Remote Accessibility to Diabetes Management and Therapy in Operational healthcare Networks.

REACTION (FP7 248590)

D9-1 REACTION services in social and cultural contexts

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Abstract	This deliverable contains an analysis performed in different EU countries and thus different social and cultural contexts about the potential services required to the REACTION platform including their main characteristics and the main differences between different countries and user groups.
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1.0	A. Kouroubali	2011-09-02	Finalized answering the reviewers' comments
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1. Executive Summary

Focus groups were conducted in four different countries to explore, needs, opinions and concerns of people involved with diabetes about new technologies and diabetes care. Analysis reveals that management of diabetes is similar across countries; however, significant differences exist in the national health system support of people with diabetes. Differences also occur based on the cultural background of people with diabetes.

Participants in general welcomed technology services for supporting diabetes self management and thought it would improve their quality of life, resulting in fewer complications. New technologies would need to be coupled with appropriate education and adjustment period to ensure appropriate and frequent use of Information and Communication Technology (ICT) capabilities.

The deliverable presents the work conducted for T9.2 Social Issues and presents in detail the organization, results, analysis and conclusions of the focus groups.

2. Terms and Definition

In the deliverable the following abbreviations are used. They are presented in alphabetical order:

C: Carer (informal such as family member)

CGM: Continuous glucose monitoring

CY: Cyprus

D: Doctor

Diabeo: Telemedicine solution shared between the diabetic patient and the treating team developed in France. It includes a mobile self-monitoring application for the daily treatment of diabetes and a web care management application shared between the patient and the diabetes team.

DT: Dietician

EHR: Electronic health record

ECG: Electrocardiograph

FR: France

FORTH-ICS: Foundation for Research and Technology-Hellas

GP: General practitioner

GR: Greece

IT: Information technologies

ICT: Information and communication technologies

N: Nurse

P: Person with diabetes

3. Introduction

3.1 Purpose, Context and Scope of This Deliverable

The purpose of this deliverable is to present the work performed for T9.2 Social Issues involving the organization of four focus groups in four different European countries, Greece, Italy, France and Cyprus. The main objective of the focus groups was to understand the relevant personal, social and cultural factors related to diabetes management and the REACTION services. The deliverable presents the methodology, results, and analysis of the focus groups in order to explore the potential impact of Reaction services beyond the boundaries of the project. The deliverable aims to make suggestions about potential features of the REACTION platform to comply with participants views and opinions.

The deliverable is based on the following context: Information and communication technologies have the potential to change health care as well as life style for people with chronic conditions. These changes are occurring concurrently and need to be considered for appropriate design of sensor-enhanced health information systems. Basic functionalities of technology services include emergency detection and alarm, disease management, health status feedback and advice as well as social and psychological support. These functionalities are combined differently based on individual conditions as well as individual needs of chronic patients and their carers.

3.2 Target Audience

The target audience of this deliverable is all REACTION partners and particularly the technical partners that will have to design appropriate technical solutions to address the requirements elicited. Clinical partners are also an important audience to identify similar views and opinions in the target user groups for clinical trials.

3.3 Outline

The remaining document is structured as follows:

The section “Methodology” describes the methodology and process used to organize and execute the focus groups, as well as the methodology used to collect and analyze the data.

In the section “Results”, the responses in the form of discussions are presented as they took place during the focus groups. The answers are presented for each question and per country. The respondents are anonymised, and are only depicted by their roles.

The section “Analysis” presents a summary of the answers for each question in the form of requirements or characteristics that participants would like to have in the system. Relevant quotes from the discussions are presented.

The section “Conclusions” gives a brief outline of the answers for each one of the themes discussed in the focus groups in the context of diabetes studies.

Finally, the section “Annexes” presents the materials used for the organization of the focus groups.

4. Methodology

4.1 Data collection and analysis

A series of four focus groups were organized in four different European countries between November 2010 and May 2011. The focus groups aimed to bring together the potential users of the REACTION platform and identify opinions, ideas, concerns, issues about using advanced technologies for diabetes management. The results of the focus groups were collected, analysed, and presented to provide the REACTION consortium with general opinions and ideas of diabetes management and new technologies in 4 European countries.

The focus groups with their title, country, location, date, time, and participant roles are listed in the following Table 1. The organizers had the posibility to decide the title for the focus group. This is why in Italy the title is different to the other ones. However, the questions discussed were the same across focus groups.

Table 1: List of the 4 focus groups.

Focus Group title	Country	Date & Time	Location	Participants
#1 Technologies for Diabetes Management	Greece	19/11/2010 10:00-13:00	IPPOKRATIO General Hospital of Thessaloniki 2nd Propedeutic Dpt of Internal Medicine 49 Konstantinoupoleos St.	2 doctors, 2 nurses, 2 patients, 1 carer (lawyer) 2 representatives of FORTH-ICS
#2 Advanced technologies for the support of long-term management of insulin-dependent diabetic patients	Italy	29/11/2010 14:30 to 18:30	Diabetes Agency, Careggi Teaching Hospital Via delle Oblate, 4, 50141 Florence	3 doctors, 2 patients, 1 dietician 2 representatives of FORTH-ICS
#3 Technologies for Diabetes Management	Cyprus	26/5/2011 17:30-20:30	Health Centre “Apostolos Loukas” 22 Ilia Papakyriakou St., Egkomi, Nicosia	3 doctors, 2 patients, 1 nurse, 2 carers 2 representatives of FORTH-ICS
#4 Technologies for Diabetes Management	France	30/5/2011 10:00-13:00	Centre Hospitalier Sud Francilien site Gilles de Corbeil, 59 Bd Henri Dunant - 91100 Corbeil-Essonnes	2 doctors, 2 patients, 1 nurse, 1 social scientist 2 representatives of FORTH-ICS

The main objective of the focus groups was to understand the relevant personal, social and cultural factors related to diabetes management and the REACTION services. The aim of the focus groups was to understand what diabetic patients, nurses, doctors as well as other healthcare professionals and informal carers expect from technology, in addition to identifying values, beliefs, hopes, concerns and needs related to the use of tele-monitoring services. Focus groups also highlight how the use of information technology could potentially change the experience of living with diabetes. Understanding societal factors is a core prerequisite for addressing ethical and social issues at the design stage of technology development. In order to explore the potential impact of Reaction services beyond the boundaries of the project, focus groups were organized in European countries that do not participate in the clinical trials foreseen in the project. They took place in Greece, Italy, Cyprus and France with a range of participants including doctors, nurses, social scientists, technical personnel, patients, carers, dieticians and lawyers. Each focus group included 6-8 participants. The representatives of FORTH-ICS were one social scientist and one technical person present in all focus groups. In one focus group, an informal carer was also a lawyer.

The questions that guided the discussions focused on several issues including information and risk management of diabetes, security privacy and confidentiality issues, quality of living, monitoring and alert systems, device and sensors design, technical skills, daily activities, concerns and suggestions. The questions were derived with the involvement of the consortium members. An email was sent to REACTION partners asking for 5-20 requirements to be discussed in the focus groups. All contributions were collected and analyzed. The questions were formulated to address the following topics:

- information,
- health management,
- devices,
- general usability and usefulness,
- privacy safety and trust,
- trust in the infrastructure,
- trust in transaction partners,
- cost.

The discussions during the focus groups were informal, encouraging all participants to express their opinion and relate their experiences with diabetes care. Moderators of the focus groups were the two representatives of FORTH-ICS. The same for all focus groups. The moderators of the focus groups guided the discussions and kept extensive notes as participants were expressing their opinions. Recording devices were not used and answers have not been attributed to specific participants. This choice was made to encourage participants to voice their opinion knowing that their answers will be anonymous (Miles and Huberman 1994). All focus groups were announced to the consortium and participation of other partners was open. However, the people of FORTH-ICS were the only participants from the REACTION consortium.

Both moderators kept notes as participants were talking. To ensure the quality of data collection, after each focus group, moderators went through their notes and cross checked them for accuracy and completeness. Participants were enrolled as volunteers without money compensation. Hence, it was not possible to involve them further. In addition, moderators analyzed their personal impressions of the discussions which were used for analyzing the data.

Focus group data was analyzed and various themes were identified across European countries. Data analysis was performed using the methodologies for qualitative data analysis as described by Miles and Huberman (1994). Data was interpreted by the moderators identifying various themes from the raw data. Raw data grouped per country and per question are presented in this deliverable in order to allow further analysis in case of need.Based on the analysis, suggestions are made that could inform the iterative design process of REACTION services.

The results section presents the discussions that occurred during the focus groups. Discussions are attributed to each question and presented per country. Some of the questions were not specifically asked because free discussion had already covered the topics. The time allocated for each focus group, the flow of the discussions and the interests of the participants determined the extent of answers of each question. Some questions have not been explicitly discussed in the focus groups, however, they have been implicitly covered by the general discussion. This is the reason why, some questions are missing answers from some countries.

4.2 Bias

The recruitement of people with diabetes introduced a bias to the sample of informants. The people selected were opinionated, talkative and spoke english. Selection was based on the personal contacts of the doctor. Generally, the people selected were aware and active about managing their condition. The group of people who are in denial about their condition, who are not actively managing diabetes, who are elderly or have serious comorbidities did not participate in the focus group, introducing the bias of opinions and issues restricted to a small sample of the general diabetic population, and probably not representative of the group that is in highest need to advanced technologies for diabetic management. Also, there was a selection bias in terms of the countries selected to organize the focus groups. However, this was due to money and time constrains. Focus groups were based on volunteering by people outside of the REACTION project, to avoid interconsortium bias. In addition, the recruitment of focus group organizers was based on personal contacts of the moderators. Moderators contacted organizations in several countries including United Kingdom, Serbia, Czech Republic, Poland, Hungary, Denmark, Spain and Belgium. These focus groups intended to give a general idea about how people involved with diabetes managements approach new technologies. Also, focus groups intended to extend the view about new technologies beyond the boundaries of the REACTION consortium. The focus groups did not in any way intend to be an extensive social analysis of diabetes management in Europ, as this would have been beyond the scope of the project's budget, time and resources.

Other biases may include reporting and translation bias. However, the cross check of collected data between the two moderators has contributed to minimize this bias.

4.3 Organization of the Focus Groups

The first step for the organization of the focus groups was to identify a doctor who would be willing to recruite participants and organize the focus group. The doctor was the contact person and all communications with participants prior to the day of the focus group were done through him/her. The contact person had the following tasks:

- organize the space where the focus group will take place (a room to fit 10 people with a projector)
- select the participants (they have to be people who are not afraid to speak and like to be involved)
- distribute the background material which includes also an invitation and an acceptance letter
- collect the signed acceptance letters
- suggest a place to order the coffee break, and to have lunch/dinner

The day of the focus group, all participants were given a folder with a notebook and pen, project leaflet, maps and dvd about Crete and a Phaestos disc as a souvenir. A brief presentation was made introducing REACTION, explaining the vision, objectives, methodology, focus, trials, architecture, etc. Then, the objectives and methodology of the focus group was presented completing the introductory session. Subsequently, all participants introduced themselves and the informal discussion started stimulated by the questions. During the coffee break, moderators reviewed the answers of the participants to check which topics have been covered so far in the discussions and which topics and questions remained to be discussed until the end of the focus group (assigning priorities).

All participants provided their contact information to receive the newsletter of the project.

During the focus group there was a coffee break, and after a lunch or dinner was offered to the participants which provided the opportunity to socialize and get to know each other further. After each focus group a thank you letter was sent to all participants.

4.4 Questions

In strict collaboration with all the consortium partners the following list of questions was prepared as a base for the moderated discussion at each focus group.

Questions about **information** aimed to identify the mental models physicians and people with diabetes use to manage the disease. Questions focused on the parameters that should be monitored and the data collected by the system, and also the data that people feel comfortable collecting and analyzing.

The questions about **health management** explored the use of alarm systems, changes due to the introduction of technology and risk management. Questions about **devices** discussed the design, functionality and wearability based on user opinions and previous experience with sensors and insulin pumps. The questions that explored **usability and usefulness** addressed the overall view of users for the Reaction platform in daily practice. Questions about **confidentiality, privacy and trust** explored user opinions about sharing of personal data over the internet, their view about data privacy and data use for research purposes. Finally, the **cost** models related to diabetes in various countries was discussed and the willingness to pay in order to have the Reaction services. The actual questions are presented in a separate section of this deliverable.

1. Information

1.1 What are your mental model and/or information loop and rules for decision making and disease management and how would you like it to be supported by the system?

1.2 Which parameters should the system monitor, collect or give back as feedback (vital signs, comorbidities, clinical history, etc.)? In what frequency? Who will use this data and how (target users)?

1.3 How would you feel if clinicians consider that other parameters (blood pressure, pulse, temperature, ECG, weight etc.) would have to be measured? How do patients / carers feel about collecting and sending such data?

1.4 Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake). Even considering the benefits, is it realistic to expect patients to be willing to constantly enter information about activities, food consumption etc.? What information and to which detail is it feasible to be entered into the system?

1.5 Nutrition has to be taken into account in the calculation of the drug dosage. Which kind of information about nutrition do you think it will be feasible and reasonable to collect consistently? Are patients willing to insert exactly the information about their nutrition?

1.6 Education **(a new theme that was raised in the discussions)**

2 Health Management

2.1 What do you think/feel about using an alarm management system? How do you think it will facilitate your daily practice or crisis management?

2.2 Will a telemonitoring system change the current care model? Will the system be able to provide a better visit management (e.g. only when really necessary)? Will patients and doctors have enough time to dedicate to this more frequent data collection, analysis and feedback? (Should disease management plan, risk management plan and lifestyle plan be part of the personalized care plan?)

2.3 Organizing the risk as short term, midterm, long term which kind of risks would you like to insert in each category?

3 Devices

3.1 How do you feel/think about wearing a system that will take measures from you and send them to your doctor/family? Which would be your maximum acceptable size for such a system? Weight? Dimensions? Other criteria.

3.2 Would a mobile device be useful for you? Which kind of device is more conformable/usable for you in your daily practice?

