Intelligent Insulin Pens

A promising technology toward smart diabetic management systems

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***Abstract*—Ever since their introduction, insulin pens have been playing a critical role within the Multiple Daily Injections. Insulin pens were originally a solution created to offer a couple of enhancements in injection. They were appreciated for their simplicity and accuracy. Recently, intelligent insulin pen technology has been introduced to offer a new direction toward enhancing the management of Multiple Daily Injections therapy. In general, technologies have always been playing a major role in the enhancement of insulin delivery; it has been more notable within the pumps therapy practices. For Multiple Daily Injections in particular, the use of technology was relatively limited, but with the introduction of intelligent insulin pens, there is an expectation that the Multiple Daily Injections therapy would elevate into a higher level of standards. Because the technology is still barely known among the groups of diabetic patients, the paper first presents a couple of assessment studies to evaluate the necessity of the intelligent insulin pen technology among diabetic patients. Based on the outcomes, patients and practitioners saw great potentials within this technology. Nevertheless, the study concluded that the intelligent insulin pens technology itself would be essential for certain groups among the diabetic patients, but for the general use, this technology could be a good alternative to the regular insulin pens. The intelligent insulin pens technology still needs to implement more functions that can serve the general diabetic patients. One feasible suggestion to achieve this goal is to extend this technology through the utilization of smart devices and ubiquitous technology. In the second stage, in order to examine the possibility of the previous point, a series of pilot studies was conducted to oversee their influence on the regular management. Based on the assessment study outcomes, a smart reminder system was proposed to test the influence on medication adherence and daily routines. The system utilizes the technology of smart devices and intelligent insulin pens. The final outcomes showed that the system could be a good support to the regular routines, and it had the potential to promote a better compliance toward the insulin medication.**

Keywords-Electronic Medicine; Diabetes Mellitus; Multiple Daily Injections; Smart Systems; Ubiquitous Technology.

I. INTRODUCTION

A. Study Overview

This paper presents a continuation of a previous qualitative study [1], which was conducted for the intelligent insulin pens technology assessment. It also includes additional results from new usability studies, interviews and a series of pilot experiments. The previous study was aiming to survey the importance of using intelligent insulin pens technology as part of the MDI therapy. In this extended study, a new goal was added to the main objective in the previous study. The new extended study aimed to test the feasibility of extending the functionality of intelligent insulin pens through the utilization of ubiquitous technologies.

The previous study highlighted the potential existed within current models of intelligent insulin pens. It concluded that the intelligent insulin pens can be a good option as an alternative to the current available instruments, but the intelligent insulin pens technology itself is not necessarily essential for the majority of diabetic patients. In the previous study, the experience of intelligent insulin pens technology was mostly based on demonstration and visual aids materials. At the current stage of this study, we had results from patients, who had actual experience with this technology itself. The study included also some opinions from a number of specialized practitioners; these results were helping to give insights about the importance of the technology from the primary care side. Additionally, the previous study highlighted the role of ubiquitous technologies in expanding the functionality of the intelligent insulin pens. The current stage of this study showed some evidence—through a couple of pilot studies—that can support the previous claimed idea.

This paper is organized in the following manner: The second part of this section gives some historical background about the evolution of the insulin pens instrument. Section II gives some information about the technologies existed within diabetes mellitus. It presents some information about the devices that have widely been used for diabetic management, and then it highlights the role of smart devices within diabetes mellitus. Section III provides some assessment studies for the intelligent insulin pens technologies. Section IV presents some pilot studies for the connectivity between intelligent insulin pens and smart devices. Finally, Section V concludes this paper by summarizing its contents and outcomes, and then it points to the limitation and future directions of this research.

B. *The Evlution of Insulin Pens*

Originally, the launch of insulin pens came in 1985 by the Danish company Novo Nordisk [2]. The main aim was to find a more practical instrument that can replace the traditional syringes and insulin vials. The introduced solution managed to ease the insulin dose administration, especially among elderly and young patients. It has always been noted for its accuracy and simplicity [3]. Currently, in most parts of the world, insulin pens have already surpassed traditional syringes, and they have become the main instrument for the MDI therapy [4]. Both types of instrument have some similarities between them, e.g., mechanical-driven motor for dosing; however, they differ in how to prepare and adjust the dose.

In the regular syringes case, patients need to insert the syringe inside the insulin vial, and then start pulling the end of the instrument to let the medication fill in. On the other hand, the vial—called cartridge here—for insulin pens is inserted inside the instrument itself. Patients just need to adjust the required amount using the dose knob at the end of the instrument, and then by pushing the button at end of the pen, the dose can easily be administered.

There are a couple of advantages of using insulin pens instead of using regular syringes. First, the pushing mechanism can prevent the air bubbles from coming inside the vial, i.e., air bubbles can reduce the accuracy of the administered dose. Second, the dose knob at the end of the pen is easier for dose adjustment and more visible to most patients. Finally, the insertion of vial inside the pen itself makes it more convenient for storage and carrying.

Nevertheless, there are still some disadvantages in using insulin pens. First, the overall cost of using insulin pens is higher when compared to regular syringes [5]. Second, the dosing mechanism in insulin pens is considered slower than regular syringes. During the dosing process, the patient needs to push through the whole insulin vial. As a result, this requires the patient to keep the instrument inside the skin few extra seconds [6]. This is to make sure that the dose has been fully and correctly drawn out of the vial. Finally, unlike regular syringes, patients cannot mix two different types of insulin in the same pen, e.g., Regular and NPH insulin; however, this is might not be a major issue since most of the new types of insulin are actually not mixable, e.g., Insulin Glargine and Insulin Glulisine.

As per the upgrading cycle of insulin pens, from the days of their introduction, insulin pens had very slow upgrading movements. Most of these upgrades were minor ones. For example, some of the upgrades were mainly related to the outer designs and weights. Others had some enhancements with the dosing process, yet the functions and mechanism concept have remained the same until just few years ago [7].

We started to see some significant upgrades in 2007 when Eli Lilly and company introduced their HumaPen® Memoir™ model [8]; it was the first model to introduce the memory function. Basically, this model can keep records of date, time and dose amount for a number of administered doses. The main purpose is to remind the patient about last taken doses in order to avoid the risks of double or missing doses. The dosing mechanism retains the same mechanism as regular insulin pens, i.e., mechanical-driven motor. The model has been discontinued due to some commercial issues [9].

In 2012, Novo Nordisk introduced the same memory function within two of their own models NovoPen® 5 [10] and NovoPen Echo® but in a totally different concept; basically, rather than keeping the records of date and time, it shows the total dosage taken within the last 12 hours. In addition to that, Novo Nordisk introduced a smaller scale dosing, i.e., scale of 0.5 unit, within their NovoPen Echo® model for young patients, who usually have higher insulin sensitivity than regular patients [11]. Once again, the dosing mechanism remains mechanical-driven like all the previous models.

A new intelligent model has recently been introduced exclusively within parts of Europe and South Korea [12]. The model was manufactured by the Korean company Diamesco Co.,Ltd, which specializes mainly in insulin pumps manufacturing. The introduced model borrowed a couple of features originally existed within pump devices. The most significant feature is replacing the dosing concept from mechanical-driven motor into digital-driven motor. The feature eliminates the need of human-force and it provides more precise dosing scale, i.e., 0.1 unit scale. Another remarkable feature is the ability to keep a large number of dosing records, i.e., more than 100 records, which can also be transferred to personal computers. This is additional to some other features such as alarming for battery and empty cartridge, pre-saving doses and countdown for dose administration. The model has been marketed in Europe as Pendiq Intelligent Insulin Pens and SmartPlus in South Korea.

