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RESEARCH ARTICLE

Treatment

Assessment of the added value of a tubeless pump: A time trade-off (TTO) study for utility elicitation of insulin delivery systems in type 1 diabetes mellitus (T1D)

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Abstract

Introduction: Automated insulin delivery (AID) systems continuously deliver insulin subcutaneously, reducing the burden of managing type 1 diabetes mellitus (T1D). However, there are limited data comparing different insulin delivery modalities, particularly regarding their impact on health-related quality of life (HRQoL). This study aimed to quantify the disutility associated with conventional insulin delivery modalities and utility gains associated with wearable, on-body, AID systems.

Methods: Health state vignettes representing different insulin delivery modalities were developed based on interviews with people with T1D alongside published literature and validated by experts. Utility values were elicited via the time trade-off (TTO) method from the general population in the United Kingdom (UK) ($n = 110$).

Results: The lowest mean utility values were observed for tubed non-AID systems (0.727), while the highest mean utility value was observed for tubeless systems with AID (0.909). The use of tubeless systems rather than tubed systems was associated with a significant increase in utility between + 0.082 and + 0.086 ($p < 0.005$), and the use of AID was associated with a significant increase in utility of between +0.096 and +0.100 versus the corresponding alternatives ($p < 0.0005$). The use of a tubeless and AID system was associated with a significantly increased utility versus all other health states ($p < 0.0001$), indicating significantly higher HRQoL.

Conclusion: This study elicited utility values for health states representing insulin delivery modalities in T1D. Results suggested that tubeless and AID systems are associated with higher health state utility in T1D, indicating that people with T1D using such systems may experience improved HRQoL.

KEYWORDS

automated insulin delivery, insulin delivery systems, time trade-off, type 1 diabetes mellitus (T1D), utility elicitation

1 | INTRODUCTION

Type 1 diabetes mellitus (T1D) is an autoimmune condition that destroys insulin-producing pancreatic β-cells, affecting 8.75 million people worldwide.[1] People with T1D require exogenous insulin via multiple daily injections (MDI) or insulin pumps to control blood glucose levels.[1,2] Maintaining glycaemic control is essential to prevent acute complications, including hypoglycaemia and diabetic ketoacidosis, and chronic complications, such as cardiovascular disease, nephropathy, and retinopathy.[2,3] Uncontrolled glucose levels can lead to discomfort, low energy, and impaired daily functioning.[4] Self management is central to T1D care, requiring frequent insulin dosing adjustments based on food intake and activity.[4] Further, the condition negatively impacts people's mental health, mainly driven by fear of hypo/hyperglycaemia and feelings of isolation or self-consciousness.[4]

While MDI requires multiple self-injections daily, insulin pumps can improve glycaemic control and quality of life, but still necessitate active user involvement and can be associated with anxiety.[5–8] Traditional pumps have limitations, including tubing, body attachment, and the need to disconnect for certain activities, which reduce compliance and glycaemic outcomes.[9–13] Tubeless pumps, designed to be worn, deliver insulin without tubing and are often waterproof, offer greater convenience and freedom of movement, though they still require user input and may disrupt sleep.[12,14,15]

Automated insulin delivery (AID) systems have been developed to continuously deliver insulin via an insulin pump using an algorithm to automatically adjust the dose in response to continuous glucose monitoring (CGM) readings. This reduces the user input required for glucose regulation, helping to alleviate the burden of managing T1D, improving glycaemic control, and reducing the risk of complications and fear of hypogylcaemia.[13]

Many AID systems use tubed pumps with their associated limitations. The first waterproof, wearable tubeless AID system combines the benefits of AID systems and the comfort and convenience of tubeless pumps.[16–19] However, data on the utility impact of tubeless systems and AID systems are lacking, being omitted from economic evaluations and technology appraisals.[20–26] This study aimed to generate utility estimates that quantify the disutility associated with conventional insulin delivery modalities for use in economic analyses and to provide insights into utility gains associated with increased convenience and improved confidence in glucose management of AID and tubeless systems.

What's new?

- Tubeless Automated Insulin Delivery (AID) showed higher health-related quality of life (health utility) in a Time Trade Off Study compared to other insulin therapy modalities including Tubed AID.
- Health-related quality of life is a key benefit of Tubeless AID and now can be quantified as a major contributor to additional Quality Adjusted Life Years (QALY).
- The finding of greater health utility with Tubeless AID aligns with the existing evidence base showing improved person reported outcomes with the Tubeless AID system Omnipod® 5.

2 | MATERIALS AND METHODS

A vignette-based study design was adopted to describe relevant T1D health states (Figure 1). In accordance with best practice guidelines, the study consisted of a qualitative phase to develop and validate the health states, followed by the quantitative phase to elicit utility values.[27]

2.1 | Choice of valuation method

Treatment-related attributes and process characteristics can impact HRQoL.[28,29] The disutility associated with these attributes is commonly included in cost-utility analyses, which are generally accepted by health technology assessment bodies. Several established methods exist for deriving health state utility values, including the EQ-5D and time trade-off (TTO); however, no clear evidence indicates which one is most appropriate for T1D. The EQ-5D is recommended by the National Institute for Health and Care Excellence (NICE) for assessing HRQoL, but, as a generic measure, is less able to evaluate process utilities (i.e., changes in utility driven by differences in treatment convenience); therefore, vignette and TTO-based methods are commonly used.[27,30] NICE accepts utilities obtained directly from the general public when generic preference-based measures are unsuitable.

Considering this, a direct utility elicitation study was conducted with a representative sample of the UK general population to quantify the disutility of existing therapies and the possible utility gains associated with the convenience of AID and tubeless systems. A brief overview of the TTO methodology is provided in the Data S1.