3.3 How would you feel about ePatch technology? (Intrusive, unsafe, etc.)

4 General Usability, Usefulness

4.1 How do you think/feel about having a system like REACTION as part of your daily practice?

4.2 Do you think our system is useful? Which could be the most critical factors and concerns for using it? (price, wearability etc)

4.3 What minimum technical skills should it require? Do you think the use of modern technology is complicated? How important is that the application is available in your language?

5 Privacy Safety and Trust

5.1 The use of the system will be enabled after the patient will sign an informed consent. Do you think this is enough? Or would you like to have the possibility to give permission for each specific action? Such as transfer, access and processing of your medical data? Do you think it is necessary/important to you that you can see which doctor/nurse/person had a look at your health data?

5.2 Would you be comfortable knowing that glucose values out of range will be sent to your doctor, formal or informal carer? Would you like to have control on what information and when it is sent? Would it make a difference if the values indicated a life-threatening situation?

5.3 Which is your perception about your own physical safety while wearing the device?

5.4 Are there any factors that could make you to have more trust in our system? Is there anything you may want to see in order to trust more in our system?

6 Trust in the infrastructure

6.1 Would you trust an Internet platform with your medical data such that doctors can access them? If the application provides information about the infrastructure risks and the measures taken to minimise these risks, will that increase your trust and acceptance of the platform?

6.2 Question for medical personnel: Do you think that the patients rule over their medical data stored on the REACTION platform (e.g., revoking a doctor's right to access certain data) would negatively impact your work? If yes, what problems do you see and do you see a way out of the problems without wholly taking away patients' rights?

7 Trust in transaction partners

7.1 If the application provides information about the way personal data is handled by the receiving parties and the arrangements the application offers to prevent or deal with privacy breaches, would that increase your trust and acceptance of the platform?

7.2 Would you like to anonymising/pseudonymising technology? Do you think it will have negative effects on the mutual trust between users and service providers?

8 Cost

8.1 How would you like the service to be covered by the insurance companies? Would patients like to pay for the service/devices (if yes, how much)? How doctors should be reimbursed for providing this service?

5. Results

5.1 Discussions per Country and per Participants

This section presents the discussions of the focus groups for each question. The discussions are presented per country and are anonymous. The following abbreviations have been used to identify the role of participants: D: Doctor, P: person with diabetes, N: nurse, C: carer, DT: dietician. Discussions in Greece and Cyprus have been translated to English by the moderators.

Statements presented below were written while participants were talking. They represent an oral discussion which, when put in paper, is ripped off all the signals and additional phrases present in a discussion. Answers are almost verbatim. Verbatim is only possible with transcription of recorded discussions, which is not the case with these focus groups (see methodology). Focus group discussions sometimes covered several issues at the same time. Discussions have broken down and presented for each question per country.

1 Information

1.1 What are your mental model and/or information loop and rules for decision making and disease management and how would you like it to be supported by the system?

GREECE

D: Each day is different for people with diabetes. There are guidelines and values for different population groups. Also, each person is a unique case. So there is a different target for each patient based also at their age. The gold standard is to have frequent measurements of glucose. 10 measurements per day are not enough to see how the glucose changes but provide us information for selecting a therapy.

P 1: I follow the following model: pre-prandial measurement for breakfast, lunch and dinner. Every two hours, about 6-7 per day, which changes based on physical activity. I take a measurement before I exercise. In case of physical activity it is necessary to have more measurements.

If my glucose levels are low, I eat something and then I exercise and after exercise my glucose level measurements are a bit high. Physical exercise raises glucose levels right after exercise. Sometimes, later in the evening, glucose levels drop. Response to physical activity depends on patient. For the past 6-7 months I take measurements before going to bed.

D: Co-morbidities can change the target value. The number of measurements has an impact on cost. The very minimum is one a day at different times, for example one day before a meal, another day 2 hours after meal etc. The measurement is fundamental.

C of P 1: Measurements are the first thing. I have succeeded with persistence and will to keep taking measurements. It is difficult to prick his finger so often, but it helps us to estimate the glycosylated hemoglobin. We act based on experience. We have learned how the body reacts and we are closer to the desired postprandial glucose levels. With conservative management, we have good results. We are at 5,5 the highest, and I believe we will go lower. The most important is to avoid hypoglycaemias. Even if he has taken a measurement in the evening, he takes one before going to sleep. He should never stop taking measurements. This keeps him in balance. We have a complete picture. It is also important to be consistent with meals, not to skip meals, what we eat, no matter where he is.

P 2: Management is based on experience. I know how much I have every day. I take two measurements during the day at random times, so that I can have an idea to inform my doctor. At the beginning, I was measuring myself more often.

D: The minimum number of measurements, we ask our patients to take, depend on the type of diabetes they have, type 1 or 2, and on how many insulin injections they make, and the type of drugs they take. A person with diabetes type 2 who takes drugs that do not cause hypoglycemias, could take fewer measurements. In order to know how well a patient is balanced, it would be good to take measurements at different times during the day, such as before meals, or after meals. Therapies are applied to several people, but no one is a robot.

Patients who are responsible like more visits. Patients who are not so responsible miss visits. It takes a long time to become a responsible patient. Pressure measurements, regular visits and other examinations are part of diabetes management.

ITALY

D: We are talking about two different diseases. For Type 1, insulin dosage depends on blood glucose levels and patient size such as body weight. When a new therapy is started, we have to consider insulin per body weight which becomes irrelevant later on. Food intake carbohydrates, glycemic index rated, glycemic load of food. Physical activity and physical and mental stress which we cannot measure but affects glycemic control.

In type 2, insulin is part of a more complex therapy. Multiple injections therapy could resemble type 1 diabetics. Overall metabolic characteristics, blood pressure, weight, comorbidities, other associated metabolic conditions (hypertension, dyslipidemia, obesity, etc.), affect choice of therapy.

D: We need to know about the meal composition to provide insulin before the food is absorbed. More important it is to determine glycemic index of food and approximate protein. Fat does not affect it.

P 1: If there is a lot of fat I prolong the bolus.

D: Determine the amount of carbohydrate load of food.

P 1: Before the meal I measure and I hope to know in advance how long it will take and what I am going to eat so that I know how much and what method I use to inject. It is not feasible to enter what I am going to eat, with how much and wait for the system to tell what I have to inject. Two hours after the meal I discover if I was right, and 5 hours later I know again if I was right. It would be nice to have a system so that I can reduce the visits to doctors. Every three months, there is a record of the corrections and probably why and can see what I ate and what kind of bolus I made. I do not need the information immediately. I do not expect the machine to tell me what bolus to inject, or the doctor.

If it was a close loop how accurate would be my input. Do I wait, or I go more or less with my average estimation, how accurate will it be? Now I estimate.

FRANCE

P 1: I take a measure before and after every meal. I do not take it always before bed time. I take it always after bed time. 2 hours after meal, the system tells me whether I am on average too high, or too low and gives me suggestion to modify. We insert data in smart phone with a proper interface.

N: Nutrition and physical activity are estimated by patient themselves.

P 1: Stess is unmanageable. If I forget I eat.

D: They have learned all this information by experience.

D: There is an educational program. The core is to teach them how to calculate carbohydrate content, also in relation to sport.

D: The postprandial is measured two hours after meal. Based on the differences of the postprandial compared to estimation they correct the bolus. With preprandial measurements they can correct the basal also using the bed time measurement.

Physical activity is estimated with absent, medium, strong. Physical activity and nutrition modifies bolus.

P 2: Diabetes is a disease which is not regular, we do not know why. The machine cannot do anything with the irregularity. There are not two weeks the same for me.

CYPRUS

P 1: Close to and during menses, women seem to have increased needs for insulin. We might need to increase basal, and with the pump we give temporary basal. Exercise also affects the amount of insulin needed. Also, nutrition and amount of protein are also important factors. We tell people who eat a lot of protein to take measurements, and to those who eat food high in fat, to change the bolus or the square.

It is best not to say Patient with diabetes, but Person with diabetes.

D: Those with Insulin pumps feel that they can manage easier changes in nutrition and lifestyle. If someone has a soldier like structure in daily life, then injections are easier. However, the pump provides greater flexibility.

P 2: I was with injections therapy 4-5 months. The pump is better, easier, especially when I want to eat more or I want to eat something different. It is also easier to manage food high in fat as we can administer insulin more slowly. I give instructions to the pump and program it when to administer insulin. The pump is already programmed to provide a certain amount of insulin per gram of carbohydrate during the day, 180.15. The pump can calculate food intake but not type of food. The insulin pump has an internal algorithm, a Bolus wizard, which, based on the carbohydrates, calculates the necessary insulin.

P 1: It is important to manage the condition based on the particular lifestyle of the person.

D: Also, the glycosylated hemoglobin is an important parameter. We measure it every 3 months, except during pregnancy that we measure once a month. It is an important parameter that shows us the regulation, the mean level of glucose.

D: Insulin resistance and insulin sensitivity depends on the definition of terms. Insulin sensitivity is how sensitive the person is to insulin, how many units of insulin are needed to lower glucose levels. There is one formula 1800/total units per day, for example 30. Insulin sensitivity is personalized; it can change during the day with the stress, or menses with women. We calculate it based on experience, for example, basal, lantus 1800/40 how many units glucose drops.

Sensitivity changes with stress, changes during the day and during the night.

1.2 Which parameters should the system monitor, collect or give back as feedback (vital signs, comorbidities, clinical history, etc.)? In what frequency? Who will use this data and how (target users)?

GREECE

D: It is important to have the value of glucose but also the direction and rate of change of glucose. The value of glycosylated hemoglobin depends on the particular person.
Measurement should be taken preprandial and postprandial. We should measure blood glucose and glycosylated hemoglobin.
It is important to avoid hypoglycaemic episodes. Hypoglycaemia is responsible for cardiac episodes. Measurements should be within a certain range. The range is smaller at the lower limit, and higher at the upper limit. When measurements are completely out of range, we repeat the measurements.
There are several parameters that need to be taken into consideration. Patients act according to experience. Ideally, they keep track of the actual glucose levels in the blood. Insulin production changes in the split of a second. It is important to have continuous monitoring to give instructions to the pump and have an alarm. There is always a deviation between the real time measurement and the analysis. We want the real time measurement. Sensors show the direction of glucose levels, higher or lower, and the rate of change. It is important to know subcutaneous levels, and levels of glucose in the blood.

ITALY

D: 4-6 is the usual number of measurements at home. The measurements are performed before meals, but should also be performed two hours after meals. In Italy we go to sleep around two hours after dinner, so the measurement after the last meal coincides with the measurement before going to sleep. This differs among countries depending on cultural differences of dinner time. We need postprandial measurement but sometimes it is not performed because usually patient is experienced and if he ate what he was supposed to eat, he does not need to check after meal. The postprandial measurements is important when patient eats something different that he was supposed to eat or is not very experienced. Furthermore, even experienced patients usually make adjustments to their meal, thus they should also check their glucose after meal.
If we take type 2 then frequency of measurements is lower. It is important to measure when we know what to do with the measurement. Otherwise we measure as little as we can.
Around 4 is the average for type 1 diabetes that patients actually perform.

P: I do over ten because I have a goal to achieve. I measure before each meal and two hours after. I do not measure before night but I will have to. In Italy two hours after dinner is 1-2 hours before bed time.
D: Most people will perform measurements before meals. Post meal measurements are not so common. We need them to determine insulin in subsequent days but not immediately so this is why they are not done on average. In general, the more experienced the patient is then he/she eats regular meals. Insulin dose should be calculated on what we eat. Formal calculations are not performed by patients. Our experience is that even patients who are formally advised to do formal calculations of carbohydrates do not do them. Experienced patients make an adjustment depending on their choices, also on the damage they have made.
D: It would be interesting to measure heart rate. Once a year, it would be interesting to have blood pressure. We use it only in emergency situations. We do not use it for changing therapy. We check it every six months. We do not need a frequent measurement.

DT: it would be interesting to have blood pressure for type 2 diabetes.

D: Glycated hemoglobin need to be measured once every 3 months. There is no need to check it every day, as it changes very slowly.

D: We have a vague idea of what is happening that we know are associated with insulin resistance, hypertension, gestational diabetes etc. Approximate idea of what is happening with insulin sensitivity and that is about it. If sensitizers work well then patient is insulin resistant. We use the standard meal load measurement to evaluate insulin resistance and sensitivity.

D: Physical activity is harder to measure. Automatic measurement would be ideal. An accelerometer or isometric activity measurement of sweating could be used in an algorithm very useful to determine insulin dose. We do not take this into account because we do not have a reliable way to indicate intensity of activity.

The body impedance sensor should take into account the sweat, in such a way to help in the estimation of isometric activity.

FRANCE

N: When we finish the education we give them the profile on the internet, and telecharge the profile on the phone with the parameters they got in the hospital. So they only need to put how much sugar they have in their meal. They add the amount of sugar of each meal.

The machine takes into account the glycemic measurement, and the amount of sugar and the machine calculates the amount of insulin, based also on the insulin resistance who is personalized.

One time per week, they synchronise with the system at the hospital that the nurse looks at.

P 1: I do it 2 times a week

P 2: I do it once a week.

N: We try to tell them to do it more often so that there is not a big package to synchronise.

D: The algorithms are tailored to the patient. Based on the nutrition the necessary insulin is calculated.

P 2: We have an automatic system that each time asks us are we going to have exercise high, medium: -30 medium, -50 for high. It is not specific though. We often cannot predict they physical activity that we will have.

N: We need to anticipate their physical activity. Because the system cannot know what kind of physical activity they will have. It is mostly geared for before the meals but not for after.

P 1: We have to get more experience on how to understand our physical activity and what we will need to do. A sensor would be helpful to tell us about how much activity we do but it varies also on the type of physical activity.

D: Continuous glucose monitoring (GCM) has to be with an automated system. Continuous monitoring delivers too much information for patients to handle and the management of this information is time consuming. When we saw the American results, we said that they cannot teach their patients. Continuous monitoring has to rely on the patients.

