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Health State Utilities Associated with Glucose Monitoring Devices

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ABSTRACT

Background: Glucose monitoring is important for patients with diabetes treated with insulin. Conventional glucose monitoring requires a blood sample, typically obtained by pricking the finger. A new sensor-based system called "flash glucose monitoring" monitors glucose levels with a sensor worn on the arm, without requiring blood samples. **Objectives:** To estimate the utility difference between these two glucose monitoring approaches for use in cost-utility models. **Methods:** In time trade-off interviews, general population participants in the United Kingdom (London and Edinburgh) valued health states that were drafted and refined on the basis of literature, clinician input, and a pilot study. The health states had identical descriptions of diabetes and insulin treatment, differing only in glucose monitoring approach. **Results:** A total of 209 participants completed the interviews (51.7% women; mean age = 42.1 years). Mean utilities were 0.851 ± 0.140 for conventional monitoring and 0.882 ± 0.121 for flash monitoring (significant difference between the mean utilities; $t = 8.3$; $P < 0.0001$). Of the 209 participants, 78 (37.3%) had a higher utility for flash monitoring, 2 (1.0%) had a higher utility for conventional monitoring, and 129 (61.7%) had the same utility for both health states. **Conclusions:** The flash glucose monitoring system was associated with a significantly greater utility than the conventional monitoring system. This difference may be useful in cost-utility models comparing the value of glucose monitoring devices for patients with diabetes. This study adds to the literature on treatment process utilities, suggesting that time trade-off methods may be used to quantify preferences among medical devices.

Keywords: glucose monitoring, medical devices, time trade-off, utility.

Introduction

Health state utilities are typically used to quantify health status and quality of life in economic modeling [1]. There is a growing body of evidence suggesting that utility may be influenced not only by health status and treatment outcomes but also by the process of receiving care [2]. These *process utilities* quantify the impact of treatment process attributes such as mode of administration and dose frequency [3,4]. Although the treatment process generally has less impact on utility than on efficacy, safety, or symptom severity [5], it does matter to patients, and it could also have a direct impact on treatment adherence, which can influence outcomes [6–9]. Furthermore, small utility differences associated with treatment process could affect the results of a cost-utility analysis and therefore have important implications for subsequent decision making.

For diabetes, an important aspect of the treatment process is self-monitoring of glucose levels [10–12]. Regular evaluation of glucose levels can guide patients and health care providers when making treatment and lifestyle decisions. For example, glucose levels may be considered when calculating a safe and effective insulin dose, assessing the impact of physical activity on glucose levels, and detecting hypoglycemia [13]. Conventional glucose monitoring requires a blood sample, typically obtained by pricking the finger with a lancing device to obtain the current glucose level [14]. In contrast, the recently developed FreeStyle Libre flash glucose monitoring system (Abbott Diabetes Care, Inc., Alameda, CA) does not require routine finger pricks [15]. Instead, patients obtain glucose readings from a sensor applied to the back of the upper arm. A subcutaneous filament (which is a part of the sensor and extends outward from the bottom skin-facing part of the sensor) monitors interstitial glucose levels and stores up to

Conflicts of interest: L.S. Matza and K.D. Stewart are employees of Evidera, a company that received funding from Abbott for time spent conducting this study. At the time of the study, E.W. Davies was also employed by Evidera. R. Hellmund is an employee of Abbott. K. Polonsky received funding for time spent on this research. All aspects of the study design, interpretation, and decision to submit for publication were determined by the authors.

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8 hours of data. Users scan the sensor with a touchscreen reader device to see their present glucose reading and an arrow indicating the glucose level trajectory. Each sensor with its filament is worn on the arm for up to 2 weeks. After 2 weeks, patients remove the sensor and apply a new one that includes a new filament.

Differences in the process of glucose monitoring could have an impact on a patient's quality of life. If this impact were quantified in terms of health state utility, it could be useful for economic modeling. Therefore, the purpose of this study was to estimate the utilities associated with conventional and flash glucose monitoring devices. Because generic preference-based instruments such as the EuroQol five-dimensional questionnaire (EQ-5D) and utility mapping algorithms for questionnaires such as the 36-item short form health survey are unlikely to be sensitive to differences in glucose monitoring, utilities were obtained using vignette-based methods, which are well-suited for isolating the utility impact of a specific treatment process.