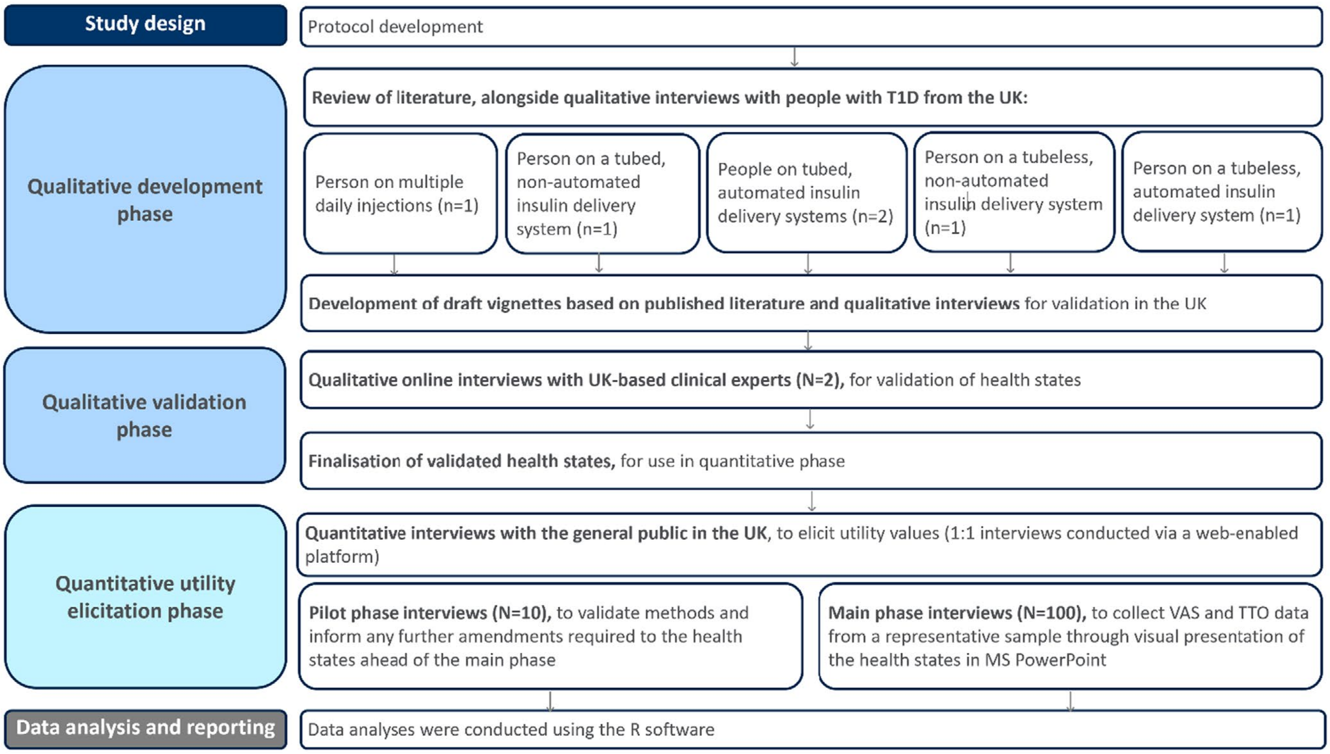

FIGURE 1 Overview of qualitative and quantitative study phases. T1D, type 1 diabetes mellitus; TTO, time trade-off; UK, United Kingdom; VAS, visual analogue scale.

2.2 | Qualitative health state development and validation

The first phase of the study aimed to define and validate the health states.

2.2.1 | Health state vignette development

To accurately describe the health status of people with T1D using different insulin delivery modalities, vignettes were developed through qualitative 1:1 interviews with six adults (aged ≥20 years), supported by literature and product labels, in line with best practice. Participants provided informed consent, and the UK NHS Research Ethics Committee granted ethics exemption for this study.

Participants needed experience with a relevant insulin delivery modality (Figure 1). Interviews explored the impact of T1D on HRQoL (e.g., daily activities, anxiety/depression, fear of hypoglycaemia, impact on work and relationships, and sleep quality). Participants provided information on the effects of different insulin delivery modalities on HRQoL; experience with various current or past modalities and related opinions were also discussed (e.g., effectiveness, safety, convenience, and ease of use).

The language used by participants to describe their experience with T1D was assessed to inform the wording of the health states. Health state descriptions were structured based on EQ-5D domains, as recommended by NICE, and included domains of importance to people with T1D who have experience using these systems.[30] The health state vignettes used clear and concise wording to avoid ambiguity and prevent misinterpretation. For the TTO, health states were labelled using letters rather than language specific to T1D or insulin delivery systems to avoid biasing participants.

2.2.2 | Qualitative validation phase

Following initial development, drafted vignettes were assessed in validation interviews with two UK-based T1D clinical experts. Their insights were used to finalize the vignettes ahead of the TTO valuation exercise.

2.2.3 | Final health states used in TTO exercise

Five health states were used in the TTO exercise, each describing the use of a different insulin delivery modality. Each written vignette was structured to present a description of the modality, the route of insulin delivery, whether insulin delivery was automated or not, and the impact of system usage on daily functioning. The full health state vignettes used in the TTO can be found in the supporting information (Figures S1–S8).