Continuous monitoring is expensive and not reimbursed in France. We did a trial to see how the education of how to understand glucose measurements and we found that continuous monitoring is nice but we know that it has to be coupled with intelligence. So diabeo with the intelligence it has makes it a better system.

N: CGM will have to have an intelligence to be able to combine information about other factors in order to work properly and be useful.

CYPRUS

P 2: Ideally, we would be able to insert to the system what kind of food we ate, instead of having the carbohydrate content of each food. Concerning exercise, and menses/period, it would be better to have an index of specific activity, for example when we have a steady menses cycle, to have a specific administration of basal insulin. Exercise impacts basal insulin.

P 1: Sensors could track the activity levels and the heart rate. There could be a combination of pedometer and heart rate measurements, based on the distance, the insulin dosage changes. Stress also affects insulin needs.

D: Important parameters are heart rate in relation to stress and exercise, in combination with other parameters to determine insulin dosage. ECG is usually not needed, except for cardiac patient.

1.3 How would you feel if clinicians consider that other parameters (blood pressure, pulse, temperature, ECG, weight etc.) would have to be measured? How do patients / carers feel about collecting and sending such data?

GREECE

P 1 and 2: We are willing to provide all relevant measurements that the physicians need.

CYPRUS

P 1 and 2: Person with insulin pump have no problem with privacy with their doctor.

1.4 Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake). Even considering the benefits, is it realistic to expect patients to be willing to constantly enter information about activities, food consumption etc.? What information and to which detail is it feasible to be entered into the system?

FRANCE

D: It is important to keep the motivation. The system should support the autonomy of the patient. Patients are fed up with more information.

CYPRUS

P 1: It is important for people with diabetes type 1 to have information. It is important to find a system that will help those who do not want to take measurements with the glucose stick and write them down. We would like to have the possibility to note our measurements on our mobile phone. It is too hard for us to write measurements on paper. Also, we have to keep track of the results of what we ate.

D: The same sensor could be used for people without an insulin pump, so the doctor could receive more information.

1.5 Nutrition has to be taken into account in the calculation of the drug dosage. Which kind of information about nutrition do you think it will be feasible and reasonable to collect consistently? Are patients willing to insert exactly the information about their nutrition?

GREECE

P 2: I write information in the notebook only when I have unbalanced glucose levels, because I believe that it is related to my nutrition. Only then I keep track.

C of P 1: We know that we will have for lunch and dinner. We prepare meals based on the guidelines. I give direction for the meals. However, I do not know if this is followed by all. What is important about nutrition, is to have the right amount, to cook the food in a healthy way, but this is not applicable for 3 times / day.

D: The type of food differs in each Country. We have different meals in different countries. In England they eat more in breakfast, but less in lunch. Quantity for meals is important. For the physical activities it would be important to find an easy way to input data. For meals it would be important to put the data of what was in the meal in the case of a measurement out of range. Input should be easily inserted. The amount of carbohydrates in food is known, but we cannot tell people what to eat. Even for exercise, it is not the same for all. It is important to know exactly what a person ate, to correlate glucose measurements with food intake. It would be useful to have such detail. However, I do not think it is feasible, because people do not know much. Many people do not know what carbohydrates are. So, we prefer to keep track of general tendencies in nutrition, rather than exactly what people eat.

P 2: The system could have the intelligence to calculate percentage of protein, carbohydrate etc, if we put the type of food we ate. Also, it could have option for portions/amount so that we can select it. Also, if glucose measurement is high, the system could ask us what we ate in detail, or have an algorithm that could tell what we ate.

D: Insulin dosage is not standard. It would be useful if the system proposed an insulin dosage. Also, it would be useful to have a system that learned in time from when things went well or not … through the combination of food / glucose measurements. The system could then provide a suggestion for insulin dosage or necessary changes. Insulin absorption is not standard. The same insulin can have different absorption rates for the same person. Insulin resistance can vary with patient and within the same patient.

ITALY

DT: if we accept the system, it would be interesting to store information of what food the person had and the type of activity. That would be an electronic diary.

P 1: Who would want to enter this information?

D: Only if it would be easier with predefined choices. The system would be acceptable and used, if the person spent 10 seconds to input information for each meal.

P 2: I would input information about meals if it was fast and easy.

DT: Do you keep diaries?

P 2: Recently a lot. If I realize that I have to write down what I eat it is not the easiest thing to do. I am moving a lot. It is hard to determine the content of each food.

DT: In Europe there is core questionnaire that have to be adapted with regional decisions. We want to ask about food. Pasta here is different to France. Spaghetti is a side dish in France. Rice is not a side dish. It is a first course. Also way of cooking pasta changes the glycemic index. If pasta is correctly cooked, for example, low cooked smaller glycemic index. Bread also differs in glycemic indexes between regions and countries. Even regional differences should be taken into account. The system should be adapted to different countries even regions and should provide relevant pictures. Protein differs less between countries depending on the cooking. But for diabetes differences are crucial.

FRANCE

P 1 and 2: We make a note in the smart phone of the portion of insulin.

N: Before the system is given to patients, patients are formulated. They know how to calculate the nutrition. They learned it in the centre. They calculate based on what they eat daily, based on a portion of sugar of 20 grams.

P 1 and 2: We are analyzed and we get our coefficient of resistance for insulin. So we note how much we eat and the system tells us how much insulin we should administer.

CYPRUS

P 2: The important thing is to learn how to calculate the amount of carbohydrate content of food. Otherwise, nothing is prohibited. It was a mistake in the old days when doctors told people not to eat certain foods. Nothing is prohibited.

D: No problem about nutrition. Patient does not have to be ashamed about any food especially in type 1 diabetes.

P 1: If I have a certain meal and I can calculate exactly the carbohydrate content, I can have better control. For example, at Mc Donald's there are exact details of the content of each food. There is a utility on the internet where we can calculate carbohydrate content of food, for example, for a carrot. It is a very useful utility and can be uploaded on mobile phones.

1.6 Education (a new theme that was raised in the discussions)

GREECE

D: The educational level of the person with diabetes and also education about diabetes are very important. To learn that they need to eat and rest, to check hands, to understand the benefits of regulating glucose levels, information about complications, to be aware in order to avoid complications. The educational leaflet and the video might not be appropriate for the elderly. It is important to provide people with simple instructions in one page that are easy to read and follow.

P 2: It is important for people with diabetes to learn what lies ahead, that something is working as a bomb inside. Only after I had the stroke I realized that I had a problem and that I had to be careful. People need to be shaken.

D: Type 2 diabetics who take pills need information about complications. It is not relevant to tell them what might happen to them in 20 years. We have to inform the young people without terrorizing them. For older people, we need to give them information so that they comply with treatment. Patient education is mandatory for the acceptance of such system. There are patients that do not accept their disease. It is important to have very simple instructions. Updated information for patient education is essential. Type 1 and type 2 need different information to obtain better adherence. For type 2, different information is necessary for young and older people. There is a yearly check that needs to be performed. It is the same for all patients. If there are comorbidities the check should be more frequent.

ITALY

P 2: By the time I used the injection therapy I knew nothing about what I should eat.

D: The system should work in combination with the doctor. The Assisted decision system will make suggestions. The doctor will provide information about routine dosage for self management of insulin. Information is needed about nutrition, and nutrients and how they affect glycemic index. Effects of physical exercise, effects of stress, what is the insulin dose required to reduce glucose after meals, symptoms of hyperglycaemia, and hypoglycaemia, how to prevent when doing physical exercise.

P 2: I want this information even though I have the disease all this years.

D: Patients up to 50 years old, prefer to be informed and receive information as much as possible to give them more freedom. The more informed the more freedom. Older ages, the attention declines, patients want to put the disease under the carpet. They want to deal with just a visit once or twice a year. The best way to educate patients in general is to put them together and have them interact together. A system that keeps patients at home without attending clinical facilities would be an obstacle. Interaction is essential between patients.

Established communities will increase responsibility and patient awareness (forums, support groups). Participation in communities is the best way of learning and making patients responsible. Patients have to exchange information. Some patients would like to lead these communities.

P 1: I participated ten years ago, I learned a lot of things, how to eat, how to manage.

D: Interactive education, not self help, but medical guidance, patients' talk, we get information and we intervene to direct discussion but we let patients to discuss.

We have a particular group with insulin pumps people who have a certain approach to management. One activity for people with multiple injections, with medical intervention newly diagnosed adults type 1, or people who are referred for the first time. Third group, multiple injections, interactive workshop, without program for type 1 patients. A group program for type 2 with insulin therapy focused on food, physical activity, life style.

Information provided by the system should not be a replacement of the support groups but should be available to us after the group participation.

They do not have reference material from us. That could be part of the platform. The interactive part is very important. It has the emotional quality.

FRANCE

D: In our mind, 100% of people with diabetes will be proposed to have this system. The nurse will educate them. Our vision is that the nurse specialists will help us. It is a team management. We plan to have a regional system to help specialists for first line follow up who will contact the specialist. And visit will be teleconsultation.

The landscape is different now. We have a good educational system. The great majority of patients are well educated patients. If they do not have societal problems, we train them to eat whatever and manage their disease. Before, they depended on the family. It is very rare to have emergency conditions. The psychological distress is difficult to manage, it occurs in adolescents, lose jobs, death etc. … for that we need to focus the resources of the team. Technology will not be able to overcome this system.

P 2: I do not speak about my disease. I manage it on my own. I call someone if I have a problem. When we meet in the hospital we exchange with other patients, or we show each other how to use the system. It helps to exchange. I was surprised with myself of how easily I used it. We do not have the time to talk or chat on internet.

P 1: My wife helps me.

N: Forum did not work so well.

D: We have two kinds of interventions: 1) Technical for the device itself for the support of the patient in the use of the device, a hotline for technical problems. 2) Motivational support, this is the core of the clinical job in order to support patients to be compliant with the management. Patient compliance with the therapy is very important and this kind of intervention (motivational support) is necessary at least in 70% of patients.

Patient education is important. Patients have been trained in case of wrong measurements.

In case of episodes, patients call on average twice a year for a hypoepisode so it is important to educate well the patient.

CYRPUS

D: The system could include gaming. In Medical School, we work on a system for education using virtual patients. People, who do not want to be involved, will not, despite the quality of the system. Education should be accessible.

D: Cyprus is small and we know each other. Once a month, there are meetings with a psychologist, clinical dietician and doctors. People are prepared before using the pump. The company prepares them. Patients pass through several phases and the first one is negative. The best management is when patient is fully involved. There is an educational team for the use of insulin pump. There is a team management now. The support team provides information to support the doctor. Nurses and psychologists act as diabetes educators, the clinical dietician. The doctor decides what the patient needs. Also, there is collaboration between private and public sector.

P 1: Education for informal carers is important to know how to handle any situation. Diabetes is a way of life. Some people were able to explain diabetes to us with simple words that we could understand. They even used comics.

2 Health Management

2.1 What do you think/feel about using an alarm management system? How do you think it will facilitate your daily practice or crisis management?

GREECE

D: It would be useful to have a mobile device to monitor patients and get an alert for inpatient and outpatients to have all information available when we need it. Also, it would be useful when a patient calls us, to automatically get their data on the screen. For inpatient care, it would be useful to have single screen to check more than one patient, like a monitor system in the ICU. We could receive lab results directly into the system.
P 2: The alarm threshold should be carefully selected. Currently, when the threshold is surmounted, the alarm terrifies the person with diabetes. It is important to have alarms that do not cause anxiety.
P 1: It would be useful if the system knew if a measurement was taken or not and send an alert a specific time.

P 2: This could be especially useful for elderly patients who are more laid back with taking measurements. Many patients are negative towards measurements. A reminder would help those who are negative towards measurements. I need a reminder because I live alone and I have cardiac problems. I take 11 pills per day. I would like to have a system acting as my mother and show interest in me. I am more aware after my strokes. If I had such a system it could help me feel less alone and use it when I do not feel well to contact my doctor and his team. This is important for many people. I am afraid for the evening hypoglycemias. Also, I would like the system to be able to contact someone on call for emergency episodes and to be able to comfort me. Also, I would like the platform to remind me of what numbers to call in case of emergency, to enable and emergency alarm and to call a certain person or centre.

D: It is important to have questionnaires for patients so that when something serious, out of the ordinary happens, to find out the exact problem and the best way to face it.

P 2: I have been negligent and I did not have people to take care of me. I did not have someone to encourage me and remind me to do what I needed to do. As a result, I did not do what I was supposed to do.

D: There are patients who do not come for their regular visits. We might need to regulate their dosage. The system will evaluate the patient continuously and make suggestions to the diabetic, who in turn can adjust their therapy.

ITALY

P 1: I check my glycaemia every morning and I make an injection, eat breakfast and go to office. I forget when I am working. It would be important for me to have a device that rings when glycaemia is too high. I know that my glycaemia changes depending on how I feel. When I stress it goes up. Sometimes I stop, I feel thirsty or nervous and then I measure and then I intervene with injection. I do not realize in the mean time this is why I would like to be reminded. I would also like to be reminded if I forgot a measurement. Alarm for measurements are important and not only for high or low glycaemia.

P 2: I was wondering if the pump has a calculation that gives an alarm two hours before you measured or injected. I also forget, I am involved in the working life and there is no regularity. The two hours after meal is two hours and a half.

D: Not enough personnel to have 24 hours a week to sustain the system. Nursing staff manages some parts but in Italy nurses are strictly forbidden to provide any treatment, decisions etc.

As a doctor I would not like any alarms. Patient should have a good bolus calculation, with physical activity and food intake and allow them to do the management. This could be used with patients of multiple injections. I would like to download the data at routine visits as an overall picture and go into single episodes and in general to look at the episodes more specifically. For example alarm for hypoglycaemic episodes. It is better to measure interstitial glucose and consider the delay. There is about 30 minute delays between the interstitial and blood glucose. It is important to consider rate of change of glucose.

