# Insulin Pump and CGM Usage in the United States and Germany: Results of a Real-World Survey With 985 Subjects

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#### **Abstract**

**Background:** This survey collected and evaluated user responses about routine tasks and preferences regarding insulin pumps and infusion sets (IIS) with comparison of intercountry differences between the United States (US) and Germany (GER), chosen for their large insulin pump populations.

**Methods:** A total of 985 subjects (534 US, 451 GER; 60% female) with type 1 diabetes on pump therapy anonymously answered 20 pump-related questions. US subjects also answered 11 questions about continuous glucose monitoring (CGM) usage.

**Results:** Length of use of insulin cartridges is shorter in US than in GER, mean (SD) 4.3 (5.0) versus 5.3 (3.2) days (P < .001), while the IIS is used longer: 3.3 (1.0) versus 2.7 (1.1) days (P < .001). Lower self-reported HbA1c levels were associated with longer use of insulin cartridges (7.3% for >3 days vs 7.7% for <3 days; P < .01), and with use of an auto-insertion device (vs manual IIS insertion) in the US (7.2% vs 6.9%), but not in GER (7.7% vs 7.9%). Only 47% of pump wearers stated that they were "very satisfied" with their pump (49% US vs 45% GER, ns). However, 98% would recommend the pump to others (95% vs 93%, ns). Analysis of CGM questions showed that 297 (60%) of 496 US responders currently wore one. Of these, 84% said they would recommend CGM to others. CGM wearers who stated they were "very satisfied" with their CGM had lower HbA1c than those who said they were "partly satisfied" (6.9% vs 7.2%).

**Conclusions:** This survey shows interesting differences in real-world use of insulin pumps in 2 large markets, and suggests areas where insulin pumps and CGMs might be improved.

#### **Keywords**

insulin pumps, continuous glucose monitors, insulin infusion sets, metabolic control

Insulin therapy by means of continuous subcutaneous insulin infusion (CSII) with a pump is a well-established therapeutic option in subjects with type 1 diabetes. However, despite 35 years of experience, our knowledge about insulin pump usage in daily practice remains limited, especially in comparison between countries. Discussions with pump users and diabetes specialists suggest that pump user practices, preferences, and attitudes differ among countries. This anonymous survey collected data about pump and insulin infusion set (IIS) preferences, and routine daily tasks, such as filling insulin cartridges and changing IIS, and levels of satisfaction in the United States (US) and Germany (GER) to evaluate a number of pump-usage aspects. The US and GER are the largest markets for insulin pumps (to our knowledge), but these 2 markets differ significantly in insurance reimbursement and health care systems; for example, in GER, type 1 patients on CSII are mainly treated in specialized diabetes practices. Therefore, the clinical treatment of patients might

differ between the 2 countries. In the US where continuous glucose monitor (CGM) usage is more common with greater access to reimbursement, subjects were asked additional questions regarding their experience and preferences with CGMs.

# **Methods**

In the US, the survey responses were received from subjects attending 15 diabetes clinics (an average of 10 subjects per

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Table I. Demographics.

| Parameter                       | Total                | US                    | GER                  | P value  |
|---------------------------------|----------------------|-----------------------|----------------------|----------|
| Number of participants          | 985                  | 534 (54%)             | 451 (46%)            | _        |
| Male                            | 392 (40%)            | 209 (40%)             | 183 (41%)            | ns       |
| Female                          | 587 (60%)            | 319 (60%)             | 268 (59%)            | ns       |
| Number of subjects in age range | , ,                  | , ,                   | , ,                  |          |
| 10-29 years                     | 169 (17%)            | 82 (15%)              | 87 (20%)             | _        |
| 30-49 years                     | 368 (38%)            | 148 (28%)             | 220 (50%)            | _        |
| 50-69 years                     | 373 (38%)            | 251 (47%)             | 122 (28%)            | _        |
| >70 years                       | 62 (6%)              | 51 (10%)              | II (3%)              | _        |
| Duration of diabetes (years)    | 25.7 (14.9) (1-72)   | 27.9 (16.3) (1-69)    | 22.8 (11.9) (3-72)   | P < .001 |
| Years with pump                 | 9.9 (7.2) (0.1-38.0) | 10.4 (7.4) (0.1-41.0) | 9.2 (6.8) (0.1-38.0) | P < .01  |
| Number of pumps previously used | 2.5 (1.9) (1-20)     | 2.8 (2.2) (1-20)      | 2.1 (1.2) (1-12)     | P < .001 |
| Last HbA1c (%)                  | 7.4 (1.2) (4.6-13.0) | 7.1 (1.1) (4.6-13.0)  | 7.8 (1.2) (5.2-12.4) | P < .001 |