2.3 | Quantitative utility elicitation process

The five health states were valued using the TTO method, applying an adapted measurement and valuation of health (MVH) protocol with the UK general public recruited according to census-based quotas.[31]

Ten pilot interviews assessed clarity and comprehension of health states; as no changes were required, resulting data were aggregated with 100 main phase respondents, producing a final sample of 110. All interviews were 1:1, web-enabled, and conducted by a trained TTO moderator, using visual aids to improve comprehension of the valuation tasks, consistent with the MVH and related protocols.[31]

Participants first completed a 0–100 visual analogue scale (VAS) 'warm-up' task to familiarize themselves with the vignettes and provide baseline comparators for TTO values. Utility values were then elicited for each health state using the TTO process with a 10-year time horizon, stopping when respondents reached a point of indecision. Vignettes were presented in a semi-randomized order: health state A (MDI) was always first, followed by states B–E in random order (consistent between VAS and TTO steps) to minimize bias.

2.3.1 | Utility data analysis

Utility values were derived from TTO results (range: 0.0–1.0) and aggregated as mean, standard deviation (SD), median, and interquartile range for each health state. Mean utility values were compared to assess the impact of insulin delivery modalities on utility, including comparisons between AID and non-AID systems, as well as tubeless and tubed systems.

Normality was tested with the Shapiro–Wilk test, and due to observed skewness, differences between health states were analysed using pairwise Wilcoxon tests, with significance set at $p<0.05$. Sensitivity analysis excluded 'non-traders' who assigned a utility of 1.0 to all health states.

Pairwise comparisons across all five health states enabled direct assessment of utility differences for each modality. To account for the increased risk of Type I error from multiple comparisons, Bonferroni correction was applied to the Wilcoxon p-values by multiplying each unadjusted p-value by the number of comparisons ($n=10$).

3 | RESULTS

3.1 | Utility valuation interview participant demographics

Demographic characteristics of members of the UK general population interviewed ($n=110$) alongside the corresponding recruitment targets derived from UK census data are presented in Table 1. To ensure that the utility elicitation interview sample was also representative of the UK general population in terms of the prevalence of diabetes, the numbers of participants with diagnosed diabetes (either T1D or T2D) were capped, with two participants with T1D and six with T2D. The number of people with diagnosed diabetes in the interview sample (either T1D or T2D) was capped to ensure it was representative in terms of diabetes prevalence.

3.2 | TTO utility results

Mean (±SD) utility values ranged from 0.727 (±0.225) for health state B (tubed, non-AID) to 0.909 (±0.127) for health state E (tubeless, AID) (Figure 2).

A significant improvement in utility values was seen between AID and non-AID systems for tubed (+0.096, $p=0.00046$) and tubeless devices (+0.100, $p<0.00001$). Furthermore, a significant improvement was seen when comparing tubeless to tubed devices for non-AID systems (+0.082, $p=0.00491$) and for AID systems (+0.086, $p<0.00001$) (Figure 3).

The utilities for health states A (MDI) and B (tubed, non-AID) were not significantly different ($p=0.14856$), but were substantially lower than the remaining three health states. The utility of health state E (tubeless, AID) was significantly higher than all other health states ($p<0.00001$), indicating significantly higher HRQoL. Additional comparisons between health state utility values can be found in Tables 2 and 3.

Following adjustment for multiple comparisons using the Bonferroni correction method, most comparisons retained their statistical significance ($p<0.05$, see Table 4). Only the comparison between health states A and C lost significance after adjustment. The Bonferroni correction method is widely accepted for pairwise tests and provides Type I error control; however, it is also conservative and may increase the risk of Type II error (false-negatives). Thus, the lack of significance for the comparison between health states A and C after adjustment may reflect the stringency of this approach rather than the absence of a meaningful difference.

TABLE 1 Demographic characteristics of utility valuation interview participants ($n = 110$).

Characteristic		Target (proportion/*n* based on UK adult population)	Actual (proportion or *n* of study sample)
Gender	Male	49.0%	49.1%
	Female	51.0%	50.9%
Age	18–29	19.7%	20.0%
	30–39	18.2%	18.2%
	40–49	17.1%	17.3%
	50–59	18.6%	18.2%
	60–69	14.7%	14.6%
	70–79	11.8%	11.8%
Marital status	Single	47.6%	47.3%
	Married or civil partnered	41.0%	40.9%
	Divorced	6.3%	6.4%
	Widowed	5.0%	5.5%
Education	Degree-level education	29.9%	30.9%
	A-level secondary education or other higher/further non-degree-level education	30.5%	50.0%
	GCSE secondary education	20.3%	
	Other education or no education or do not know	19.3%	19.1%
Employment	Full-time	41.8%	41.8%
	Part-time	15.4%	17.3%
	Not working	21.3%	19.1%
	Assumed retired (≥65 years)	21.5%	21.8%
Region	Scotland	8	8
	Northern Ireland	3	3
	Wales	5	5
	Northwest England	11	12
	Northeast England	4	5
	Yorkshire and The Humber	8	9
	West Midlands	9	10
	East Midlands	7	9
	Southwest England	9	10
	London	13	14
	Southeast England	14	15
	East of England	9	10
Diabetes diagnosis	T1D	2 (maximum)	2
	T2D	7 (maximum)	6

Note: Right hand column is the actual proportion or *n* of the study sample.
Abbreviations: T1D, type 1 diabetes; T2D, type 2 diabetes; UK, United Kingdom.