P 1: I would like to have support from a physician when I am ill. It is not easy to manage glycaemia when I am sick. Have some contact, chat, be able to discuss my problem. In small emergencies I would like to talk to the doctor, even with email.

D 2: I would like to have an alarm for hyperglycemia.

P 1,2: We would like a reminder to check glucose two hours after injection

P 1: Alarm for out of range measurements especially during nights if we use continuous glucose measurements, for example, an alert during hypoglycaemia during the night. I do not wake up during the night and when I wake up, I have a rebound. I want to wake up, when I am out of range, either too low or too high.

D: Could be interesting for patients to provide output for the patients to visualize average glycemia, or daily mean values, insulin on board, estimation of (hb1c) in a graphical way.

FRANCE

D: We are developing a system of alarms using a specific algorithm.

N: So far we have a manual alarm. The system is a bolus calculator. It is better than a simple calculator. The system tells them how much to administer.

P 1 and 2: It is a clever alarm we get.

D: 120 patients were managed with diabeo. Published results on journal diabetes care. We will be able to manage more patients with the automatic alarms that will be implemented in the next version. The new generation will have alarms for our objectives. Based on the results I will have an alarm. A user interface will help us visualize also the information.

P 2: We would like that the system gives us an alarm if we forgot to enter data. I forget some times. Don’t forget … There is no place to put postprandial dinner, and before lying in bed. Need column after dinner.

D: There are different alarms for type 1 and type 2. We have alarms for type 2 diabeo. We will ask patients if they agree to have these reminders. It is important to have a specialized people who will manage an emergency situation. The main task is to help patient in performing well. For diabeo, the first month is important to set the technical aspects and motivate the patient.

CYPRUS

P 1: There are different sounds for reminders. I would like to insert a reminder at a different time from those specified but I cannot. I would like to take a picture of the food, and the system, based on this picture, to decide my insulin dosage.

D: Reminders are based on individual people. Type 2 diabetics need fewer reminders. It would be useful to have a flexible system of reminders that the doctor can set according to the individual needs of the person.

P 2: We would like to have emergency alarms in case of hypoglycemia. The system could contact the relevant person. I was in the car when I had a hypoglycemic episode, I stopped but could not communicate, I could not think to eat a candy, I did not know where I was.

C of P 2: We would like to get an alarm through sms, and to know the exact position of the person through gps. It would be better to be oversensitive. Alarm in case of hypoglycemia or hyperglycemia with sms warning with GPS position.

P 1: I do not feel all hypoglycemic episodes the same way.

P 2: When my sugar levels are not good I fight with my husband.

C of P1: It would be good to have a pump with 3G, and gps tracking for emergencies. Also, information should be uploaded to a common server that both the doctor and the husband could access and be ready to help. The carer should be notified first.

D: We have EHR but we do not have reminders.

P 1: I would also like a confirmation that the catheter of the pump has been inserted/placed correctly.

C of P 1: If we accept diabetes it does not affect our lives. The problem is hypoglycemic episodes. I would like to know how to react no matter where I am. I would like to know what the person is doing, driving, is at work etc.

P 1: 50% of diabetes management is acceptance and understanding. It is important to know what diabetes means for me, also to have an education mechanism and a support group to encourage us to improve management. Information is very important.

2.2 Will a telemonitoring system change the current care model? Will the system be able to provide a better visit management (e.g. only when really necessary)? Will

patients and doctors have enough time to dedicate to this more frequent data collection, analysis and feedback? (Should disease management plan, risk management plan and lifestyle plan be part of the personalized care plan?)

GREECE

D: It would be good to have a camera and take a picture once a year of diabetic patients. We do not have permanent personnel for telemonitoring. We need a workflow model. Probably the use of doctors mobile phones would help. We have 10000 patients with diabetes to be checked 2-3 months. There are only 4000 patients active. Responsible patients would like to have 1 visit per month and they would like face to face visit and if this is hard to achieve, then every 2 months in the worst case. Virtual visits are OK but face to face real visits are preferred.

We have a 24 hour centre and we have people on call, so we could operate continuous monitoring. However, we would need a dedicated person to answer calls, and monitor progress. Also, there should be a specialized call centre to handle calls. The diabetic centre closes, it is not on call. Emergency episodes are handled in the pathology clinic. There are too many diabetic patients. We do not have enough staff for our needs, we do not have enough room in the centre, we do not have the basics that the law specifies. We do not dieticians, social worker, psychologist, special laboratory. Our responsibilities are many.

A diabetic call centre would need to have protocols of how to handle emergencies based on yes and no questions.

N: It would be useful if the system contacted the emergency ambulance service. I have two children and I do not know what to do if I had an emergency. Elderly patients cannot understand an automated system. They think that there is a person that talks to them.

P 2: I would like to visit my doctor once a month to discuss all my questions and concerns.

D: The system cannot replace personal contact between patient and doctor. However, it could increase the time between visits. It is important to discuss with patients news about diabetes management etc. A remote teleconsultation system could decrease the time of visits, but we would need the right organization. Type 1 diabetes do not come so often because of their responsibilities. Teleconsultations would help them minimize the time they spend on doctor visits.

ITALY

D: I believe there are 4 loops. The first loop is in the hospital with the doctor checking the insulin dosage proposed by the system. The second loop is at home again with doctor checking the insulin dosage proposed by the system. The third is at home directly to experienced patients who will decide without the intervention of a doctor. The fourth is closed loop to the insulin pump.

We would not like to work on night shifts to give alerts. We give cell phones to limited number of patients who are nice, and polite. Loops with doctor checks are unfeasible. Specialists do not work at night and cannot afford the continuous check of insulin for a large number of patients. A bolus calculator with each patient without doctor check, would provide the information to the informed patient and the patient decides. It would be a more feasible solution. It will have to be provided to well instructed patients.

P 2: if I have to come every three days then there is no need for transmission.

D: It would be good to have a good analysis of measurements and trends. The trend and the speed of change are important. This is an alarm for the patient not the doctor.

Face to face visits are very important, it had different emotional quality and it is part of the therapy, there is a psychological factor to our work. Video conference even high quality cannot substitute physical visits. Patients have to know the information about their disease and perform their choices.

Heart rate is more important than blood pressure. Information should come from somewhere else, no need of continuous monitoring such as lipid profile. But this information is fundamental for risk calculation. We have a risk calculator, the problem is the definition of algorithms is not easy at all. Levels are different from one country to the other. It is impossible to build a universal algorithm for the risk evaluation. Family doctors are using it. Health search database in the US is nice. To see improvements needed. US calculations seem more dramatic. In order to build a good risk calculator it is important to have good epidemiological data.

FRANCE

P 1: The doctor can call us.

N: I look at my computer once a week for all patients. We have 40 patients, because it takes a lot of time to check the patients.

P 2: We also use a paper diary

D: We are in a transition time now. We have done a national evaluation 120 patients in a trial, published, (diabetes care).

P 1: It is not so easy to be in contact with the nurses or the doctor.

N: We have some rebel patients and more classical patients.

P 2: we meet twice a year.

P 1: We meet twice a year. We are in more frequent contact with the nurse and the paramedics but if things go well we do not need to have contact. We measure glycemic hemoglobin every 3 months. We do not address to the generalist.

N: Patients send information every 3 days or once a week. In case of emergency they send the information immediately and call the doctor.

D: Consultation face to face is done 2 a year. Check up once a year, examination foot, and retinopathy etc. hemoglobin is measured every 3 months.

P 1,2: We do not have a problem to send the information to the doctor. We prefer to write it in the phone as we get the answer immediately. As our question is what is the insulin dose we need. We have no problem to have continuous glucose monitoring with wearable sensor but only if it is not obtrusive.

D: We are in discussion with our partners, commercial and technical to persuade them that it is not enough to have electronic systems. We need a system that will do well, but we need to have extra provider time to allow for the system to do well. We were able to demonstrate that professional time investment helps twice better that just giving the system by itself. We need to define what the best tasks are for the nurse.

So when the nurse sees something wrong we phone the patient and help them to manage, or give solutions. My feeling is that the best way to contact the patient is when there is no more information which means that the patient is fed up with the system. The core of our business is to motivate the patients.

N: The key is to be able to persuade them to use it. Interventions are 20% technical and 80% motivational. The first month is important for the technical aspect but the motivation is continuous. It is good for 6 months, and then they stop, we need to help them at the point where they stop especially when the values are out of range.

Technical interventions depend on the patient and the type of smart phone they buy and the type of network they have. They need a connection with web not wap, if they do not have web the application does not work. We also need to do tests to check compatibility.

D: I do not care if a measurement is wrong. Our patients are professional to react to unusual measurements. When there is distress we have unusual measurements. We have a special emergency call for extreme cases such as ketoacidosis in adolescents.

P 2: We do not call immediately when there is a problem. I try to understand my condition day after day and wait to be able to manage it on my own. Having the system and being able to call someone in an emergency, offer strong psychological support for us.

D: We have a nurse to handle patients with distress. 5% of patients consume the majority of time.

N: The percent of patients that are well educated has increased over the years. 100% of type 1 that have access to the service can benefit from a high level of technical assistance. Social and psychological situation are important. The problem is not a matter of knowledge, which plays a small part in chronic diseases, it is the willingness and distress that plays the most important role.

P 2: There is a significant difference with the use of technology. I know myself. Without diabeo I would wait a few days before acting. With diabeo, it tells me what to do instead of waiting as I did before. It is a coaching device. I know myself in practice. Before diabeo, with high blood glucose I waited, I knew that I had to modify my insulin but I did not dare to do it. I knew what I had to do but I did not do it. With diabeo, I act. I do what it tells me to do. The system facilitates the calculation, and reminds me what to do. I get the reassurance I need for the intervention I have to make.

D: We selected patients that invested in their disease, but unable to achieve glucose control. After the system they were able to improve. With continuous measurements, there is a limitation of knowledge. We cannot explain to patients what to do with 290 measurements per day.

Psychological distress of patient is not currently managed and it is very difficult to be managed. Support for psychological distress is paramount and clinical people should be focused on that. Access to diabeo improves patient education. Education depends on psychological and social situation. People with many problems cannot manage properly their chronic disease.

P 2: Practical application of knowledge improves with the use of diabeo. It helps me to manage my condition better.

CYPRUS

P 1: Electronic feedback is important to me, as I see average values, and my measurements. I download them with a usb and we upload them to the pump webpage so that the doctor can see them. We are in constant communication with the doctor.

The sensor takes measurements every five minutes during the night. We check insulin and glucose. It says what we ate. We can enter exercise. It would be useful to have also the exercise.

There is a lag time of 15 minutes because measurement is subcutaneous and it is not the actual blood measurement.

D: Telemonitoring is more important for type 1 but probably less important for type 2. Several people do not feel like or are not involved to record glucose measurements.

P 1,2: We would like to have an improved glucometer that could send our results directly to the PC. It is a big effort to record them by ourselves. We would like an automated system, where we could also record what we ate so that we can make correlations and work closely with dieticians. Automatic availability of measurements is very important.

D: People who have sensors go to medtronic website, download results and send them to the doctor by email.

2.3 Organizing the risk as short term, midterm, long term which kind of risks would you like to insert in each category?

CYPRUS

P 1: Short term: hypoglycemia and hyperglycemia. Also the catheter might be obstructed, but there is no way to know unless have hypoglycemia, or toxicity. This is why we have to take frequent measurement of glucose.

D: Long term risks are: cardiopathy, retinopathy, nephropathy, etc. Type 2 diabetes that remains uncontrolled for a long period can result in serious problems.

D: Compliance with the therapy is the most important factor. Some people do not want to follow a therapy so they do not visit the doctor. We try to attract them with educational programs that promote diabetes self-management. If there was a registry of diabetics, it could send automated sms on their mobile phone or their PC with educational material about losing weight, compliance to pharmaceutical therapy, regular testing, etc. Technology can help in maintaining contact with patients, in informing the patient and in having better compliance and outcomes.

3 Devices

3.1 How do you feel/think about wearing a system that will take measures from you and send them to your doctor/family? Which would be your maximum acceptable size for such a system? Weight? Dimensions? Other criteria.

GREECE

D: Devices have to be light, and small in size. The patient should not feel wired, not like the pump. It should be a pad and all communication should be done wireless. It should be easy to use, with large letters visible to elder people, or people with impaired sight. It is important that people with impaired sight (a comorbidity in diabetes) should be able to use the technology. Also, the menus should be in the national language. Menus with icons are better to those with letters.

Sensors are helpful but might cause psychological problems. They do not involve pricking.

ITALY

P 2: Now with the pump I have control of my diabetes, before I didn't. I have the pump for three years and I have no problems with the machine. I use it in the car and even at the beach without problems. Before, I injected different kinds of insulin. Now with the pump is a big progress.

D: there are patients that do not like so much the insulin pump because it is too intrusive. Basal management is a lot better with insulin pump. Multiple injection therapy is the first choice at present but if adverse events are too many, insulin pump is proposed to patients.

Patient preferences are different with the insulin pumps. Issues such as external device could be uncomfortable. Something outside the body can be seen as an obstacle. We are not as in northern Europe where pump is less intrusive because of clothing. There is an issue of how easy it is to correct insulin dosage. Here we propose insulin pumps to those who are not perfectly controlled with multiple injections, which is the first therapy of choice. Insulin pumps coupled with traditional finger tips.

P 1: it would be nice to have something like a watch. I want a device which is comfortable, small, easy to carry, something like an iphone. I want a watch, not something on me. I would wear something not visible, and something that does not hurt, and that I cannot bump it. I want something rechargeable, environmentally friendly to refill it.

P 2: Ideally, the device would be the same as our phone. I do not have a problem to wear the epatch.

D:[Demonstrates the patch pump]. The dimensions are 6x3cm of the patch pump. The future one will be thinner. It is disposable and should be changed when reservoir is empty. Currently, it lasts about 3-4 days.

CYPRUS

P 1: We would like to change the option of the pump about time suspension. Currently, there are the options for ½ and 1 h. It would be useful to be able to set suspension time in minutes.