This latest model of the intelligent insulin pens was used as the main subject within this stage of the study. This model was used within the usability studies to test the use of technological solutions within MDI therapy. It was used also within the pilot studies that test the integration between ubiquitous technologies and the intelligent insulin pens technology.

II. THE ROLE OF TECHNOLOGIES IN MANAGING DIABETES

This section gives a brief background about the role of technology in facilitating and enhancing the insulin delivery. It also highlights the differences between the Insulin pumps and MDI therapies from the technical side. Lastly, it gives some background about the current uses of smart devices under the diabetes mellitus.

A. *Technologies and Insulin Deliveries*

Among the distinctive types of insulin delivery for diabetes mellitus, insulin pumps rely heavily on technologies. The use of technologies in insulin pumps has made them distinguishable with multiple features for diabetic management [13]. For example, pumps now can keep updating you about insulin and glucose levels running within the body; they can ease the calculation of bolus doses by providing a built-in list for food data associated with carbohydrates values; lastly, they can keep records of doses, which can also be synced to personal devices like PC and smart devices. Furthermore, the technological nature of insulin pumps has allowed easily creating new models with new functions.

One remarkable example, which can elaborate this point, is the insulin pump pad— known as Omnipod in the market [14]. Unlike the other insulin pumping models, pump pad comes tubeless packed in one single unit. Each unit of these pump pads is packed with all the necessary components for insulin pumping delivery, i.e., the insulin reservoir, cannula and infusion set. Each unit is also embedded with wireless connectivity module. The patient can set the infusion and doses through a dedicated wireless remote. The main advantage here is providing a solution that allows more flexible movements, and eliminates the exposure of skin to the outer environment. The last two points have always been major hindrances within pumping delivery, especially among patients, who are doing heavy activities like athletics [15].

The inclusion of wireless modules within pumps has opened the door to create more new solutions such as the semi closed-loop pumps [16]. The solution is integration between the pump devices and continuous glucose monitoring devices (CGM). Basically, the patient can view the CGM readings directly on pumps, and then the patient can adjust the delivery rate manually according to the readings. The CGM module can issue an automated suspension of insulin fusion in the case of Hypoglycemia detection. The method is still suffering from some technical issues due to the inaccuracy of CGM reading, but it is still under continuous enhancements. If developers managed to create a CGM with accurate reading, it will be possible to create what is called the closed-loop pumping solution [17]. This is the optimal automated solution, which can imitate the actual work of human pancreas.

Although the technological enhancement within pumps, such as the inclusion of wireless communication, opened the door to create more creative solutions, it invited some new challenges here as well. For example, the controlling through remote devices makes the pumps vulnerable to communication risks like hacking and malicious attacks. Some earlier articles reported that a couple of experiments could manage to hack and control pump pad remotely in the absence of patient's awareness [18]. A couple of solutions have been proposed to avoid such an issue but it is still getting a major attention from the researchers [19]. The point here is there is a need to give careful consideration to the challenges associated within any new proposed technical solutions.

On the other hand, as it was stated before, insulin pens have mostly remained simple without any sophisticated technologies for quite some time. Insulin pens, which have been used for MDI therapy mainly, rely heavily on the patient's cognitive skills and some other companion devices like glucometers. For MDI routines in particular, there are

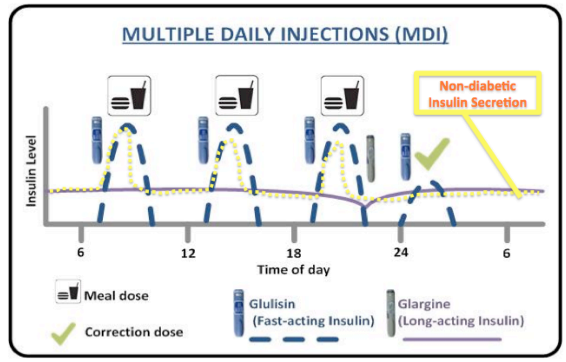

Figure 1. Multiple Daily Injections (MDI).

two types of doses (Figure 1). The first type is Basal, i.e., long acting dose, which lowers the glucose level out of the dining time, e.g., between meals or sleeping time. The dosage amount is usually determined by the primary care and should be taken within a fixed period of time, i.e., every 24 hours; for example, the Glargine type in Figure 1. The other type is called bolus, i.e., short (fast)-acting dose, which is usually taken before or after meals. The patient needs to know the value of the carbohydrates intake in order to adjust the dose according to that value; for example, check the Glulisin type in Figure 1. The patient needs also to measure the glucose level before taking any dose, especially in the morning, in order to check if the dose needs any adjustment or not. For example, if the glucose level is lower than the regular, the patient needs to decrease the usual dose, and if the glucose level is higher, then the dose has to be increased. This is to avoid the occurrence of any Hypo/Hyperglycemia episodes. The main purpose from having these two different types is to imitate the normal insulin secretion in non-diabetic individuals.

Therefore, glucometer devices are considered vital within MDI routines. Nevertheless, the technology within glucometer is mostly simple without any sophisticated features. Some recent models have started the implementation of simple smart features such as smart indicators and directions [20]; however, there are some other models that managed to include sophisticated features such as wireless connectivity for cloud computing utilization [21]. As per CGM, they were mainly developed for pump users only, but there were some researches that showed benefits of using CGM within MDI routines [22]. Aside from the glucometers, smart devices can also be used within the MDI therapy; however, their uses are currently limited. More details will be given in the next section about the uses of smart devices within the diabetes mellitus.

MDI and insulin pumps are still holding the top positions among other methods for external insulin delivery. Both methods have their own pros and cons within their uses. For example, insulin pumps have been remarkable for their glycemic control performance [23], but at the same time, they require extensive training to master, and require continuous on-body attachment. On the other hand, insulin pens within MDI, require almost no effort to master, and

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
Hight-tech and upgradability	Lower	Higher

they are greatly flexible to use, but at the same time, they require much dedication to doses management from the patient's side. Table I gives a brief summary for the differences between MDI and insulin pumps therapies [1].

Nevertheless, as it was implied within this section, there is a wide gap between them in terms of technological utilization. Insulin pumps have evolved greatly into better shapes than their early days, while insulin pens have almost remained unchanged. Technology has great potential to ease the complicated management of diabetes. MDI routines need to follow the same footsteps as insulin pumps. They need to start effectively utilizing some of the latest available technologies, such as cloud computing, wireless communication or smart devices. The intelligent insulin pens as mentioned before could be a good step toward this point. The solution kept some of the features originated within regular insulin pens, such as dosing flexibility, but at the same time, it implemented several new features never existed before, such as the digital-driven motor.

B. Smart Devices and Diabetes

Most smart devices available now in the market have powerful processing and multitasking capabilities. Beside the basic functions, i.e., making calls or messages, you can also browse the Internet, take pictures or even play video games on them. In addition to that, with the current generation of wireless network, the connectivity within these devices has become so high. The previous listed features of smart devices have made them more likable among their users. Moreover, because the user interfaces within these devices have become easier and manageable than previous generations of user interfaces, regular users, who lack deep technical knowledge, can now use these devices more skillfully than before [24]. Smart devices are now playing major roles within our daily routines: shopping, entrainment, education and of course healthcare as well.

For diabetes in particular, there is an enormous number of applications developed specifically for the diabetic users. Most of these applications circulate around four types of functions: patient's records, decision support, education and social communication [25].