Values are frequency (percentage) or mean (SD) (range). Not every respondent answered every question, so total responses are mostly less than the total of 985 participants.

practice), from pump users at the yearly Taking Control of Your Diabetes conference (106), and from an online survey (281). In GER, staff at diabetes specialty practices handed out surveys. Nineteen practices sent questionnaires back with an average of 26 subjects per practice.

Demographic information was collected (gender, age group, year of diagnosis, years of pump wear, number of different insulin pumps worn, and last HbA1c), followed by 20 pump-usage questions. The pump questions addressed items like pump model, choice of IIS, and frequency of unexplained high blood sugars, occlusion alarms, need to change IIS early due to a high blood sugar, and so on. In GER, 1 additional question about CGM familiarity was asked, while 11 additional questions regarding CGM usage were asked in the US. The questionnaires did not contain information that allowed identification of subjects. Selection of subjects was inclusive without brand preference. The survey was conducted in both countries between the end of November 2013 and middle of February 2014. Copies of either version of the survey can be provided on demand.

To compile results, responses were entered manually from the questionnaires into an Excel spread sheet. Care was taken to identify and correct data entry errors by running appropriate checks. Seven duplicate responses, 4 responses that lacked credibility, and 5 that were <50% complete were identified and deleted by 1 of the authors who is a diabetes clinical specialist and wears an insulin pump (JW). Not every question was answered by each participant, so the number of total responses for a given question was often below the total number of approved participants (985). For some questions multiple responses were possible.

Data analysis and statistical analysis were performed in Excel. Data are expressed as mean (SD) (range) or as frequencies. Statistical comparisons were made by means of unpaired tests for normally distributed data (*t* test) or a chisquare test for 2 or more categorical variables.

#### Results

#### Demographics

In total, survey results from 985 individuals were collected. Table 1 shows demographic data of the responders in total and separately for the US and GER. More females than males (60 vs 40%) filled out the questionnaire (which took usually <10 minutes) with a similar gender distribution in each country. Equal numbers of pump users were in the age ranges of 30-49 years and 50-69 years. Pump users in the US that answered this survey were older and had a longer duration of diabetes than those in GER. The average duration of diabetes of pump users was nearly 26 years with a duration distribution of <1 to 72 years. In total, participants had used an insulin pump for nearly 10 years with just over 1 year longer usage in the US than GER. On average, participants had previously used 2 to 3 pumps, with those in the US having worn more pumps than those in GER (2.8 vs 2.1 pumps worn). Metabolic control of all subjects was acceptable with an average HbA1c of 7.4%; however, self-reported metabolic control among US subjects was lower than that of those in GER (7.1 vs 7.8%).

# Insulin Pump Preferences

The different pump preferences used by the subjects are listed in Table 2. Pumps used were most often Medtronic Inc (47.4%), followed by Roche Diagnostics (21.3%), Animas® (12.9%), and Insulet Corporation (7.4%), with certain differences in this respect between the US and GER.

#### Insulin Cartridges

Most participants regarded removing and replacing the insulin cartridge as "easy" or "very easy" (Total 86%; US 83%, GER 89%) in both countries, with only 3% (4%; 1%) regarding this as "difficult" or "very difficult," with slightly more difficulty

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**Table 2.** Frequency of Pump Model and Percentage by Manufacturer.