The sensor bothers me. I would prefer a small, water resistant device. Also, the pump might falter. One time, while I was administering bolus, the pump was disconnected and I did not realize it. Sometimes, it hurts if people touch me. Also, sometimes, when I insert the catheter, I hit a vessel and I start bleeding, or I start bleeding even when I remove it. It is important how to insert the pump. We use the sensor when needed.

The pump is big. We would prefer an implant. Also, it would be nice to be able to charge it with solar energy, instead of a battery.

We would like to have a pump without a cord, only the catheter, with a small vial, and a sensor to measure glucose. We like small and unobtrusive sensors.

The insulin pump is not the best solution for everybody it is more flexible, but there are people which prefer to manage their diabetes with insulin shots.

P 2: We have more freedom with the pump than with the injections. We might need 5 injections per day, and sometimes, depending on what we ate, we might need 7. There is more automation with the pump.

There are also more responsibilities with the pump. It requires checking glucose more often, 4 or more times per day. It can be dangerous in the hands of someone who is not trained.

3.2 Would a mobile device be useful for you? Which kind of device is more conformable/usable for you in your daily practice?

GREECE

P 2: A mobile device is more useful, like an iphone, with a large screen.

D: An iphone size device would also be usuful to doctors.

ITALY

D: A Patch pump of Roche is a lot better than traditional pump. Injection is in the patch. It provides better quality of life for patients. The Omnipod device is remotely controlled and wireless. Dimensions are about 7x3cm.

FRANCE

D: We have developed diabeo in windows 6 mobile, which is no longer in the market. Now, we are developing a new application in andoid, and iphone, which will be ready at the end of the year.

P 2: I did not accept diabeo at the beginning. The doctor had to talk to me a lot to get it. I do not like phones, and I am not a good user of technologies. I do not want to feel that my life is continuously controlled. But after a while, I said why not and I used it. It was not difficult. I am happy with it.

D: The extra time patients need for data entry is very small and the benefits are huge.

N: The doctor knows how patients will react. We gave them a non synchronizing device to test it. After, we asked them if they wanted to invest. To get diabeo, patients have to buy the smart phone.

3.3 How would you feel about ePatch technology? (Intrusive, unsafe, etc.)

GREECE

P 2: It should be waterproof so that we do not have to take it off when we shower. It should be small at the size of a business card and to last for more than a week. Ideally, diabetes sensors would be included in the epatch. An automatic system to control glucose in the epatch.

ITALY

P 1: I would not like to have a device on my body. I do not feel safe with something mechanical because it could break. It is my issue. I can find in the future something I feel sure about that maybe I would like to use.

FRANCE

P 2: I have so many devices, one to read the glycemia, the pump, the mobile…

P 1: I do not like the pump for psychological reasons. I prick myself but I feel independent. With the pump, I would feel as if I am on a life support device. I have to do everything, and tell the pump what to do. I do it then myself with the injection. I hate the idea of having permanent catheter. I do not need it as I am so well regulated.

D: There are patients who prefer injection shots and patients who prefer insulin pump. There are objectives for each time of day, min max of blood glucose before each measurement, they know what to expect, the range of measurement.

CYPRUS

P 1: It will depend on where the epatch would be placed, also, on the colour. Epatch is better to put in places of body where not visible, especially when we are at the beach.

4 General Usability, Usefulness

4.1 How do you think/feel about having a system like REACTION as part of your daily practice?

ITALY

D: I would propose a closed loop system for each diabetic patient. I believe that it would change the life of type 1 diabetic patients.

4.2 Do you think our system is useful? Which could be the most critical factors and concerns for using it? (price, wearability, etc.)

ITALY

D: If it is simple with little need for information it will be proposed to all patients. It would depend on sophistication of the system. If it were complicated I would promote it to people who have difficulty to do glycemic control with other methods. It will also depend on how much time the patient will need to spend with the system. We would not want to create stress to those who do proper management. If it was simple it could also be used as safety net. If the system would require half an hour or an hour every day, then no, I would not propose it to all patients.

D 2: It would be useful for young people or people who have ability with electronic devices not to be anxious. Knowing how the glycemia is going it would be stressing. We should have a selection of the information desplayed.

4.3 What minimum technical skills should it require? Do you think the use of modern technology is complicated? How important is that the application is available in your language?

ITALY

D: 95% in Italian. It would be dangerous if not in our language. We want user-friendly software for nutrition that is culturally adapted.

5 Privacy Safety and Trust

5.1 The use of the system will be enabled after the patient will sign an informed consent. Do you think this is enough? Or would you like to have the possibility to give permission for each specific action? Such as transfer, access and processing of your medical data? Do you think it is necessary/important to you that you can see which doctor/nurse/person had a look at your health data?

GREECE

P 2: It is very important to be open about our condition, once we decide to use the system. We need information about the system before we start using it, what data will be visible and to whom. We want to know who sees our data to be able to contact this person. We want to know who sees what data. Also, it would be good to receive an alert that someone saw the data, that the data was transmitted safely, a message that will confirm that all communication is private and safe. It is important to know the person who will answer on the other side of the system.

D: Patients would like to know who will have access to the data. Patients are ready to try technology that will improve their quality of life.

ITALY

P 2: I do not mind what information the doctors check. It is the concept of bank transparency. No other way to find a solution or a therapy if I do not give some of the info. I do not care about sensitivity of information.

P 1: I would like to know who used my data. I want to know all this information. I want to know if the doctor will use my data for other purposes. I would like to have a list of names that will have access to my data. Also, a warning for who will use my data will be nice. If the information goes to my regular doctor then I have no problems.

D: If data are anonymised, they can be used for research without patient consent, only with ethical committee consent. This is the law in Italy if data are collected in routine clinical practice. We have to inform ethical committee but not patients. Retrospective studies on mortality for example.

FRANCE

P1: I do not care who will use the data.

D: Data belongs to the patient. We ask the patient if they authorize us to use it for research purposes. We use informed consent with diabeo. We ask if we can use data anonymously. The question will be different if it would be used for commercial purposes.

P 1: If it was to advance the progress of management of disease, to improve the research I would not mind. But I would like to know who uses it. The moral responsibility stays with the doctor to guard the benefits of the patients.

CYPRUS

P 1: It is better for the person to know who has access to data and who sees the data in order to give consent. If they are anonymised, tracked with a number then it is a different story.

C of P 1: On the internet, data are not anonymised.

D: Patient has to give the authorization to doctors to access their data. Patient demographics are better when not visible and not associated with measurements.

5.2 Would you be comfortable knowing that glucose values out of range will be sent to your doctor, formal or informal carer? Would you like to have control on what information and when it is sent? Would it make a difference if the values indicated a life-threatening situation?

ITALY

D: When patients hide information from doctors, is usually the doctor's fault. As a doctor I am a consultant. I have to give advice but it depends on priorities, and values of the patient. I have to accept patient decisions even though it will worsen health status, or limit expectancy. Some doctors try to force patients to modify lifestyle with a moral attitude. The patient will hide information if there is a moral attitude. I have prescriptions, I am not judging them so they do not have to hide anything. Older patients who have had other doctors with other attitudes would sometimes hide information, for example if they had glucose monitoring they might change values. Patients should be able to make informed choices and adhere to personal values. It is important to adhere to the concept of patient empowerment.

All info is important. Same information is brought manually to the doctor.

5.3 Which is your perception about your own physical safety while wearing the device?

ITALY

P 1: I do not like the epatch, afraid that something will break and provide inaccurate results. If I thought it would be safe I would try it. I want to have control of the device. I see it as a tool. I want to decide when I do something. I want to have the control over the device. I do not like something that will just stay on me.

D: Malfunctioning is a problem now, the glucose meter has inaccuracies. Currently, there is no legislation for the required accuracy of glucose meters. They are auto-certified by the manufacturer and this is a real problem. The only legislation is the American legislation adopted by France and Spain. Accuracy: maximum distance of actual value: at least 20% in at least 90-95% of measurements. In Italy no need to verify accuracy.

CYPRUS

P 1 and 2: We would like to have an alarm in case of occlusion or malfunctioning of insulin pumps.

5.4 Are there any factors that could make you to have more trust in our system? Is there anything you may want to see in order to trust more in our system?

ITALY

D: Formal studies of accuracy with methodology of test, calibration and frequency of calibration.

P 1 and 2: We want to know that what we are using has been tested. Then we decide how long it takes to check the epatch on our body. It could have a different accuracy on each one body. We trust our doctors and what they will tell us.

6 Trust in the infrastructure

6.1 Would you trust an Internet platform with your medical data such that doctors can access them? If the application provides information about the infrastructure risks and the measures taken to minimise these risks, will that increase your trust and acceptance of the platform?

GREECE

D: Trust is gained over time. If our collaboration is good, without problems, then trust is built.

P 2: I would like the system to show my picture to the doctor so that he remembers me. We want more information about the platform.

ITALY

D: Medical data do not have the same commercial value as bank accounts, or credit cards, so how much time people would invest in compromising such data. Some people hide diabetes if looking for a job, or insurance companies. Usually there is no social blame with diabetes. Probably there are other diseases that are more sensitive (e.g. AIDS) but in general some people do not like to make others aware of the disease.

P 2: The problem for me is that the data could be lost. We do not want alerts for this.

DT: The system should be checked for safety that data is not mixed between patients.

FRANCE

P 1 and 2: Internet security is not important compared to the fact that we can have a better diabetes management but a secure website would help.

P 2: I use internet for everything. I feel the same for my data.

P 1: Until now no one has access outside of the people who should.

D: We inform the patients that it is secure site and comply with the international standards. The transmission is encrypted.

6.2 Question for medical personnel: Do you think that the patients rule over their medical data stored on the REACTION platform (e.g., revoking a doctor's right to access certain data) would negatively impact your work? If yes, what problems do you see and do you see a way out of the problems without wholly taking away patients' rights?

GREECE

D: Patients have to be informed about how their data is going to be used. Also, doctors are bound by the medical confidentiality.

CYPRUS

D: Data belong to people and people’s decisions are respected. The patient is responsible for their data and it is the patient who gives the authorization to doctor and not vice versa.

7 Trust in transaction partners

7.1 If the application provides information about the way personal data is handled by the receiving parties and the arrangements the application offers to prevent or deal with privacy breaches, would that increase your trust and acceptance of the platform?

7.2 Would you like to anonymising/pseudonymising technology? Do you think it will have negative effects on the mutual trust between users and service providers?

GREECE

D: Transmission should be encrypted and should be decrypted at the side of the doctor or patient respectively.

CYPRUS

D: Anonymisation is the best solution. Only people who handle the data should know to whom the data belong.

8 Cost

8.1 How would you like the service to be covered by the insurance companies? Would patients like to pay for the service/devices (if yes, how much)? How doctors should be reimbursed for providing this service?

GREECE

D: The system should be covered by the hospitals. We want something useful, applicable, and cheap. Insurance should cover diabetics to avoid inequalities. Diabetics should have access to new technologies. The cost should be reasonable. Large dissemination lowers cost. The main cost of diabetes management is due to complications. Currently the glucometer is covered by the insurance and has no cost for patients. The same philosophy should be maintained at least for the sensors distributed with this system.

ITALY

D: The cost of an insulin pump is from 4-5 thousand Euros, and 17 Euros every three days is the cost for disposables. Patient would have liked to have refills instead of disposables for environmental purposes. Using Omnipod the cost of the pump is 1000 Euros and the cost of disposables is 25 Euros. This cost changes in Italy from Region to Region. Each Region has its own regulations. The regional health service in Tuscany covers the cost of insulin pump disposables and glucometer by the public insurance. But continuous monitoring is covered only in specific circumstances, pregnancy, ketoacidoses, and when level of risk is high. However, reimbursement for type 1 is going towards covering all expenses. Type 1 in Italy is covered well in all regions. For Type 2 the situation is different. Usually other regions are worst than in Tuscany.

I think that the answer is simple. Any expenditure for the treatment of diabetes is reimbursed. Patients are not willing to pay anything, so patients expect to be fully reimbursed, they pay taxes.

How much would someone pay for reimbursement of the system: it depends how wide is going to be its use. Currently, sensors are distributed freely to all patients practicing sports even if not professionals. The health system is willing to pay a large number of money for small number of patients. So if more patients use the REACTION platform then more reimbursement the health system will provide for its use. It is important to demonstrate clinical advantage. If it is more expensive than pumps or sensors then, we will have to demonstrate clinical superiority versus what is available.

FRANCE

D: We are in the process to be reimbursed by the financial security system who asked us to expand our experience with trial of 600 persons. We are commercializing it to sell it.
The system will be reimbursed, by the public insurance. Reimbursement will also cover the nurse time for patient management. Visits can be virtual.

There is a cost for improvement of software, and technical maintenance, and to pay the extra paramedical cost to help doctors / specialists to explain the system. There will be a new job, such as telemedicine nurse, first line of contact, so that the specialist does only what is necessary.

French philosophy is that care should be free. It is a matter of principle. We do not pay anything even for consumables. GP makes prescription for consumables.

P 2: I would pay for it as it is useful. I had more fear how I would be able to use it. We would pay for it. It is already an investment. We would like to have it as part of reimbursement. It is matter of principle. The diabetic associations are strong with them. We do not have to pay anything for diabetes. General practitioners will renew prescriptions.

CYPRUS

P 1,2: We have to pay for sensors and the hospitals give us very little money back. Public insurance in Cyprus covers part of the population. Insulin pumps are covered by insurance. No e-prescriptions for consumables. Have to go to specific doctors to write prescription of consumables.

We would be willing to pay depending on the cost. We would pay if the cost was 10 Euros per month, but we would not pay if it was 300 Euros.

D: I would pay for the system depending on how much time I would need to use it.

6. Analysis

6.1 Participant Analysis

Participants were asked to present themselves. No additional information was recorded about their demographics as this was considered a breech for their privacy and beyond the scope of the deliverable.