Patient's records functions are mainly related to any diabetic data, such as the daily blood tests, daily doses, carbohydrate intake and burned calories. Most of these applications require the patients to enter the data manually, but few of them can be synchronized with glucometers or other sensors for direct data upload [26].

For decision support functions, they are mainly related to the management of daily activities, i.e., medication, meals and exercise. For example, the collected diabetic data can be used to create charts known as trends. These trends can be observed to detect any fluctuation within the patient's glucose values. Additional useful applications are functions like medication reminders and carbohydrates ratio calculators. The previous listed functions can help the patient to take the right decisions regarding the attempted routines, such as doing more exercises, consuming the proper amount of carbohydrates or taking the right amount of dosages.

For education functions, they generally give information related to the diabetes itself, such as guidelines, tips about medication and food or deep knowledge about symptoms and side effects. There are some applications—still under clinical trials—that aim to make these applications more personalized; these applications can give information based on the patient's profile [27].

As per the communication functions, they are mainly related to the communication between patients and practitioners or through social media, i.e., FACEBOOK, Blogs or Internet groups. Communication with practitioners can help smoothing the exchange of information between the two parties or setting up regular follow-ups. For social media, it is an alternative way to find some support outside the clinics. Through this communication, patients can be out of their diabetic isolation, and they can share some of their diabetic experience among other members.

With all the previous functions and features, using smart phones under the diabetes mellitus is still considered a non-standard practice and very limited [28]. Most of these applications are still not recognized by official organizations, such as US Food and Drug Administration (FDA) [29]. The absence of these types of recognition makes them barely known among practitioners and less trusted for recommendations.

Moreover, some functions could be useful, but it might be difficult for some patients to handle them without enough experience. For example, providing trend charts for analysis can be useful, but not all the patients can interpret them smoothly without experts' aid.

For communication functions in particular, security and reliability of information are critical issues here. For example, concerning the communication through social media, the major issues come from the authenticity of provided information; some of this information can actually be advertisement disguised as users' comments [30]. Providing false diagnoses or medication to the patients without the practitioners' supervision can lead to multiple high risks. Similarly, advertisement can take advantage of social media to advertise products by giving false comments or recommendations. Keeping Internet groups or forums free from false information and advertisement is still a big challenge within social media for healthcare.

Finally, most of the standard diabetic gadgets are closed-sources, i.e., they do not share their data protocols with third parties. As a result, most of these applications lack the capability to sync data with standard diabetic devices. The diabetic management by itself is a difficult mission; adding extra tasks like the manual data entry to the key mission would not be appealing to some patients. Few diabetic gadgets in the market have started to utilize the powerful environment of smart devices, but it is still very limited and needs more support from specialized organizations and practitioners [31].

In general, most of the efforts focus on how to digitize the long-established diabetic practices. For example, rather than noting the daily blood test results in the patient's diabetic physical diary, the patients can instead write them digitally on their smartphones. Nevertheless, in reality, both methods are requiring the same amount of efforts and time; furthermore, the data on the phone is not being utilized smartly to enhance the patient's daily management. The main point here is that rather than focusing on creating solutions that would only digitize usual practices related to diabetes, it would be more ideal to create smart solutions, which can ease the diabetic tasks or encourage a better compliance. For example, a more practical solution is to provide a way to upload all the data to the phone effortlessly, and then utilize them to provide smart functions or directions, e.g., tagging them with some other diabetic data automatically. There are few diabetic gadgets applied the previous example. An American-based company Telcare Inc developed a new type of cloud-based glucometer [32]. The glucometer utilizes the cellular communication to upload patient's daily blood test automatically to any personal devices through a cloud server. Some other developers created glucometer kits that can be attached to the smartphone itself, and then the phone itself can do all the glucometer functions like any standard devices [33].

III. ASSESSMENT OF INTELLIGENT INSULIN PENS TECHNOLOGY AMONG DIABETIC PATIENTS

This section gives details about the assessment study conducted for the intelligent insulin pens. It highlights the research method first, and then it states all the collected results. Lastly, the section concludes with a brief discussion about the observed results.

A. Assessment Study and Research Method

Qualitative surveys and interviews were conducted through two stages among individuals related to the diabetes mellitus. The first stage was conducted through online communities. This was either by sending them direct emails or by recruiting them through online groups [1]. The second stage was conducted physically through specialized clinics. 25 individuals were recruited through the Ministry of Health Training, Postgraduate Studies and Research Center in Jeddah, Saudi Arabia.

In addition to that, during this stage, oral interviews were conducted as well among practitioners related to diabetes mellitus. The total number of participants in both stages was 101 diabetic individuals, and the number of interviewed practitioners was 5 individuals.

The study was focusing on patients who were using insulin medication as part of their treatment. All the cases that reported using oral medication only have been excluded from this study. The questions were directed toward patients or their caregivers. The questions focused on the following information: patients' general information (i.e., age, gender, use of smart devices, etc.); patients' diabetic information (i.e., period of diagnoses, diabetes types, types of insulin therapy, data management, etc.); patients' Hypo/Hyperglycemia encounter (i.e., number of episodes, possible reasons, etc.).

During the second stage, additional experiments have been conducted: first observing the administration of doses using regular insulin pens, and then observing the patients while using intelligent insulin pens.

In the last two parts of the survey, the questions were focusing on intelligent insulin pens in particular; for example, best features, expected improvement or overall impression. The last part focused on the future direction of intelligent insulin pens; in particular, it concerns the potential in the connectivity between smart devices and intelligent insulin pens. Lastly, interviews with practitioners were concerning the following information: the use of smart devices under diabetes mellitus; the preferred format for patients' records; the overall impression for the intelligent insulin pens; and the overall impression for the connectivity with smart devices. The summary of results and experiments are enlisted below in the next section.

B. Summary of the Assessment Study Results

1) Patients' General Information: As per the groups of age, 32% of the participants were from the young and teenage groups. Participants, who were between the age of 20s and 40s, were about 39%. The remaining participants

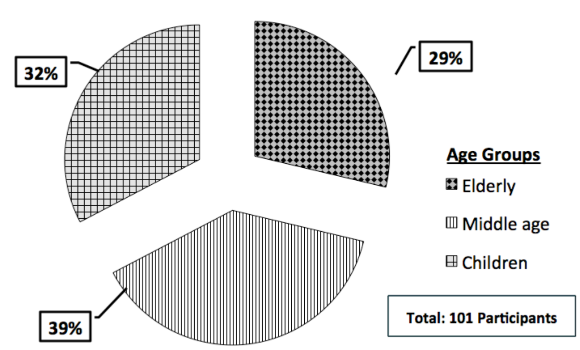

Figure 2. Total number of participants & age groups.

29% were in the age of 50s or above (Figure 2). Female and male participants were about 56% and 44%, respectively. We inquired about the usage of smart devices within daily routines, we found that 81% of the participants were using smart devices regularly, the remaining 19% indicated either non-use of smart devices or use of simple devices only, i.e., landlines and regular cell phones.

2) Patients' Diabetic Information: The majority of participants were from the Type 1 group 66%, while the remaining 34% were from the Type 2 group. Participants, who were diagnosed recently with diabetes, i.e., less than 5 years, were about 25% of the whole group. Participants, who had more than 15 years of diabetic experience, were about 43%. The remaining 32% were having between 5 to 15 years of diabetic experience.