Methods

Health State Development

Two health state descriptions (often called vignettes or scenarios) were drafted and refined on the basis of expert clinician input, device instructions for use, and literature review. Telephone interviews were conducted with two clinicians (a UK endocrinologist [MD] and a US clinical psychologist [PhD] who specialized in diabetes) to inform health state development. Questions focused on patients' typical experiences with diabetes and glucose monitoring. Later, the clinicians reviewed multiple drafts of the health states and provided comments regarding their clarity, comprehensiveness, and accuracy.

A literature review was conducted to support the health state content, focusing on diabetes symptoms [16–20], treatment, glucose monitoring, [11,13,21–25], and the two glucose monitoring approaches represented in the health states [15,26]. Further information about the glucose monitoring devices was obtained from the instructions for use that accompanied each device [14,27].

The two health states were identical in their description of a patient with diabetes requiring insulin injections and checking glucose levels about 3 times per day (see Appendix A in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2016.10.007). Published guidelines vary regarding the number of times glucose levels should be checked each day, with recommendations depending on the type of diabetes and treatment regimen [13,19,20,22,28,29]. For the current health states, a frequency of 3 times per day was selected based on consideration of the multiple guidelines and input from clinicians. Although the frequency of glucose monitoring varies among patients, 3 times per day is a common testing frequency among patients treated with multiple daily insulin injections [30].

The health states differed only by the method of glucose monitoring (conventional and flash). Therefore, any preference difference between the two health states can be attributed specifically to differences in glucose monitoring strategies. To avoid potential bias, none of the study materials named the glucose monitoring devices, and health states were not numbered or lettered. Instead, they were referred to by color (purple and blue) appearing on the border of the health state cards.

To ensure respondents understood the glucose monitoring process, each health state was presented with the corresponding glucose monitoring device, and the interviewer explained how each statement in the health states corresponded to the device parts. The device parts were presented on a device display page, which included materials necessary for 2 weeks of glucose monitoring (see Appendices B and C in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2016.10.007). After reviewing each health state and device display page, participants watched a brief instructional video demonstrating how each device is used.

Participants

Participants were required to be at least 18 years old, residing in the United Kingdom, able to understand study procedures, and able and willing to give informed consent. The inclusion criteria did not require that participants meet any specific clinical criteria because interviews were intended to yield utilities that may be used in cost-utility analyses for submission to health technology assessment agencies, which often prefer that utilities represent general population values [31–33]. Participants were recruited via newspaper and online advertisements.

Pilot Study

The health states were tested in a pilot study with 19 general population participants in London (10 women; mean age = 37.9 years; age range = 20–59 years). Health states were valued in time trade-off (TTO) interviews. The TTO methodology varies across studies, and the pilot study explored several variations of TTO procedures [34]. Two time horizons (10-year and a time horizon based on each respondent's self-reported life expectancy) and two trading increments (5% and 10%) were tested.

Pilot study participants consistently reported that the health states, device displays, and demonstration videos were clear and easy to understand. Some participants suggested minor revisions in formatting and word choice, and the study materials were edited accordingly. All TTO time horizons and trading intervals yielded utility scores in a similar range. The 10-year time horizon was selected for use in the subsequent main study because it was relatively easy for participants to understand and complete. In addition, this time horizon is consistent with many published studies including the commonly cited Measurement and Valuation of Health Study that derived tariffs for the EQ-5D [35,36].

Utility Interview Procedures and Scoring

After finalizing the health states and methods on the basis of the pilot study, the health states were rated in a TTO valuation study in Edinburgh and London in March 2015. All participants provided written informed consent, and the study was approved by an independent institutional review board (Ethical & Independent Review Services, Study No. 14158).

The order in which the two health states were presented was randomized (i.e., half reviewed the conventional monitoring first, and the other half reviewed the flash monitoring first). For each health state, participants reviewed the health state text and materials on the device display page, with guidance from the interviewers. During this process, interviewers introduced the health state and explained the device materials (presented on the device display page) using a standardized script. After the participants indicated that they understood the health state and device, the video was shown as a review of the device procedures.