3 Diabetic centres, 1 private endocrinologist
Doctors: 10
Endocrinologists, gerontologist/geriatrics and general practitioners
People with diabetes: 8, one participant is also dietician
Carers: 3, one mother and two husbands.
Note: No carers for Italy or France. Participants with diabetes liked to have their privacy and not involve personal carers into their condition.
Nurses: 4, one nurse responsible for monitoring using diabeo system. One nurse is also has also Type 1 diabetes.
Other professionals: 1 dietician /epidimiologist, 1 social scientist
Participants with diabetes have a very close relationship with their doctor.

6.2 General Analysis

Participants with diabetes and their carers are interested in receiving updated information. The doctor is the main source of information.
Information provides awareness and facilitates the management of the disease.

6.3 Analysis Based on Individual Questions

The discussions have been analyzed to identify common themes and ideas. The analysis is based on the raw data as presented in section 5 “Results”, but also in personal impressions of the two moderators who participated in the focus groups. As a result some of the information may not be directly traceable back to the raw data as presented in section 5.

1. **Information**

1.1 What are your mental model and/or information loop and rules for decision making and disease management and how would you like it to be supported by the system?

Disease management

Different management for type 1 and type 2:

- For Type 1, initial insulin dosage depends on blood glucose levels and patient size such as body weight. Physical activity (each person with diabetes responds differently to exercise), menses in women (increased need for insulin close and during menses), and physical and mental stress, which cannot be measured (estimation can be done with a pulse meter), affect glycemic control (basal).
- For type 2 overall metabolic characteristics, blood pressure, weight, comorbidities and other associated metabolic conditions (hypertension, dyslipidemia, obesity, etc) affect choice of therapy.

Glucose measurements

Glucose measurements are important in both cases, but type 1 requires more frequent measurements.

Doctors would prefer to have more frequent measurements, while people with diabetes prefer fewer measurements (less involvment and pain).

Pre-prandial and after meal (usually 2 hours) is commonly accepted.

Measurement at bed time is also important.

Extra measurements are necessary, specially related with exercise.

After meal measurements help in checking the bolus.

Before meals and other measurements help in checking the basal.

Target glucose level should be personalized (at least based on age and co-morbidities).

Additional parameters

Bolus evaluation should be done with the meal composition (carbohydrate, glycaemic index and approximate proteins). In case of fat food bolus can be administered slowly (using pumps).

Teach patients should be taught on how to evaluate the carbohydrates and generally the meal composition.

Nutrition and physical activity are estimated/evaluated by patients. Any automation or help (reduction of manual operations) in these estimations will improve usability.

Insulin administration

Pump provides greater flexibility and manages easier changes in nutrition and lifestyle. If someone is a soldier in daily life, then injections (insulin shots) may be the best solution. Some insulin pumps have an internal algorithm, a Bolus wizard, which, based on the carbohydrates, calculates the necessary bolus insulin.

Medium – long term indicators

Glycated haemoglobin is an important parameter in the medium & long term management. It is usually measured every 3 months, except during pregnancy that is measured once a month.

1.2 Which parameters should the system monitor, collect or give back as feedback (vital signs, comorbidities, clinical history, etc.)? In what frequency. Who will use this data and how (target users).

Glucose measurements and bolus calculation

In type 1 or generically insulin dependent diabetes, it is a common practice to collect preprandial glucose measurements. Also the direction and rate of change (trend and speed of change) of glucose are important.

Measurements should be within a certain target range. The range is smaller at the lower limit, and higher at the upper limit. When measurements are completely out of range, then they are repeated.

Postprandial measurements (two hours after meal) are important but not always done. They are necessary when the bolus calculation was not performed properly (patient not experienced) or patient had changes in the real meal compared to the initial estimation. Based on the postprandial measurements patient can perform a bolus adjustment.

Measurements should be performed before and after each meal and at bed time.

There are cultural differences among different countries in Europe and in some cases (e.g. Italy) the after dinner measurement is at the same time of the bed time measurement and thus the last one does not need to be performed. Also the different cooking in different countries can impact in the glycaemic index and load of different food.

Experienced patient can perform proper self-management, but person with diabetes must be trained in performing the estimation of carbohydrates in their meals and it may require some time for any person in order to become experienced.

Calculation of bolus should take into account also the insulin resistance and algorithms should be tailored on each patient.

Type 2 diabetes requires fewer measurements. For type 2 it can be useful to measure also the blood pressure (only in emergency situations without any need of frequent measurements).

Medium – long term indicators

Glycated hemoglobin needs to be measured once every 3 months (every month in pregnancy).

Other parameters (short-term management) and their measurement/estimation

In some situation a standard meal load can be used in order to evaluate if patient is insulin resistant or sensitive. This parameter varies very much from person to person.
Physical activity is difficult to measure. Automatic measurement would be ideal. An accelerometer or isometric activity measurement of sweating (body impedance) could be used in an algorithm very useful to determine insulin dose. Actually such sensors are not very accurate but it is important to have at least an estimation. A sensor would be helpful to tell about how much activity has been done but it varies also with the type of physical activity. Exercise changes the required basal insulin.
In women also the menses change the required basal insulin.
Sensors could track the activity levels and the heart rate. Stress also affects insulin needs and its estimation might be made based on the heart rate. ECG is not needed, except for cardiac patient.

Notes on CGM

Continuous measurements can help in avoiding hypoglycaemic episodes.
CGM without any intelligence does not make any sense, since patients cannot be able to manage properly this huge amount of data. CGM will have to have an intelligence to be able to combine information about other factors in order to work properly and be useful.

1.3 How would you feel if clinicians consider that other parameters (blood pressure, pulse, temperature, ECG, weight etc.) would have to be measured? How do patients / carers feel about collecting and sending such data?

All participants were willing to share all necessary data with their physicians.

1.4 Portable device should allow patients to complete the acquired data set with questionnaire or additional information (status, activity, food intake). Even considering the benefits, is it realistic to expect patients to be willing to constantly enter information about activities, food consumption etc.? What information and to which detail is it feasible to be entered into the system?

The system should require the minimum amount of input from patients and support patient autonomy. Ideally, information will be put in the system through sensors. In diabeo, patients enter their glucose measurements, their food intake (carbohydrates) and their activity (little, moderate, intense). This input is made electronically. The majority of patients explained that did not like to use paper for tracking any measurements. Mobile phones are preferred. Ideally, there could be images of food and patients would not have to calculate carbohydrate content, also activity could be tracked so that activity tracking becomes more sophisticated[1].

1.5 Nutrition has to be taken into account in the calculation of the drug dosage. Which kind of information about nutrition do you think it will be feasible and reasonable to collect consistently? Are patients willing to insert exactly the information about their nutrition?

Nutrition differs among countries and these differences have to be taken into consideration when designing a system. Differences occur in the type of food usually eaten for breakfast, lunch or dinner, but also in the amount of food eaten in each meal.
Ideally, doctors would like to know exactly what the person ate, in order to correlate it with the measurements. However, this requires an extensive knowledge about food, which most people do not have.

> *The system could have the intelligence to calculate percentage of protein, carbohydrate etc, if we put the type of food we ate. Also, it could have option for portions/amount so*

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[1] This information is derived from various parts of the discussions, not just those presented in the results section for Q 1.4.

> *that we can select it. Also, if glucose measurement is high, the system could ask us what we ate in detail. […]* [2] *It would be useful if the system proposed an insulin dosage.[GR]*

Diabeo in France, provides this service to people, suggesting the insulin dosage based on the measurements and the food intake. This appears to be very useful to users of diabeo. Time for entering the information is important and will determine acceptance and use

> *It would be easier with predefined choices. The system would be acceptable and used, if the person spent 10 seconds to input information for each meal.[IT]*

Education about how to calculate carbohydrate contents of food minimizes anxiety about food intake. However, this does not occur to the same degree across countries.
A system that would allow the selection of a meal based on icons would be preferred as it is perceived as a faster alternative to noting food content.

1.6 Education

Education was not part of the initial questions but was raised in all four focus groups as an important component of diabetes management.

Education is very important for diabetes management. The general educational level of a person plays an important role for absorbing diabetes specific education. Education about diabetes management differs across countries.

> *The landscape is different now. We have a good educational system. The great majority of patients are well educated patients. If they do not have societal problems, we train them to eat whatever and manage their disease. Before, they depended on the family. [FR]*

There should be an extensive education plan to help people understand nutrition, its relation to insulin and the content of food in terms of carbohydrates, protein and fat.
Also, education should be targeted for short and long term complications of diabetes and provided in such a way that people may absorb it and understand it rather than appearing as scary future scenarios of what may or may not happen.

The more informed people are about their disease, the more information they are willing to receive. In general, people interested in diabetes and self management are open to receive new information and new knowledge about medical advances, management etc.

Education may be offered in a variety of ways, including informal group meetings, interaction among patients, medical guidance, communities, leaflelts, gaming, dvds etc.

Education supports people with diabetes to become autonomous and depend less on their family and more on their own knowledge.

Education should also be targeted towards informal carers as they also need to be prepered to handle emergency situations and complications.

> *Education for informal carers is important to know how to handle any situation. Diabetes is a way of life. Some people were able to explain diabetes to us with simple words that we could understand. They even used comics. [CY]*

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[2] […] indicates missing text that is present in the raw data, but no point to include it in the quotation.

2 Health Management

2.1 What do you think/feel about using an alarm management system? How do you think it will facilitate your daily practice or crisis management?

There are several alerts considered as important for participants.

These alerts are:

- A reminder to make a measurement
- A reminder to administer insulin
- An alert to specific list of people in case of an emergency episode such as hypoglycemia
- An alert when glycemia is too high or too low
- An alert to the nurse or doctor in charge in case of abnormal values
- An alert in case data has not been entered into the system
- Reminders about doctor visits
- Reminders about regular check up for eyes, legs, heart etc.
- GPS traking of the person in case of emergency
- Alerts to verify data transmission and delivery
- Alerts about device functions (eg that catheter of pump has been inserted properly)

Reminders and alerts should be flexible and adjustable so that the user can customize them based on their lifestyle. Also, they should be formed to avoid panicking the person, rather, to provide support, and encouragement.

2.2 Will a telemonitoring system change the current care model? Will the system be able to provide a better visit management (e.g. only when really necessary)? Will patients and doctors have enough time to dedicate to this more frequent data collection, analysis and feedback? (Should disease management plan, risk management plan and lifestyle plan be part of the personalized care plan?)

Organizational issues with telemonitoring

Usually there are no permanent personnel available for telemonitoring. In case there is a 24 hour centre with people on call, theoretically the continuous monitoring might be operated. However, it would be necessary a dedicated person to answer calls, and monitor progress.

In Greece the involved hospital has 10000 patients with diabetes to be checked every 2-3 months. There are only 4000 patients active and responsible. There are too many diabetic patients. Hospitals do not have enough staff for the current management of all diabetic patients. Telemonitoring (in order to be successful) should not add further duties but change the current care model and allow a better management. There would need the right organization and protocol.

A diabetic call centre would need to have protocols of how to handle emergencies based on yes and no questions.

It would be useful if the system will be able to contact the emergency ambulance service. An automated system may create problems with elderly people, elderly patients cannot understand an automated system, since often think there is a person that talks to them.

The care team should include dieticians, social worker, psychologist, special laboratory. However, most centres do not have such team.

Doctors would not like to work on night shifts to give alerts. They give cell phones to limited number of patients who are nice, and polite. Loops with doctor checks for any bolus of any patient are unfeasible. Specialists do not work at night and cannot afford the continuous check of insulin for a large number of patients. A more feasible solution is a bolus calculator with each patient without doctor check which provides the information to the informed patient and the patient decides. Patients have to be well instructed.

Protocol needs for telemonitoring

In France the telemonitoring works with the following protocol: patients send information once or twice a week. In case of emergency they send the information immediately and call the doctor. The data to be telemonitored are entered manually by the patient on a mobile phone.

There is a weekly check of the data operated by a nurse. When the nurse sees something wrong the patient is called on the phone and helped to manage.

More frequent contacts with the nurse and the paramedics but if things go well there is no need to have contact with doctors.

Telemonitoring is more important for type 1 but probably less important for type 2. Several people do not feel like or are not involved to record glucose measurements.

Continuous monitoring should not be obtrusive. If continuous monitoring implies the manual management of such huge amount of data, then it is clearly unfeasible.

Application of a specific but effective protocol can reduce the need of frequent communication with doctors. Such cultural difference is present in France where patients do not communicate so often with doctors but they are fully satisfied with the existing protocol.

There are glucometers and insulin pumps which allows the patient to upload (manually with the help of a USB stick) the measurements in a webpage so that the doctor can see them. These systems allows also for taking into account the food intake, but exercise cannot be entered (even patients would like to).

Patients would like to have an improved glucometer that could send automatically the results directly to the PC (in order to avoid the big effort to record them by themselves). Automatic transmission and availability of measurements is very important.

Virtual and face-to-face visits

A quite common number of face-to-face visits is twice a year.

Responsible patients would like to have 1 visit per month and they would like face to face visit (discuss questions and concerns) and if this is hard to achieve, then every 2 months in the worst case. Virtual visits are OK but face to face real visits are preferred.

The system cannot replace personal contact between patient and doctor. However, it could increase the time between visits.

Face to face visits are very important, they have different emotional quality and are part of the therapy, there is a psychological factor in doctors' work. Video conference even high quality cannot substitute physical visits.

Main role of doctors in telemonitoring

The core of doctor's business is to motivate the patients. The key is to be able to persuade them to use it. Interventions are 20% technical (depending on the patient ability and the smart phone) and 80% motivational. The first month is important for the technical aspects but the motivation has to be cared continuously. Patients follow the protocol for some time and at a certain time they stop; at this point doctors and all the staff need to help them at the point where they stop especially when the values are out of range.

The willingness and distress play the most important role. It is important to handle patient with distress (often due to social and psychological situation). Psychological distress of patient is not currently managed and it is very difficult to be managed. Support for psychological distress is paramount and clinical people should be focused on that. People with many problems cannot manage properly their chronic disease.

Patients' training and feeling with telemonitoring

Patients are trained to react to unusual measurements and to understand their conditions day after day and to operate self-management.

