

# Intelligent Insulin Pens

A luxurious instrument or an essential gadget ? — A qualitative study

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**Abstract**—Insulin pens were first introduced in 1985. Since their introduction, insulin pens have been remarkable for their simplicity and accuracy. They have played a major role in the Multiple Dose Injection therapy (MDI). Until today, insulin pens, along with insulin pumping therapy, have been considered the only two reliable methods for external insulin delivery. Nevertheless, there has been always a wide gap between the two from the technological perspective. While pumps were enhancing through the utilization of several technologies, insulin pens have not had any major upgrades for a long period. Just recently, a couple of specialized diabetes companies have just introduced new types of intelligent insulin pens to the diabetes market. In this paper, we gave a brief introduction about the intelligent insulin pens technologies, and then we drew some general technological comparison between insulin pens and pumping equipments. In addition, we wanted to evaluate the current status of intelligent insulin pens technology among diabetic community, we went through a number of case studies among patients and obtained some feedback from their sides. We summarized the results from the case studies, and then we followed that by some discussions regarding the current technologies and our future vision for intelligent insulin pens. We believe that rather than focusing only on the development of intelligent insulin pens itself, we suggest that developers should give more focus on utilizing current ubiquitous technologies (i.e., smart devices, cloud computing, wearable computing, etc.). The main focus should aim on creating applications that can ease the diabetic management mission, and promote a better diabetic patients' compliance.

**Keywords**—*Electronic Medicine; Diabetes Mellitus; Insulin Therapy; Ubiquitous Computing; Cloud Computing*

## I. INTRODUCTION

### A. Brief History

Insulin pens were first introduced in 1985 by the Danish company *Novo Nordisk* [1]. From that time, insulin pens have managed to promote a better adherence to insulin medication, and despite their high costs compared to regular syringes, insulin pens have always been remarkable for their accuracy and simplicity. Consequently, this led them to be the most convenient instrument for Multiple Dose Injection therapy (MDI) [2]. During their lifecycle, insulin pens had a series of several upgrades—mostly, minor ones (i.e., size, smoothness, shapes, etc.), but none of them had any major upgrades with high-tech functions [3]. The cycle has remained like that until

*Eli Lilly* and company came in 2007 and introduced their *HumaPen® Memoir™* model. It was the first model that had electronic components and memory ability within its system. It could record time, date and dosage amount for a certain number of taken doses [4]. This encouraged *Novo Nordisk* in 2012 to release their own version of memory function in two of their models *NovoPen® 5* [5] and *NovoPen Echo®* [6]. Although the previous models had electronic components within their systems, the dosing action remained totally mechanical (i.e., force-driven motor). The Intelligent Insulin Pen *Pendiq®*, produced by the German company *Pendiq GmbH*, and manufactured by the Korean company *Diamesco Co.,Ltd*, was the first model to come and change the concept from “mechanical dosing” into “electronic dosing” (i.e., electronic driven-motor). In addition to that, the pen introduced several useful functions, which never existed before in any models [7]. Until today, it remains the only insulin pen model available with high-tech features within its system.

### B. Comparisons Between MDI and Pump Therapies

For many years, there were several attempts to invent new methods for insulin delivery, but till this moment, only MDI and insulin pump have remained the most preferred methods among insulin dependent patients. Each one of these two methods has its own positive and negative aspects; yet from the technological side, there has been a wide gap between them. Table I summarizes the general comparisons between insulin pens and insulin pumps.