After the participants had reviewed both health states along with the device materials and videos, they were asked which of the two they would prefer. The TTO task then began, with participants rating the health state that they were randomized to review first, followed by the second health state. Following commonly used TTO procedures [1], participants were offered a choice between spending 10 years in the health state being rated or shorter lengths of time in full health. The duration of time in full health was varied in 6-month increments in the following

order: 10 years, 0, 9.5, 0.5, 9, 1, 8.5, 1.5, 8, 2, and so on. For each health state, the utility score was calculated based on the choice in which the respondent is indifferent between y months or years in the health state being evaluated (i.e., 10 years) and x months or years in full health (followed by "dead"). The resulting utility estimate (u) is calculated as $u = x/y$.

After completing the TTO valuation, participants were asked to indicate their preference between the health states on a 7-point scale ranging from "strongly prefer flash glucose monitoring" (1) to "strongly prefer conventional blood glucose monitoring" (7).

Statistical Analysis Procedures

Statistical analyses were completed using SAS version 9.2 (SAS Institute, Cary, NC). Continuous variables were summarized in terms of means and SDs, and categorical variables were summarized as frequencies and percentages.

Results

Sample Characteristics

A total of 210 participants attended the interviews. One of the 210 participants was unable to complete the utility interview procedures. Therefore, the analysis sample included 209 respondents (104 from London and 105 from Edinburgh; their demographic characteristics are presented in Table 1). Nineteen participants (9.1%) reported having diabetes.

Health State Utilities and Preferences

Before the TTO valuation, most of the participants (n = 186; 89.0%) said they preferred the flash glucose monitoring health state over the conventional one. Some (n = 20; 9.6%) preferred the conventional health state, and a few (n = 3; 1.4%) had no preference.

The flash health state had a significantly higher mean utility value (0.882) than the conventional health state (0.851) (mean difference = 0.030; $P < 0.0001$) (Table 2). Of the 209 participants, 78 (37.3%) had a higher utility score for the flash health state, whereas only 2 (1.0%) had a higher score for the conventional health state. Most (n = 129; 61.7%) had the same utility score for both health states. Utilities ranged from 0.175 to 0.975 for the flash health state and from 0.125 to 0.975 for the conventional health state. A broad range of utility scores is common in TTO valuation studies, but it should be noted that most of the scores were in the upper range, and SDs were relatively small (0.121 for the flash health state and 0.140 for the conventional health state). Only 9 of the 209 respondents had a utility score of less than 0.600 for either health state.

Responses to the 7-point preference scale indicate that most participants preferred the flash glucose monitoring device (Table 1).

Table 1 – Participants' characteristics (N = 209).

Characteristic	Statistics
Age (y), mean ± SD	42.1 ± 16.2
Sex, n (%)	
Male	101 (48.3)
Female	108 (51.7)
Ethnicity, n (%)	
White	163 (78.7)
Mixed	10 (4.8)
Asian	19 (9.2)
Black	13 (6.3)
Other*	2 (1.0)
Marital status, n (%)	
Single	110 (52.6)
Married/living with partner	71 (34.0)
Other†	28 (13.4)
Employment status, n (%)	
Full-time work	79 (37.8)
Part-time work	46 (22.0)
Unemployed	14 (6.7)
Other‡	70 (33.5)
Education level, n (%)	
University degree	92 (44.0)
No university degree	117 (56.0)
Preference for glucose monitoring health states on a 7-point scale§, n (%)	
(1) Strongly prefer sensor-based	136 (65.1)
(2) Moderately prefer sensor-based	36 (17.2)
(3) Slightly prefer sensor-based	13 (6.2)
(4) Neutral with no preference between health states	4 (1.9)
(5) Slightly prefer conventional	7 (3.3)
(6) Moderately prefer conventional	8 (3.8)
(7) Strongly prefer conventional	5 (2.4)

TTO, time trade-off.
* Other ethnicities include Hispanic (n = 1) and South American (n = 1).
† Other marital status includes divorced (n = 18), separated (n = 4), widowed (n =5), and "other unspecified" (n = 1).
‡ Other employment status includes retired (n = 29), student (n = 28), homemaker/housewife (n = 6), disabled (n = 5), and carer (n = 2).
§ This 7-point scale was completed after finishing the TTO utility task.

Discussion

Most of the respondents (89%) preferred the flash glucose monitoring over the conventional one, and this preference was reflected in health state utilities. The mean difference of 0.030 between the two health state utilities is similar to previously reported differences among health states differing in treatment process attributes such as dosing strategy, treatment convenience, and screening/testing procedures [2]. Furthermore, current data indicating a preference for the flash system are consistent with positive impressions of patients who used the device in a clinical trial [15]. Overall, present findings indicate that there is a measurable difference in preference between the two glucose monitoring strategies.