| Pump brand and model              | Total | US     | GER |
|-----------------------------------|-------|--------|-----|
| Accu-Chek Combo                   | 155   | 7      | 148 |
| Accu-Chek Spirit                  | 52    | ,<br>7 | 45  |
| Animas IR 1250                    | 1     | Í      | 0   |
| Animas 1020                       | 7     | 7      | 0   |
| Animas OneTouch Ping              | 104   | 104    | 0   |
| Animas Vibe                       | 14    | I      | 13  |
| Asante Snap                       | ii    | 6      | 5   |
| Dana Diabecare R                  | 0     | 0      | 0   |
| Minimed Paradigm X15              | 15    | 11     | 4   |
| Minimed Paradigm 522,<br>722, X22 | 349   | 239    | 110 |
| Minimed Paradigm Veo<br>530G      | 98    | 32     | 66  |
| Insulet OmniPod                   | 72    | 49     | 23  |
| Tandem t:slim                     | 57    | 57     | 0   |
| Other                             | 39    | 7      | 32  |
| Company                           |       |        |     |
| Percentage by Manufacturer        |       |        |     |
| Roche Diagnostics                 | 21%   | 3%     | 43% |
| Animas Corporation                | 13%   | 21%    | 3%  |
| Asante Solutions Inc              | 1%    | 1%     | 1%  |
| Medtronic Inc                     | 47%   | 53%    | 40% |
| Insulet Corporation               | 7%    | 9%     | 5%  |
| Tandem Diabetes Care              | 6%    | 11%    | 0%  |
| Other                             | 4%    | 1%     | 7%  |

perceived in the US than in GER. The remaining patients marked "neither." Almost 20% of participants described collecting the components needed to fill the cartridge as "neutral" to "very difficult" (18%; 19%; 18%), with no significant differences between the 2 countries; 29% (31%; 26%) stated that there were a "few too many" to "entirely too many" steps involved in changing the cartridge. More than one-third (36%; 47%; 22%) of the subjects regarded the number of steps involved in filling the cartridge as a "few too many" to "entirely too many."

Although the mean time needed to fill the cartridge was 5 (3.9) (0.5-45.0) minutes, the time reported by the US participants was a bit longer (5.2 [4.3] [0.5-45] minutes) than that reported by the GER participants (4.7 [3.2] [0.5-30.0] minutes; P < .05). In the US, 5% (29 of 516) of subjects reported that it takes them >10 minutes to fill the cartridge compared with 4% (15 of 426) of those in GER.

# Insulin Infusion Set Preferences and Changing the Set

The different types of IIS currently used by participants are listed in Table 3. The most commonly used Teflon® infusion

Table 3. IIS Currently Used.

| Name of IIS  | Total     | US        | GER       |
|--|-----------|-----------|-----------|
| Accu-Chek Ultraflex/<br>FlexLink <sup>T,B</sup>      | 98 (11%)  | 14 (3%)   | 84 (20%)  |
| Accu-Chek Tender <sup>T,M</sup>                      | 30 (3%)   | 13 (3%)   | 17 (4%)   |
| Accu-Chek Rapid D <sup>S,M</sup>                     | 107 (12%) | 4 (1%)    | 103 (25%) |
| Animas inset/MiniMed mio <sup>T,A</sup>              | 128 (14%) | 106 (21%) | 22 (5%)   |
| Animas Comfort/<br>MiniMed Silhouette <sup>T,B</sup> | 140 (15%) | 125 (25%) | 15 (4%)   |
| Animas Contact<br>MiniMed Sure-T <sup>S,M</sup>      | 113 (12%) | 32 (6%)   | 81 (20%)  |
| Deltec Cleo 90 <sup>T,A</sup>                        | 16 (2%)   | 16 (3%)   | 0 (0%)    |
| MiniMed Quickset <sup>T,B</sup>                      | 208 (23%) | 149 (30%) | 59 (14%)  |
| (Insulet) mylife<br>OmniPod <sup>S,A</sup>           | 57 (6%)   | 37 (7%)   | 20 (5%)   |
| Other  | 18 (2%)   | 6 (1%)    | 12 (3%)   |
| Total for each                                       | 9Ì7 ´     | 505       | 412       |

Values are frequency (percentage). Superscript letters: A, autoinserter; B, both; M, manual insertion; S, steel; T, Teflon.

set is Quick-set®, while the most commonly used steel infusion set is Accu-Chek Rapid-D. Overall, Teflon IIS make up 70% of the IIS used, while steel IIS make up 30%. Steel IIS were used less in the US (7.2%) compared to GER (45%). Insulet Omnipod® uses a Teflon cannula IIS, and it makes up most of the remaining IIS.