Having the system and being able to call someone in an emergency, offer strong psychological support for the patients. The system is a coaching device because it tells the patient what to do instead of waiting a few days before acting. The system facilitates the calculation, and reminds the patient what to do.

<u>Risk calculation</u>

Some parameters do not need to be monitored for the glucose/insulin management but only for the risk calculation (e.g. lipid profile). The definition of algorithms is not easy at all and thresholds for risk are different from country to country (due to cultural and lifestyle differences). It is impossible to build a universal algorithm for the risk evaluation. In order to build a good risk calculator it is important to have good epidemiological data.

2.3 Organizing the risk as short term, midterm, long term which kind of risks would you like to insert in each category?

Risks are associated with compliance to therapy.

> *Short term: hypoglycemia and hyperglycemia. Also the catheter might be obstructed, but there is no way to know unless we have hypoglycemia, or toxicity. This is why we have to take frequent measurement of glucose. [CY]*
>
> *Long term risks are: cardiopathy, retinopathy, nephropathy, etc. Type 2 diabetes that remains uncontrolled for a long period can result in serious problems. [CY]*

3 Devices

3.1 How do you feel/think about wearing a system that will take measures from you and send them to your doctor/family? Which would be your maximum acceptable size for such a system? Weight? Dimensions? Other criteria.

Generally, insulin dependent diabetics fit in the following categories, those who use the pump, those who prefer injections, and those who are open to the pump but have not yet used it. The Reaction platform should be designed to be used by people who use the pump as well as people who use injections.

The people who use the pump would like smaller, less obtrusive devices.

The pump introduces the element of trust, as the person does not rely on personal calculations, but on the calculations of the device. This is also the case with the diabeo. A device that proposes insulin dosage is a trusted source more than personal judgement/calculations. They act as personal assistants.

However, pumps are not acceptable by all. There are those who see them as life support devices and hence do not accept them. Also, they are viewed as risky for malfunctioning, or hurtful as they could be bumped and involve a catheter.

> *Devices have to be light, and small in size. The patient should not feel wired, not like the pump. It should be a pad and all communication should be done wireless. It should be easy to use, with large letters visible to elder people, or people with impaired sight. It is important that people with impaired sight (a comorbidity in diabetes) should be able to use the technology. Also, the menus should be in the national language. Menus with icons are better to those with letters. [GR]*
>
> *It would be nice to have something like a watch. I want a device which is comfortable, small, easy to carry, something like an iphone. I want a watch, not something on me. I would wear something not visible, and something that does not hurt, and that I cannot bump it. I want something rechargeable, environmentally friendly to refill it. [IT]*

3.2 Would a mobile device be useful for you? Which kind of device is more conformable/usable for you in your daily practice?

A mobile device is useful at the size of an iphone with a large screen, light and small in size. There are people who do not like mobile devices, however, when the benefits are significant, change occurs.

> *I do not like phones, and I am not a good user of technologies. I do not want to feel that my life is continuously controlled. But after a while, I said why not and I used it. It was not difficult. I am happy with it. [FR]*
>
> *The extra time patients need for data entry is very small and the benefits are huge. [FR]*

3.3 How would you feel about ePatch technology? (Intrusive, unsafe, etc.)

ePatch should be waterproof, small at the size of a business card, and should last more than one week. The epatch should have sensors and automatic glucose control included. Also, it will depend on the color. Preferably the color should render the epatch difficult to detect.

There are participants who view the epatch as they view insulin pumps. They do not like it because they feel they cannot control it and that it could break.

4 General Usability, Usefulness

4.1 How do you think/feel about having a system like REACTION as part of your daily practice?

A closed loop system could potentially change the life of type 1 diabetic patients. From the general discussions with people in France, it became clear that the two participants, who use diabeo to manage diabetes, could not imagine their lives without it.

4.2 Do you think our system is useful? Which could be the most critical factors and concerns for using it? (price, wearability, etc.)

Simplicity, usefullness, amount of information and time required. It will depend on the sophostication of the system. Also, it is important that the system supports self-empowerment of patients without additional stress.

4.3 What minimum technical skills should it require? Do you think the use of modern technology is complicated? How important is that the application is available in your language?

The minimum skills should be those of using a mobile phone. All participants wanted the system to be in their own language. Also, the system should be easy to use with a big screen, and menus with visible letters to be legible and understandable.

5 Privacy Safety and Trust

5.1 The use of the system will be enabled after the patient will sign an informed consent. Do you think this is enough? Or would you like to have the possibility to give permission for each specific action? Such as transfer, access and processing of your medical data? Do you think it is necessary/important to you that you can see which doctor/nurse/person had a look at your health data?

The general opinion of participants is that they want to sign an informed consent and they want to know who has access to their data. They want to know who is on the other side of the system, that their data is private and safe. Also, participants would like to have a list of names of people who will have access to the data.

Generally the system should have the following features to comply with all respondents opinions:

- Informed concent
- Alert of who saw what data
- A list of people who have access to data

Participants did not have these concerns if only their doctor had access to their data. Also, if data were to be used for other purposes it should be anonymised.

5.2 Would you be comfortable knowing that glucose values out of range will be sent to your doctor, formal or informal carer? Would you like to have control on what information and when it is sent? Would it make a difference if the values indicated a life-threatening situation?

Participants had no problem sharing all information with their doctor. As one participant illustrates:

> *When patients hide information from doctors, is usually the doctor's fault. […] Some doctors try to force patients to modify lifestyle with a moral attitude. The patient will hide information if there is a moral attitude. [IT]*

5.3 Which is your perception about your own physical safety while wearing the device?

Insulin pumps are considered wearable technologies and some participants like them and some don't. Participants who did not like the pump, did not like the epatch. This is about perception of control. There are participants who want to have control over the device and they feel that wearable devices do not allow them control.

Malfunctioning and acuracy of the device are also concerns.

5.4 Are there any factors that could make you to have more trust in our system? Is there anything you may want to see in order to trust more in our system?

The technology should have gone through extensive testing with formal studies of accuracy, calibration and frequency of calibration. Generally, patients trust the technologies recommended by their doctors.

6 Trust in the infrastructure

6.1 Would you trust an Internet platform with your medical data such that doctors can access them? If the application provides information about the infrastructure risks and the measures taken to minimise these risks, will that increase your trust and acceptance of the platform?

The following quotes illustrate participant beliefs about data and trust:

> *Trust is gained over time. If our collaboration is good, without problems, then trust is built. [GR]*
>
> *Medical data do not have the same commercial value as bank accounts, or credit cards, so how much time people would invest in compromising such data. [IT]*

Patients were more concerned about data being lost, or mixed between patients. Participants in France illustrate their priorities:

> *Internet security is not important compared to the fact that we can have a better diabetes management but a secure website would help. [FR]*

> *I use internet for everything. I feel the same for my data. [FR]*

6.2 Question for medical personnel: Do you think that the patients rule over their medical data stored on the REACTION platform (e.g. revoking a doctor's right to access certain data) would negatively impact your work? If yes, what problems do you see and do you see a way out of the problems without wholly taking away patients' rights?

The data belong to the patients and patients should be informed about how their data is going to be used. The authorization for handling the data should be given by the patient. Generally, each patient is in direct contact with one specialist, or nurse and their relationship is based on trust.

7 Trust in transaction partners

7.1 If the application provides information about the way personal data is handled by the receiving parties and the arrangements the application offers to prevent or deal with privacy breaches, would that increase your trust and acceptance of the platform?

Participants believed that encryption for the transmission of data is important.

7.2 Would you like to anonymising/pseudonymising technology? Do you think it will have negative effects on the mutual trust between users and service providers?

Anonymization of the data is the best solution, if data were to be used for purposes other than communication between doctor and patient.

8 Cost

8.1 How would you like the service to be covered by the insurance companies? Would patients like to pay for the service/devices (if yes, how much)? How doctors should be reimbursed for providing this service?

The opinion of the respondents is that the system should be covered by the public insurance. Diabetes consumables are provided for free, and respondents feel that the same policy should apply to new technologies. Type 1 diabetes is generally well covered by public insurance in the four countries. Type 2 diabetes is not so well covered.

> *Currently the glucometer is covered by the insurance and has no cost for patients. The same philosophy should be maintained at least for the sensors distributed with this system. [GR]*

> *I think that the answer is simple. Any expenditure for the treatment of diabetes is reimbursed. Patients are not willing to pay anything, so patients expect to be fully reimbursed, they pay taxes. [IT]*

> *French philosophy is that care should be free. It is a matter of principle. We do not pay anything even for consumables. [FR]*

Countries with national health systems, and public insurance have good coverage of diabetes consumables. However, this is not applicable to countries, such as Cyprus, without national health systems. In Cyprus, public insurance covers only part of the population.

Reimbursement will depend on extend of use, and on the cost of the system. The clinical advantage of the system should be demonstrated to persuade governments and insurances to invest. Also, clinical superiority against available technologies should also be demonstrated.

Cost can be minimized with new technologies that allow refils for diabetic consumables instead of disposables, and energy saving technologies such as pump operating with solar energy instead of battery.

Diabeo is in the process of being accepted as a system for widespread use in France covered by public insurance. The process to reach this stage involved, clinical trials of over 600 people. Cost of diabeo includes improvements of the software, technical maintenance, telemedicine nurse as first point of contact for users, trainers to help doctors/specialists to explain the system. However, people with diabetes who use diabeo are willing to make an investement in order to use the system because it is very useful to them.

Generally, people with diabetes are willing to pay a small amount, or make an initial investment on devices if the system/platform/tool helped them improve self management of their condition.

> *I would pay for it as it is useful. I had more fear how I would be able to use it. We would pay for it. It is already an investment.[FR]*
>
> *We would be willing to pay depending on the cost. We would pay if the cost was 10 Euros per month, but we would not pay if it was 300 Euros. [CY]*

6.4 Cultural Variability

From the focus groups discussions it has been derived that diabetes management is similar across the four countries analyzed. However, there are cultural differences that need to be taken into consideration to ensure dissemination of REACTION platform across Europe. Nutrition habit is the main difference observed across countries. The meals differ in size, and time of consumption as well as type of foods. Also, the way of cooking of the same food, e.g. pasta, may differ across countries and often across regions within the same country. Also, education about calculation of food content differs across countries. It is very important that diabetics are correctly formulated before using a system. Formulation, includes, knowing how to correctly calculate carbohydrate, protein and fat content of foods. In general, the amount and extend of education provided to diabetic patients varies across countries.

Also, it is important that the system takes into consideration the individual differences between users in terms of their reaction to insulin in combination with food intake, exercise, stress, etc. Insulin calculation should be based on individualized algorithms.

Another significant difference includes the preferences of individuals about the devices they are willing to use. There are individuals that do not like wearable devices, also those who would like devices to act as a personal advisor. Overall, people who use insulin pumps are willing to try wearable devices, while those who do not like pumps and prefer injection management, also, do not like wearable devices.

People with diabetes also differ about their view towards their disease. People in Cyprus do not consider themselves, as ill, therefore do not like to be called patients, but rather people with diabetes. In addition, people may prefer to minimize visits to the doctor and want to feel completely autonomous, while, others prefer frequent visits to the doctor, or frequent communications with the doctor. A system, that aims to minimize visits to the doctor in order to decrease cost and increase convenience, need to take into consideration users who would prefer frequent contact with the doctor.

Cultural background is involved in whether people are open about communicating their disease, asking for help and support, while others prefer secrecy, autonomy and self management with minimum social contact. Cultural differences also occurred in the organization of health care, care teams and patient doctor relationships.

7. Conclusions

This deliverable provides general opinions about diabetes management and new technologies. These opinions may result in formal or informal requirements. The consortium may consider how the information of this deliverable could be used to inform the development of the REACTION services.

These findings are in accordance with those of other studies about technology management of chronic conditions (Bostocka, 2009; Verhoeven, 2007).

The basic conclusions as they are derived from the focus group discussions are presented below in brief for each group of questions. This list does not aim to be inclusive of all relevant data for each theme, but only as this has been derived from the discussion analysis.

.

7.1 Information

Important information to keep track and analyze includes nutrition, physical activity and personalized reaction to insulin (insulin sensitivity, rate of insulin absorption, etc.)

Extensive education is needed to allow people with diabetes to perform self-management and be self sufficient. Education defers based on the target group, eg age, type of diabetes, type of therapy etc. Education includes calculation of carbohydrate content of food, education about what diabetes is, simple education to carers and family, education for empowerment.

7.2 Health Management

The system should provide several alarms to encourage measurements, administration of insulin and support in case of emergency episodes. Telemonitoring may prove time consuming without showing the necessary benefits. A system should not replace face to face contact between patient and doctor however, it can assist patients to be self reliant and confident.

7.3 Devices

Participants expressed their preference for devices with the following characteristics: comfortable, small, light, unobtrusive, mobile (iphone) or watch, waterproof, with menus in national language, large screens, visible menus, interfaces for data entry with minimum time and information requirements, devices that do not hurt, and are easy to use

7.4 General Usability and Usefulness

New technologies for diabetes management should provide empowerment, support for self-management, and be able to act as consultants and even as company.

7.5 Privacy, Safety and Trust

It is important to have patient consent forms, technologies that are tested thoroughly, anonymised data, encrypted transmission, list of names of those who have access to data, alerts about transmission, alerts about who saw the data, alerts about malfunctioning, information about the device.

7.6 Cost

In principle it should be free as diabetic consumables are (covered by national health systems). Minimum investment on technology based on perceived benefits.