Although the vignette-based method appears feasible for estimating utility associated with glucose monitoring, it should be noted that influential health technology assessment guidelines have stated a preference for utilities derived via generic measures. For example, the National Institute for Health and Care Excellence Guide to the Methods of Technology Appraisal indicates a preference for utilities derived via the EQ-5D to maximize "consistency across appraisals" [32]. This guide, however, says that utilities derived via other methods may be acceptable for economic modeling when the EQ-5D is not "appropriate." Assessment of process utilities is likely to be a situation when the EQ-5D would not be appropriate. A generic instrument designed to assess overall health status or quality of life may not be sensitive to utility differences stemming from specific treatment process attributes.

Table 2 – Health state utility scores* (N = 209).

Two diabetes health states differing only in glucose monitoring strategy, mean ± SD		Difference between health states, mean ± SD	t Test comparing the two health state means	
Sensor-based (flash) glucose monitoring	Conventional glucose monitoring		t Statistic (paired)	P value
0.882 ± 0.121	0.851 ± 0.140	0.030 ± 0.053	8.3	<0.0001

TTO, time trade-off.
* These scores were obtained via TTO interviews, and they are on a scale anchored with 0 representing dead and 1 representing full health.

A systematic review of process utilities suggests that consensus may be developing regarding methods for these studies [2]. Of the 15 studies identified in this review, only 1 used a generic preference-based measure (the six-dimensional health state short form), whereas the other 14 used vignette-based methods. An advantage of the vignette-based approach is that it can isolate the utility impact of a specific treatment process by holding all aspects of a health state constant except for the treatment process attribute.

Still, it is important to consider the limitations of the vignette method. Vignettes for the present study were drafted carefully on the basis of clinician input and published literature, whereas additional procedures ensured that participants understood the devices (i.e., device display pages, thorough standardized explanations, and videos). However, a vignette cannot include every aspect of a patient's health and treatment, and therefore vignette-based studies are inherently limited by the accuracy and level of detail in the health state descriptions. Furthermore, comparability between vignette-based utilities and utilities derived from actual patients is not entirely clear.

One aspect of vignette construction that has been previously discussed is whether the disease should be named. In the present study, both health states named the disease (diabetes) and treatment (insulin). Some studies have suggested that naming the disease can influence the utility scores, although other studies have reported that the disease label did not affect results [37–39]. Some researchers recommend omitting the label to avoid risk of bias, whereas others prefer to include the label to ensure that the health state is clear and unambiguous. The present health states named the disease and treatment for two reasons. First, this information was necessary to provide context for glucose monitoring. Without a basic introduction to diabetes, respondents would not have understood why glucose monitoring was necessary. Second, the result of greatest interest in this study was the difference between the two health states. Even if the label would shift the scores upward or downward, this shift would have the same effect on both health state utilities, with little or no impact on the difference between utilities. Therefore, when designing this study, it was thought that the label would add clarity and context to the health states without biasing the key result.

Like many TTO studies, the interviews were conducted with a general population sample, rather than patients with the relevant medical condition. Some health technology assessment guidelines emphasize that utilities should represent the general population or societal perspective [31,32,40,41]. One advantage of using a general population sample is that results may be comparable with general population valuations of other health states in other studies, which is important if utilities from multiple sources are used in the same cost-utility model. Still, the limitations of this sampling approach must be acknowledged. First, the sampling procedures and sample size were not sufficient for the present sample to be considered nationally representative. Second, the extent to which the present general population utilities would be consistent with utilities derived from patients with diabetes is not known. Based on personal experience, some patients could prefer the convenience of the flash system, whereas other patients may not be interested in the flash system because they are comfortable with the conventional approach.

Overall, the present study adds to the growing body of research examining treatment process utility. Although previous studies have identified utilities associated with a range of treatment process attributes such as mode of administration and dose frequency [2], the present study is the first to quantify the utility impact associated with ongoing use of medical devices. Results provide potentially useful values that may be used to compute quality-adjusted life-years for cost-utility models focusing on treatment and management of diabetes.

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Supplemental Materials

Supplemental material accompanying this article can be found in the online version as a hyperlink at http://dx.doi.org/10.1016/j.jval.2016.10.007 or, if a hard copy of article, at www.valueinhealthjournal.com/issues (select volume, issue, and article).

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