TABLE I. COMPARISON BETWEEN INSULIN PENS AND INSULIN PUMPS

Comparison between insulin pens and insulin pumps		
Features	Insulin Pens	Pumps
Level of accuracy and precision	Lower	Higher
Flexibility and convenience	Higher	Lower
Costs	Lower	Higher
Performance and glycemic control	Lower	Higher
Level of risks	Lower	Higher
Ease of mastering	Higher	Lower
Level of complexity	Lower	Higher
High-tech and upgradability	Lower	Higher

Overall, insulin pumps have always been featured with high-tech type of equipments, while MDI, using insulin pens, have remained just simple without any sophisticated parts. Nevertheless, the technological nature of insulin pumps have made them highly extendable; for example, modern pumps right now can show you the current level of insulin within body, calculate bolus (i.e., meal doses) from an internal carbohydrates database, create reports from the collected data and transfer data (e.g., reports or records) to other devices (i.e., PCs or smart phones) [8]. One notable example, which shows the extendibility of pumps technologies, is the utilization of wireless technologies within pump devices. Some pumps now are embedded with wireless modules to make them tubeless and packed as one complete unit—contains the pump, cannula and medication. Once they are placed on the skin, they can be operated wirelessly through an external remote. The advantage here is that the skin is prevented from the exposure to the outer environment, and at the same time, it does not hinder daily activities and movements [9]. The researches on enhancing the operation of insulin pumps are still going on till today, and the latest trend is focusing on creating what is called a closed-loop artificial pancreas (i.e., a fully automated system for insulin dosing) [10].

The notable downside about pumps is that they require much dedication and training to master their operation, while on the other hand, insulin pens are still considered simple and easy to master. In addition to that, insulin pens do not require on-body attachment—taken when they are just needed, while pumps in contrast require constant on-body attachment, which is considered bothersome for some patients.

We can consider the German *Pendiq*® insulin pen model as the first attempt in creating a solution between pumps and regular insulin pens. It borrowed some of the sophisticated features existing within pumps, such as precise scales and dose recording, and at the same time it kept the simplicity and convenient features of insulin pens.

Here, we can raise a question: “Is this type of in-between solution essential for diabetic management?” We conducted a couple of survey and qualitative analysis among individuals from the diabetic communities. The main aims were evaluating the importance of intelligent insulin pens within diabetic management, and then guiding these kinds of researches toward new approaches, which promote a better diabetic patients' compliance.

The paper is organized in the following manner: In Section 2, we present our research method and summary of results. In Section 3, we present a brief discussion and analysis based on the obtained results. The discussion highlights the status of current technologies and our vision for future solutions. Finally, in Section 4, we conclude this paper by summarizing its contents and outcomes, and then pointing to the limitation and future directions within this research.

## II. ASSESSMENT AND QUALITATIVE STUDY AMONG DIABETIC PATIENTS

### A. Research Method

We conducted qualitative surveys and interviews among individuals in diabetes communities either by sending them direct emails, or recruiting them through diabetes Internet groups. The total number of participants was **76 individuals**.

We surveyed only individuals who were under insulin therapy as part of their medication. We excluded all the cases that reported they were not using insulin during the time of study. We directed the questions to either the patients themselves or their caring persons; this also included practitioners, who were related to diabetic healthcare. The questions focused on the following information: patients' diabetic profile (i.e., age, gender, period of diagnoses, diabetes types, etc.); patients' diabetic management (i.e., types of insulin therapy, data tracking, data management, etc.); patients' diabetic daily condition (i.e., Hypoglycemia vs. Hyperglycemia). The last two parts from the study focused on surveying current technologies of smart insulin pens (i.e., best two functions features, expected improvement in their diabetic management or overall impression) and on surveying patients' views about future technologies (i.e., communication with smart devices and ubiquitous technologies).

### B. Summary of Results

**Patients' profile:** The majority of our participants were from the middle age groups 45%, i.e., between the age of 20s and 40s, while young and teenage groups came in the second place 40%. The remaining groups were people in their 50s or above 15% (Figure 1). Female groups were about 61% and male groups were about 39%. The majority were from the Type1 groups 80%.