3.3 | Sensitivity analysis

Six respondents were classified as 'non-traders' and were removed for the purpose of this sensitivity analysis (results in Data S1). The mean utility value of each health state decreased slightly compared with the main analysis (by up to 0.0132); however, the ranking of health states remained unchanged. Health state B (tubed, non-AID) had the lowest mean utility value (0.711), while health state E (tubeless, AID) had the highest (0.904). Differences between tubed versus tubeless devices and AID versus non-AID devices were unchanged, with improved utility values for

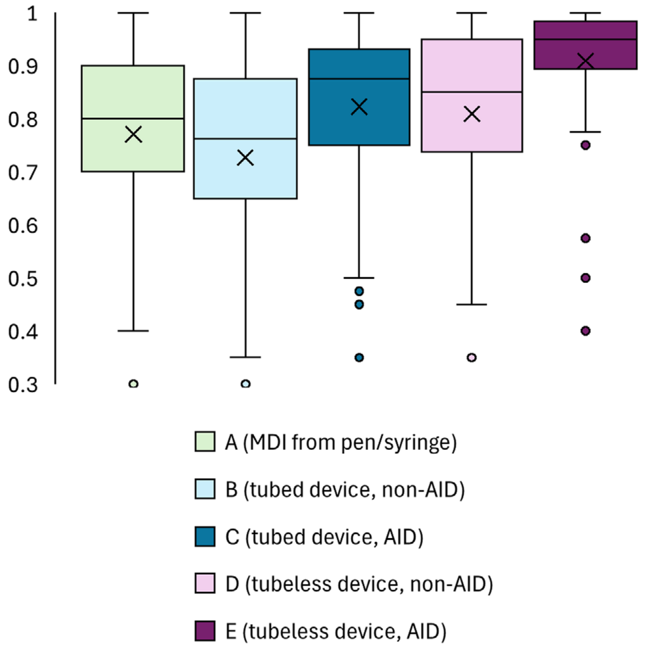

FIGURE 2 TTO utility value per health state ($n = 110$). × indicates mean; horizontal line indicates median; box rectangle indicates interquartile range (Q1–Q3); whisker lines indicate minimum and maximum (excluding outliers); outliers are defined as scores at least 1.5 the interquartile range above or below Q1 or Q3, respectively. AID, automated insulin delivery; Q1, first quartile; Q3, third quartile; TTO, time trade-off.

tubeless and AID systems. The results of the sensitivity analysis are included within the supporting information (Table S1).

3.4 | VAS scores

Mean (±SD) VAS scores per health state followed the same ordering as mean TTO values (Figure 4 and Table 5). Again, the score of health state B (tubed non-AID) was comparable to that of MDI, but the incorporation of either a tubeless design or AID was associated with increased perceived HRQoL. VAS scores were systematically lower than TTO values, as expected according to the characteristics of these measurement methods.[32]

In addition, the mean VAS score for health state E (tubeless, AID) (71.99) was higher than that of 'own health (today)' (70.72), with mean scores for all other health states being relatively lower (50.05–61.07).

4 | DISCUSSION

This TTO study estimated utility values according to preferences of the UK general population for five health states representing insulin delivery modalities in T1D. Health states varied by insulin delivery method (pen, tubed system, tubeless system) and by level of integration with the CGM (non-AID vs. AID) to examine the impact of each characteristic on utility.

The lowest mean utility values were observed for tubed systems without AID (0.727) and for MDI (0.771), while the highest was for tubeless AID systems (0.909). Tubeless systems had significantly higher utility values than tubed systems (+0.082 and + 0.086, respectively [$p < 0.005$]), and AID systems rather than non-AID systems (+0.096 and + 0.100, respectively [$p < 0.0005$]). These improvements in HRQoL appear cumulative across modalities, with the difference between the lowest and highest health states (+0.182) consistent with direct comparisons. The cumulative difference between health state B and health state E would be expected to be +0.178 to +0.186, which is consistent with the +0.182 difference seen when comparing these health states directly. Sensitivity analyses and VAS scores supported these findings, which align with participant-reported outcomes from clinical trials showing improved T1D distress, satisfaction, and EQ-5D scores with tubeless and AID systems.[14,33]

Health state B (tubed, non-AID) received a lower mean utility value than health state A (MDI), indicating lower HRQoL. Some participants noted that health state A offered a greater sense of control and eliminates concerns about hygiene, commenting that '[*health state A] higher score as do not have the device attached*' and '[*health state B] still have to do the calculations, carry around and wear the device ... active lifestyle and hygiene would cause problems*'. In contrast, health state E (tubeless systems with AID) was associated with the highest utility, with participants highlighting its convenience, freedom, and minimal physical impact, stating the health state is '*close to normal life'* and that managing T1D with these devices is *'almost as good as normal life with a little inconvenience*'. VAS scores followed the same trend as TTO values but were systematically lower, reflecting methodological differences.[32] VAS, a simple rating scale, lacks strong anchors to 'death' or 'full health' and tends to produce more conservative scores. TTO, in contrast, requires explicit trade-offs between life quality and duration, often yielding higher utility values due to the cognitive and emotional engagement involved.

Previous studies have investigated the utility impact of different attributes of treatment with insulin or other injectable treatments in people with T1D. Evans et al. conducted a TTO in the UK and found that moving from fixed to time-flexible basal insulin dosing increased utility by +0.016 to +0.013 in the general population and +0.004 to +0.015 among people with diabetes.[20] Similarly, Matza et al. found utility gains (+0.007) for concentrated mealtime bolus insulin compared with