For insulin therapy, participants who indicated using two types of insulin at the same time were about 62% of the whole group. The remaining 38% indicated using one type of insulin only, i.e., long acting in the case of type 2 and fast acting in the case of pump users. Most of the participants 72% reported that they were using insulin pens (and occasionally syringes as well), while syringes only users were about 17%. Participants, who were under insulin pumping, were about 11%.

We inquired the participants about the mistakes during insulin administration, i.e., missing doses, double doses or inaccurate dosage. 24% of participants reported that they were frequently running into some mistakes with their insulin administration, while 39% were sometimes running into some mistakes. The remaining 37% reported that they were rarely running into any mistakes.

For keeping records of diabetic data, 57% of participants were keeping tracks of daily blood tests; 21% of participants were keeping tracks of carbohydrates intake; 44% of participants were keeping tracks of daily insulin doses. 41% of participants indicated that they preferred physical format, i.e., physical dairies, while 37% of them preferred the digital ones. Only 20% of participants reported that they preferred both ways—digital and paper—at the same time. The remaining 2% of participants indicated another preferences other than the two methods, such as the usage of voice memo or self-memory.

We inquired the participants, who were using smart devices regularly, about the usage of smart devices under diabetic management. Only few participants 30% indicated using their smart devices for their diabetic management (Figure 3).

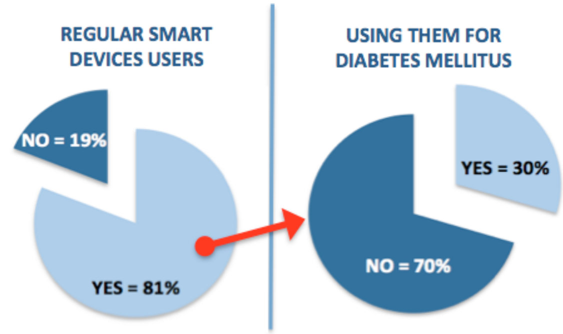

Figure 3. Smart devices users.

3) Patients' Hypo/Hyperglycemia Encounter: 35% of participants reported that they were frequently running into Hypoglycemia episodes every month, while 31% were sometimes running into Hypoglycemia episodes every month. The remaining 34% reported that they were rarely running into any Hypoglycemia episodes every month. 45% of participants reported that they were frequently running into Hyperglycemia episodes every month, while 35% were sometimes running into Hyperglycemia episodes every month. The remaining 20% reported that they were rarely running into Hyperglycemia episodes every month. The likely main reasons for encountering Hypoglycemia were due to: 51% insufficient amount of carbohydrates in meal, 27% excessive activities, 21% over medication or mistakes and only 1% for other reasons, i.e., not from the specified list, such as illness, high insulin sensitivity or oversleeping. On the other hand, the likely main reasons for Hyperglycemia were due to: 62% extra amount of carbohydrates in meal, 16% lack of activities, 12% insufficient amount of insulin or mistakes and 10% indicated other personal reasons, i.e., not from the specified list, such as stress, illness or poor control.

4) Patients' Views about Intelligent Insulin Pens Technology: Latest technologies of intelligent insulin pens were presented to the participants. The presentation was done through two stages. The first stage was done through demonstration and visual aids embedded within the survey materials. The second stage was done through interviews and a couple of usability studies. It was found out that the majority of the participants 80% never heard of or used intelligent insulin pens before this study.

After that, remarkable features available within current models were highlighted within a list, and then the participants were asked to pick the most preferable features, i.e., the ones 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
   (e.g., blockage, dosing countdown and low battery).
3. Syncing data to PC.
4. Precise scale
   (i.e., 0.1 unit scale).
5. Pre-saving time period and dosage amount
   (i.e., automatic dosing adjustment).

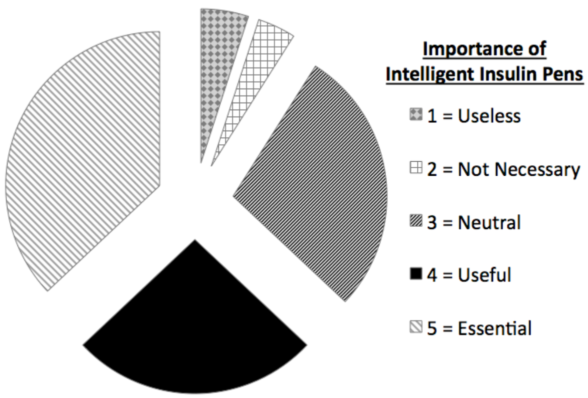

Figure 4. Importance of intelligent insulin pens.

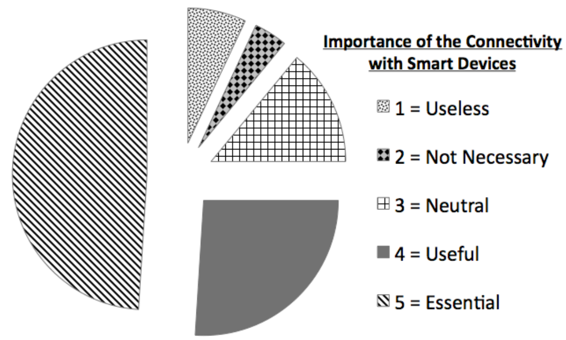

Figure 6. Importance of the connectivity with smart devices.

6. Switching between manual and digital modes (i.e., in case of battery outage).

Following that, the participants were inquired about the expected improvements after using this type of technology. The majority of the participants were expecting to encounter fewer 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 in the rank.

The participants were asked about hindrances that would prevent them from obtaining this type of technology. The top hindrance went to the availability within the local market. High cost came as the second one. Complexity and then compatibility with insulin brands came as the least two reasons.

Finally, the participants were asked to rate the importance of intelligent pens for diabetic management. In the scale of 5 = essential to 1 = useless, 37% of participants thought that intelligent insulin pens would be 5 = essential for them, while 26% could be 4 = useful. On the other hand, 4% of the participants thought it could be 2 = unnecessary, and 5% thought it could be 1 = useless for diabetic management. The remaining groups 28% were 3 = neutral about them (Figure 4).

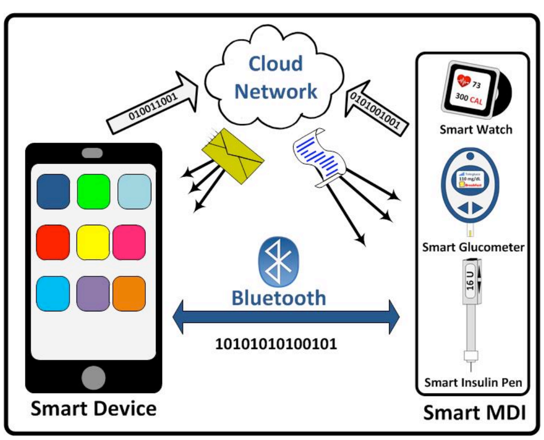

Figure 5. Connectivity with smart devices.

5) Patients' Views about the Connectivity between Intelligent Pens and Smart Devices: In the last section, assuming that intelligent insulin pens and other diabetic devices could have the capability to communicate with smart devices (Figure 5), and at the same time, they could manage to provide the following functions:

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

The participants were asked once again how they would evaluate the importance of using smart devices under this vision. Similarly, in the scale of 5 = essential to 1 = useless, 49% of the participants rated this type of communication as 5 = essential, while 26% rated as 4 = useful. One the other hand, 4% the participants considered this as 2 = unnecessary and 7% as 1 = useless. The remaining 14% were 3 = neutral to the idea (Figure 6).