**Patients' diabetic management:** For insulin delivery, 67% of participants reported that they were using insulin pens (and syringes sometimes), while patients, who were using syringes only, were about 22%. Insulin pump users were about 15%. 58% of participants reported that they either frequently or sometimes were running into some mistakes with their insulin

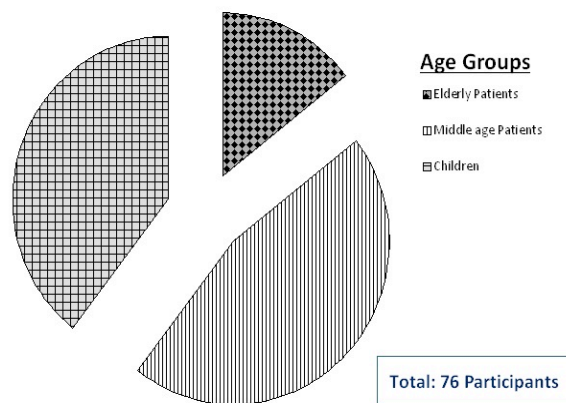


Figure 1. Total number of participants & age groups

medication (i.e., missing doses, double doses, inaccurate dosage, etc.). For diabetic daily management, 66% of participants were keeping tracks of glucose level data, 26% of participants were keeping tracks of nutrition data and 53% of participants were keeping tracks of insulin doses. 42% of participants reported that they were preferring paper format (i.e., physical dairies) for keeping their records, while 34% of them were preferring digital format. Only 21% of participants reported that they preferred both (digital and paper) formats at the same time. The remaining 3% of participants indicated another preferences other than the two methods, such as the usage of voice memo or self-memory. We surveyed about smart devices utilization for diabetic management as well; we found out that most of the participants were regularly using smart devices 79%, but only few were using them for diabetic management 29%.

**Patients’ diabetic daily condition:** As per diabetic daily conditions, 79% of participants reported that they either frequently or sometimes were encountering episodes of Hypoglycemia, while 84% of participants reported that either sometimes or frequently were encountering episodes of Hyperglycemia. The noted reasons for encountering Hypoglycemia were due to: 50% insufficient amount of carbohydrates in meal, 29% excessive activities, 20% over medication or mistakes and only 1% indicated other reasons (i.e., not from the specified list), such as illness, high insulin sensitivity or oversleeping. On the other hand, the noted reasons for Hyperglycemia were due to: 58% extra amount of carbohydrates in meal, 21% lack of activities, 12% insufficient amount of insulin or mistakes and and 9% indicated other personal reasons (i.e., not from the specified list), such as stress, illness or poor control.

**Patients’ views about intelligent insulin pens technologies:** We presented the patients with latest technologies of intelligent smart pens through demonstration. visual aids and few usability studies. We found out that the majority of the patients 79% never heard of or used smart insulin pens before this survey. After that, we highlighted the current features available within current models through a list, and then we asked the participants to pick the most preferable features considered essential for the diabetic management. The highlighted features were (ranked by the highest collected scores from patients’ sides):

- 1) *Memory feature (i.e., keeping records of doses, date and time).*
- 2) *Alarming system (blockage, dripping and low battery)*
- 3) *Transferring data to PC through diabetic management software.*
- 4) *Precise scale (i.e., 0.1 unit scale).*
- 5) *The ability to switch between manual and digital mode in case of emergency (e.g., in case of battery outage).*
- 6) *Pre-saving time period and amount for doses (i.e., automatic repeatable dosing process).*

As one can see in the list, the memory feature was ranked as the most useful feature within current technologies. Following that, we questioned the patients about the expected improvements after using this type of technology. The majority

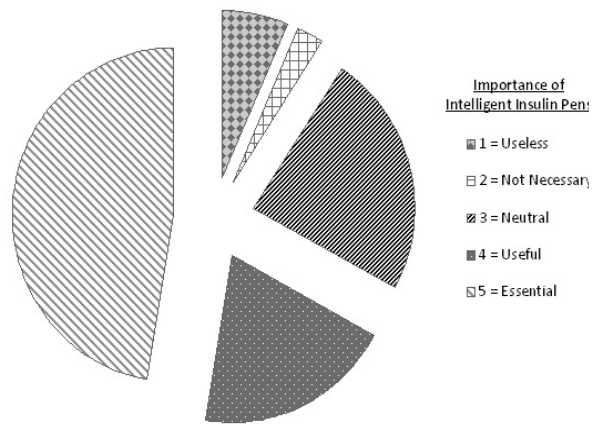


Figure 2. Importance of intelligent insulin pens

of the participants were expecting to encounter less Hypoglycemia and Hyperglycemia episodes. Easier management and data collection came in the second place. precise dosing capability for each meal and then encountering fewer mistakes came as the last two expected improvements in the rank.