Roche Diagnostics supplies Accu-Chek® IIS, while ConvaTec manufactures the majority of all other IIS under a variety of brand names. Therefore, the majority of IIS used by participants are distributed by these 2 companies (ConvaTec 64%, Roche Diagnostics 26%); ConvaTec supplied 82% of IIS used by the US participants and Roche Diagnostics supplied 49% of IIS used by the GER participants.

Altogether 88% (85%; 90%) of participants regarded connecting an IIS to the pump as easy or very easy, 11% (12%; 9%) stated neither, and 2% (2%; 1%) felt that it is difficult or very difficult, with no significant difference between the US and GER. Although 77% (73%; 82%) of participants did not find that priming and inserting the IIS involved too many steps, 23% stated that they would like this process to be simpler, with 27% in the US and 18% in GER describing the steps as "a few too many" to "entirely too many."

The average time needed to prime, insert, and attach an IIS to the skin was 4.7 (0.5-30.0) minutes, with no difference between countries. In the US, more people inserted the IIS with an autoinserter than manually (296 [57%] vs 182 [35%]; P < .001), while autoinserter usage is lower in GER where steel IIS that are inserted only manually are more widely utilized (154 [35%] vs 249 [57%]). The use of an auto-insertion device was associated with higher HbA1c levels in the US but not in GER (7.2% [n = 296] autoinserter vs 6.9% [182] manual in US [P < .001]; compared to 7.7% [154] vs 7.9% [249] in GER). The number of people who used an Omnipod,

which has an internal insertion device, was higher in the US than GER (49; 9% vs 23; 5%).

Some participants (34%; 38%; 30%) reported that they change their IIS "always or "often" at the same time of day; however, 50% in GER reported that they do this only "rarely" or "never" compared to 34% in the US (P < .001).

# Length of Cartridge and IIS Use

Of 861 responses, 49% used their IIS and insulin cartridge the same length of time, while 46% used their cartridge longer than their IIS and 4% used their IIS longer than their cartridge. Insulin cartridges were used for an average of 4.7 (4.3) days, shorter by 1 day in the US than in GER (4.3 [5.0] vs 5.3 [3.2] days; P < .001). Among 890 responses, 11% used a cartridge <3 days, 31% used it 3 days, and 58% used it >3 days. Longer use of insulin cartridges was associated with lower HbA1c values when used for 3 days or longer (7.3%; 793; 89%) than when used less than 3 days (7.7%; 97; 11%) (P < .001) with a modest reduction of 0.1% in the HbA1c for 3 days usage.

The mean duration of IIS use from 908 responses was 3.0 (1.1) (1-10) days, with longer use in the US than in GER (3.3) [1.0] vs 2.7 [1.1] days; P < .001). While >50% of all participants reported that they "never" or only "rarely" used the IIS longer than recommended (53%; 46% US; 61% GER), nearly 20% report that they did this "often" or "always" (19%; 25%; 12%). The percentage of participants who sometimes, often or always used their IIS longer than recommended was higher in the US (54%) than in GER (39%). Among all participants, 35% used an IIS <3 days, 41% used it 3 days, and 24% used it >3 days. It is interesting that although steel IIS are recommended to be used for 2 days by manufacturers, steel IIS were actually used longer (3.7 days) than Teflon IIS (3.3 days) in the US, and also used longer than recommended although shorter than Teflon IIS in GER (2.6 vs 2.8 days).

Length of use of IIS was not related to HbA1c levels. Those who have used an insulin pump longer tended to also use cartridges (P = .07) and IIS (P = .10) longer. Overall, 49% of participants used their cartridge and IIS the same length of time, 4% used the IIS longer, and 46% used the cartridge longer than the IIS.

The most common reason stated for using an IIS longer than recommended was to save time. This was stated more frequently in GER (52 US vs 66% GER; P < .001; total 57%). In contrast, to save money was stated more frequently in the US than in GER (32 vs 16%; P < .05; total 26%). The percentage of participants who used an IIS until a problem occurred was comparable between the US and GER (16 vs 19%; total 17%).