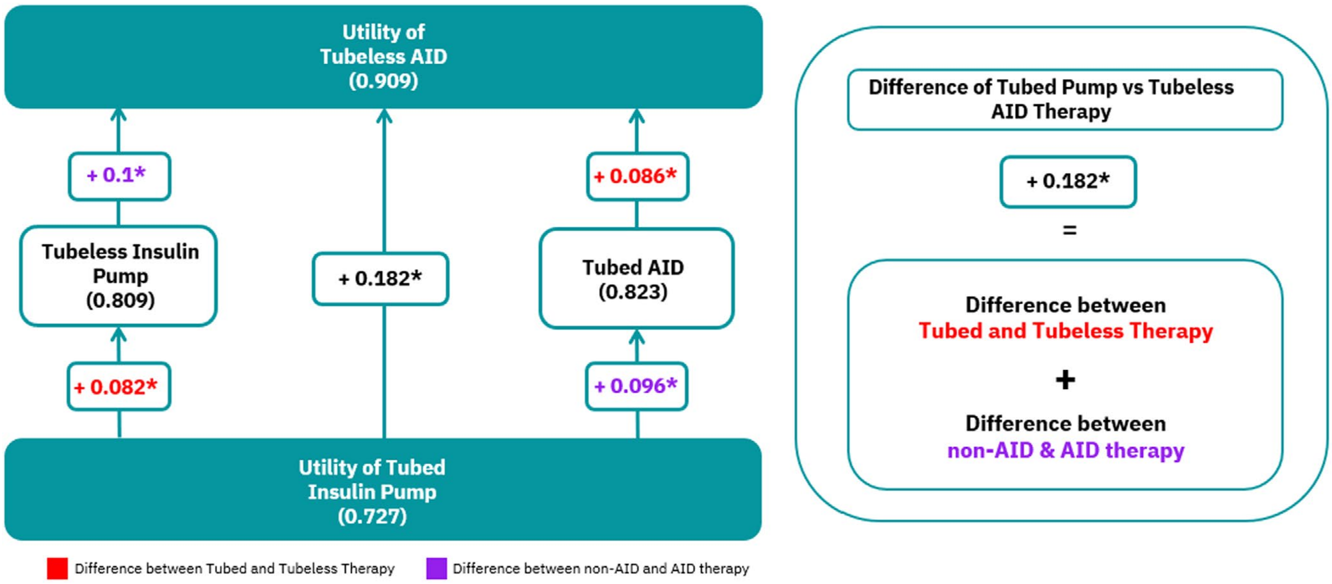

FIGURE 3 Diagram showing the consistency between the difference in utility between tubed and tubeless insulin pump therapy and between non-AID and AID therapy. AID, automated insulin delivery. Differences between tubed insulin pump therapy and tubeless AID (+0.182) equals the difference between tubed and tubeless pump therapy plus the difference between non-AID and AID therapy. $*p<0.05$.

TABLE 2 TTO utility values per health state ($n=110$).

	T1D managed using...				
	A	B	C	D	E
	MDI	Tubed, non-AID	Tubed, AID	Tubeless, non-AID	Tubeless, AID
Mean	0.771	0.727	0.823	0.809	0.909
SD	0.197	0.225	0.172	0.177	0.127
Median	0.800	0.763	0.875	0.850	0.950
Q1	0.700	0.650	0.750	0.750	0.900
Q3	0.900	0.875	0.925	0.950	0.983

Abbreviations: AID, automated insulin delivery; MDI, multiple daily injections; Q1, first quartile; Q3, third quartile; SD, standard deviation; T1D, type 1 diabetes mellitus; TTO, time trade-off.

standard insulin.[21] Another study by Matza et al. showed higher utility of +0.031 for flash glucose monitoring (0.882) compared with conventional monitoring (0.851) in the general population.[22] The magnitude of utility gains observed for tubeless versus tubed systems (+0.082 and +0.086) and AID versus non-AID (+0.096 and +0.100) is more than twice as large as those reported in previous utility studies for T1D, highlighting the substantial positive impact of these technologies on people managing the complex burden of T1D.

4.1 | Strengths and limitations

To the best of the authors' knowledge, this is the first study to elicit utility values for various insulin delivery modalities for the management of T1D. Results from this study provide a useful resource to demonstrate the disutility associated with conventional insulin delivery systems and utility gains associated with the increased convenience and improved confidence in the management of glucose with both tubeless and AID systems.

The results are dependent on the accuracy of vignette descriptions and the ability to convey health states to respondents unfamiliar with these modalities. As this study was industry-funded, potential bias cannot be excluded; however, vignette development followed NICE best practice, incorporating qualitative interviews with people living with T1D and validation by clinical experts to ensure all key HRQoL dimensions were systematically addressed.[27,30] Vignettes were presented in line with these recommendations. TTO interviews used established

TABLE 3 Significance of differences in mean health state utility values, by pairwise Wilcoxon testing.

		A	B	C	D	E
		MDI	**tubed, non-AID**	**tubed, AID**	**tubeless, non-AID**	**tubeless, AID**
A	MDI	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*
B	tubed, non-AID	$p = 0.14856$	*n/a*	*n/a*	*n/a*	*n/a*
C	tubed, AID	$\mathbf{p = 0.02981}$	$\mathbf{p = 0.00046}$	*n/a*	*n/a*	*n/a*
D	tubeless, non-AID	$p = 0.14735$	$\mathbf{p = 0.00491}$	$p = 0.43660$	*n/a*	*n/a*
E	tubeless, AID	$\mathbf{p < 0.00001}$	$\mathbf{p < 0.00001}$	$\mathbf{p < 0.00001}$	$\mathbf{p < 0.00001}$	*n/a*

Note: bold p values indicate a significant difference in mean utility value between two health states ($p < 0.05$).
Abbreviations: AID, automated insulin delivery; MDI, multiple daily injections; n/a, not applicable.

TABLE 4 Significance of differences in mean health state utility values, by pairwise Wilcoxon testing, following adjustment for multiple comparisons.