We asked the patients what types of hindrances would prevent them from obtaining this type of technology. The top hindrance went to the high cost. Availability within the local market came as the second one. Complexity and then compatibility with insulin brands came as the least two reasons.

Finally, we asked the patients to rate the importance of intelligent pens for diabetic management. Overall, 67% of participants thought that smart insulin pens were either essential or useful for diabetic management, while only 9% thought they were not necessary or useless for diabetic management. The rest 24% were neutral about them (Figure 2).

**Patients’ views about future technologies:** In the last section, imagining that intelligent insulin pens could have the ability to communicate with smart devices through various methods, and they could manage to provide the following functions (Figure 3):

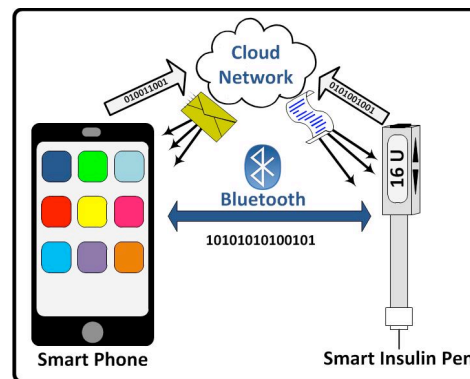


Figure 3. Connectivity with smart devices through different methods

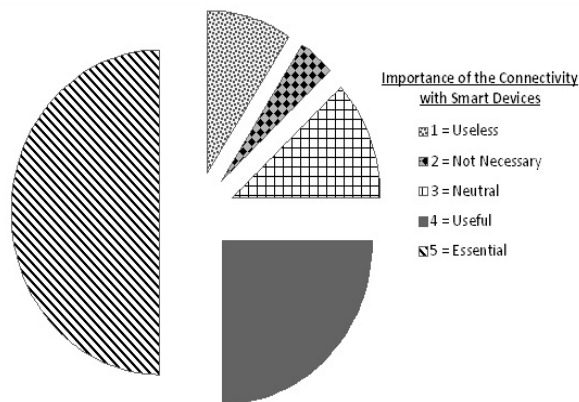


Figure 4. Importance of the connectivity with smart devices

- 1) Automated reminders and confirmation for doses
- 2) Automated data collection and synch with software managers
- 3) Warning and error detectors while dosing
- 4) Remote controlling through smart devices

We asked our participants once again how they would evaluate the importance of using smart devices under this vision. 75% of the participants rated this type of communication as either essential or useful, while only 13% the participants considered this as either not necessary or useless. The rest 12% were neutral to the idea (Figure 4).

We also asked the participants which feature from the above could be considered essential for their management. The automated reminder and collection features were ranked as the first and second respectively, while the warning and remote controlling features were ranked the third and fourth respectively.

### III. DISCUSSION AND ANALYSIS

#### A. Opinions about Current Technology

In general, although the collected data showed that most of the participants had little knowledge about intelligent insulin pens, but the idea of using them, as a part of the diabetic management routine, was still welcomed among them. However, it is difficult to infer the absolute popularity of the insulin pens, as compared with the pumping equipments, from this current survey of patient feedback.