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

6) Results from the Usability Study: Within the second stage of the interviews and usability study, we added a two extra experimental sessions. The first session was to evaluate the compliance while administering the doses, while the second session was to evaluate the intelligent insulin pens usability. Among the 25 participants 22 of them reported using insulin pens to take their doses. The patients were observed while administering their own doses with insulin pens. The recommended instructions state that the patient should wait few seconds before removing the pen from the body [6]. Among the 22 cases, only 4 cases did not follow the appointed instructions. As for the other patients, they were following the recommended instructions but the waiting time to take out the pen varied from patient to patient.

After that, we gave instructions to all the 25 participants explaining the use of intelligent insulin pens. The model used in this experiment was the intelligent insulin pen manufactured by Diamesco Co., Ltd [12]. Most of the participants managed to use the intelligent pen on their own after repeating the instruction at least once after the first set of instructions. Some of the positive comments that we got from the participants were: the large screen makes the dosing more visible and easier for adjustment; the digital-motor eliminates the need for finger-force; the pen gives countdown before removing the pen from the body.

For the other functions, such as viewing memory data or replacing cartridges, there were some difficulties in mastering them among the participants. The participants needed to follow the instructions multiple times in order to manage these functions on their own. Some of the negative comments that we got regarding the intelligent pens were: the intelligent pen was considered heavier and bulky compared to regular insulin pens. Also, some patients considered the intelligent pen slower in dosing compared to regular ones. This is because the used model forces you to prim the pen before dosing. Some patients believed that the priming step should be optional here rather than being compulsory.

7) Results of the Oral Interview with Diabetic Practitioners: Table II provides the list of participants along with some brief information. Regarding the recommendation of using smart devices under diabetes mellitus, the 1st P.C., 2nd P.C. and 4th P.C. pointed out that they were using smart devices regularly, but they were lacking the experience in finding any application under the local language for their recommendation. The 3rd P.C. pointed out that she was using smart devices regularly and at the same time she was recommending using them for diabetic management; i.e., mainly for dose reminders and monitoring calories through wearable sensors. The 5th P.C. pointed out that he was also using smart devices regularly and was recommending his patients to use smart devices as well. Most of the recommendations were for communication with the primary care, blood test applications and diabetic education as well. Both of them did not point to any specific applications.

TABLE II. PARTICIPANTS OF ORAL INTERVIEWS

Primary Care (P.C.)	Age	Gender	Intelligent pen technology rate	Connectivity with smart devices rate
1st P.C.	30-49	Female	4	5
2nd P.C.	30-49	Female	3	4
3rd P.C.	30-49	Female	5	5
4th P.C.	30-49	Female	5	5
5th P.C.	30-49	Male	3	4
Rating scale of 5 = essential to 1 = useless				

As per the preferred format for patients' records, the 1st P.C. and 2nd P.C. pointed out that they preferred both types of format, i.e., digital and paper, since there were some patients that have limited technical skills. They wanted to keep it flexible for all patients. The 3rd P.C. preferred paper format; she thought that generating digital record was still too difficult for the majority of patients. The 4th P.C. preferred using digital format to avoid any misreading of patient's data due to bad handwriting or any similar issues. The 5th P.C. preferred digital format in order to keep them within his PC as references.

As per the intelligent insulin pens technology, after conducting a couple of experiments, the 1st P.C. chose dosage auditing system and the alarming functions as her best features available within current models. She pointed out that the auditing system would give more background regarding the patient's daily routines, while the alarming system would keep the patient alerted and assure a proper dose administration. The 2nd P.C. thought that the intelligent pen with the current features had limited uses, which might not be useful for all types of patients. The 3rd and 4th P.C. appraised the auditing system and PC data syncing functions. They thought that both features would help them to understand the patient better and keep more references about them. Additionally, they believed that both features would help the patients effectively as they would able to associate the data with their daily routines. In this way, it would reduce the number of encountered Hypo/Hyperglycemia episodes. Moreover, it would prevent missing or duplicating doses. The 5th P.C. thought that the audit system and digital-motor were good features, but he still believed that not all patients would able to use the intelligent pens smoothly without any difficulties. The overall rate of the intelligent insulin pens technology for each P.C. was summarized in Table II.

For the main hindrances that might prevent the patients from obtaining this technology, the 1st P.C. and 2nd P.C. thought that the availability within the local market would be a major concern here; in addition to that, the 1st P.C. thought that the auditing system itself might actually be a possible hindrance for using such a technology. Some patients have the habit of concealing part of their daily information while reporting to their primary care. So using such a device would stop them from keeping up with these habits. The 3rd P.C.

and 5th P.C. listed high prices and complexity—especially among elderly—as the main hindrances for using this technology. The 4th P.C. thought that both high cost and local availability would be the main hindrances for obtaining this instrument.

For the connectivity with the smart devices, the overall rate regarding this capability was summarized in Table II. The 1st P.C. thought that the automated reminder function would be the first choice for her. The 2nd and 5th P.C. thought that the automated data collection feature would be extremely important, as it would ease the mission of collecting patients' data. The 3rd and 4th P.C. thought that providing an interactive interface would allow different types of features, such as easy control, flexible dose adjustment or carbohydrates ratio calculation.

C. *Discussion and Analysis of the Assessment Study*

Overall, the data showed that most of the participants had no experience with the intelligent insulin pens before this study, but the overall ratings of intelligent insulin pens were mostly positive among the participants. Few cases had negative views toward the technology. Most of these cases were patients, who have been under insulin pumps therapy. There were still quite a number of participants, around 28%, who do not mind this technology, but at the same time they cannot see great advantages in its usage. It is still difficult to have an absolute conclusion about the importance of the intelligent pens—as compared to other methods—from this study only.

As per the evaluation of the intelligent pens features, Memory feature was ranked the first in the scoring rank. There were about 63% of participants who reported liability of dosing errors, either frequently or occasionally. So apparently, the memory feature would get the major attention among these participants.

In the second place came the alarming feature. The feature was probably appreciated as it helps to keep the patients alert about battery and insulin cartridge level, and at the same time, it also helps to assure a better dose administration, i.e., because of the automated alarm countdown while administering the dose. It would save the effort of doing the counting manually.

For the precise scale and data transfer both features got a lower rank than the previous two. This was because only certain groups would appreciate these features. Precise scale is certainly critical for those who might have high insulin sensitivity. The case is common among children and athletics. In our data, young participants were about 32% of the group, while people, who picked the excessive exercises as the main reason for Hypoglycemia, were about 27%. Both groups were not dominant in the sample, so certainly precise scale would not get a higher rank than the previous two features.

Similarly, for transferring data to PC, the feature got lower ranks than the other features. The feature itself has the potential to ease the collection of doses records. Nevertheless, the group who reported keeping tracks of daily doses was less than half, about 44%. Many participants among the other groups did not appreciate the importance of doses records collection; so, as a result, the feature of transferring data to PC was less appreciated among these individuals. On the other hand, the feature itself was greatly appreciated by primary cares; it would ease monitoring the adherence of insulin medication among patients.

Pre-saving doses got a lower rank within the list; although the majority of the participants 62% were using two types of insulin, the feature was assumed to get a higher rank and gain more appreciation from the patients. Nevertheless, because some patients make regular adjustment in daily bases for each meal to match the carbohydrates intake, it could be possible that this feature would be meaningless to them. Pre-saved dose function will limit the flexibility of adjustment. Basically, patients will keep re-adjusting all the pre-save doses similar to the regular manners. The feature could be more appreciated if they were for example implemented with some smart features; for example, like including an alarm or warning for not taking the dose during the usual time. Such a feature could be useful for those who would frequently forget to take their meal doses either before or after their meal.