		A	B	C	D	E
		MDI	**tubed, non-AID**	**tubed, AID**	**tubeless, non-AID**	**tubeless, AID**
A	MDI	*n/a*	*n/a*	*n/a*	*n/a*	*n/a*
B	tubed, non-AID	$p = 1.0000$	*n/a*	*n/a*	*n/a*	*n/a*
C	tubed, AID	$p = 0.2981$	$\mathbf{p = 0.0046}$	*n/a*	*n/a*	*n/a*
D	tubeless, non-AID	$p = 1.0000$	$\mathbf{p = 0.0491}$	$p = 1.0000$	*n/a*	*n/a*
E	tubeless, AID	$\mathbf{p < 0.0001}$	$\mathbf{p < 0.0001}$	$\mathbf{p < 0.0001}$	$\mathbf{p < 0.0001}$	*n/a*

Note: bold p values indicate a significant difference in mean utility value between two health states ($p < 0.05$).
Abbreviations: AID, automated insulin delivery; MDI, multiple daily injections; n/a, not applicable.

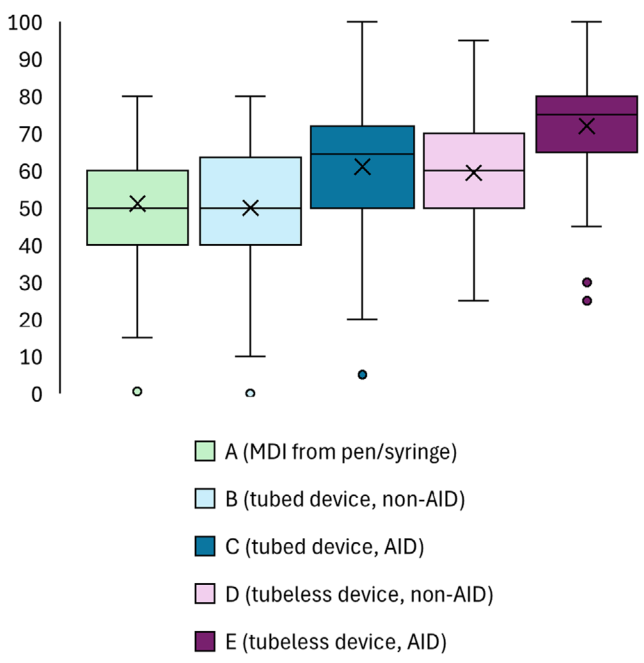

FIGURE 4 VAS scores per health state ($n = 110$). × indicates mean; horizontal line indicates median; box rectangle indicates interquartile range (Q1–Q3); whisker lines indicate minimum and maximum (excluding outliers); outliers are defined as scores at least 1.5 the interquartile range above or below Q1 or Q3, respectively. Q1, first quartile; Q3, third quartile; VAS, visual analogue scale.

methodologies, and participants' understanding was assessed by independent researchers. The general public's mean 'own health' VAS score was consistent with prior utility studies.[21,22]

A limitation is the generic nature of the vignette descriptions, which do not capture the heterogeneity of individual device use or the full lived experience of T1D. This may affect the applicability to specific insulin delivery systems and real-world challenges faced by participants. However, this was an intentional design choice to generate broadly applicable utility values rather than compare commercial devices.

The cross-sectional design and reliance on hypothetical health state valuations may introduce uncertainty regarding real-world HRQoL. While this may limit generalizability to individual devices, vignettes were carefully crafted using qualitative interviews, literature, and product labels. Importantly, qualitative comments from the general public in this study, such as the inconvenience of tubes and benefits of AID, closely resembled issues reported by actual users.[34–36] For example, Tzivian et al. reported that pump users experienced improved HRQoL and greater dosing precision than those using MDI; '*I have much more control with the pump, because I can adjust insulin doses*

TABLE 5 VAS scores per health state and for own health today (n = 110).

		T1D managed using...				
		A	B	C	D	E
	Own health today*	MDI	Tubed, non-AID	Tubed, AID	Tubeless, non-AID	Tubeless, AID
Mean	*70.72*	51.20	50.05	61.07	59.48	71.99
SD	*17.95*	15.39	16.17	16.34	14.13	13.84
Median	*75.00*	50.00	50.00	64.50	60.00	75.00
Q1	*60.00*	40.00	40.00	50.00	50.00	65.00
Q3	*85.00*	60.00	63.00	71.50	70.00	80.00

*Italicized values relate to VAS scores.

Abbreviations: AID, automated insulin delivery; MDI, multiple daily injections; Q1, first quartile; Q3, third quartile; SD, standard deviation; T1D, type 1 diabetes mellitus; VAS, visual analogue scale.

if necessary, and adjust the time for basal insulin'.[34] Beltrand et al. reported higher satisfaction among users of tubeless pumps or hybrid closed-loop systems compared with MDI, while Tanenbaum et al. reported the experience and burden of wearing insulin pumps as a barrier to use.[35,36] In previous tubed insulin pump users, Stocco et al. reported mainly positive wearability experiences when using tubeless pumps, freedom in clothing choices, and flexibility of insertion site: '*not getting tangled in the long line…because it's just there…I feel like less of a robot…[it] makes you feel like you're not attached to something*'.[37]

Utility values were derived from a sample representative of the UK general population per census data and other sources, aligning with NICE guidance. However, this approach has limitations, including the restricted understanding of the general public regarding the lived experience of specific health states. This may lead to overestimating the convenience of some devices or underestimating the ability of people with T1D to adapt over time.[38] Conversely, eliciting utility values from people with T1D may lead to unrealistically high values from a general population perspective due to adaptation.[38] As these utilities are intended to inform health economic evaluations to determine society's willingness to pay, a general public perspective may be more relevant than the perspective of individuals living with the condition who may have different levels of expectation and tolerance.

5 | CONCLUSION

This study has elicited utility values for five health states representing insulin delivery modalities in T1D, with a focus on assessing the potential utility gain from the use of tubeless and AID systems. Among wearable insulin delivery systems, the use of tubeless systems rather than tubed systems, and AID systems rather than non-AID systems, was associated with a significant increase in utility, indicating significantly higher HRQoL. The methods and findings of the current study will allow for these utility values to be used in economic modelling of innovative insulin delivery systems in T1D and may contribute to improving access to these systems among people with T1D.