8. References

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9. Annexes

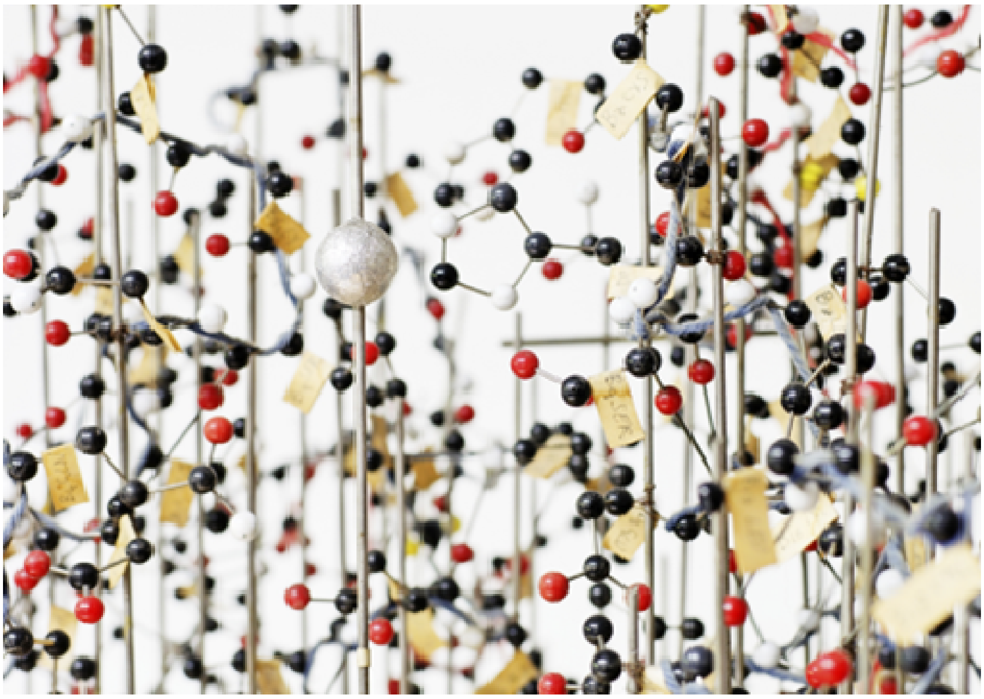
9.1 Background Material

9.2 Invitation Letter

9.3 Acceptance Letter

9.4 Thank you letter

A Professional Service Platform for Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks



Focus Group on

[enter title]

[enter address]

[enter date and time]

Background description

Diabetes mellitus has reached worrying proportions in western countries making, diabetes one of the fastest growing chronic conditions. Diabetes has been estimated to affect 60 million Europeans. Given the increasing trends towards sedentary lifestyles and obesity related problems, this number is expected to increase in the coming years.

Diabetes can cause many complications if the disease is not adequately controlled. Adequate treatment of diabetes, as well as increased emphasis on blood pressure control and lifestyle factors, may reduce the risk of long-term complications. Self-management of diabetes is an area that offers exceptionally good prospects, both in clinical and business terms. ICT may offer useful capabilities to improve illness prevention and safety of care facilitate active participation of patients and enable the personalisation of care, allowing new opportunities in health and disease management.

REACTION is a four year European project which started in March 2010. It is partly funded by the European Commission under the 7th Framework Programme. REACTION aims to develop an intelligent service platform, providing remote monitoring of glucose levels with diabetes management and therapy to patients in different healthcare regimes across Europe. If successful, the REACTION platform will be able to execute various clinical applications, such as monitoring of vital signs, feedback provision to the point of care, integrative risk assessment, event and alarm handling as well as integration with clinical and organisational workflows and external Health Information Systems. In the next three years, a range of REACTION applications will be developed with the aim of improving continuous blood glucose monitoring (CGM) and tight/safe glycaemic control for improved insulin therapy management.

REACTION’s contribution to diabetes management is twofold. On the one hand, the REACTION service platform will help diabetic outpatients to better control their disease, with prompt feedback from formal carers and medical systems and appropriate risk assessment services that can be deployed in any healthcare system in Europe. On the other hand, REACTION is expected to have an impact on formal carers in hospital wards by improving glycaemic control of admitted patients with diabetes using continuous blood glucose monitoring (CGM) and therapy feedback.

Focus Group on [Enter title]

Objectives

This focus group is the [enter number of focus group] of a series of four focus groups that will take place in different European countries between November 2010 and July 2011. The results of the focus groups will be collected, analysed, and formulated in terms of requirements which will be used to give direction to the requirements engineering process. The main objective is to understand the relevant personal, social and cultural factors related to potential REACTION services. We aim to understand what diabetic patients, nurses, doctors as well as healthcare professionals and administrators expect from technology and what values, beliefs, hopes, concerns and needs are related to the use of REACTION services. We aim also to learn how the use of information technology could potentially change the experience of living with diabetes. Understanding societal factors is a core preliminary requisite for addressing ethical and social issues at the design stage of technology development.

Main themes to be explored

Please, read the following paragraphs and contemplate on these subjects before the day of the focus group.

<u>Perception of autonomy and the balancing of personal goals:</u> A person who is afflicted with diabetes and, e.g., high blood pressure runs greater risks of heart attack or stroke. With the use of technology he or she can regain a measure of autonomy. On the other hand, becoming dependent on monitoring technologies can be seen as a threat to autonomy. Patients may be unwilling to disclose every instance of non-optimal blood sugar level to their physician. Diabetes is not just a physical condition, but also a social and psychological one. On the one hand, the use of monitoring technologies could help attain personal goals such as physical health, which bodes well from the perspective of disease management. On the other hand, the use of monitoring technologies could increase the level of medical surveillance on personal lifestyle thus harming personal goals in one's social life.

<u>Protection of personal data:</u> Electronic Healthcare Networks require, in order to work, the processing of personal data. Data protection is a right protected by Article 8 of the EU Charter of Fundamental Rights. One of the objectives of data protection is to avoid the use of data concerning health for purposes different than disease management and, in particular, by someone who may abuse such information. At the same time, redirecting health data can be a successful part of the treatment of disease using remote monitoring systems. The difficulty for patients is to be able to discern whether they are giving away their information to trustworthy persons and not to someone who may abuse their data. The patient may have an interest in knowing which categories of information are transmitted and/or retained, or not? The patient may want to control any use of his or her personal data and be asked for consent. In addition to issues of Data protection, the question of a patient's trust in the use of an internet platform in conveying personal medical information will be explored. In particular it will be important to gauge the potential user's perceptions of the level of security that can be provided by such platforms.

<u>Patient-care provider relationship:</u> REACTION may bring about profound changes that change patient participation in the healthcare service. It may imply that a patient,

sitting at home, will have measurements (glucose level, weight, blood pressure) taken and sent electronically to the doctor or the nurse. This would require actions from patient, carer and healthcare provider, reducing the level of face to face interaction. This model is significantly different to the usual model of patient physician relationship of face to face interactions. On one hand it could introduce convenience, frequent monitoring, and better management, while on the other hand, it might affect the patient's perception of the level of attention and guidance he or she is receiving from the care provider.

Health management: Participation requires that patients regularly enter lifestyle data into the platform. In principle all information may be considered relevant, however patients may be more comfortable with the use of some parameters rather than others. Individuals may want to decide by themselves their level of engagement in the REACTION platform, for instance selecting which parameters they provide and also what level of feedback they receive, including the right not to know. Application of the platform will result in a novel way of interaction and practice diabetes management for patients, carers and health providers.

Agenda

- Welcome and introductions
- Presentation of the Project
- Objective of the Focus Group
- Discussion, Conclusions

INVITATION LETTER

FOR PARTICIPATION TO THE REACTION FOCUS GROUP

FORTH-ICS
Foundation for Research & Technology-Hellas
Institute of Computer Science
100 N. Plastira St., Heraklion, Crete, 70013, Greece
(DATE)

Important Links:
Project website: http://www.reaction-project.eu

For further information:
ICT for Health - European Commission – Information society and Media DG
Office: BU31 06/41 B-1049 Brussels | Phone: +32 (0)2 296 41 94 - Fax: 02 296 01 81
Email: eHealth@ec.europa.eu I http://ec.europa.eu/information_society/activities/health/

Project coordinator
Atos Origin, Atos Research and Innovation, Albarracín 25, 28037 Madrid, Spain
Lydia Montandon | Tel: (+34) 91214 8616 | email: lydia.montandon@atosresearch.eu | www.atosorigin.com

Focus Group Coordinator
ICS-FORTH
Angelina Kouroubali, email: kouroub@ics.forth.gr, Tel: (+30) 6938281222

Dear Madam, Sir**,**

We would like to invite you to participate in a focus group on ***Technologies for Diabetes Management*** organized under the aegis of the EU FP7 project REACTION.

REACTION is a project partly funded by the European Union Seventh Research Framework Program which aims to develop a service platform providing remote monitoring of glucose levels and diabetes management and therapy for patients. The development of the REACTION platform aims to provide various clinical applications, such as monitoring of vital signs, feed back to the point of care, risk assessment, event and alarm handling in addition to integration with clinical and organisational workflows and external Health Information Systems. REACTION services target patients with type 1 or type 2 diabetes focusing mostly on insulin-dependent patients. The applications aim to improve continuous blood glucose monitoring (CGM) and tight/safe glycaemic control, allowing improved insulin-therapy management. Please visit the website of the project for more information http://www.reaction-project.eu

A key component of this process involves obtaining important input from doctors, nurses, patients and carers, in addition to learning from their experience and expertise. To this end, we are sponsoring a series of focus groups around Europe to hear and learn from constituencies interested in diabetes issues and new technologies. The main goal is to identify perceptions, opinions, beliefs and attitudes towards the technology which going to be developed by REACTION. Focus groups can help us to document specific examples of the implementation of e-health technologies and to learn from participants' opinions about how to improve the implementation of services in diabetes monitoring.

The focus group will be held in ***(location and address)*** *on* ***(day), (date)*** from ***(time)*** to ***(time)***, with a **coffee break** from ***(time)*** to ***(time)***. At the end of the focus group meeting, there will be **lunch** offered to the participants at ***(time)*** in ***(restaurant name)***. The gathering will include **8-10** participants and will be moderated by Dr. Angelina Kouroubali, affiliated research scientist at FORTH-ICS (email: kouroub@ics.forth.gr, mobile: +30 693 82 81 222) and Mr. Franco Chiarugi, senior electronic engineer at FORTH-ICS (email: chiarugi@ics.forth.gr).

If you wish to participate in the REACTION focus group, we kindly ask you to read carefully the terms and conditions specified in the Letter of Acceptance attached to the present invitation. If you accept the said terms and conditions, then please complete, sign and send us the attached Letter of Acceptance in order to participate to the REACTION focus group. Please return to **(onsite contact name for each focus group & contact info)** the signed by yourself Letter of Acceptance.

Upon receipt of your signed Letter of Acceptance, we will send you an information sheet about the REACTION project and a brief background note regarding the topics that will be discussed during the meeting.

We are appreciative of the time you have taken to consider our request and look forward to hearing from you soon. If you have any specific needs relating to your participation, please let us know so that we can accommodate them.

Yours sincerely,

____

Dr. Angelina Kouroubali
Organizer of Focus Groups for the REACTION Project

ACCEPTANCE LETTER

FOR PARTICIPATION TO THE REACTION FOCUS GROUP

FORTH-ICS
Foundation for Research & Technology-Hellas
Institute of Computer Science
100 N. Plastira St., Heraklion
Crete, 70013, Greece
(DATE)

Dear Madam, Sir**,**

A) Please be mindful that if you wish to participate to the REACTION focus group you are kindly requested to read carefully the following terms and conditions of this Letter of Acceptance; If you agree with and accept such terms, in order to participate to the said focus group please sign below this Letter of Acceptance and return it to us according to the terms set out in the attached Invitation Letter. In particular,

B) Please be mindful that participation to the REACTION focus group is on a voluntary, non-paid/remuneration-free, non-exclusive basis; This means that participation to the meeting will not grant you any kind of any benefit, right, title, remuneration or other type of payment of travel, attendance costs, expenses incurred claims, nor give any other benefit, right, title or claim over the research work or the technology devices, or the intellectual and/or industrial property, publication, confidential information related rights that REACTION will produce in the next years;

C) Please be mindful that participation to the REACTION focus group for the purpose of providing REACTION your opinions as above mentioned, any personal data and other information you shall provide REACTION needs to comply with the European Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. For this purpose REACTION asks you to provide your consent to collect and use your information or personal date for the above mentioned purposes of REACTION, hereby by means of signing-acceptance this letter of invitation, once you have accepted to participate to the focus group under the terms of this invitation; Within this scope we would like also to inform you that your name, as the names of other participants, will remain strictly confidential; Opinions expressed during the meeting will not be associated in any way to specific names or identifiable persons; Any data you shall provide will be mainly treated as statistical data and shall be collected and used always with respect to the provisions of the European Directive 95/46/EC;

D) Please be mindful also that any information presented to you by any means (electronic or other) related to REACTION is strictly confidential and as such is disclosed to you on a strict need-to-know basis according to the provisions of section 10 of the REACTION Consortium Agreement and for the purposes of this invitation; This means that by accepting to participate to the focus group you also accept to comply with such non-disclosure of confidential information or else confidentiality related rules and ethics; thus, you are not allowed to disclose to any other party and/or to use by any means such confidential information without the prior written consent of the concerned hereby disclosing REACTION party, ***FORTH-ICS.***

In the forthcoming weeks we will send you an information sheet about the REACTION project and a brief background note regarding the topics that will be discussed during the meeting.

We appreciate your consideration of our request and look forward to hearing from you soon. If you have any specific needs related to your participation, please let us know so we can accommodate them.

If you agree with and accept the above mentioned terms & conditions A to D in order to participate as such to the REACTION focus group, please return this to **(onsite contact name for each focus group & contact info)** completed below with your full name & signature & and date of, within five (5) days from receipt of the attached Letter of Invitation.

STATEMENT OF ACCEPTANCE

I ____ ***(your full name)***, the undersigned below, today in ___________________***(place)***, as of today,________________ ***(date of signature)***, certify that I have read carefully the above terms and conditions A to D of the present Letter of Acceptance and acknowledge to you that I have understood, I agree with & accept unconditionally as such to participate to the REACTION focus group taking place in _____________________________***(place and date)*** according to the terms and conditions applicable in the Letters of Invitation & Acceptance.

Yours sincerely, _____________________