Finally, as per the ability to switch from digital mode to manual mode, this feature would be useful in the case of battery outage; however, with the availability of the alarm feature, it became less meaningful; because it can notify when the battery would reach low level. Moreover, in such a case, the patient can switch to regular insulin pens without the need to switch to the manual mode itself.

The question here now is how important this technology would be for diabetic patients. Most patients saw some promising potentials within this technology, but we need to look deeper into the actual characteristics of the technology itself. The two unique features within the current technologies are the data memory and precise scale. For the use of data memory in particular, if the patient is among the individuals, who regularly encounter dosing mistakes—like one of the 24% of our participants, then this kind of solution can be essential in order to avoid any risks of serious Hypo/Hyperglycemia. Similarly, if the patient is one of the individuals, who have high sensitivity to insulin, this kind of solution will provide a high flexibility of dose scaling. Other than this, both features will be great options for general groups; the patient might not need to use them in regular bases, but in some occasions, they would be handy, i.e., during busy schedules or heavy exercise routines. The large data memory itself might be useful as reference for individuals like primary cares, but for the patients, it would be more useful if they can be associated with other diabetic data to enhance the self-management.

In general, most of the patients were hoping for a fewer number of Hypo/hyperglycemia episodes after using this technology, but at the same time, in the data, participants indicated that the most likable reason for these episodes was due to inaccurate carbohydrates intake. Encountering these episodes because of mistakes came as the least reason among the other ones. Unfortunately, there is no feature available within current models, which can give precise carbohydrate intake values, i.e., like the one available within pumps. From the hindrance side, participants and primary cares indicated that the availability within local market and high prices would be the two likely reasons for passing on this technology. Unluckily, current models are still suffering from one of these two issues or both. For high cost in particular, high cost can be a hindrance, but if the solution could justify its effectiveness, patient might pass on costs for the favor of ideal performance. This case can actually be observed among the users of insulin pumps. Although pumps are well known for their high costs, they are still a popular solution among Type1 patients, especially in United States. This is because pumps have been known for their remarkable performance and convenient management [34].

During our usability study, complexity as well got some attention also among some participants and primary cares. Intelligent pens were noted for being a little complicated than regular insulin pens, however, mastering them is still not hard as the insulin pumps. The complexity in our data could not get a higher value because most of the participants were from the middle-aged groups. If most of the participants were from the elderly groups, we might see a higher value for complexity as a hindrance.

We can conclude here that current solutions of intelligent pens can be essential for certain groups of patients, but for the general, it is a good option if the patient could justify their needs over the existing hindrances.

IV. CONNECTIVITY OF SMART DEVICES AND INTELLIGENT INSULIN PENS

In our last section of our survey questions, which was related to the connectivity with smart devices, we saw some changes within the evaluation of intelligent insulin pens under the proposed vision. We could see some evident movement from the neutral group side to the positive group side. There were some other movements from the neutral sides to the negative sides but they were only few, especially among users who do not use smart devices regularly. We inquired the patients to pick the most desirable feature among the proposed list in order to locate the start point of our pilot studies. Since the patients were more concerned about creating solution that would remind them automatically about their own doses, we decided to conduct a series of experiments under this vision. The main objective is to test their usability and effectiveness on the regular management.

This section gives some details regarding a series of pilot studies, which were conducted to test the feasibility and usability of connecting intelligent insulin pens technology with smart devices. The section first gives some background about the current smart technology and their capabilities, and then it states some details about the proposed system used for this study. After that, the section highlights the experiment details, and then it lists all the observed results. Lastly, the section concludes with a brief discussion and analysis about the obtained results.

A. The Role of Ubiquitous Technologies in Enhancing the Intelligent Insulin Pens

The intelligent insulin pens showed some potential in providing a couple of helpful features for insulin delivery; however, the technology still needs more improvement to make them highly effective for the majority of diabetic patients. The issue is that this improvement could lead to some major concerns, such as additional manufacturing cost or complicated user interface. Intelligent insulin pens have already a huge difference in their prices compared to regular insulin pens. Moreover, mastering its use is not straightforward as regular insulin pens; it requires some time to fully adopt the user interface and handle all the functions. This means adding more features within the unit in the future, such as carbohydrates calculators or smart reminders functions, would raise the cost of each unit, and it could complicate the interface even further.

Alternatively, rather than adding extra processing modules within the unit itself, we can focus on the connectivity with ubiquitous technologies, such as smart devices and cloud computing. As it was stated before, smart devices are remarkable for their powerful processing capability and simple user interface. They can act as an extension unit for intelligent insulin pens to do some sophisticated tasks such as automated reminder function or automated dose adjustment.

In addition to that, technologies such as cloud computing can play a major role in this type of extension. Exchange of data and commands could effortlessly be managed between the two technologies through the cloud communication. Multiple sectors, e.g., communication, gaming, e-commerce, etc., are already utilizing the cloud computing technology within their practices; yet, the healthcare sector is still a little bit slow in following the same example [35]. The reasons could go back to the differences between regulations in handling healthcare data [36], or the risks associated with the multiple threats surrounding the cloud technology [37]. Nevertheless, we cannot ignore how helpful the cloud computing have become in handling our daily data. Luckily, experts are aware of this potential and they are trying multiple ways to overcome the risks associated with the healthcare data [38].

B. The Proposed Reminder System

General recommendations state that the patient should associate medication time with daily routines, e.g., bedtime or mealtime; however, additional recommendations suggest using reminder systems to back up daily routines; the reason is that daily routines are liable to changes or alteration. Studies found out that smart devices are the most common way among patients to remind themselves about their own medication [39], and several other studies proved that the use of smart devices managed to improve the adherence among patients [40][41].

Nevertheless, most of the results from these studies were relying on patients' self-reporting. Unfortunately, it was found that self-reporting were liable to alteration and human-errors [42]. For this reason, it would be better to create smart

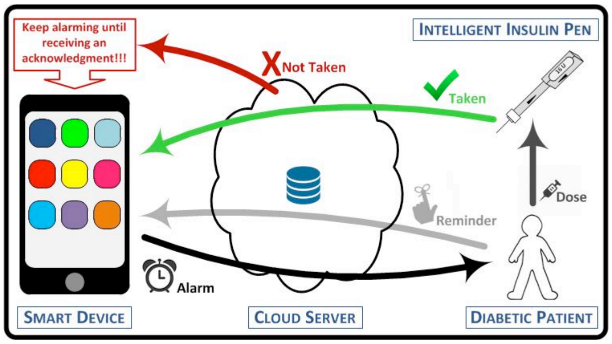

Figure 7. Cloud-based reminder system.

solutions that can automatically keep tracks of dose administration.

There are some examples from several conducted studies concerning the previous point. One study applied the gamification concept to keep tracks of the medication and adherence level [43]. In this study, the patients competed with each other through social media to maintain the highest rank of adherence level among the group members. Other studies used wearable computing to keep tracks of medication routines [44].

Following the same directions, we proposed a smart cloud-based reminder system using smart devices and intelligent insulin pens. With the proposed system, we conducted a couple of pilot studies to test the usability of the system and its potential among diabetic patients.

The suggested system (Figure 7) is similar to some cloud-based reminders system available within current generation of smart devices, i.e., Apple®'s iPhone or Android based devices. In these devices, as soon as the user would set a reminder, it would be activated automatically in all the devices associated with the user's account through the cloud services; similarly, the user can deactivate, i.e., check the reminder, from any device available in hands at that moment.