# Unexplained High Blood Glucose Levels

Those who reported having <1 unexplained high blood glucose value (UHBG) per week tended to have a lower HbA1c

compared to those who reported >1 UHBG per week (7.1% [304 users] vs 7.5% [555 users]; P < .16). Among other causes, UHBGs were attributed to failure of the IIS itself (leaks, kinks, blood in the line, etc) or to skin problems at the infusion site (poor absorption, scarring, etc). UHBGs were less frequently attributed to occasional or frequent site issues in the US than GER (60%; 79%%), while this was less frequently attributed to a bad IIS in the US than GER (44%; 84%, P < .001). No association was found between UHBGs and those who attributed this problem to a bad infusion set or to infusion site issues. UHBG values were more frequently attributed to occasional or frequent site issues in the US compared to GER (79 vs 60%; P < .001).

#### **Occlusion Alarms**

Of all participants, 80% reported that they had <1 occlusion alarm a month, with slightly fewer occlusion alarms in the US than in GER (77% vs 83%). HbA1c levels tended toward being lower in those who experienced <1 occlusion per month (7.3%) versus those who experienced  $\geq 1$  occlusion per month (7.6%; P = .09).

#### Data Downloads

Of participants, 43% never downloaded data from their pump, with more subjects reporting they had never done this in GER (57%) than in the US (32%; P < .001). Only 20% of those who had downloaded data said they were "very satisfied" with this process. More subjects in the US than in GER were "partly dissatisfied" or "very dissatisfied" with the data download procedure (17 vs 7%).

# Satisfaction With Insulin Pump Therapy

Only 47% of all participants were "very satisfied" with their insulin pump, with a slightly lower percentage in GER (45%) than in the US (49%). Another 37% say they were "partly satisfied" while 15% said they were "neutral" to "very dissatisfied" with their current pump. Even so, a large majority said they would recommend an insulin pump to others (95% yes, 1% no, 4% not sure), and this held true for both countries (US 93%, 1%, 5%; GER 96%, 1% and 3%).

# What Participants Liked Most and Liked Least About Insulin Pumps

Participants were asked to comment in their own words what they liked and disliked about their insulin pump. Utilizing a modified framework analysis, hundreds of different responses were grouped into 8 common response categories about what they liked and 13 common responses about what they didn't like about insulin pumps (Table 4). Pump users tended to describe their likes in general concepts such as convenience, flexibility, and better glucose control. Regarding

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Table 4. Insulin Pump Likes and Dislikes (US and GER).

|   | Number of times mentioned | % of responses |
|---|---------------------------|----------------|
| Likes                                       |                           |                |
| Design                                      | 249                       | 27             |
| Convenient handling                         | 244                       | 26             |
| Flexible dosing                             | 168                       | 18             |
| Communication with CGM/<br>BG meter         | 126                       | 13             |
| Good glucose control                        | 67                        | 7              |
| Size  | 53                        | 6              |
| Flexible basal rates                        | 22                        | 2              |
| Customer service                            | 11                        | I              |
| Dislikes                                    |                           |                |
| Design flaws/insufficient display/batteries | 196                       | 28             |
| Size  | 126                       | 18             |
| Handling                                    | 76                        | 11             |
| Issues with IIS                             | 74                        | 10             |
| Time required to change and fill cartridge  | 56                        | 8              |
| Alarms too soft/false alarms                | 51                        | 7              |
| Having to wear a pump                       | 35                        | 5              |
| No communication with CGM                   | 31                        | 4              |
| Selection of boluses is limited             | 21                        | 3              |
| Frequency of change of IIS                  | 16                        | 2              |
| Priming infusion line                       | 15                        | 2              |
| High costs                                  | 13                        | 2              |
| Customer service                            | 7                         | 1              |

dislikes, they mentioned specific personal annoyances such as having to wear a pump, not hearing alarms, too many IIS failures, and cost.

#### Continuous Glucose Monitoring

With minimal CGM adoption in GER, only 1 question was asked, with 72% of respondents saying they knew what was meant by the term "continuous glucose monitoring" ("kontinuierliches Glukosemonitoring"). This compared with 96% of respondents in the US. Among 496 US responders (93%),

- 297 (60%) currently used a CGM (for 35.4 months; average HbA1c 6.9%)
- 87 (18%) had previously used a CGM (for 2.7 months; HbA1c 7.4%)
- 65 (13%) had never used a CGM but would like to (HbA1c 7.1%)
- 47 (9%) had never used a CGM and didn't plan to (HbA1c 7.1%)

Of 278 participants (93%) who responded to the question about how many days they wear the CGM system in a typical month, 68% stated they use it more than 3 weeks each month,

12% used it about 3 weeks a month, 10% used it 1-2 weeks a month, and 10% used their CGM about 1 week per month. When wearing a CGM, 54% of participants said they looked at their CGM display >15 times a day, 20% looked at it 11-15 times a day, 12% looked at it 6-10 times a day, and 14% viewed the screen 5 or fewer times a day.