AUTHOR CONTRIBUTIONS

All authors attest they meet the ICMJE criteria for authorship. Jackie Elliott, Colin Hopley, Danielle Riley, Olivia Dodd, and Luis Val Maranes, Marko Thomas, and Melanie Littlewood contributed to study conceptualization, study design, data analysis, data interpretation, and preparing and editing the manuscript. All authors have approved the final manuscript and agree to be accountable for all aspects of the work.

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CONFLICT OF INTEREST STATEMENT

At the time of this research, Colin Hopley, Marko Tomas, and Melanie Littlewood were employed by Insulet Corporation when this research work was completed. Research execution was delivered by Danielle Riley, Olivia Dodd, and Luis Val Maranes, who were employed by Adelphi Values PROVE™ at the time this research was commissioned by Insulet Corporation. Jackie Elliott was employed by Sheffield Teaching Hospitals at the time this work was completed and received no fee for this study. Jackie Elliott has received speaker/advisory board fees from Abbott, Boehringer Ingelheim, Dexcom, Glooko, Insulet Corporation, Eli Lilly, Novo Nordisk, Roche, Sanofi, and Ypsomed.

DATA AVAILABILITY STATEMENT

The full datasets generated and analysed to inform the conclusions drawn within the manuscript during the current study are available from the corresponding author on reasonable request.

REFERENCES

1. IDF. Type 1 diabetes. Accessed July 26, 2024. https://www.idf.org/aboutdiabetes/type-1-diabetes.html
2. Lucier JWR. Type 1 Diabetes. https://www.ncbi.nlm.nih.gov/books/NBK507713/
3. Dhaliwal RW. Management of Type 1 diabetes in older adults. *Diabetes Spectr*. 2014;27(1):9-20. doi:10.2337/diaspect.27.1.9
4. Vanstone M, Rewegan A, Brundisini F, Dejean D, Giacomini M. Patient perspectives on quality of life with uncontrolled type 1 diabetes mellitus: a systematic review and qualitative meta-synthesis. *Ont Health Technol Assess Ser*. 2015;15(17):1-29.
5. Oldham V, Mumford B, Lee D, Jones J, Das G. Impact of insulin pump therapy on key parameters of diabetes management and diabetes related emotional distress in the first 12 months. *Diabetes Res Clin Pract*. 2020;166:108281. doi:10.1016/j.diabres.2020.108281
6. Pease A, Lo C, Earnest A, Kiriakova V, Liew D, Zoungas S. The efficacy of Technology in Type 1 diabetes: a systematic review, network meta-analysis, and narrative synthesis. *Diabetes Technol Ther*. 2020;22(5):411-421. doi:10.1089/dia.2019.0417
7. Payk M, Robinson T, Davis D, Atchan M. An integrative review of the psychosocial facilitators and challenges of continuous subcutaneous insulin infusion therapy in type 1 diabetes. *J Adv Nurs*. 2018;74(3):528-538. doi:10.1111/jan.13463
8. Grant P, Dworakowska D, DeZoysa N, Barnes D. The impact of anxiety and depression on patients within a large type 1 diabetes insulin pump population. An observational study. *Diabetes Metab*. 2013;39(5):439-444. doi:10.1016/j.diabet.2013.06.003
9. Berget C, Messer LH, Forlenza GP. A clinical overview of insulin pump therapy for the Management of Diabetes: past, present, and future of intensive therapy. *Diabetes Spectr*. 2019;32(3):194-204. doi:10.2337/ds18-0091
10. Pettus JH, Zhou FL, Shepherd L, et al. Incidences of severe hypoglycemia and diabetic ketoacidosis and prevalence of microvascular complications stratified by age and glycemic control in U.S. adult patients with type 1 diabetes: a real-world study. *Diabetes Care*. 2019;42(12):2220-2227. doi:10.2337/dc19-0830
11. Boughton CK, Hovorka R. New closed-loop insulin systems. *Diabetologia*. 2021;64(5):1007-1015. doi:10.1007/s00125-021-05391-w
12. Kulzer B, Freckmann G, Heinemann L, Schnell O, Hinzmann R, Ziegler R. Patch pumps: what are the advantages for people with diabetes? *Diabetes Res Clin Pract*. 2022;187:109858. doi:10.1016/j.diabres.2022.109858
13. Sherr JL, Heinemann L, Fleming GA, et al. Automated insulin delivery: benefits, challenges, and recommendations. A consensus report of the joint diabetes technology working Group of the European Association for the study of diabetes and the American Diabetes Association. *Diabetologia*. 2023;66(1):3-22. doi:10.1007/s00125-022-05744-z
14. Kong YW, Yuan CY, Kiburg K, et al. Treatment satisfaction with Omnipod DASH in adults with type 1 diabetes: a nonblinded 1:1 randomized controlled trial. *J Clin Endocrinol Metab*. 2024;109(8):1984-1995. doi:10.1210/clinem/dgae088
15. Zisser HC. The OmniPod insulin management system: the latest innovation in insulin pump therapy. *Diabetes Ther*. 2010;1(1):10-24. doi:10.1007/s13300-010-0004-6
16. Insulet. About Omnipod 5® system. https://www.omnipod.com/en-gb/what-is-omnipod/omnipod-5
17. Renard E, Joubert M, Villard O, et al. Safety and efficacy of sustained automated insulin delivery compared with sensor and pump therapy in adults with type 1 diabetes at high risk for hypoglycemia: a randomized controlled trial. *Diabetes Care*. 2023;46(12):2180-2187. doi:10.2337/dc23-0685
18. Polonsky WH, Hood KK, Levy CJ, et al. How introduction of automated insulin delivery systems may influence psychosocial outcomes in adults with type 1 diabetes: findings from the first investigation with the Omnipod® 5 system. *Diabetes Res Clin Pract*. 2022;190:109998. doi:10.1016/j.diabres.2022.109998
19. Hood KK, Polonsky WH, MacLeish SA, et al. Psychosocial outcomes with the Omnipod® 5 automated insulin delivery system in children and adolescents with type 1 diabetes and their caregivers. *Pediatr Diabetes*. 2023;2023(1):8867625. doi:10.1155/2023/8867625
20. Evans M, Jensen HH, Bøgelund M, Gundgaard J, Chubb B, Khunti K. Flexible insulin dosing improves health-related quality-of-life (HRQoL): a time trade-off survey. *J Med Econ*. 2013;16(11):1357-1365.
21. Matza LS, Osumili B, Stewart KD, et al. Patient preferences and health state utilities associated with mealtime insulin concentrations among patients with diabetes in Italy. *Diabetes Ther*. 2020;11:319-330.
22. Matza LS, Stewart KD, Davies EW, Hellmund R, Polonsky WH, Kerr D. Health state utilities associated with glucose monitoring devices. *Value Health*. 2017;20(3):507-511. doi:10.1016/j.jval.2016.10.007
23. Godoi A, Reis Marques I, Padrão EMH, et al. Glucose control and psychosocial outcomes with use of automated insulin delivery for 12 to 96 weeks in type 1 diabetes: a meta-analysis of randomised controlled trials. *Diabetol Metab Syndr*. 2023;15(1):190. doi:10.1186/s13098-023-01144-4
24. Jendle J, Reznik Y. Use of insulin pumps and closed-loop systems among people living with diabetes: a narrative review of clinical and cost-effectiveness to enable access to technology and meet the needs of payers. *Diabetes Obes Metab*. 2023;25(Suppl 2):21-32. doi:10.1111/dom.15087
25. National Institute for Clinical Excellence. Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes. https://www.nice.org.uk/guidance/ta943
26. Scottish Health Technologies Group (SHTG). Closed-Loop Systems and the Artificial Pancreas for the Management of T1DM. https://shtg.scot/our-advice/closed-loop-systems-and-the-artificial-pancreas-for-type-i-diabetes-mellitus-t1dm/
27. Matza LS, Stewart KD, Lloyd AJ, Rowen D, Brazier JE. Vignette-based utilities: usefulness, limitations, and methodological recommendations. *Value Health*. 2021;24(6):812-821. doi:10.1016/j.jval.2020.12.017
28. McEwan P, Baker-Knight J, Ásbjörnsdóttir B, Yi Y, Fox A, Wyn R. Disutility of injectable therapies in obesity and type 2 diabetes mellitus: general population preferences in the UK, Canada, and China. *Eur J Health Econ*. 2023;24(2):187-196. doi:10.1007/s10198-022-01470-w