We would like to apply the same concept for doses reminder; however, rather than allowing the patients to deactivate the reminder alarm manually, the device should automatically check the collected records within the intelligent pens 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 the patient until it would make sure that the patient has taken the required dose.

This system would be specifically useful for the daily basal type of doses, i.e., background insulin doses such Glargine or Detemir.

This type of doses requires to be taken within a fixed period of time, i.e., 12 or 24 hours, in order to assure a better glycemic control [45]. Applying this type of systems can encourage the patient to adopt a better compliance to the diabetic management and, consequently, the patient would keep maintaining a high level of adherence to the medication.

C. The Pilot Studies and Research Method

Three usability studies were conducted with 13 participants in total; each one of this study lasted 3 weeks. The first two experiments were part of another study [46]. Additional study was conducted and analyzed for this research. Table III summarizes the information concerning the participants.

All the patients were using Insulin Glargine as part of their medication. Three individuals withdrew in the middle of the study due to a couple of reasons, i.e., busy schedule or technical difficulties, while the remaining ten participants continued till the end of the studies. The experiments in the studies were split into two phases.

The first phase of the experiment lasted 10 days. It focused on the interaction of patients with the intelligent insulin pens and measuring the patients' adherence level.

The second phase of the experiment also lasted 10 days; however, this time the focus was on the interaction between the patients and the proposed cloud-based reminder system. The adherence level was measured here as well to oversee the influence of the system on this data.

For the first phase, the patient was asked to follow the same usual routines for taking the basal dose using the intelligent pens. For the second phase, the patient had to use the proposed reminder installed within the personal smart device. The patient was directed to take the medication every day on the same determined time. The patient was allowed to take the medication within 30 minutes earlier or 30 minutes later from the appointed time. Basically, the system will check the data within the intelligent insulin pen. If the required dose was taken, the reminder would automatically be deactivated, and then a confirmation message would be sent to the patient. If the administration of the dose could not be confirmed, snooze would be activated for every 10 minutes. The snooze would be kept activated until either the

TABLE III. LIST OF PARTICIPANTS

ID	Gender	Usage of Smart Devices	Age	Study Completion
P1	Male	High	21-39	YES
P2	Male	Low	60-75	YES
P3	Male	High	40-59	YES
P4	Female	Average	40-59	YES
P5	Female	High	40-59	YES
P6	Male	Low	60-75	YES
P7	Female	Average	40-59	YES
P8	Male	Low	60-75	YES
P9	Female	Low	60-75	YES
P10	Male	High	40-59	YES
P11	Female	Average	21-39	NO
P12	Female	Low	40-59	NO
P13	Male	Low	40-59	NO

confirmation or until a period of 30 minutes from the first alarm. After that, a message would be sent to the patients stating that "the dose was not administered within the appointed time and it should be administered as soon as seeing this message".

The system was partially based on the Wizard of Oz prototyping concept [47], but from the patients' side the system actions were fully automated. The main tools used for this experiment were:

1. 4 x intelligent insulin pens.
2. 4x portable laptops with pre-installed diabetic management software.
3. Smart reminders with cloud feature installed in the patient's personal devices.

The level of adherence was measured based on SANOFI's directions for their insulin Glargine [48], i.e., "once a day" and "within 24-hour". If the patient managed to take the dose within the assigned period, a full score would be given. If the patient administered the dose outside the assigned time, a half score would be given. If the patient did administer the dose during that day, no score would be given.

We conducted another measurement to evaluate the speed of response to the issued alarms. Table IV summarizes the scoring method for the response speed. After that, one day was dedicated to collect participants' feedback for both phases.

D. Summary of the Pilot Studies Results

1) Scoring Data: Figure 8 summarizes the results of the adherence level before and after applying the cloud-based reminder system, while Figure 9 summarizes the scores for the response speed to the alarm system. For the level of adherence, most of the patients had either the same level of adherence or slightly better after applying the system, while four cases showed notable differences within the measured level, especially for the second and third participants.

For the response speed level, the results of the cases showed that most of the participants were likely respond the second alarm. This means that this group might require a medium level of alarming, i.e., at least two to three snoozing alarms. Three cases showed an immediate response to the alarming system, which means this group might require a low level of alarming, i.e., maximum two snoozing alarms. Two cases only showed a low level of response speed to the alarming system, which means they might need more than three alarms in order to administer their medication on time.

2) Patients' Feedback: Most of the participants had positive views toward the systems. The participants' opinions have been grouped according to their reminding behavior before using the system.

For those who used to have a regular reminder system, like remainder apps or devices, they considered the system as an upgrade to the usual reminders. This was because the

TABLE IV. RESPONSE SPEED SCORES

Scores	Period of time	Patient's Awareness
5	Before the time	Mostly responded before the 1st alarm
4	On time	Mostly responded to the 1st alarm
3	10 minutes passed	Mostly responded to the 2nd alarm
2	20 minutes passed	Mostly responded to the 3rd alarm
1	30 minutes passed Or more than 30 minutes earlier	Mostly responded to the last alarm or miscalculated the assigned time
0	Dose not taken	

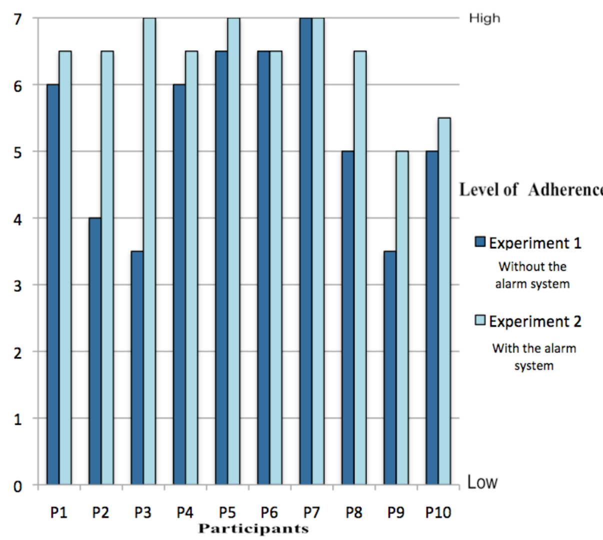

Figure 8. Level of adherence results.

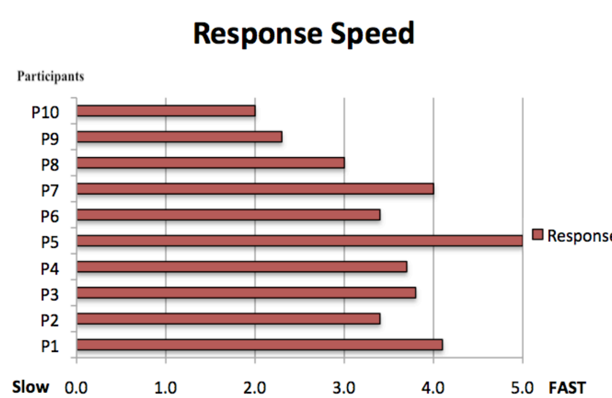

Figure 9. Response speed results.

system could automate the snoozing function and post-acknowledgment for the doses.

For those who were associating their dose time with daily habits, they reported that the system was as good backup for the daily habits. They felt that the system is more reliable because daily habits were liable to changes or alteration.

For those who were not following any of the previous two methods, they felt that the system helped a lot to maintain the dose time, especially under busy schedule routines.

The ability to run the system on multiple devices was apprised a lot. When one device would be down for any reason, the second one will act as a backup.