In a regression analysis, HbA1c levels were found to be inversely and significantly associated with months of CGM wear (P < .05) and number of times per day that the CGM results were looked at (P < .01). The formula describing this interaction was "HbA1c =  $7.4253 - 0.0050 \times$  Months of Current CGM Wear  $- 0.0241 \times$  Times per Day CGM Looked At." Thus HbA1c levels would be expected to decrease by 0.06% for each year of wear, but more importantly by 0.12% for each additional 5 times a day the CGM screen is viewed.

Of those currently on a CGM, 72% used a Dexcom CGM (6% on a Dexcom seven®plus and 66% on a Dexcom G4® PLATINUM continuous glucose monitoring system), while 27% used a Medtronic insulin pump with an integrated CGM (Enlite<sup>TM</sup> Glucose Sensor or Guardian® REAL-Time System), and 1% used an Abbott FreeStyle Navigator<sup>TM</sup> CGM. Cost of CGM systems in the US was fully reimbursed for 32% of participants and partly reimbursed for 53%, while 15% paid for the CGM themselves. For a preferred location to view CGM results, 43% of respondents wanted to view CGM information on a pump screen, 27% on a smartphone, 22% on a separate device, and 8% on a wristwatch.

# Satisfaction With CGMs

Participants reported personal benefits from wearing a CGM, with 81% saying the CGM helped them recognize hypoglycemia better, 65% said they had less fear of hypoglycemia, 82% found they were better able to recognize hyperglycemia, and 70% reported that their CGM provided them better glycemic control with a lower HbA1c.

Of 384 participants who currently wore or had previously worn a CGM, 80% said that they were very or partly satisfied with CGM and 84% said they would recommend a CGM to others. People who were "very satisfied" with their CGM had a significantly lower average HbA1c of 6.9% (195; 52%) compared to 7.2% for those who said they are "partly satisfied" to "very dissatisfied" with their CGM (183; 48%) (P < .01). Among 35 participants who said they were "very dissatisfied" with CGM, 31 were no longer wearing a CGM and the other 4 were using older generation CGM systems.

The hundreds of different answers provided by the subjects in their own words were grouped into 6 response categories about what the subjects liked about their CGM systems and 9 categories about what they didn't like (Table 5). Trend analysis was the most liked topic and insufficient accuracy was the most disliked topic.

Table 5. CGM Likes and Dislikes (US Only).

|  | Number of times mentioned | % of responses |
|--|---------------------------|----------------|
| Likes                                      |                           |                |
| Trend analysis/pattern analysis            | 102                       | 28             |
| Alarms with hypoglycemia                   | 84                        | 23             |
| Knowing glucose level all times            | 83                        | 23             |
| Better control/avoid hypoglycemia          | 49                        | 14             |
| Alarms with hyperglycemia                  | 23                        | 6              |
| Feeling safer                              | 18                        | 5              |
| Dislikes                                   |                           |                |
| Insufficient accuracy                      | 91                        | 28             |
| 2 devices on the body                      | 73                        | 22             |
| False-alarm/quality of alarms              | 37                        | 11             |
| Insertion issues                           | 37                        | 11             |
| Costs/missing coverage                     | 36                        | 11             |
| Size/comfort                               | 26                        | 8              |
| Difficult fixation                         | 15                        | 5              |
| Need for frequent calibration/<br>handling | 10                        | 3              |
| Duration of sensor usage                   | 6                         | 2              |

#### **Discussion**

The results of this survey provide insight into the daily practices and personal opinions of nearly 1000 pump users in 2 countries that have a relatively high percentage of people on insulin pumps. It is of interest to note that the number of publications about user surveys of this type is relatively small.