First, let us observe the current features in the latest intelligent insulin pens models, the memory function was ranked as the most useful feature, at the same time, over half of the participants 58% reported about having mistakes with their doses. This could explain why this feature was considered significant and ranked higher than the other features. Nevertheless, the remaining percentage, for those who reported no mistakes, is quite large too. Also, if we go and look back at the results related to the causes leading to Hypoglycemia and Hyperglycemia episodes among participants, it was found that dosage mistakes were marked third in place among the other causes for both cases. This can imply that the memory feature

could be essential only for certain group (i.e., for those who are having serious issues with their own memory), but for the rest, it could be a convenient feature to raise the assurance factor [11]. Similarly, for the precise scale (0.1 U), this feature is critical for those who are having high insulin sensitivity, children as an example [12], but not necessarily it is the same case for other patients. Precise scale feature was ranked as the fourth in place; probably, this feature did not get a higher rank because the majority of participants were from the middle age group (i.e., insulin sensitivity is not critical among this group). Data transfer is similar to the previous two; it only eases the process for those who would like to keep records about their doses. In our data, this was only less than half of the participants, which explains why this feature did not get a higher rank. The other features mainly ease the dosing process, but they do not necessarily help promote a better adherence to the insulin medication itself, for example, unlike the same feature available in latest pumps, patients cannot keep tracks of the current level of insulin while using intelligent insulin pens.

We can conclude here that the current technology of intelligent insulin pens can be a convenient instrument, but not an essential solution for the general type of patients, who are under insulin therapy. This means that they can offer useful features, but they might not guarantee a better management for insulin therapy. In contrast, if we go back and look at the pumps features in the previous section regarding the comparison between MDI and pump technologies, many of the pumps features promote a better management process, which, as a result, leads to a better adherence to insulin medication. Achieving a high level of insulin adherence can help achieve a tight glycemic control as well. (i.e., few episodes of Hypoglycemia\Hyperglycemia). If we return to the results section, and then observe the results related the expected improvements after using intelligent pens, we will find most of the participants were concerned about the encounter of Hypoglycemia and Hyperglycemia episodes. This is actually a common issue among diabetic patients. Generally, we will find many concerned patients, who are looking for convenient ways that would help them minimize the fluctuation in their glucose readings.

#### B. Next Steps in Technology Development

Dr. John Walsh gave an interesting design for intelligent insulin pens in his own website [13]. If we want to follow the same suggested model by adding some high-tech features, such as carbohydrate calculator or insulin level tracker, there is a high risk that this would cause a negative impact on the unit cost and simplicity of use.

Cost was ranked as the highest hindrance within our collected data. If we compare the unit price of the intelligent insulin pens and average price of regular insulin pens, you will find a noticeable difference between the two. Nevertheless, high cost does not necessarily imply a product failure. For example, pumps have always been known for their high costs—even under insurance coverage, but many patients still favor pumps over MDI for their performance and remarkable outcomes [14]. So, this implies that patients are willing to pass on costs as long as they can achieve a better level with their glycemic control.

Simplicity was always a winning factor in insulin pens, and at the same time, it could be the main reason for their slow movements within the technological development [15]. When we did a comparison between the intelligent insulin pens and regular insulin pens, it was obvious that the intelligent insulin pens way of use was slightly more complicated than the usual ways, but it was not as complicated as pumps, which require longer training to master. The point here is that when you add more functions to a certain device, you will need to add more controls to it, and the more controls you would have, the more complex it would become [16].

An alternative approach to the previous solution is to focus on the communication with smart devices and ubiquitous technologies. Smart devices today (e.g., *Apple*®'s *iPhone* and *iPad* or *Android* based devices) are remarked for their simplicity of use—even among non-technical users [17][18]; moreover, they have a powerful processing capability with a multiple way of communication (e.g., WiFi, Bluetooth and cloud computing). In the next sections, we will go through some details regarding this point; this will be followed by a suggested example to support our argument.

### C. Smart Devices and Diabetes

Current smart devices have high connectivity and processing capabilities. They offer different types of functions, and allow achieving multiple kinds of tasks instantly (i.e., phoning, gaming, music players, photographing, Internet surfing, etc.). As a result, people have become more attached to them more than before. Nowadays, smart devices connectivity is being utilized to create smart systems with unique features. For example, Google created their own Smart Glasses system by utilizing the connectivity between smart phones and wearable computing [19].