Few cases showed less appreciation to the system. The main reason could be that their use of smart devices was limited to basic functions only, i.e., calling or messaging only. The most notable negative feedback was the inability to customize the alarming system. The sound level and type of tunes were limited in the systems, this sometimes caused some inconvenient for the participants; it caused missing at least the first alarm in a couple of cases.

The other negative view was the Internet communication dependency. Since the system relies heavily on the cloud servers, it requires keeping the devices connected to the Internet all the time. Sometimes it is hard to maintain this condition due to communication lost or weak signals.

The patients were inquired about the main reasons for not administering the dose on time while using the system. Some cases reported that they were receiving the alarms but they could not take the dose on time because they left their digital pens at home or office. Another cases were due to heavy sleeping; some participants missed the alarm while sleeping because the sound was not loud enough to wake them up. Another reason was due to the engagement of certain activities that prevented them from being excused to take their own doses on the appointed time, i.e., being in a meeting or giving some lectures.

E. Discussion and Analysis for the Pilot Studies

The pilot studies were divided into two phases of pilot studies. The first phase was focusing on observing patients' regular routines, while in the second phase, patients were asked to rely on the proposed reminder system for managing the doses time; the proposed reminder system here acted as an extension feature for the intelligent insulin pens. The purpose was to see the influence of the applied reminder system on the patients' compliance.

After evaluating the obtained results for adherence, we found that participants, who were using regular reminder systems or daily routines to remind themselves about the doses, had some advantage from the system. First, the participants managed to maintain the same high adherence level in the second experiment without any extra effort, i.e., no need to adjust the reminder manually. Second, the system was more reliable because all the confirmation and snoozing processes were done automatically without any external alteration. This system among these types of patients could act as a good support for the regular daily routines.

For the participants, who were not following any methods to remind themselves about their own doses, benefited more from the proposed reminder system. Even under busy schedule, participants achieved to maintain a better management for their own doses. This kind of system could help this type of patients to sustain a better compliance toward the medication directions.

As per the second measurement related to the alarm response. The response speed results showed that this kind of system should offer some customization level personalized for each user. For example, people, who have limited uses of smart devises, might need to be reminded more frequently than regular cases; similarly, heavy sleeper might need a louder or more noticeable notification to wake them up.

As per the patients' feedback in using the system, the use of intelligent insulin pens along with this kind of reminder system was greatly appreciated among most of the participants. Also, since this system is utilizing cloud services, it can be available within multiple numbers of personal devices. This would make the system more portable and convenient for use.

Some cases, especially among participants with limited technical knowledge, had less appreciation to the whole system, which combines intelligent insulin pens and the proposed reminder system. The reasons could go back to the limited uses of smart devices or to the hindrances available within intelligent insulin pens technology itself.

For a final word about future development within this types of researches, For systems that are similar to the proposed reminder system within this research, these kinds of systems rely heavily on using an advanced type of devices, which can record and exchange data among other devises. The exchange of data should be done in an intuitive way, which do not require the user's involvement, such the communication through cloud computing. In our proposed system, unfortunately, current model of intelligent insulin pens do not have the capability to achieve the previous function, which allows exchanging the doses data with other devices automatically. The study relied on other methods, such as the Wizard of Oz, in order to the give intuition of automated data exchange to the participants within this study. Future development of intelligent insulin pens might need to focus on how to make the data exchange smoother and intuitive for the users, such as the utilization of cloud communication.

On the other hand, among the feedback in this study, some of the participants showed some concerns toward the use of intelligent pens technology itself, such as large size or complicated user interface. Such hindrances would directly affect the overall convenience of the whole system. In this study, the system relies heavily on using intelligent insulin pens for data collection. Nevertheless, if the intelligent insulin pens are not user friendly enough, then the user will not able to utilize useful functions such as the reminder system. In the future, when creating new solutions, developers should try to retain some of the convenience originated within former solutions, for example, in our particular case, regular insulin pens are being noted for their lightweight design, which ease carrying them around, while on the other hand, the design of intelligent insulin pens is considered bulky compared to regular insulin pens. It could be difficult to find a good balance between enhancement and convenience, but the main objective is how to make a new introduced solution more appealing among the users. At the end, the ability to use the technology without difficulties will contribute in simplifying the diabetic management itself.

V. CONCLUSION AND FUTURE WORK

In general, technology has had a significant role in enhancing the insulin therapy. This was noted evidently within the evolution of insulin pump therapy. For MDI, before the arrival of intelligent insulin pens technology, the use of technology was limited to a couple of diabetic gadgets such glucometer and smartphones. The advent of intelligent insulin pens technology could be a promising evolution toward a smart MDI management system. Nevertheless, in order to examine the intelligent insulin pens necessity among diabetic patients, a couple of assessment studies were conducted among insulin dependent individuals.

The assessment studies included a couple of question related to the diabetic management and evaluation of the intelligent insulin pens technology. The study required a group of diabetic patients, who were mainly relying on insulin as part of their diabetic treatment. . The recruitment for participants was done initially through online communities, and then physically through diabetic clinics at alter stage.. The outcome of the study found that the patients in general had positive opinions toward the technology itself. The memory function was the most favorable feature among the other ones. The patients were still longing for more features and upgrades from these kinds of technology of intelligent insulin pens.

Judging on the outcomes, we found that the technology in its current shape could be essential for certain diabetic groups, but for the general insulin dependent patients, the technology could be a better alternative if the patient could justify the needs and overlook its current hindrances. In order to make the technology more functional for general diabetic group, more functions should be made to enhance the diabetic management itself.

Nevertheless, approaching such a goal might have a negative impact on the cost and complexity of the technology itself. Alternatively, we suggest focusing on the connectivity between this technology and ubiquitous technologies, such as smart devices and cloud computing. To demonstrate this point, a couple of pilot studies were conducted based on the outcomes of the assessment study.

The pilot studies included a Wizard of Oz prototype system tested among insulin dependent patients. The suggested system was a smart reminder system, which utilizes a couple of technologies like intelligent insulin pens, smart devices and cloud communication. The outcomes of the study were mostly positive among the patients. It is believed that the proposed system could be a good support for the daily diabetic management, and it would help to promote a better compliance toward the insulin medication. A couple of negative outcomes were observed, which were likely related to the limited uses of technologies. The main goal is to simplify the management of diabetes mellitus itself. For this reason, future developments should focus in how to keep new technologies user-friendly as much as possible. Failing to maintain this might affect negatively on the usage of these introduced technologies, and it would complicate the diabetic management even further.

Finally, there were a couple of limitations within this study. First, the sample size of the participated patients was relatively small. Results from this study cannot be representative. If we need to have an absolute conclusion about the intelligent insulin pens technology evaluation, we need to collect a large sample size that would be enough for statistical type of studies. Moreover, the conducted usability testes were short period studies, which were enough to observe the overall impression and collect limited information. Longer period studies can inspect more on the positive and negative outcomes of using the technology, and it can oversee the influence on the glycemic control. Similarly, for the smart reminder system pilot studies, the system was based on the Wizard of Oz prototyping, which was enough to collect some impression about the function itself and observe the interaction with the system.

Future studies should implement a full working prototype for a longer period of study. The goal is to find more about the positive and negative impacts while using the system, and once again, to observe the influence on glycemic control. These kinds of long-term studies require at least three months of continuous experiments and direct supervision from diabetic practitioners. We hope by investing in these studies, we would able to provide a contribution toward simplifying the complexity of diabetic management.

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