currently several well conducted and recent publications to help glucose monitoring policies for adults with non-insulin requiring diabetes, but not for youth with insulin requiring diabetes. Summary of additional comments by question follows.

Question 1: Three commenters felt the subcategories in question 1 should be modified based on the population to better illustrate potential complications.

The subcategories are updated.