Within diabetic management, there are multiple types of applications available within smart phones, which have been created to help patients to manage their diabetic daily routines; however, if you would go back and look at the summary of our results, you would find that 79% of the participants were using smart devices, but only few of them 29% were using them for diabetic management. In one of our study, after conducting a couple of reviews to these applications, we found that the most notable reason, for that low usage, was they were actually adding extra workload rather than saving. Most of these applications lack intuitive features and require a lot of dedication from the patients' side; for example, some of these applications require patients to enter their daily information manually each time; they lack the automated entry capability. The task for managing diabetes by itself is exhausting and require so much dedication; so if the tools are not going to be intuitive and smart enough, they are just going to be bothersome rather than helpful.

In the result section, you remember that the participants gave generally a positive rating to the communication of smart devices with intelligent insulin pens. This was under the conditions that smart devices could provide a couple of useful functions for diabetic management. If the patients could not sense a benefit from this type of communication, they would simply be neutral or negative about this idea. So we can

conclude that unless smart devices would provide practical functions that would help effectively with diabetic management, they are just going to remain an optional tool for diabetic management.

### D. Connectivity of Smart Devices and Intelligent Insulin Pens

A US company, called *Telcare Inc.* [20], released a cellular based glucometer, named by the same name as the company (*Telcare BGM*). As soon as the patient makes a blood glucose test, it will automatically send the record to all the registered devices through the cloud server. The good part here is that rather than downloading the data from the glucometer into the personal devices each time, all the data can be automatically available for the patient anytime in any of the patient's personal device.

Imagine that same above feature can be applied within intelligent insulin pens. So as soon as the patient would take the required dose, the intelligent pen will send that record automatically into the cloud server, and then from the cloud server into the diabetic manager software installed in the patient's devices. This will ease the process for creating the daily diabetic trend (i.e., glucose level data associated with other information), which is considered valuable information for diabetic management. As we have mentioned before, the use of diabetes management apps might not be that beneficial for all patients, but with technologies like the cloud, the process of entering patient's daily data can be totally automated, and as a result, it will save the time and efforts.

There are several types of communications today, which allow a direct communication between different types of devices (e.g., Bluetooth, ZigBee, WiFi, etc.), but the current trend and most promising one is the communication through cloud technology. Although a lot of sectors (e.g., communication, gaming, e-commerce, etc.) are already utilizing the cloud computing technology effectively today, the healthcare sector is still a little bit slow in adapting this technology [21]. The reasons might go back to the differences between regulations in handling healthcare data globally [22], or the risks associated with the multiple threats surrounding the cloud technology [23]. Nevertheless, we cannot ignore how useful the cloud computing have become in handling our daily data; there is actually a huge grow in the size of usage because of that. Healthcare can also benefit from the cloud technology either through the cost reduction, better health service at home or continues processing of medical data [24]. The good news is that experts are aware of this potential and they are trying multiple ways to overcome the sensitivity within the healthcare data.

We are suggesting here some applications, as an example, which can utilize the cloud technologies and smart devices to encourage a better diabetic routines:

The suggested system (Figure 5) is similar to the current iOS "Reminders" cloud-based system; in the *Apple*®'s "Reminders" app, as soon as the user would set a reminder, it will be activated in all the devices associated with the user's iCloud account. The user can deactivate (i.e., check the reminder) from any device available in hands at that moment. Imagine that we can apply the same concept for doses