Most pump users in this survey are in moderate to good metabolic control based on self-reported HbA1c values that average 7.4%. This is in line with many other studies of insulin pumps, for example, Riveline et al reported an average HbA1c level of 7.8% among 424 patients on CSII in France.<sup>2</sup> The average HbA1c of 7.1% for US participants in this survey is similar to the average self-reported HbA1c level of 7.0% in a questionnaire/survey of over 10,000 pump wearers by Hammond et al in Europe and North America.<sup>3</sup> However, it is substantially lower than 7.8% found among GER subjects in this survey, as well as the average HbA1c of 7.7% reported from the T1D Exchange Clinic Registry participants, of whom 59% utilize CSII therapy.<sup>4</sup>

We acknowledge that this survey has certain limitations. The reason for the difference in the glucose control, measured by self-reported HbA1c levels, in the 2 samples can be a selection bias, that is, patients in the US and GER were recruited at different settings, which might have an impact on patient motivation, age, truthfulness, and so on. The way the data were collected contributes to the fact that the patients in the US sample are older than GER respondents, have had diabetes longer, have more years of CSII experience, and have worn more pumps. It might also be that the US patients

with their lower HbA1c used more insulin than those in GER (this was not a topic in this survey), although 1 of the few studies where this was measured found that pump patients with higher average glucose levels used more insulin per day than those who were in better control.<sup>5</sup>

The survey highlights a number of aspects of pump technology and education that can be improved:

- 1. In GER, 77% used their cartridge >3 days, compared with 42% of US subjects. Usage time for cartridges depends on factors like the size of the cartridge used by individual patients, daily insulin requirements, and length of use recommendations by the manufacturer. Shorter usage time for cartridges in the US may be related to the greater utilization of Animas insulin pumps that have a 200-unit cartridge (21% vs 3% in GER), and perhaps to more widespread usage of the 180-unit versus 300-unit Medtronic cartridge in the US (not a topic in this survey). As mentioned, the higher daily insulin requirements might also partly explain the difference in cartridge use, but we did not evaluate cartridge size or daily insulin requirements in this survey.
- In the US, IIS were used for an average of 3.3 days, compared wit 2.7 days in GER. In the US, 32% used an IIS >3 days, compared with GER where only 16% used an IIS longer than 3 days. This may be due to the more widespread use of Teflon IIS in the US (85% vs 51% in GER), as well as longer use of steel IIS in the US. Longer usage of IIS may also be related to a preference to save time or money, even if reimbursement is available. Some people may change their cartridge or IIS on a regular schedule, while others may wait until a convenient time is available or until a problem arises. Although the numbers are small, it is interesting that steel IIS were used for an average of 3.7 days in the US with no impact on the average HbA1c value (7.1% steel [34 users] vs 7.2% Teflon [464 users]). Assuming that sterile technique is appropriately used, many individuals appear able to wear steel IIS longer than the 2 days that is currently recommended. These data suggest that additional research is warranted on optimal length of use and failure-resistant design for both cartridges and IIS.
- 3. Responses and comments indicated that participants experienced frequent issues regarding the IIS, especially with occlusions, unexplained hyperglycemia, and having to change the IIS early due to hyperglycemia. However, no association was found between HbA1c levels and the frequency of suspected issues with either the IIS itself or the skin site. Even so, improved IIS design and skin attachment might enhance IIS reliability and length of usage. The finding that IIS are used longer than periods recommended by manufacturers and that this is associated

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with a trend toward lower HbA1c values appears to run against findings in other studies. Our study was much larger than the 12 subjects studied by Schmid et al,<sup>6</sup> where IIS trouble started on day 3 of use with slanted Teflon Comfort/Silhouetted IIS, as well as the 24 subjects in a study by Thethi et al, where trouble started on day 2 with the IIS type not stated.<sup>7</sup>