29. Valentine W, Norrbacka K, Boye KS. Evaluating the impact of therapy on quality of life in type 2 diabetes: a literature review of utilities associated with treatment-related attributes. *Patient Relat Outcome Meas*. 2022;13:97-111. doi:10.2147/prom.S322390
30. NICE. NICE health technology evaluations: the manual. Accessed August 6, 2024. https://www.nice.org.uk/process/pmg36/resources/nice-health-technology-evaluations-the-manual-pdf-72286779244741
31. Oppe M, Rand-Hendriksen K, Shah K, Ramos-Goñi JM, Luo N. EuroQol protocols for time trade-off valuation of health outcomes. *PharmacoEconomics*. 2016;34:993-1004.
32. Morimoto T, Fukui T. Utilities measured by rating scale, time trade-off, and standard gamble: review and reference for health care professionals. *J Epidemiol*. 2002;12(2):160-178. doi:10.2188/jea.12.160
33. Riveline JP, Renard E, Weinstock R, et al. Quality-of-Life Benefits for Adults Living with Type 1 Diabetes Using the Omnipod 5 System Compared with Insulin Pump Therapy: Results from a Randomized Controlled Trial. *EASD*. 2024.
34. Tzivian L, Sokolovska J, Grike AE, et al. Quantitative and qualitative analysis of the quality of life of type 1 diabetes patients using insulin pumps and of those receiving multiple daily insulin injections. *Health Qual Life Outcomes*. 2022;20(1):120. doi:10.1186/s12955-022-02029-2
35. Beltrand J, Benhamou PY, Choleau C, Braithwaite B, Bonin A, Riveline JP. Experience of people with diabetes treated with insulin delivery Systems in France: a comparative analysis of multiple daily injections, tubeless pumps, tubed pumps, and hybrid closed loops. *Diabetes Ther*. 2025;16(2):289-306. doi:10.1007/s13300-024-01682-8
36. Tanenbaum ML, Hanes SJ, Miller KM, Naranjo D, Bensen R, Hood KK. Diabetes device use in adults with type 1 diabetes: barriers to uptake and potential intervention targets. *Diabetes Care*. 2017;40(2):181-187. doi:10.2337/dc16-1536
37. Stocco A, Trawley S, Kong YW, et al. "You can hide it if you want to, you can let it be seen if you want to": a qualitative study of the lived experiences of Australian adults with type 1 diabetes using the Omnipod DASH® system. *Diabetes Res Clin Pract*. 2024;208:111123. doi:10.1016/j.diabres.2024.111123
38. Whitehead SJ, Ali S. Health outcomes in economic evaluation: the QALY and utilities. *Br Med Bull*. 2010;96:5-21. doi:10.1093/bmb/ldq033

SUPPORTING INFORMATION

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

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