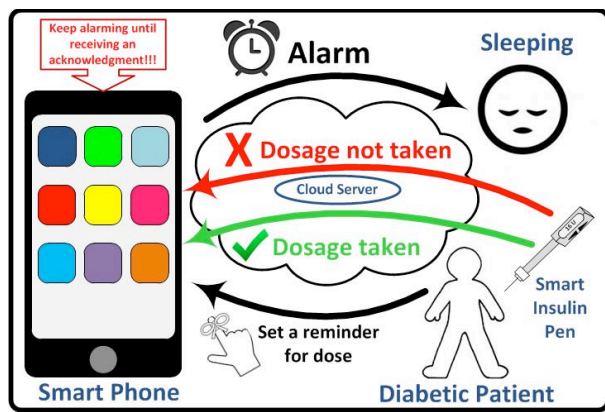


Figure 5. A cloud-based doses reminder system for MDI therapy

reminder; however, rather than letting the patients deactivate the reminder alarm manually, the device should check the collected records and verify if the patient has taken the required dose or not. If the device could not find the required record, it would keep snoozing until it would make sure that the patient has taken the required dose. This system can be useful for the daily basal type of doses (i.e., background insulin dose such as Glargine or Detemir). This type of doses requires to be taken within a fixed period of time (within 12 or 24 hours) in order to assure a better glycemic control [25]. Applying this type of systems can encourage the patient to follow a better adherence to the medication. Remember in our collected data, patients ranked the reminder system and automated collection of dose records as the most desirable features within the communication between intelligent insulin pens and smart devices.

Diabetic technology has probably advanced a lot in the last recent years, but diabetic researchers might need to expand their vision by utilizing technologies, such as cloud computing and smart systems, and offer more smart ways to manage the diabetes milieu.

#### IV. CONCLUSION AND FUTURE WORK

Since their early days, insulin pens have been known for their simplicity and accuracy among MDI therapy adopters. Nevertheless, insulin pens were too slow in catching up with their counterpart, the pumping therapy, which have been known for their continues enhancements all the way long. Intelligent insulin pens models have recently been introduced to the market—as a new attempt to raise insulin pens technology to the next level. In order to evaluate the necessity of this technology, we conducted a couple of case studies among a group of insulin dependent patients. The case studies involved a couple of questions related to diabetes mellitus management itself among this group, and the evaluation of current and future vision about intelligent insulin pens. We thought that the current technologies could be an optional instrument for general patients, and only essential for those who have serious issue with their active memory, or for those who have high insulin sensitivity. We concluded that future enhancement of intelligent insulin pens should target general patients and focus on easing the diabetic management

activities—for example, adding features like carbohydrate calculators or insulin level trackers; however, we have some concerns regarding this point, we think that enhancing the technology within pens themselves might cause a negative impact on the final product—elevation of unit price and complexity of use. We suggest an alternative approach that focuses on the utilization of current ubiquitous technologies, such as smart devices and cloud computing. Smart devices today are featured with high utilities and processing power. Cloud technology as well has grown effectively in the recent years. In our particular case—the diabetes milieu—we believe that these types of technologies can be utilized to provide many useful applications for diabetic management, which could help saving a lot of workload associated with diabetic management routines.

Finally, we want to point that our conducted study was too limited. First, the sample size was a small number. Results from small sample size are not representative. So if we want to have an absolute opinion about replacing regular pens with intelligent insulin pens, we need to collect a larger sample size, which can be enough for conducting a statistical analysis. Second, the collected data were mostly from online communities. This means that the data will exclude patients who have limited technological background, or who have limited access to the wide world network. A Future move can focus on recruiting people through medical centers and clinics, and let them doing the surveys during their regular visits. Lastly, the participants' feedback was based on demonstration, visual aids and few usability studies. This type of feedback cannot uncover all the pros and cons related to the usage of intelligent insulin pens. More longer and deeper usability studies are needed in order to provide a full picture about the effectiveness of intelligent insulin pens for insulin therapy.

Future studies should also focus on the importance of using technologies, such as smart devices, within diabetic management, and how to make them more accessible for most patients. Also, in order to support the argument concerning the communication of intelligent insulin pens with smart devices, we suggest creating prototypes that utilize latest technologies, such as cloud computing, and test their usability among diabetic patients. We hope that these findings would provide a positive contribution toward simplifying the complexity of diabetic management.

#### ACKNOWLEDGMENT

Our thanks to DiabetES FB group and all the people who helped us with survey recruitment process. Also, our thanks to Ms. Hadia Nusrat for her consultation.

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