- 4. It is not clear whether our results indicate that the presence of IIS issues mandates shorter length of IIS use, or whether certain individuals or certain techniques enable longer usage. Clinical research studies that explore how IIS fail and why some individuals are able to use IIS longer than recommended with little or no impact on their HbA1c level could provide answers that would help many people on pumps. It is of interest that UHBGs were less often associated with the IIS in the US compared to GER, even though auto-insertion devices are more commonly used in the US and these devices are associated with rates of initial failure as high as 8.9% to 15%. 9,10
- 5. People on insulin pumps usually change or refill the cartridge with insulin and change the IIS every 2 to 5 days. Only 43% of respondents described the removal and replacement of the cartridge as "very easy" and only 37% described the collection of components as "very easy." Improvements in the cartridge filling process might be welcomed by many people on insulin pumps.
- 6. Design of insulin pumps turned out to be the most liked and most disliked aspect, and handling of the pump was the second most liked and third most disliked aspect of pumps. Survey participants expressed a preference for smaller pump sizes and more convenience regarding IIS and cartridges. Only 47% of participants said they were "very satisfied" with their current pump, suggesting that developers are likely to benefit from placing more focus on pump design. Redesigns of user interfaces are already underway to minimize user data entry errors in response to the recent Human Factor initiative of the FDA. 11,12 Hopefully, this will translate into easier handling as well.
- 7. CGM systems have been available for >10 years. Days of wear per month in our study was nearly identical to a recent survey of 100 CGM users in England where 71% said they used their CGM >75% of the time. 13 Although having a large number of respondents from Southern California and about half responding to an online survey may bias our survey toward people more likely to use a CGM, the prevalence of CGM usage at 60% among US respondents suggested a high acceptance of this technology. This can be compared with an earlier 21% prevalence of CGM use among participants in the Type 1 Diabetes (T1D) Exchange Clinic Registry, of whom 59% wore

- an insulin pump.4 The T1D registry was started in September, 2010, with CGM usage evaluated 1 year after participants enrolled, so it will include more outdated CGM systems than our more recent survey. A discontinuation rate of 41% in the T1D registry for these older CGMs from the time of enrollment to 1-year follow-ups is much higher than among our participants where only 9% had previously worn but were not currently wearing a CGM for a variety of reasons. Another 16% wanted to try a CGM. Among US responders' likes and dislikes about CGMs, trend lines was the most favored feature while device inaccuracy was least favored. Very few complaints were expressed about frequency of calibration being too high or that the duration of sensor usefulness was too short.
- Overall, responses suggest that CGM users understand how to avail themselves of the current technology but that they would prefer greater accuracy and more control over alarms in these devices. Concerns about CGM accuracy can often arise when discordant glucose values are observed on a CGM screen compared to the glucose meter used for calibration. However, it should be kept in mind that both methods measure glucose in different physical compartments. Results from this survey conform with current assessments of CGMs by clinical specialists as well as research underway by industry to improve CGM technology. 14,15 Among people who wear an insulin pump, the perceived benefits of CGM use appears to be widespread. Acceptance and ongoing use of CGM technology have been closely tied to user beliefs about accuracy. This survey supports this conclusion by finding lower HbA1c values among those who said they are "partly or very satisfied" with their CGM compared to those who were "neutral to very dissatisfied" (7.0% [226] vs 7.6% [37], P = .03).

The results obtained with this survey provide insight into day-to-day pump usage in the US and GER, and CGM usage in the US. A more detailed evaluation may be worthwhile to explore the variety of factors that impact device choices, such as those found here in the US and GER, and how these factors might impact survey results obtained in intercountry surveys.

From the demographics, a higher percentage of females answered this survey and a higher percentage of insulin pumps are worn by women. Steel IIS are more widely used in GER than the US, and it is interesting that days of actual wear for Teflon and steel IIS is longer than recommended by manufacturers with no impact found on self-reported HbA1c levels. Autoinserters are more frequently used in the US. Data downloading is problematic for most pump wearers in both countries. Although new pump designs are beginning to appear, many current insulin pumps are direct descendants of

designs and technology that have existed for many years. There appears to be significant room for innovation as well as acceptance of diabetes devices. More innovative pumps and CGM systems with improved designs have recently entered the market or will do so soon. This may increase market uptake, especially if wearers experience greater ease of use along with improved clinical outcomes.

In summary, this survey exposes interesting differences between user practices and attitudes in the US and GER, while showing that there is room for improvements in insulin pump therapy and CGM systems.

#### **Abbreviations**

CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; GER, Germany; IIS, insulin infusion set; UHBG, unexplained high blood glucose; US, United States.

# **Declaration of Conflicting Interests**

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: JW is a consultant for a range of companies that develop new devices and therapeutic options for the treatment of diabetes. LH holds shares in the Profil Institute for Metabolic Research, Neuss, Germany, and the Profil Institute for Clinical Research, San Diego, USA. LH is consultant for a range of companies that develop new diagnostic and therapeutic options for the treatment of diabetes.

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